



**The Tamil Nadu Dr. Ambedkar Law University**  
தமிழ்நாடு டாக்டர் அம்பேத்கர் சட்டப் பல்கலைக்கழகம்  
State University Established by Act No.43 of 1997  
NAAC Accredited



**DEPARTMENT OF INTELLECTUAL PROPERTY LAW, IP CELL**

**A REPORT ON THE ONLINE CERTIFICATE COURSE ON  
PATENT LAW:**

**POLICY AND GOVERNANCE**

**AT**

**THE TAMIL NADU DR. AMBEDKAR LAW UNIVERSITY**

**FROM 4<sup>TH</sup> FEBRUARY – 29<sup>TH</sup> APRIL, 2023**



**REPORT ON THE ONLINE CERTIFICATE COURSE ON  
PATENT LAW: POLICY AND GOVERNANCE**

**FROM 4<sup>TH</sup> FEBRUARY – 29<sup>TH</sup> APRIL, 2023**

**BY**

**THE DEPARTMENT OF INTELLECTUAL PROPERTY LAW, IP  
CELL &  
IQAC, THE TAMIL NADU DR. AMBEDKAR LAW UNIVERSITY**

**Report Prepared By**

SANDEEP S KUMAR

VINU SREE G

MADHUMITHA C L

MERVYN THOMAS BIVIN

(Students of LLM, Intellectual Property Law Department, TNDALU)

**Headed By**

Dr. LUCKY GEORGE (HOD)

Dr. P. BRINDA

Dr. M. SUNIL GLADSON

Mrs. AARTHI RATHNA

Ms. K. RADHUKA

Mr. JEFFRY ANDREW

## BROCHURE:



**The Tamil Nadu Dr. Ambedkar Law University**  
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### **Online Certificate Course on Patent Law: Policy and Governance** **February – April, 2023**



**Department of Intellectual Property Law & IP Cell** (established by the Patent Information Centre, Tamil Nadu State Council for Science & Technology) of the **Tamil Nadu Dr. Ambedkar Law University, Chennai** have introduced the course with the objective to provide a platform for candidates who are pursuing for Patent Agent Examination to gain knowledge of Patent Law and its importance for Innovation and growth of economy as a whole.



#### **Eligibility & Fee**

Students Graduated in any Discipline/ Research Scholars/ Practitioners/Academicians/ Teachers or any other persons who are interested in gaining knowledge of Patent Law. The Course fee is Rs. 5000 **limited to only 100 students (first come first serve).**



## **Admission Process**

Applicants are required to fill the Google Form Link and last date for registration is February 1, 2023. Google form link:

<https://forms.gle/LjNDcAEfHMXZ5YHc7>



## **Methodology**

The teaching methodology involves interactive lectures by eminent academicians, practicing lawyers, IP professionals and students. Basic reading materials will be provided to registered candidates. Candidates are required to submit a written submission on a topic and have to undergo an evaluation assessment at the end of the course. The course will be conducted online only and no hard copy of either the reading material or assignment or examination shall be sent to the candidate or accepted from the candidates. **Attendance is mandatory and a certificate is awarded on successful completion of the course. The candidate has to score at least 50% marks to clear the course.** The candidates obtaining less than that shall not be given the certificate.

## **Scheduled Date of the Course**



The course is conducted **online on Saturdays and the duration of the entire course is three months commencing from February, 2023.** The class timings are tentatively fixed at 3 pm to 5 pm. The detailed course schedule is informed upon registration.



## Course Outline

- Introduction to Patent Agent Examination – Preparation Strategies (Paper – I & II and Viva-Voce)
- Interpretation of each and every Sections/ Rules of Indian Patent Act, 1970 and Patent Rules, 2003 with illustrations, examples and case laws:
  - Patentable Subject Matter - Concept of Invention and its new dimensions
  - Patentability Criteria
  - Role of Judiciary in determining patentable subject matter
- International Conventions and Treaties related to Patent Law and PCT Procedures
- Basics of Patent Claims and Specification Drafting:
  - Identifying novelty of the invention
  - Drafting claims strategically based on novel features
  - Comparative analysis of drafting requirement with respect to various jurisdiction
  - Important points to consider while drafting a patent specification.
- Filing of Patent Application – Procedures and Documentations
- Anticipation, Patent of Addition, Publication and Examination of Application, Grant of Patent, Restoration of Lapsed Patent, Amendment of Application and Specification
- Opposition – Pre-grant and Post-grant, Revocation and Surrender of Patents
- Claim Interpretation - Interpretive Methodology and Sources of Evidence
- Infringement and Defenses - Doctrines of Infringement - The Literal Rule, Doctrine of Equivalence/Pith and Marrow and Patent Misuse Doctrine – Jurisdiction – Burden of Proof – Reliefs – Injunction – Groundless Threats
- Software Patents - Business Method Patents - Standard Essential Patents – FRAND Licensing
- Bio-technology Patents - Patenting of Human Genes - Legal, Ethical and Social Issues
- Pharmaceutical Patents - Compulsory Licensing, Bolar exception, parallel import and Doha Declaration.



### **SCHEDULE:**

#### **Online Certificate Course on Patent Law: Policy and Governance**

**February – April, 2023 Saturday's 3:00 pm to 5:00 pm**

<b>S. No</b>	<b>Date</b>	<b>Resource Person</b>	<b>Topic</b>
1.	04-02-23	Dr. T. Ramakrishna, Professor of Law National Law School of India University, Bangalore	Introduction to Patent Law and Patentability Criteria
2.	11-02-23	Dr. I G Rathish Assistant Professor, Inter University Centre for IPR Studies (IUCIPRS), CUSAT	Overview of Prior Art Search and Drafting a Patent Specification and Claims
3.	18-02-23	Dr. Sudhir Kochhar Ex-ARS, Former ADG (IPR) and National Coordinator (NAIP/ICAR)	Patenting in Agriculture: Academic and Legal Perspective
4.	25-02-23	Dr. S.P. Subramaniam, Deputy Controller of Patents & Designs, Patent Office  Dr. M Sunil Gladson, Assistant Professor in School of Excellence in Law	Inventive step and Sec 3 (d) of Patent Act  Inventions Not Patentable
5.	04-03-23	Dr. Athira P.S Assistant professor, NUALS, Kochi	Biotechnology patents- Patenting of Human Genes- legal, Ethical and Social Issues

6.	11-03-23	Dr. I G Rathish Assistant Professor, Inter University Centre for IPR Studies (IUCIPRS), CUSAT	Claim and Specifications
7.	18-03-23	Dr. Asha R Research Officer at the IPR facilitation cell of Inter University Centre for IPR Studies(IUCIPRS), CUSAT	Patent Filing Procedure and Oppositions
8.	25-03-23	Dr. Yogesh Pai Associate Professor, National Law University, Delhi	Software Patents and FRAND Licensing Right
9.	01-04-23	Dr. Kavitha Chalakkal is currently an Assistant Professor in Inter University Centre for IPR Studies, CUSATMs.  Arathi Ashok Assistant Professor in IPR at the School of Legal Studies, Cochin University of Science and Technology, Kochi	International Treaties and Conventions- PCT  Pharmaceutical patents
10.	15-04-23	Mr. M. Mahindra Prabu, Assistant Professor in Tamil Nadu National Law School, Trichy	Drafting & Interpretation of Specification and Claim
11.	29-04-23	Mr. A K Rajaraman, Advocate, High Court of Madras	Patent Infringement and Litigation



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The Tamilnadu Dr. Ambedkar Law University



### LIST OF PARTICIPANTS:

**Online Certificate Course on Patent Law: Policy and Governance**  
**February – April, 2023, Saturday's 3:00 pm to 5:00 pm**

Registration No.	Name	Education Qualification	Institution	Mobile No.
23P001	Nivedha	BBA	TNDALU	8939047842
23P002	S Shangamithirai	LL.M	Govt. Law College Madurai	8903783185
23P003	Deepegaa M	B.Sc Agriculture	TNDALU	7200233098
23P004	Harinishree	B.Tech LL.M	TNDALU	9566179985
23P005	Pradeepti K G	B.Pharma, M. Tech. LL.B	Central Law College Salem	9943097000
23P006	Mariya Fatima	LL.M	VIT	7667359139
23P007	S Sathesh	LL.B	Govt. Law College Madurai	9486126046
23P008	Manoj Kumar S	B.Sc. LL.B Hons.	TNDALU	8122602468
23P009	A. Anchirppa	LL.M Ph.D	Central Law College Salem	7708499399
23P010	Goutham Maiyalagan	B.Tech, PGDM	NLSIU	8939176426
23P011	P. Balamuruga	BA LL.B Hons.	TNDALU	8072125311
23P012	Viveak Balaji S	B.E	Individual	9042265770
23P013	Naveen	B.Com LL.B	TNDALU	6383955298



23P014	M.Suresh	LL.M	Govt. Law College Theni	9626751509
23P015	S. Suganya	LL.M Ph.D	VIT	8220895176
23P016	Aehahini N	LL.M	Chennai Dr Ambedkar government law college, Pudupakkam	7010453445
23P017	Treasa Louis	M.Tech LL.B		9884922855
23P018	Sharmila Banu M	B. Pharm LL.B	TNDALU	9840577521
23P019	Meyyappan Kumaran S	LL.M	TNDALU	9940409375
23P020	D Deva	LL.B	Government Law College, Chengalpet	9443000896
23P021	Radhuka. K	LL.M	TNDALU	9884620008
23P022	Anusha S	B.A Corporate Economics and LL.B	Lucas TVS Limited	9940574316
23P023	Alex Biju	BA LL.B	Lucas TVS Limited	8825426683
23P024	T K Vaishnavvi	BCA LL.B Hons.	Parasarans law office	8939402870
23P025	Mohamed Fazil M	M E	Govt. Law College Madurai	7845453338
23P026	K.Shyam Srinivasan	LL.M	TNDALU	9150209096
23P027	Dr.P.K.Devan	M.E Ph.D	R.M.K.College of Engineering & Technology	9444801774
23P028	Keerthana	B.E LL.B Hons. M.Sc		9003206080
23P029	Manasa S	BBA LL.B	TNDALU	9486951428

23P030	Vyshnavi Neelakanta Pillai	LL.M		7904383274
23P031	Sumit Rose	M.Sc., Ph.D., PGDEL(SOEL)	Presidency College	9962116469
23P032	Santhosh N	B.Tech MBA	Government Law College, Salem	9994520282
23P033	Deepikka R S	B.Tech, MBA, LLB(Hons)	TNDALU	9498003757
23P034	U R Manisha Priyadharshini	LL.B HONS.	Bharat University	7305404805
23P035	Dr T Monika	B.S.M.S, MD(SIDDHA)	Siddha Clinical Research Unit, New Delhi.	9150720984
23P036	Ragupathy	Diploma ME	Transport Department	9842294314
23P037	Harsith S	Bsc. Biochemistry	TNDALU	9500174399
23P038	Navin Afsal N	Bachelor of Engineering, pursuing LLB	Chengalpattu Government Law college	9791998510
23P039	Anstein Rone J	B Tech Chemical Engineering	Sri Venkateswara College Of Engineering	9791054180
23P040	Pramila J	Doctrate in chemistry	Government law College Chengalpattu	9962029068
23P043	J Bala Rama	M.Sc.,M.Phil	Government Law College Theni	9994963102
23P044	Monica suresh	LL.B	TNDALU	9345319820
23P045	Vignesh Pandian B	B.A.,LL.B(Hons.)	M/s. Vikram Ramakrishnan	9940203125
23P047	Jeevitha p	BBA LLB(HONS)	TNDALU	9952754475

23P048	Lavanya Narayanan	LLB Hons	SOEL	9840024265
23P049	Jaiganesh L	M.D (Siddha)		6383193787
23P050	Grace Jency Gnanammal J	PhD		9486073383
23P051	Saranya L	B.A.B.L		7812846357
23P052	Dr. Parimala D	MDS	Mahatma Gandhi Postgraduate Institute of Dental Sciences	9344376096
23P053	Mitesh Ravishankar	B. Com, L.LB (Hons)	SV&R Partners	9094813014
23P054	Rajesh Anouar Mahimaidoss	B.E, LL.B	ADVOCATE	9487409867
23P055	Palaniappan N	MCA, Ph.D.	The Gandhigram Rural Institute - Deemed to be University	9442194473
23P056	K. Madhavan	MCA., MBA., M. Phil., NET., (P.hd)	TNDALU, SOEL	9789882156
23P057	Ramakrishnan.K.R	B.TECH,LL.M	Advocate	9094260412
23P058	Gokulraj Ayyanram	bba llb	VIT Chennai	9080455376
23P059	Aarthi Rathna R	M.L.,	Soel TNDALU	9884064332
23P060	Punit Sadarangani	Post Graduate	Unilever India Exports Limited	8652318968
23P061	Suhaina Fathima S	MSc.ANALYTICAL CHEMISTRY	National College Trichy	9994702411
23P062	G Saritha Devi	MPhil Microbiology	Kemin Industries South Asia	9444528404

			Private Limited	
23P063	Swetha R S	B.A.,LL.B (HONS.), LL.M	M/S. P. Pillaivinayagam	9597596867
23P065	Dharani Devi Palanisamy	B.Tech IT	Sri Eshwar college of Engineering, Coimbatore	9488135451
23P066	D.Kesavan	B.PHARM, M.TECH,L.L.B	jagan's College of Pharmacy, Nellore	9003267777
23P067	Janani S.K	LLB Hons	TNDALU	9498349267
23P068	Udhayakumar S	Ph.D	CSIR-Central Leather Research Institute	9789825808
23P069	R Chitra Devi	LL.B	Ambedkar Government Law College, Theni	9894178259
23P070	Dinesh Kumar M			9047079392
23P071	S.Mohanasundaram			7904466565
23P072	M Kannan			9894344876
23P073	Tamizhmani T			7358316993
23P074	Shaitan Singh	BE Civil	Jai Narayan University, Jodhpur (Rajasthan )	9414672860
23P075	Dr R Deepalakshmi		TNDALU	9884440230
23P076	S.Yogeshwar	M.Sc. Bio Chemistry		
23P077	shalini.L	LL.M	TNDALU	9444728783
23P078	B. Sridevi,	LL.M	Advocate	9841622590

## **ATTENDANCE**

**PLEASE DOUBLE CLICK THE FILE BELOW TO OPEN THE  
ATTENDANCE OF PARTICIPANTS**



29.04.2023-  
ATTENDANCE .xlsx

### **VIDEO RECORDING LINKS:**

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## DETAILS OF THE RESOURCE PERSON:



**Dr. T. Ramakrishna, Professor of Law Chair Professor (IPR)** B.Sc. (1974), LL.B. (1977), LL.M. (International Law), (1979) all from Mysore University, M.A. (Political Science and Public Administration) (1984) Karnataka University, Ph.D. (Intellectual Property Rights) (2000), Mysore University. He was a Lecturer (1979-1988), Reader (1988-1994), and Professor (1995-2002) all at Vidyavardhaka Law College, Mysore and its Principal (1992-2002). He was Visiting Faculty at the Department of Post-Graduate Studies & Research in Law, Mysore University, and Karnataka Police Academy (1990-2002). He Joined the NLSIU as Professor (2002). Presently he holds the Intellectual Property Rights Chair [IPR Chair] of the Ministry of Human Resources and Development at the NLSIU, is the Coordinator of the Centre of Intellectual Property Rights Research and Advocacy [CIPRA] at the NLSIU, and the Team leader of the FSTP project. He is member of different Expert committees constituted by Indian Intellectual Property Office, National Biodiversity Authority, Protection of Plant Varieties and Farmers' Rights Authority, Copyright Office and member of Institutional Ethics Committees.



**Dr. I G Rathish**, is working as Assistant Professor, Inter University Centre for IPR Studies (IUCIPRS), CUSAT since August 2015 and is also a registered Indian Patent Agent. He teaches students of IUCIPRS along with taking coursework classes for research scholars from various departments in CUSAT. He is also entrusted with the task of facilitating filing of patents among teaching and research fraternity and sensitisation of IPRs across various academic forums. He is also the coordinator of the IPR Facilitation Cell at IUCIPRS. He holds a PhD degree in Chemistry, with 11 research publications in peer reviewed journals. A compound developed by him reached advanced stages of testing against cancer cell lines at National Cancer Institute, U.S.A. He has 6 research scholars working in the area of IPR under his guidance for a PhD degree. He is an Expert Committee Member (IPR) of Kerala State Biodiversity Board (KSBB) thematic expert Committee and patent facilitator for Startups - Scheme for Facilitating Startups Intellectual Property (SIPP) under Govt. of India. He has drafted and filed 15 patent applications in India including two international patent applications. Specialized in the area of

patent filing and related matters, he was also instrumental in propelling the invalidation of key patents of rival pharmaceutical companies at various Judicial and quasi-judicial forums. Prior to joining CUSAT, he has worked for around 7 years in a couple of reputed MNC Pharmaceutical companies in R&D and Patents Department respectively.



**Dr. S.P. Subramaniyan**, Deputy Controller of Patents & Designs, Patent Office (Southern Region), M.Sc (Organic Chemistry); Ph.D (Pharmaceutical science), Worked as Government Analyst for 7 years in Central Drugs Laboratory, Min. of Health & Family Welfare, Kolkatta and then 2 years as quality control Officer for Agricultural Produce in the Min. of Agricultural and Co-operation. For the past 22 years working in the Patent Office, Chennai, Min. of Commerce & Industry in various capacities, the work involves to grant a patent for the

chemical and pharmaceutical patent applications filed in India. Adjudicated many pre-grant, post-grant oppositions and patentability related matters of pharmaceutical related patents as a Quasi-Judicial Authority and issued many decisions, which are submitted and referred in many higher Courts. An anti-cancer drug GLEEVEC, HIV drug VALCYTE etc are refused in India even though it was granted more than 40 countries. Undergone training in Japanese Patent Office, Tokyo on intellectual property rights. One of the members to attend the UN council, Standing Committee on Patents to negotiate various matters pertaining to patents on behalf of India. Member of Patent Expert and panel expert in some Universities and Institutes.



**Dr. Athira P.S** was awarded PhD in Law from the Department of Law, University of Kerala, for her doctoral thesis on "Stem Cell Research: Legal Dimensions". She completed her LL.M. in Constitutional and Administrative Law on merit scholarship, securing First Rank with Distinction from the Department of Law, University of Kerala and her LL.B with Second Rank from the University of Kerala. She was awarded the Sachivothama Shashtiabdapurthi Memorial Prize Gold Medal, Justice Muthunayagom Memorial Prize, Justice T Krishnan Nair Memorial Gold Medal Endowment, Justice M. Fathima Beevi Endowment and Malloor K. Govinda Pillai Gold Medal for Law from the University of Kerala. She has been an invited speaker and delegate in many international forums such as the International Research Conference held under the aegis of the National University of Singapore and the 49th Asia-Pacific Academic Consortium for Public

Health Conference (APACPH) 2017, held in Yonsei University International Campus, Korea. She has to her credit many publications in reputed International and National Law Journals. She has participated as resource person in training programmes as well as international and national seminars conducted by organizers such as the Institute for Shipboard Education and University of Virginia, Ministry of Electronics and Information Technology, Vellore Institute of Technology School of Law, Department of Law, University of Kerala, School of Legal Studies, CUSAT among others. She has also presented peer-reviewed papers in international and national seminars and has attended UGC refresher courses and several faculty development programmes. She had participated in moot courts during her graduation and won prizes for presentation as well as memorials in international and national Moot court competitions. During her tenure in NUALS, she has organized many academic programmes including international and national seminars, workshops, essay competitions, IP-specific talk shows etc, as the Director of the Centre for Intellectual Property Rights. Even prior to that she had organized the first of its kind national seminar in Kerala, on the legal status and rights of sexual minorities. She is a member of the NUALS Research Committee and is a Research Guide in the University. She is a member of the UG Board of Studies, and also been in the organizing committees of many institutional programmes such as Annual Convocations and Moot Court Competitions. As the Faculty-in-charge of Alumni NUALS, she had organized the First Alumni Meet of the University in November, 2017. Her areas of interest include Intellectual Property Law, Health and Bioethics, and Equality of Rights.



**Dr Yogesh Pai** specializes in intellectual property (IP) law and has research interests at the interface of IP with competition, trade and economic policy. He is currently the Co-Director of Centre for Innovation, Intellectual Property and Competition (CIIPC) at National Law University Delhi. He is also in-charge of the IPR Chair at NLU Delhi established by the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India. Yogesh is currently a scholar at CIP2, George Mason University, Washington D.C., where he was previously the Thomas Edison

Fellow (2017-18). In the fall of 2012, Yogesh visited the School of Law, University of Washington as the Asian Law Centre short-term Visiting Scholar. Yogesh served on the roster of consultants with the World Trade Organisation as a regional expert for Regional Trade Policy Courses (RTPC) and a Tutor with the WIPO Academy Distance Learning Programme. Yogesh is



on the Editorial Board of the WIPO-WTO Teachers Colloquium Annual Research Papers. In 2013, Yogesh was nominated as a legal member in a committee constituted by the Ministry of Health, Government of India, for invoking provisions of compulsory licensing under the Patents Act, 1970, in the context of affordable healthcare. Yogesh was also the member of an expert committee constituted by the Ministry of Commerce to study the need for utility models in India (2013). He was also part of the Committee for Evaluation and Continuation of the Scheme of Promotion of Copyright and IPR Beyond the 12th Five Year Plan (2012- 2017) constituted by the DIPP, Ministry of Commerce. Yogesh has submitted his PhD with the Inter-University Centre for IPR Studies, CUSAT, Kochi in the area of Standard-Essential Patents in India.



**Dr. M. Sakthivel** Assistant Professor of Law at Guru Govind Singh Indraprastha University, New Delhi, Graduated in Law, The Tamil Nadu Dr. Ambedkar Law University, Chennai . He completed his Post Graduation with specialization in IPR and Environmental Law, School of Legal Studies, CUSAT, Kerala and conferred with doctoral degree from the IUCIPRS, CUSAT, His book titled “Broadcasters Rights in the Digital Era: Copyright Concerns on Life Streaming” has been published by BRILL - NIJHOFF in 2020. He is the recipient of the Young Asian IP Scholar Award from the Singapore Management University. He was the visiting faculty of Indian Law Institute, New Delhi and currently visiting faculty at National Institute of Criminology and Forensic Science, Rohini, New Delhi.



**Mr. A K Rajaraman**, graduate from Cochin University of Science and Technology specialized in Intellectual Property Laws. Attached with Mr. A.A.Mohan Associates as Associate Lawyer for 3 year from 2008-2011 and started to look after cases independently since 2011. Presently practicing on his own with core focus on Property laws, Trademark, Copyright and Patent related issues ranging from registration to litigation. At High Court of Madras, I have been appearing before writ courts, original side, appellate side etc. Also handling cases at National Company Law Tribunal and Debt Recovery Tribunal. Took part in various litigation and regularly handling IP related cases before all forums including Trademark Registry, Patent office, Intellectual Property Appellate Tribunal, High Court and Various District Courts. IP consultant for (Sakshi TV, Narayani Research Institute, Odessey Technologies P. Ltd Barat Building Construction P Ltd Vummidi Enterprise), etc. and Board Member – Peer Review Group of

International Journal of Law and Social Sciences. And also handling tax related cases before Madras High Court for KPMG India (Audit firm) And guest lecturer at Pondicherry University.



**Dr Kavitha Chalakkal** is currently an Assistant Professor in Inter University Centre for IPR Studies, CUSAT. She had worked formally as Assistant Director (Research) and Assistant Professor (Senior Grade) in Lloyd Law College. She has an experience of more than 8 years in academics and in national and international non-governmental sector. Dr. Chalakkal received her PhD (2014) in International Environmental Law from the Jawaharlal Nehru University, New Delhi, after completing her L.L.M. in Intellectual Property and Environmental Law (2006; Cochin University of Science and Technology, Kerala) and M.Phil. in Public International Law (2008; Jawaharlal Nehru University). She received her bachelor degree (L.L.B.) from Kerala University in 2003. Before starting her career in academics, Dr. Chalakkal worked with various non-government organizations. Dr. Chalakkal has also developed study modules (2016) for Post-Graduate Courses for the e-Pathshala project of the Ministry of Human Resources Development, Government of India. Dr. Chalakkal has many publications and presented papers in various international and national conferences. She has also won best paper and presenter awards in two international conferences. She is a member of the World Commission on Protected Areas and World Commission on Environmental Law, International Union for Conservation of Nature (IUCN). Dr. Chalakkal was the Fox Foundation Fellow (2009-10), Yale University, USA and is also a Research Fellow (2018), China-South Asia Legal Research Center, China Law Society.



**Dr. Asha R** is working as Research Officer at the IPR facilitation cell of Inter University Centre for IPR Studies (IUCIPRS), CUSAT since July 2018. Did BSc and MSc in Chemistry from Kerala University and PhD from Rajiv Gandhi Centre for Biotechnology Trivandrum Kerala with CSIR fellowship. She has 7 research publications in international peer reviewed journals on the topic antimicrobial peptides and presented papers in various national and international conferences. She is also qualified DST women scientist C and also a recipient of DBT travel grant. Being registered Indian patent agent she is currently engaged in facilitating patent searching, filing and drafting. Resource person in many IPR webinars and associated with various national and international bodies in IP related matters.



**Ms. Arathi Ashok** Currently employed as Assistant Professor in IPR at the School of Legal Studies, Cochin University of Science and Technology, Kochi, India. Previously has worked as Research Officer with the MHRD Chair on IPR established by the Government of India at Cochin University of Science and Technology from February 2013 to August 2014 and Assistant Professor and Faculty of IPR at Hidayatullah National Law University, Raipur, from July 2010 to November 2012. Completed LL.M. with second rank from Cochin University of Science and Technology, Kochi, in 2010 with specializations in Intellectual Property Laws and Labour Laws and LL.B. from M.G. University in 2008. Recipient of (1) Dr. V. Kesavankutty Memorial Gold Medal and Certificate of Merit for securing Second Rank in LL.M. Examination for the year 2010 (2) Adv. M. M. Cherian Memorial Gold Medal and Certificate of Merit for securing highest mark in Labour Law in LL.M. Examination for the year 2010, and (3) Certificate of Merit for excellent performance in LL.M. Examination 2010 by Sarada Krishna Satgamaya Foundation for Law and Justice [Formerly Justice V.R. Krishna Iyer Foundation for Law and Justice]. Published articles with various national and international publishers including Springer and acted as Resource person and presented papers at various national and international venues including Singapore Management University. Has completed various on-line courses from foreign Universities and Institutions like World Intellectual Property Organisation (WIPO), the University of Edinburgh, The Hong Kong University of Science and Technology, etc.



**Mr. M. Mahindra Prabu**, Assistant Professor in Tamil Nadu National Law School, Trichy University Rank Holder in B.A.B.L & M.L Courses respectively. Awarded Honourable Justice P.A. Bhagawathi Endowment Gold Medal in the subject of Human Rights and International Law [B.A.B.L]. Awarded Honourable Justice Ramaswamy Memorial Award for Best Outgoing Student [B.A.B.L]. He started his academic career as a Guest Faculty in School of Excellence in Law, Chennai. He also worked as Project Associate in MHRD IPR Chair, IIT Madras. His areas of interests are Property Law, Intellectual Property Law and International Law.



**Dr. Sudhir Kochhar**, Ph.D. (Plant Breeding), Ex-ARS, Former ADG (IPR) and National Coordinator (NAIP/ICAR) has diverse experience in ICAR of over 40 years in agricultural research, coordination and policy perspective; in-plant breeding, plant genetic resources and IPR management; All India research coordination of under-utilized crops, and consortia-based basic and strategic research financed under National Agricultural Innovation Project (NAIP). Dr. Kochhar is highly trained, and acclaimed resource person in the fields of: IPRs in agriculture and plant varieties, agro-biodiversity and plant genetic resources policy and processes. He is trained in Parliamentary Processes and Procedures, and also as UPOV Trainers' Trainer. He made salient/ key backstop contribution in the enactment/ amendment of The PPV&FR Bill, 1999, The Biodiversity Bill, 2000, and The Patents (Amendment) Acts, 1999, 2002, 2005 besides the Mauritian Plant Act, 1976 and GMO Bill, 2002 (on deputation), and the ICAR's IPR & Tech Transfer management guidelines 2006. Dr. Kochhar headed IPR Unit ICAR briefly in its foundation stage as Assistant Director General (IPR), and was Member, NBA's Committee on Agro-biodiversity as Amicus curiae for over nine years.



தமிழ்நாடு டாக்டர் அம்பேத்கர் சட்டப் பல்கலைக்கழகம்  
The Tamilnadu Dr. Ambedkar Law University



# **COURSE MATERIAL – PART I**

## **ONLINE CERTIFICATE COURSE ON PATENT LAW: POLICY AND GOVERNANCE**

**COMPILED BY:**

**ORGANISING COMMITTEE**

**TAMIL NADU Dr. AMBEDKAR LAW UNIVERSITY**

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## LIST OF CASE LAWS

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16.	Graham v. John Deere Co.,	383 US 1 (1966)
17.	Sankalp Rehabilitation Trust v. Hoffmann–Roche	OA/8/2009/PT/CH
18.	Enercon (India) Limited v. Alloys Wobben	IPAB order no. 174 (2013)

## HISTORY OF INDIAN PATENT LAW

The history of intellectual property system in India can be traced back to 1856. The first legislation on the subject was Act VI of 1856 regarding protection of inventions based on the British Patent law of 1856. As per this legislation, a system was introduced in India, in the form of grant of certain privileges to an inventor of new manufacture for a period of 14 years. The Act was re-enacted with some modifications as the Act XV of 1859 in which patent monopolies were called '*Exclusive Privileges*'. According to this legislation, an inventor of a new manufacture, by filing a specification disclosing the invention, could obtain the '*Exclusive Privileges*' of making, selling, and using the invention in India and authorising others to do so for the term of 14 years from the date of filing of such a specification. In 1872 the Patents & Designs Protection Act was passed which was followed by Protection of Inventions Act of 1883. These Acts were consolidated as Inventions & Designs Act 1888. Subsequently, the Act 1888 was replaced by the Indian Patents & Designs Act 1911 (IPD ACT 1911) which established for the first time, in India, a combined system of patent and design protection under the management of Controller of Patents & Designs. The IPD Act 1911 was in force when India attained independence on 15th August 1947.

The socio-political and economic changes brought about in the country required a new set of laws for patents. The aim was to ensure that patents are not worked to the detriment of the consumer or to the prejudice of the industrial development in India.

### **I. Tek Chand Committee**

In 1948, the Government appointed a Patents Enquiry Committee under the chairmanship of Dr. Bakshi Tek Chand, a retired judge of the Lahore High Court to review the working of the IPD Act 1911 and to see whether the Indian patent system was in line with national interests. The final report of the Committee was submitted in 1950. The recommendations of the Committee were largely modelled on the Patents Act 1949 of United Kingdom. The Patents Bill was introduced in the Lok Sabha on 7 December, 1953 and the bill lapsed with the dissolution of the first Lok Sabha.

### **II. Rajagopala Iyengar Committee**

A fresh attempt was made by the government in 1957 when another committee was appointed under the chairmanship of Justice N. Rajagopala Ayyangar to study and recommend changes



to the patent law in India.<sup>1</sup> Both the Tek Chand Committee and the Ayyangar Committee found that a vast majority of Indian patents were held by foreigners and most of them were not worked in India. The Ayyangar Committee recommended the retention of the patent system despite its shortcomings. The recommendations of the Ayyangar Committee, particularly the recommendations on patents for food, medicine or drug along with few other changes were introduced as the Patents Bill 1965 on 21 September 1965. A Joint Parliamentary Committee studied the Bill and submitted its report along with certain amendments to the Lok Sabha on 1 November 1966. Though the amended Bill was moved in the Lok Sabha on 5 December 1966, it lapsed with the dissolution of the third Lok Sabha on 3 March 1967. The Patents Bill was again introduced in 1967 with certain amendments. This time around, both the Houses of the Parliament passed the Bill and it received the Presidential assent on 19 September 1970. The Patent Rules were published in November 1971. The Act and the Rules came into force on 20 April 1972.

### **III. Patents Act, 1970**

The Act brought about the abolition of product patents for food, medicine or drug which was earlier granted under the IPD Act 1911. For the first time, the Patents Act brought about the distinction between process and product patents for pharmaceutical substances. The Act also contains a long list of inventions which are not patentable. The Repealing and Amending Act 1974 and the Delegated Legislation Provisions (Amendment) Act 1985 brought about certain changes to the existing law. The Act has so far seen three major amendments, all of which were done as a part of the exercise to conform the Indian patent laws to the obligations under the TRIPS Agreement of the WTO.<sup>2</sup>

#### **a) Patents (Amendment) Act, 1999**

India was obliged to introduce product patents for pharmaceutical substances under the TRIPS Agreement. The TRIPS Agreement, however, provided for a 10-year transition period for developing countries that were in the process of extending product patent protection to areas of technology not capable of protection in its territory. As India did not provide for product patents for pharmaceutical substances, it availed of the transition period which ended on 31 December 2004.

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<sup>1</sup> Justice N Rajagopala Ayyangar, 'Report on the Revision of the Patent Laws', September 1959.

<sup>2</sup> Arts. 27 to 34, TRIPS Agreement.

The TRIPS Agreement required the countries under transition to provide for a means by which patent applications for pharmaceutical and agricultural chemical products can be filed. This was popularly called the 'mail-box' or the 'black-box' system. This system of entertaining applications was based on the patentability criteria as laid down in the TRIPS Agreement as applied on the date of filing in India, or where priority is available and is claimed, on the priority date of the application. The applications filed through the 'mail-box' were to be processed by the Indian Patent Office only after the expiry of the 10-year transition period which came to an end on 31 December 2004.

The TRIPS Agreement also provided for another interim arrangement consequent to the application of product patents for pharmaceuticals made through the 'mail-box'. In case of an application for product patent has been made under art. 70(8)(a) of the TRIPS Agreement, Exclusive Marketing Rights (EMR) shall be granted for a period of five years subject to certain conditions. The protection available under EMR was very similar to the one extended by a product patent. India was expected to have the mail-box system and EMR in place from the date on which the TRIPS Agreement came into force, i.e., 1 January 1995. Thus, the effect of the 10-year transition period which exempted India from implementing product patents was nullified by the introduction of EMR, as art. 70(9) which introduced EMR with immediate effect clearly stipulates that it shall prevail over art. 65 which grants the 10-year transition period. As a result, India could not enjoy the benefits of the transition period.

India delayed the implementation of the above two measures till March 1999. These measures were introduced only after United States lodged a complaint against India before the Dispute Settlement Body of the WTO. The Patents (Amendment) Act 1999 introduced provisions for 'mail-box' applications and EMR with retrospective effect from 1 January 1995.

#### **b) Patents (Amendment) Act, 2002**

The Patents (Amendment) Act 2002, passed on 25 June 2002 was a further step in conforming Indian patent laws to the obligations under the TRIPS Agreement. The Patents (Amendment) Act 2002 and the Patents Rules 2003 came into force on 20 May 2003. The changes introduced by the amendment Act includes:

- i.** uniform patent term of 20 years from the date of application;

- ii. provision for publication of application after 18 months whether or not the application is accepted;
- iii. provision for third parties to obtain marketing approval from regulatory authorities within three years before the expiration of the patent term;
- iv. provision for increased penalty for unauthorised claim of patent right and for refusal or failure to supply information;
- v. provision for appeals against the order of Controller and Central Government and application for rectification of register of patents to the Intellectual Property Appellate Board;
- vi. provision for filing international application under PCT simultaneously with an application filed before the Controller in India; and
- vii. provision for protection of bio-diversities and of traditional knowledge.

**c) Patents (Amendment) Act, 2005**

The Patents Bill 2003 was introduced to bring about the third conforming amendment to the Patents Act. The Bill however lapsed after its introduction in the Rajya Sabha on 22 December 2003. As the deadline for complying with the TRIPS Agreement was nearing, the Government introduced the Patents Ordinance 2004 on 26 December 2004. The ordinance was, by and large, an improvement on the Patents Amendment Bill 2003. The ordinance was succeeded by the Patents Amendment Bill 2005 which was introduced in the Lok Sabha and the Rajya Sabha on 22 March 2005 and 23 March 2005 respectively. The Amendment Act of 2005 came into force with retrospective effect from 1 January 2005. The salient features of the Amendment include:

- i. the omission of section 5 and the consequent introduction of product patents for pharmaceutical substances;
- ii. the omission of chapter IV A dealing with EMR;
- iii. provisions for acceptance of complete specification and advertisement of the same stand omitted;
- iv. provision for publication of the application of patent was introduced, opposition can be made at the time of publication on the same ground on which the grant of patent can be opposed and opposition can be made within 12 months after the grant of patent;

- v. prior written permission of the Controller required for a resident of India to apply for any patent in a foreign country;
- vi. though registration of assignments is still required, the assignment of patent shall be valid even if it is not registered;
- vii. provision for sealing of patent has been omitted and no suit for infringement can be instituted before the date of publication of application; and
- viii. advertisements and notifications in the Official Gazette replaced by publication in the Official Journal.

## PATENTABLE SUBJECT MATTER

For the grant of a patent in India, certain essential conditions stipulated under the Patents Act have to be satisfied. These are:

- i. An application for a patent should be made at the Patent Office;
- ii. Any person, whether an Indian or a foreigner, whether an individual, company or the government, may apply for a patent provided that such person is the ‘true and first inventor’ of the invention or his assignee or the legal representative of a person entitled to apply under the Patents Act<sup>3</sup>;
- iii. Such an application can be made either be made separately or jointly by the aforementioned persons and the application should disclose the ‘best method’ of performing the invention known to the applicant for which he is entitled to claim protection<sup>4</sup>;
- iv. The application should also define the scope of the invention in the claim<sup>5</sup>;
- v. The invention, as disclosed in the application, should satisfy the three prerequisites - the invention must be new, should involve an inventive step, and must be capable of industrial application<sup>6</sup>; and
- vi. Additionally, the invention should not be an invention excluded under section 3 and 4 of the Patents Act.

### **I. Invention under Patents Act, 1970**

Section 2(1)(j) defines an invention as a new product or process involving an inventive step and capable of industrial application. A ‘new invention’ refers to an invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with the complete specification. In other words, the subject matter has not fallen in public domain or that it does not form part of the state of the art.<sup>7</sup>

‘Invention’ includes both products and processes. In the case of a product patent, the article or apparatus itself, which is the end product, qualifies for a patent protection. In the case of

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<sup>3</sup> Section 6, Patents Act, 1970.

<sup>4</sup> Section 10 (4)(b), Patents Act, 1970.

<sup>5</sup> Section 10 (4)(c), Patents Act, 1970.

<sup>6</sup> Section 2(1)(j), Patents Act, 1970.

<sup>7</sup> Section 2(1)(l), Patents Act, 1970.

process patent, the patent protection is limited to a particular process through which the end product is attained. Anything that is in the knowledge of the public or is disclosed to the public cannot be regarded as an invention under the Act. An invention need not be a complicated advancement in technology. Even a simple invention, so long as it is novel or new, would be an invention. An improvement can also be an invention.

## **II. Improvement as Inventions**

It is normally expected that the patentee would specify in the specification the distinguishing features of his application which improve upon the existing level of knowledge and show how such an improvement will constitute an invention. The definition of the term ‘invention’ does not expressly include an improvement or a modification.<sup>8</sup> However, the Patents Act covers improvements that amount to a patentable invention. To qualify as an invention, an improvement must by itself satisfy the test of patentability. An improvement or modification of an earlier patent may qualify for a patent as a patent of addition.<sup>9</sup> Mere workshop improvements, devoid of ingenuity, will not qualify for a patent. But, there appears to be no clear principle to differentiate a workshop improvement from a patentable improvement. Superior utility, comparative excellence, efficient production and qualitative improvement of the product should be taken into account in determining whether an improvement amounts to a patentable invention.

## **III. Inventions not Patentable**

Apart from satisfying the three prerequisites of novelty, inventive step and industrial application, to qualify for a patent, an invention should not be excluded from the categories mentioned in sections 3 and 4. These sections contain a list of inventions that are not patentable. They are listed below:

<b>S. No.</b>	<b>Exceptions</b>	<b>Section</b>
1.	Frivolous inventions and inventions contrary to natural laws	3(a)
2.	Inventions contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment	3(b)
3.	Discovery not an invention	3(c)
4.	Inventions related to known substances etc.	3(d)

<sup>8</sup> The definition of invention under the Indian Patents and Designs Act 1911 did include an improvement.

<sup>9</sup> Section 54, Patents Act, 1970.

5.	Inventions pertaining to mere admixture	3(e)
6.	Inventions pertaining to mere arrangement, re-arrangement or duplication	3(f)
7.	Method of agriculture or horticulture	3(h)
8.	Methods of medical treatment of humans and animals	3(i)
9.	Plant and animal varieties	3(j)
10.	Business method, computer programme per se etc.	3(k)
11.	Literary, dramatic, musical or artistic work etc.	3(l)
12.	Scheme or rule	3(m)
13.	Presentation of information	3(n)
14.	Topography of integral circuits	3(o)
15.	Traditional knowledge	3(p)
16.	Inventions relating to atomic energy	4

**i. Section 3(a)**

Any invention which is frivolous or which claims anything obviously contrary to well established natural laws is not patentable. A patent involving a revolutionary concept will not be entertained if the person of average skill in the art would not be able to fill in the missing details from his own knowledge or following reasonable trial and error.

**Example:**

- 1) Different types of perpetual motion machines alleged to give output without any input. This is against established natural law.
- 2) Machine/devices which violate the third law of thermodynamics.

**ii. Section 3(b)**

Inventions whose primary or intended use or commercial exploitation is contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment are not patentable. The phrase ‘serious prejudice to human, animal or plant life or health or to the environment’ was introduced to accommodate and clarify the expanding meaning of the words ‘public order or morality’. The jurisprudence of the European Patent Office in interpreting the scope and meaning of the words ‘public order or

morality' will be relevant as the above provision is similar to art 53(a) of the European Patent Convention.

In the *Harvard Onco-mouse* case<sup>10</sup>, the invention involved a provision of a type of test animal useful in cancer research, which helped in a reduction in the amount of testing on animals. The case involved conflicting issues pertaining to the basic interest of mankind to remedy widespread and dangerous diseases on one hand, and the protection of environment against the uncontrolled dissemination of unwanted genes and cruelty to animals on the other hand. The Examining Division held that the invention was useful in developing new and improved human anti-cancer treatments for the benefit of mankind, and concluded that the invention could not be considered as immoral or contrary to public order.

**Example:**

- 1) A process for the preparation of a beverage by the incorporation of a substance which is likely and/or will cause cancer but also increases the nourishment value of the beverage.
- 2) A product that causes pollution to atmosphere.

**iii. Section 3(c)**

Generally an idea or a discovery cannot be a subject matter of a patent. A practical application of an idea or a discovery can, however, qualify for a patent. A method of identifying diamonds by means of photographic records of their X-ray diffraction patterns (topograms) was held to be a patentable invention.<sup>11</sup> Thus, mere discoveries or ideas cannot be the subject matter of a patent, but discoveries or ideas which have a technical aspect or make a technical contribution will be patentable. Further, a discovery of any living or non-living thing occurring in nature could not qualify for a patent protection.

**Example:**

- 1) Raman effect
- 2) Saha equation
- 3) a plant like neem

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<sup>10</sup> T19/90 Harvard/Onco-mouse, [1991] EPOR 525 (Exam Div).

<sup>11</sup> De Beers Consolidated Mines Ltd's Application, [1979] FSR 72 (CA).



#### **iv. Section 3(d)**

Section 3(d) includes a category of inventions pertaining to known substances and known processes that are not patentable. The mere discovery of a new form of a known substance which does not enhance the known efficacy of that substance is not patentable. Similarly, the mere discovery of any new property or new use for a known substance or of a mere use of a known process, machine or apparatus, unless such known process results in a new product or employs at least one new reactant, shall not be a subject matter of a patent. The above provision will prohibit the filing of Swiss claims under the Patents Act. A detailed explanation of this section will be given under chapter relating to pharmaceutical patents.

**Example:** Finding a new property or a new use of known turmeric powder as an agent for treating AIDS.

#### **v. Section 3(e)**

Any substance obtained by a mere admixture cannot be regarded as an invention if it results only in the aggregation of the properties of the components. Similarly, a process for producing such a substance shall not be regarded as an invention. A mixture of different kinds of medicines, forming a cocktail of drugs, to cure multiple diseases will not be a patentable invention. For instance, a composition of two drugs, i.e., Paracetamol (Acetaminophen) and Ibuprofen for curing fever and pain or a process of preparation thereof, will not be patentable as the composition is a mere admixture of two drug components resulting in an aggregation of analgesic and anti-inflammatory actions of their respective components. But a distinction has been drawn with regard to admixture resulting in synergistic properties. The Patent Office does not consider an admixture which results in unexpected results or synergistic properties as a 'mere' admixture and may regard such mixtures to be patentable.<sup>12</sup>

#### **Example:**

- 1) A detergent composition consisting of a known active ingredient and a carrier wherein the carrier does not possess any activity (inert) and does not play any part in the activity of the composition is not patentable even if the active ingredient used is new.

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<sup>12</sup> Manual for Patent Office Practice and Procedure, Patent Office.

- 2) Slow release pharmaceutical compositions (tablets) in which the carrier employed releases the active ingredient in a particular environment ( i.e., synergistic action of the carrier on the active ingredient) is patentable.

**vi. Section 3(f)**

A mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way cannot be the subject matter of a patent. A mere collocation will not qualify as an inventive step.<sup>13</sup>

**a) Workshop Improvements**

A workshop improvement is a normal development of an existing manner of manufacture which does not involve anything novel to be outside the probable capacity of a person skilled in the art. To qualify as a patentable invention, an improvement on something known before or a combination of different matters already known should be something more than a mere workshop improvement, and must independently satisfy the test of invention. For an improvement to be patentable, it must yield a new result or a new article hitherto unknown. It is possible for a combination of old, known integers to be combined in such a manner that by their working they produce a new process or improved result. The Supreme Court has held that the mere collection of more than one integers or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent.<sup>14</sup>

**Example:** An umbrella comprising an electric motor having a fan propeller fitted on its shaft and housed at the top of the umbrella arranged to blow air downwardly and electric supply means for the electric motor. In substance, the said umbrella consists of a combination of two parts namely, umbrella and electric motor having a propeller fitted to the shaft. The electric motor is mounted at the upper end of the umbrella. The umbrella and the electric motor shaft are well known devices. As for their functioning, both these known devices function in their usual known way quite independently of each other. Accordingly, the combination does not have any inventive step and is not a patentable invention under this provision of the Act.

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<sup>13</sup> Sabaf SPA v. MFI Furniture Centres Ltd, (2005) RPC 10 (HL).

<sup>14</sup> Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries, AIR 1982 SC 1444.

**vii. Section 3(h)**

A method of agriculture or horticulture cannot be the subject matter of a patent under the Patents Act.

**Example:**

- 1) A method of spraying insecticides on a field to prevent insects from harming the plants.
- 2) A method of watering plants.
- 3) A method of watering plants.

**viii. Section 3(i)**

Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free from disease or to increase their economic value cannot be a subject matter of patent.

**Example:**

- 1) A process for treatment of human being suffering from malignant tumour by conducting an operation to remove the tumour.
- 2) A method of reducing gastric secretions in a mammal by the systematic administration of certain compounds into the mammals.
- 3) A method of treatment for reducing dental plaque in the mouth of a human being by administering a drug to the patient.

**ix. Section 3(j)**

Plants and animals, in whole or in their parts, are excluded from patent protection. Seeds, varieties and species are also included under this section. The section also excludes 'essentially biological processes'. However, micro-organisms can be a patentable invention. Plant varieties are protected by a sui generis system under the Protection of Plant Varieties and Farmers' Right Act 2001. A detailed explanation of this section will be given under chapter relating to biotechnology patents.

**Example:**

- 1) A new plant or an improvement of an existing plant.
- 2) New Seeds or improved seeds.

**x. Section 3(k)**

A mathematical or business method or a computer program per se or algorithms is not patentable under the Patents Act. In India, patent protection is not afforded to business methods and computer programs though art 27 of the TRIPS Agreement does not exclude them from patentability. Computer programs are excluded from patent protection as they are protected as a literary work under the Copyright Act, 1957. Though patent for a computer program per se is not patentable, a claim expressed as a computer arranged to produce a particular result and computer programmes which have the effect of controlling computers to operate in a particular way may be the subject matter of a patent. The prevailing view is that where the subject matter as claimed makes a technical contribution to the known art, the patentability should not be denied merely on the ground that a computer program was involved in its implementation. A detailed explanation of this section will be given under chapter relating to software patents.

**Example:**

- 1) Computer software *per se*
- 2) A hardware incorporating a software
- 3) Mathematical algorithms

**xi. Section 3(l)**

Matters which are subject matters of copyright protection cannot be the subject matter of a patent. A copyright infringement action may be clubbed along with a suit for infringement of a patent if both the issues flow from a common set of actions.<sup>15</sup>

**Example:**

- 1) A text book on History
- 2) A text book on computer learning

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<sup>15</sup> Gandhimati Appliances Ltd v. LG Varadaraju (2000) 3 MLJ 85 (DB).

**xii. Section 3(m)**

A mere scheme or rule or method of performing mental act or method of playing game cannot be patentable. An invention may lie in an idea or in the way in which the idea is carried out or both. Such an idea must either suggest a new way of making something or it should show a new way of producing a new article.

**Example:**

- 1) An indoor game
- 2) Rules for playing an indoor game

**xiii. Section 3(n)**

The Act excludes a presentation of information from the ambit of patent protection. Therefore section 3(n) will include both novelty in information and novel methods of presenting information.

**Example:** Presentation of a paper through power point

**xiv. Section 3(o)**

Topography of integrated circuits cannot be the subject matter of a patent protection. Topographies or lay-out designs of integrated circuits are governed by the Semiconductor Integrated Circuits Layout-Design Act, 2000.

**Example:** Three dimensional configuration of an electronic circuit used in microchip / semiconductor chip.

**xv. Section 3(p)**

An invention which is a part of traditional knowledge cannot be the subject matter of a patent. Similarly, an aggregation or duplication of known properties of traditionally known component or components is also excluded from patent protection. An invention based on traditional knowledge may be opposed or revoked under the Patents Act on the ground that the invention is anticipated.<sup>16</sup>

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<sup>16</sup> Section 25(1)(k) and 64(1)(q), Patents Act, 1970

**Example:**

- 1) New use of turmeric powder
- 2) Basmati rice

**xvi. Section 4**

Section 4 prohibits the grant of patents for inventions relating to atomic energy. It is widely accepted that countries can provide for security exceptions for the protection of essential security interests relating to fissionable material. Even if a patent is granted for an invention relating to atomic energy, the same may be revoked under section 65 of the Patents Act. The provision relating to atomic energy inventions are contained in section 20 of the Atomic Energy Act, 1962.

**Example:**

- 1) Nuclear reactors
- 2) Uranium, Plutonium etc.

# PATENTABILITY CRITERIA

## I. NOVELTY

Novelty of an invention is a fundamental requirement for securing a patent. It must be noted that novelty is not something which can be proved or established; only its absence can be proved or established. Once the subject-matter (invention) in question is not statutorily prohibited from patenting, the next question to be considered is whether the subject matter is novel, non-obvious and has utility. The novelty is determined considering the knowledge available anywhere in the world on the date of filing the application for patent for the invention. The determination of novelty of an invention strictly consists of consideration two aspects - the invention claimed for protection and the prior art information available in the concerned field.

### A. Understanding 'state of the art'

In the absence of a statutory explanation of the expression 'state of the art', despite its introduction into the Patents Act by the Patents (Amendment) Act, 2005, it would be beneficial to see how state of art has been understood in the United Kingdom and European Union. Section 2(2) of the UK Patents Act, 1977 defines the constituents of the state of the art as:

The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way.

The definition in art. 54(2) of the EPC is given below:

The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.

An invention is considered to be new if it is not anticipated by prior art. Prior art simply denotes the total comprehensive knowledge that existed prior to the filing of or priority date of a patent application on the relevant subject. The knowledge of an invention in order to be considered as relevant prior art should satisfy any one or more of the following:

- i. By the description of the invention in a published writing or document or in any other tangible form – Prior Publication
- ii. By description of the invention in spoken words uttered in public, such a disclosure is known as oral disclosure – Prior Public Disclosure
- iii. By the use of the invention in public or by putting the public in a position where any member of the public may access to it – Prior Public Use

## **B. Prior Publication**

Prior publication usually refers to publication in any document made anywhere in the world. Section 64(1)(e) expressly refers to ‘documents referred to in section 13’ for determining the state of the art. Publication implies that something that is published is ‘made available to the public’. As a prior publication includes a publication made in India or elsewhere, it would include documents in foreign language published in a foreign country.

### **i. Mosaic of Publications**

The documents must be read on their own merit and it would not be appropriate to join together a number of documents, the combined reading of which will produce the effect of anticipation of an invention. Proving anticipation is not like solving a jigsaw puzzle where a person may collect a variety of information and try them out in different possibilities to make sense. Rather, the disclosure should be clear, specific and unambiguous. A mosaic of extracts taken from various annuals and treatises spread over a number of years cannot be used for proving anticipation. But a group of papers, containing cross-references to each other, making a series of disclosure, will not be regarded as a mosaic of extracts and may be used for proving anticipation. However, in the case of determining obviousness, unlike novelty, it is permissible to make a ‘mosaic’ out of the relevant documents, if such a mosaic can be put together by an unimaginative man with no inventive capacity.

### **ii. Notional Skilled Addressee**

Identifying the information conveyed by the document will be as important as identifying the document itself. The document will be seen through the eyes of a notional skilled addressee who has common general knowledge of a particular art. The notional skilled addressee is a person who represents the public. Being a notional entity, the skilled addressee may also be a team of men who possess technical knowledge and all the relevant arts to fully understand the



import of the document. The skilled reader may require the language of the publication to be translated to him. He may also require the meaning of technical terms or unfamiliar ideas to be ascertained from a scientist. But once he has got this, he must be able to make the product from what is disclosed by the prior publication.

### **C. Prior Public Disclosure**

An invention may be publicly known by oral disclosure or by written disclosure. An invention can become 'publicly known' by a prior oral disclosure if the information about the invention was communicated to any member of the public who was free in law and equity to use it as he pleased. Even the sale of a single unit of an invention will amount to disclosure if the purchaser was free in equity and law to use it as he liked.

#### **i. Enabling disclosure**

A disclosure to be effective against novelty had to be an enabling disclosure, i.e., it must disclose a method of working the invention. Section 10(4)(a) of the Patents Act requires every complete specification to 'describe the invention and its operation or use and the method by which it is to be performed'. The absence of such a description can be a ground for revocation under section 64(1)(h). Such description should 'enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention'.

### **D. Prior Public Use**

An invention may not be considered as new if it was put to prior public use. Though the Patents Act makes prior secret use in India a separate ground for revocation,<sup>17</sup> it excludes secret use for the purpose of determining lack of novelty.<sup>18</sup> The purpose of s 64(1)(e) is to protect prior users. A person who is already manufacturing an article or has previously manufactured it, or had put it into use, should not be stopped from doing what he had done before. The grant of a patent should be curtailed where it can result in prohibiting prior users of the article from continuing to use such an article. This would be the case even if the prior user did so in complete ignorance of the scientific technology involved in the invention. The protection will be available to him even if he had manufactured the article by chance and later found out that it had particular advantages or was useful for particular purposes. If another

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<sup>17</sup> Section 64(1)(l), Patents Act 1970.

<sup>18</sup> Section 64(2)(a), Patents Act 1970.

person invents a process for manufacturing the same thing, the latter person will not be entitled to stop the prior user from doing what he was doing before.

No patent shall be granted for inventions taken out of public use, processes and products already made available to the public. Public use, in other words, is use by which an invention is made available to the public. A matter that is publicly used does not mean actual use by the public. It refers to 'use in a public manner and not secretly'. If the manufacturing or selling of any article gives the public knowledge about the article, it will amount to prior use of the article. It is not required to show that through such use the public has acquired knowledge of the invention. Prior public use will include practice of an invention and prior public sale of the goods.

#### **i. Samples and Free Distributions**

Samples sent to prospective customers, the disclosure of which was not made a subject of confidence, before the date of the patent with a view to obtain orders for the goods when they become patented will amount to a prior use.<sup>19</sup> Free distribution of an article before the date of patent can also amount to a prior use. Even the gift of a single unit can constitute anticipation of the invention.<sup>20</sup>

#### **ii. Experiment, Research and Trial**

The Patents Act excludes secret trials for the purpose of determining the state of the art. Experiment, research and trial of an invention must be done under the veil of secrecy as disclosure of information about the invention can jeopardise the rights in the invention. To this extent, the use of the words 'secret trial' and 'secret use' in section 64(2) will be sufficient to cover research, experiments and trials. Experiments should be interpreted to mean experiments with a view to discovering something not disclosed and not the ordinary method of trial and error which involve no inventive step and generally are necessary in applying any discovery to produce a practical result. The use of a patented invention solely for uses reasonably relating to the development and submission of information required under any law will not amount to infringement.

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<sup>19</sup> Lallubhai Chakubhai Jariwala v. Chimanlal Chunilal & Co, AIR 1936 Bom 99.

<sup>20</sup> Fomento Industrial SA Biro Swan Ltd v. Mentmore Manufacturing Co Ltd, (1956) RPC 87.

## **II. INVENTIVE STEP**

Section 2(1)(ja) defines inventive step as follows:

‘inventive step’ means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.

The obviousness of an invention has to be determined with reference to ‘the state of the art’. The statutory exceptions to anticipation contained in sections 29 to 34 will be relevant for determining ‘what was publicly known or publicly used in India or what was published in India or elsewhere’. For the purpose of section 64(1)(f), no account shall be taken of any personal document, secret trial or use and importation for reasonable trial or experiment as detailed in section 64(2).

Inventive step refers to the ingenuity in making the leap from the closest prior art which was not obvious to a person skilled in the art. The Patents Act refers to ‘inventive step’ and ‘not obvious’ co-jointly, for if an invention is to ‘involve an inventive step’ it should certainly be ‘not obvious’ to a person skilled in the art. In other words, if it is established that the ‘alleged invention is or was at the material date obvious as that word is commonly used, then it follows that it did not involve any inventive step’.<sup>21</sup> The policy behind the above provision is to ensure that a person ‘should not be prevented by a statutory monopoly from doing something which, at the date of the patent, was obvious’.

### **A. Ingredients of Inventive Step**

The ingredients of inventive step as defined in s 2(1)(ja) of the Patents Act may be analysed as follows:

The feature of an invention should involve (1) (i) technical advance as compared to the existing knowledge or (ii) economic significance or (iii) both, and (2) such a feature should make the invention not obvious to a person skilled in the art.

#### **i. Technical Advancement or Economic Significance**

Technical advancement is an inherent characteristic of inventive step which has been recognised by the courts to be a prerequisite for satisfying the test of inventive step.

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<sup>21</sup> Van der Lely NV v. Bamfords Ltd., (1963) RPC 61.

Technical advancement over existing knowledge implies an advance over the state of the art, which is an essential condition to be satisfied for the grant of a patent, the absence of which can be a ground for challenge by opposition or revocation proceedings. Though the courts have not directly dealt with economic significance of an invention as a consideration in determining its inventiveness, there have been discussions on the commercial success of an invention and its evidential value in determining inventiveness. In certain cases, the courts have tried to keep the element of commercial requirement outside the scope of the inventive step. It has been held that obviousness refers to technical obviousness and not commercial obviousness.

## **ii. Obviousness**

Obviousness is the antithesis of inventiveness. What is obvious cannot be inventive and what is inventive cannot be obvious. The issue of obviousness has to be determined on the particular facts of each case. Whether an alleged invention involves an inventive step is a mixed question of law and fact, which will depend on the circumstances of the case.

### **a) ‘Windsurfing’ Test**

It is a four step test laid down in windsurfing case<sup>22</sup>. The four steps are:

- 1) **Identifying the Inventive Concept** - The court will have to first identify the inventive concept embodied in the claim of the complete specification in issue. This will require a purposive construction of such a claim. A purposive construction will determine the scope of such a claim and the characteristics of all the items falling within its scope so as to define the inventive concept of all the elements of claim.
- 2) **Identifying the Person Skilled in the Art** - The second step would be for the court to identify the person skilled in the art, i.e., the notional skilled addressee to whom the patent is addressed. The court should put itself in the shoes of the person skilled in the art at the priority date of the claim and impute to him the ‘common general knowledge’ in the art as on that date. The court will have to determine whether at the relevant time, the skilled man perceived any problem which required to be solved.
- 3) **Identifying the difference between Prior Art and the Inventive Concept** - The third step involves the identification of the matter closest to the prior art, i.e., the matter cited as being ‘known or used’, and compare the same with the invention claimed. This will

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<sup>22</sup> Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd., (1985) RPC 59.

require the identification of what the prior art teaches the person skilled in the art and then comparing the difference between the prior art and the inventive concept. In considering the prior art, the person skilled in the art will be expected to look into ‘carefully and completely’ into all the materials that form a part of the state of the art. To prove obviousness, it has to be shown that the invention was obvious to the person skilled in the art, and not, what may in a sense be, obvious to the inventor. As the issue of inventive step is decided objectively, evidence with regard to how a problem was approached at the relevant time by the patentees, by his rivals or by others may be considered, as ‘what they did may provide significant signposts leading to the answer to the objective test’.

- 4) **Deciding whether the difference makes the Invention Obvious** - The court has to ask the question: whether the difference between the closest prior art and the alleged invention would have been obvious to a person skilled in the art or whether the difference would require any degree of inventiveness? The court should arrive at an answer without taking into account any knowledge of the alleged invention. The court should be cautious not to fall into the ‘trap of hindsight reasoning’.

**b) ‘Pozzoli’ Test<sup>23</sup>**

In this case, the court stated that in considering the question of obviousness, it should follow these steps:

- 1) Identify the notional ‘person skilled in the art’ and the relevant common general knowledge of that person;
- 2) Identify the inventive concept of the claim in question or, if that cannot be readily done, construe it;
- 3) Identify what, if any, differences exist between the matter cited as forming part of the state of the art and the inventive concept of the claim or the claim as construed; and
- 4) Viewed without knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

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<sup>23</sup> Pozzoli Spa v. BDMO SA & Anr, [2007] EWCA Civ 588.

### **c) 'Graham' Test<sup>24</sup>**

The court set out a tripartite test for obviousness:

- 1) Identify the scope and content of the prior art;
- 2) Identify the differences between the prior art and the claimed invention; and
- 3) Identify the level of ordinary skill in the pertinent art.

### **d) Secondary considerations**

Notwithstanding the above tests laid down by the court, there can be certain factors considered by the court before reaching a conclusion on obviousness, these are:

- 1) The commercial success of the invention;
- 2) Whether the invention satisfied a long-felt need in the industry;
- 3) Failure of others to find a solution to the problem at hand; and
- 4) Unexpected results.

### **iii. Person Skilled in the Art**

'Person skilled in the art' is a person who has read the prior art and knows how to proceed in the normal course of research on the basis of what he knows of the state of the art. He does not need to be guided step-by-step, and can work his way through. He reads the prior art as a whole and allows himself to be taught by what is contained in it.<sup>25</sup>

In *Enercon (India) Limited v. Alloys Wobben*<sup>26</sup>, IPAB laid down certain factors to be determined while considering person skilled in the art, these are:

- 1) The person skilled in the art (PSITA) to determine non-obviousness has no territorial limits and may not be an Indian person.
- 2) The PSITA is not described as either 'ordinary' or 'average' for the purpose of non-obviousness. He is not a dullard and has a certain modicum of creativity.
- 3) The Indian Patent Act requires a PSITA to judge non-obviousness; and in the context of enablement, the person should be one 'who has average skill and average knowledge.'

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<sup>24</sup> *Graham v. John Deere Co.*, 383 US 1 (1966).

<sup>25</sup> *Sankalp Rehabilitation Trust v. Hoffmann-Roche*, OA/8/2009/PT/CH.

<sup>26</sup> IPAB order no. 174 (2013).

Hence, there exists a clear difference in the PSITA (the obviousness person) and the person who has average skill (enablement man).

- 4) Indian law tests inventive step through the eyes of 'PSITA' and not US Person Having Ordinary Skill in the Art (PHOSITA) or European 'Person of Ordinary Skill in the Art' (POSITA), who are both 'ordinary' by definition.

### **III. INDUSTRIAL APPLICATION**

The phrase 'capable of industrial application' is defined in s 2(1) (ac) as,

'capable of industrial application' in relation to an invention, means that the invention is capable of being made or used in an industry.

Under the old definition of 'invention', an invention to be patentable had to be useful in addition to being a new manufacture. The present definition of invention does not expressly provide for the utility of an invention as a criterion for a grant of a patent. However, lack of utility still remains a ground on which a patent can be revoked.<sup>27</sup> The old definition stipulated the condition that for an invention to be patentable it must relate to a new and useful manner of manufacture. The interpretations of the terms 'manufacture' and 'useful' under the old provision may be used to understand the scope of the term 'industrial application'. The phrase 'capable of industrial application' implies usefulness or utility.

#### **E. Manufacture – Meaning**

Manufacture may mean the manufacture of a product or a manufacturing process. It generally denotes either the manufacture of a vendible article or a new process to be carried on by known implements or elements acting upon known substances, and ultimately producing some other known substance, but producing it cheaper or in a more expeditious manner, or of a better or more useful kind. Generally a process of manufacture is considered to be new if it results in a new product or it uses new starting materials or it employs a novel combination of steps even if such steps themselves may not be per se novel. A 'process of manufacture' is independent of the substance produced by the manufacture. It has a distinct identity of its own. It is thus possible for a patent to be claimed in respect only of a new process of manufacture. Whether a process of manufacture involves novelty and an inventive step so as to qualify as an invention would thus be a mixed question of law and fact and would depend

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<sup>27</sup> Section 64(1)(g), Patents Act, 1970.

mainly upon the circumstances of each case. No uniform tests can be laid down to determine it.

#### **F. 'Vendibility' test**

The vendibility test is applied to determine whether a process of manufacture can be subject matter of a patent. The test requires three conditions to be satisfied. First, the invention should result in the production of some vendible product. Secondly, it should improve or restore the former condition of a vendible product. Thirdly, it should have the effect of preserving from deterioration some vendible product to which it is applied.<sup>28</sup> The vendibility test is a yardstick to determine whether a process of manufacture would qualify for a new invention. In the case of a patent for a product, the end product will in itself amount to a manufacture, and thus there is no confusion as to whether it amounts to a manufacture. However, in the case of a patent for a process, the process would amount to a manufacture only if it results in the production of some tangible vendible product. A vendible product is a thing which may be passed on from one person to another upon the transaction of purchase and sale.<sup>29</sup>

#### **G. Meaning of 'Industry'**

At one point of time, intellectual property was also known as industrial property. Industry or trade was the area in which intellectual property could be applied. Similarly, 'commercial application' and 'industrial application' have been regarded as related terms, and have been used alternatively. The term 'industry' should be given a wide interpretation. To qualify as an invention, the claim must be tied down to the industrial activity so that it becomes a valuable invention restricted to its proper sphere.<sup>30</sup>

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<sup>28</sup> *GEC's Application*, (1943) 60 RPC 1.

<sup>29</sup> *Dimminaco AG v. Controller of Patents and Designs*, (2002) IPLR 255.

<sup>30</sup> *Halliburton Energy Services Inc v. Smith International (North Sea) Ltd.*, (2006) RPC 2.



# **INTERNATIONAL CONVENTIONS RELATED TO PATENT LAW**

By virtue of being a founding member of the WTO, India is a party to the Agreement on the Trade Related Aspects of Intellectual Property Rights, 1994. As a consequence of its WTO membership, India became a member of the Paris Convention, 1967 and the Patent Cooperation Treaty, 1984 on 7 December, 1998 and of the Budapest Treaty on the International Recognition of the Deposit of Micro-organism for the Purposes of Patent Procedure, 1977 on 17 December, 2001.

## **I. PARIS CONVENTION**

The International Convention for the Protection of Industrial Property was signed in Paris in 1883. The Convention enshrines the principle of 'national treatment' and reciprocity by requiring one member country to afford to the nationals of another the same protection it affords to its own nationals. It also introduced, for the first time, a method of claiming priority for applications made in a foreign country. Article 4 provides that where an application for patent has been made in one convention country and corresponding applications are made in other convention countries within 12 months from the date of first filing, the subsequent applications will be entitled to the priority date of the first application. These principles are contained in chapter XXII of the Patents Act, 1970. India signed the Paris Convention in 1998.

## **II. PATENT CO-OPERATION TREATY (PCT)**

The PCT, administered by the WIPO was signed in Washington on 19 June 1970. It had as its objects, inter alia, 'simplifying and rendering more economical the obtaining of protection for inventions where protection is sought for in several countries'. Like the Paris Convention, the PCT enables the applicant to claim priority from the date of filing the application. The provisions of the PCT are not in derogation of the Paris Convention and as such shall not be interpreted to diminish any rights under the Paris Convention. An application preferred as a single international application in one of the receiving offices will have the right of priority from the date of filing. As a signatory to the PCT, India aligned its laws to the obligations under the PCT through the Patents (Amendment) Act, 2002. The said amendment provided that every international application filed under the PCT designating India shall be deemed to

be an application made under the Act. Chapter III of the Patents Rules, 2003 enumerates the details of international applications under the PCT.

### **III. TRIPS AGREEMENT**

The TRIPS Agreement is a step towards the international protection of intellectual property rights. The TRIPS Agreement had a lasting effect on the changing values with regard to intellectual property laws in developing countries. In effect, TRIPS was a consolidating agreement, as it required member nations to comply with arts. 1 to 12 of the Paris Convention, 1967. TRIPS is also regarded as a standard-setting agreement, as it increased the level of standards with regard to patentability, rights, disclosure requirements, exceptions to patentability, authorised uses and term of the patent. The impact of the TRIPS Agreement on the Patents Act, 1970 has been well documented. The provisions of the TRIPS Agreement pertaining to patents have been fully incorporated into the Patents Act, 1970 through a series of amendments culminating with the Patents (Amendment) Act, 2005. Some of these provisions have already come under judicial scrutiny. India is a signatory to the TRIPS Agreement since its inception in 1995. The TRIPS Agreement is binding on all its signatories.

### **IV. DOHA DECLARATION**

In the Ministerial Conference held Doha in November 2001, a Declaration on the TRIPS Agreement was adopted in respect of Public Health. The Declaration recognizes WTO members' right to protect public health and in particular to promote access to medicines for all. The Doha Declaration will be instrumental in interpreting those provisions of the TRIPS Agreement that have been incorporated into the Patents Act, 1970. The declaration states that member countries shall have the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted. It also states that the TRIPS Agreement 'can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'.

## **V. BUDAPEST TREATY**

The Treaty provides for the deposit of micro-organisms in an International Depository Authority (IDA) where a deposit is necessary to satisfy the requirement of sufficiency of description of patent law for inventions relating/involving micro-organisms or the use of the micro-organisms. According to the Treaty a member State which allows or requires the deposit of micro-organism for the purposes of patent procedure must recognize for such purposes the deposit of the microorganism with any IDA irrespective of its location. According to the Treaty a practice has been developed now, to deposit the sample of the living entity (biological material) involved in any of the International Depository Authorities (IDAs) such as ATCC. When the biological materials are deposited with such an authority in the manner prescribed, the authority provides an accession number. This accession number when quoted in the patent document (specification) serves as the equivalent description of the invention satisfying the condition of sufficient disclosure of the patent law. It is also beneficial to provide a written form also about all the available information about the biological material wherever possible, in addition to the above said accession number. The reference made to the accession number, provided by the Depository Institution for the biological material, in the specification is considered as part of the description of the invention. It should be noted that the sample of the biological material involved must be deposited with the depository authority at the latest on the date of filing the application for patent or if priority is claimed, on the date of the priority. The accession number of the deposited biological material supplements the description of the said material so that a person in the art is able to identify the type of material involved in the invention.



தமிழ்நாடு டாக்டர் அம்பேத்கர் சட்டப் பல்கலைக்கழகம்  
The Tamilnadu Dr. Ambedkar Law University



# **COURSE MATERIAL – PART II**

## **ONLINE CERTIFICATE COURSE ON PATENT LAW: POLICY AND GOVERNANCE**

**COMPILED BY:  
ORGANISING COMMITTEE  
TAMIL NADU Dr. AMBEDKAR LAW UNIVERSITY**

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## LIST OF CASE LAWS

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3.	Letraset Ltd. v. Rexel Ltd.	[1973] FSR 302
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9.	Technip France SA's Patent	(2004) RPC 46
10.	Genentech Inc's (Human Growth Hormone) Patent	(1989) RPC 613
11.	Hoechst Celanese Corp v. BP Chemicals Ltd.	[1999] FSR 319
12.	Rodi and Wienenberger AG v. Henry Showell Limited	(1969) RPC 367 (HL)
13.	Shining Industries v. Shri Krishna Industries	AIR 1975 All 231
14.	Harris' Patent	(1985) RPC 19
15.	Elliott Brothers (London) Ltd's Application	[1966] FSR 334

## **SPECIFICATION**

- I.** Sections 9 to 11 of the Patents Act, 1970 deals with specification, its contents and its priority dates. The corresponding rules are contained in rules 13 to 16 of Patent Rules, 2003. Section 7(4) states the every application shall be accompanied by a specification. Section 137 deals **PROVISIONS**

with multiple priorities and rule 21 with filing of priority document.

### **II. KINDS OF SPECIFICATIONS**

#### **A. Provisional Specification and Complete Specification**

The Patents Act requires that every application, other than an international application, shall be accompanied by a provisional or a complete specification. Provisional specification helps in the determination of priority of patents. The object of filing a provisional specification is more manifest in cases where there are similar inventions which give rise to competing applications. Where two or more persons develop similar concepts and make competing applications for patents for the same invention, in different parts of the world, the priority of the co-pending applications is determined on a ‘first-to-file’ basis. The application which is filed first in time before the appropriate scrutinising authority will be accorded precedence over the later application. This may be so even if an incomplete specification is filed in place of a complete specification. The provisional specification should describe the true nature of the invention, and such description should be the same as that claimed in the complete specification.

Where only a provisional specification is filed at the first instance along with the application, the complete specification shall be filed within 15 months from the date of filing of the application.<sup>31</sup> The 15-month time period granted for filing the complete specification after the provisional specification has been filed allows the applicant to develop, improve and perfect the invention. The applicant may eventually decide to abandon the application if the results are not promising. However, if the applicant intends to pursue the application, it may file a complete specification within the stipulated time. The time period between the filing of the provisional and complete specifications also helps the applicant to maintain the priority date and file international applications.

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<sup>31</sup> Section 9(1), Patents Act, 1970.

The Patents Act does not define or distinguish the two kinds of specifications. In fact, it stipulates certain common requirements for both provisional and complete specification.<sup>32</sup> But a reading of the Patents Act and the Patents Rules indicates that the provisional specification is a temporary specification which is filed in lieu of, and eventually to be followed up by, a complete specification. The Controller may also direct a specification to be treated as a provisional specification.<sup>33</sup> The complete specification can accommodate improvements made in the invention, which are not mentioned in the provisional specification. A complete specification filed after a provisional specification may include claims in respect of developments and additions made to the invention as described in the provisional specification, if such developments and additions are of such nature that they would entitle the applicant to make a separate application for a patent under s 6.<sup>34</sup> A provisional specification need not end with the claims.<sup>35</sup>

Though both provisional and complete specifications are required to be made in the same form (Form 2), certain distinctions can be seen between the two. A provisional specification needs to satisfy the twin requirements of describing the invention and having a title that sufficiently indicates the subject matter of the invention. But a provisional specification need not describe the manner in which the invention is to be performed. Similarly a provisional specification need not disclose the best method, end with a claim or be accompanied by an abstract as these requirements are specific to a complete specification.<sup>36</sup> It is not intended to contain a complete description of the thing so as to enable any workman of ordinary skill to make it, but only to disclose the invention in its rough state until the inventor is able to perfect its details.

A provisional specification cannot be filed along with a convention and PCT application. The Patents Act requires a complete specification for such applications.<sup>37</sup> However, the additional requirements of drawings and model, which the Controller may require applies equally for both provisional and complete specification. The Act requires a complete specification to be filed within 12 months (or within 15 months where an extension is sought) from the date of filing the application with a provisional specification, failing which the application shall be deemed to have been abandoned by the applicant.

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<sup>32</sup> Sections 10(1) and (2), Patents Act, 1970; Rule 13(1), Form 2, Patents Rules, 2003.

<sup>33</sup> Section 9(3), Patents Act, 1970.

<sup>34</sup> Section 10(7), Patents Act, 1970.

<sup>35</sup> Form 2, Patents Rules, 2003.

<sup>36</sup> Section 10(4), Patents Act, 1970.

<sup>37</sup> Section 136, Chapter XXII, Patents Act, 1970.



### **i. Common Complete Specification**

In the case of multiple applications accompanied by provisional specifications, made by the same applicant pertaining to inventions that are cognate or where one invention is a modification of the other, the Controller may, if he is of the opinion that such inventions constitute a single invention, allow a single complete specification to be filed in respect of all the provisional specifications. The period within which the complete specification is to be filed shall be computed from the date of filing of the earliest provisional specification.<sup>38</sup>

### **ii. Complete Specification treated as Provisional Specification**

In cases where an application is accompanied by a specification purporting to be a complete specification, the Controller may, upon the request of the applicant made within 12 months of filing the application, treat such specification as a provisional specification and proceed with the application.<sup>39</sup> This grants the applicant further time to file the complete specification. The 12 month time period was introduced by the Patents (Amendment) Act, 2005, before which the applicant was entitled to make a request ‘at any time before the acceptance of the specification’.

### **iii. Cancellation of Provisional Specification**

An applicant may request for the cancellation of a provisional specification under certain circumstances. A cancellation of provisional specification can be requested where a complete specification is filed following a provisional specification or where a complete specification is filed after the specification purporting to be a complete specification is treated as a provisional specification under subsection (3) of section 9, and the applicant requests the Controller to post-date the application to the date of filing of such complete specification. Such an action can affect the priority date of the application.<sup>40</sup>

## **III. REQUIREMENTS OF COMPLETE SPECIFICATION**

A complete specification should satisfy the requirements stipulated under the Patents Act. It shall begin with a title that sufficiently indicates the subject matter of the invention,<sup>41</sup> fully

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<sup>38</sup> Section 9(2), Patents Act, 1970.

<sup>39</sup> Section 9(3), Patents Act, 1970.

<sup>40</sup> Section 9(4), Patents Act, 1970.

<sup>41</sup> Section 10(1), Patents Act, 1970.

and particularly describe the invention,<sup>42</sup> disclose the best method of performing the invention,<sup>43</sup> end with the claim defining the scope of the invention,<sup>44</sup> and be accompanied by an abstract.<sup>45</sup> Additionally, a complete specification may further be supplemented by drawings and models or samples.<sup>46</sup> The object and purpose of filing a complete specification is to enable a reasonably well-informed artisan dealing with the subject-matter with which he is familiar (person skilled in the art) to make the thing, so as to make it available for the public at the end of the term of the patent. In keeping with this important object, the decisions of the courts involving patents will usually include a reproduction of the relevant claims or a brief summary of the specification.

The contents of a complete specification are also commonly referred to as contents of a patent. In effect, it is the complete specification which is eventually granted as the patent. A specification is a composite document which comprises various components. Each of these components performs particular functions which are detailed below. The main contents of a complete specification and its accompaniments include:

1. Title;
2. Abstract;
3. Description of invention;
4. Claims;
5. Drawings;
6. Models or Samples.

#### **A. Title**

Every specification shall begin with a title which sufficiently indicates the subject matter of the invention. The disclosure of the title of the invention is a common feature of both provisional and complete specification. The title of the invention discloses the specific features of the invention. It contains a brief statement of the invention disclosed in the specification, and indicates the technical field to which the invention relates to. The

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<sup>42</sup> Section 10(4)(a), Patents Act, 1970.

<sup>43</sup> Section 10(4)(b), Patents Act, 1970. Also See Van der Lely NV v. Ruston's Engineering Co Ltd, (1993) RPC 45.

<sup>44</sup> Section 10(4)(c), Patents Act, 1970.

<sup>45</sup> Section 10(4)(d), Patents Act, 1970.

<sup>46</sup> Section 10(2) and (3), Patents Act, 1970.

Controller has the power to exclude irrelevant matters from the title which in the Controller's opinion are not necessary to elucidate the invention.<sup>47</sup>

## **B. Abstract**

The abstract is an accompaniment filed along with the specification. Normally, an abstract is not a part of the specification. But in the case of an international application designating India, the abstract shall be taken as a part of the complete specification.<sup>48</sup> The abstract shall begin with the title of the invention disclosing the specific features of the invention in not more than 15 words.<sup>49</sup> The title to the abstract may be same as the title to the invention. The abstract of the patent can be used as a preliminary tool for search. The title should reveal, in a gist, the specific features of the invention mentioned in the abstract and the abstract, in turn, should be a concise summary of the specification.<sup>50</sup>

The main function of an abstract is to provide technical information. The Patents Act makes this clear by empowering the Controller to amend the abstract so as to provide better information to third parties. Additionally abstracts can be used as an efficient tool for search and examination of patents. An abstract should be drafted in a manner that it constitutes an efficient instrument for the purpose of patent search, and it should be possible for a person reading the abstract to assess whether there is a need to read the specification.<sup>51</sup> In case the Controller feels that the abstract does not provide technical information on the invention as required, he may amend the abstract for providing better information to third parties.<sup>52</sup> Though an abstract can be used as an efficient instrument of patent search, it may not be used for interpreting the scope of the patent.

Normally, an abstract should not be more than 150 words, and shall contain the following information: (1) it should clearly indicate the technical field to which the invention belongs; (2) it should describe the technical problems to which the invention relates and the solution to the problem through the invention; (3) it should disclose the principal use or uses of the invention; (4) for chemical and pharmaceutical substances, it should contain the chemical formula which characterises the invention; (5) if the specification contains any drawing, the

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<sup>47</sup> Rule 13(5), Patents Rules, 2003.

<sup>48</sup> Section 10(4A), Patents Act, 1970.

<sup>49</sup> Rule 13(7)(a), Patents Rules, 2003.

<sup>50</sup> Rule 13(7)(b), Patents Rules, 2003.

<sup>51</sup> Rule 13(7)(e), Patents Rules, 2003.

<sup>52</sup> Section 10(4), Patents Act, 1970.

same should figure in the abstract; and (6) every main feature illustrated in the abstract shall be followed by a reference sign used in that drawing.

### **C. Description of the Invention**

The description of an invention is one of the foundations on which the patent system is built. The description is the chief source of information about the invention which may be used for search or examination of a patent. Apart from being regarded as a legal document, a patent specification performs the function of a technical document in so far as the technology pertaining to the invention is disclosed. Matters such as the importance of the invention, the issues addressed by the invention, the improvement upon the existing state of technology form a part of the description.

A complete specification shall fully and particularly describe the invention and its operation and use, and the method by which it is to be performed. The description should sufficiently describe the starting material used in the invention. As the protection is claimed for the invention, the applicant shall disclose the best method of performing the invention which is known to the applicant. A description usually begins by giving a background or introduction to the invention. It will contain the prior art in that particular field as found in earlier patents, and scientific documents in that particular field. The description forms the body of the specification in which the state of the prior art and the contribution made by the applicant is disclosed. Further, the description will disclose the invention for which the protection is claimed.<sup>53</sup> The details about how the invention addresses the problem it proposes to solve is also described. The description will also contain the meaning of technical terms used in the patent. Reference to any drawings, models or samples is also made in the description. As the Patents Act requires the disclosure of the best method of performing the invention, the description should contain such a disclosure. The matters which are not necessary for the elucidation of the invention may be excluded from the description.<sup>54</sup>

#### **i. Description of Biological Material**

In the case of biological material mentioned in the specification, the applicant should satisfy the requirements mentioned in sub-section (a) and (b) of section 10(4). If the applicant does not describe the biological material in the manner required, and if the biological material is

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<sup>53</sup> Section 10(4)(b), Patents Act, 1970.

<sup>54</sup> Rule 13(6), Patents Rules, 2003.

not available to the public, then, the applicant shall deposit such material in an international depository authority under the Budapest Treaty. The applicant has to fulfil the following conditions:

- 1) The deposit of biological material shall be made not later than the date of filing the patent application in India and a reference thereof shall be made in the specification within three months from the date of filing of the application.<sup>55</sup>
- 2) The characteristics required to correctly identify the biological material such as name, address of the depository institution, date and number of deposit shall be included in the specification.<sup>56</sup>
- 3) The access to such material is available only after the date of application of patent in India or if a priority is claimed, then, after the date of the priority.<sup>57</sup>
- 4) The specification should disclose the source and geographical origin of the biological material.<sup>58</sup>

#### **D. Claims**

The chief function of the claim is to define the scope of the invention for which protection is claimed. The claim is that part of the specification primarily designed for delimitation. In other words, the claim limits the monopoly of the patent.<sup>59</sup> The function of the claims has been best-described by Lord Russell of Killowen in *Electric & Musical Industries v. Lissen Ltd.*<sup>60</sup> as following:

*The function of the claims is to define clearly and with precision the monopoly claimed so that others may know the exact boundaries of the area within which they will be trespassers. Their primary object is to limit and not to extend, the monopoly. What is not claimed is disclaimed. The claims must undoubtedly be read as part of the entire document, and not as a separate document. Nevertheless, the forbidden field must be found in the language of the claims, and not elsewhere.*

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<sup>55</sup> Section 10(4)(ii)(A), Patents Act, 1970; Rule 13(8), Patents Rules, 2003.

<sup>56</sup> Section 10(4)(ii)(B), Patents Act, 1970.

<sup>57</sup> Section 10(4)(ii)(C), Patents Act, 1970.

<sup>58</sup> Section 10(4)(ii)(D), Patents Act, 1970.

<sup>59</sup> Section 10(4)(c), Patents Act, 1970.

<sup>60</sup> [1938] 4 All ER 221.

Every complete specification should end with a claim or claims. As a matter of practice the specification will include many claims some of which are broad and general, and others which are more specific. The object achieved in having many claims is that some of them may be upheld even if others are struck down. As the Patents Act limits an application to a single invention, the claims too shall relate to a single invention. The claim may also relate to a group of inventions which are so linked together to form a single inventive concept.<sup>61</sup> The claims shall be clear and succinct, and shall be fairly based on the matter disclosed in the specification. In fact, a patent may be revoked if the scope of any claim of the complete specification is not sufficiently and clearly defined or if any claim of the complete specification is not fairly based on the matter disclosed in the specification.<sup>62</sup> The Controller has the power to exclude irrelevant matters from the claims.<sup>63</sup> The complete specification may include further claims in respect of developments and additions made to the invention which did not form part of the provisional specification.

#### **E. Drawings**

Drawings are optional features of a specification. They perform the function of explaining the invention. They are required when the description, and the claim do not sufficiently and clearly describe the invention. Drawings may be supplied either by the applicant on its own accord or by a request made by the Controller. Where drawings are supplied by the applicant on their own accord, they shall accompany the specifications to which they relate to.<sup>64</sup> Where the drawings are required by the Controller, they may be supplied when such requisition is made.<sup>65</sup> They shall be supplied along with the specification, if required by the Controller. Drawings shall normally be deemed to form a part of the specification. Thus disclosure of an invention through drawings will be interpreted as the disclosure of a specification. Drawings may form a part of both provisional and complete specification. Where the applicant desires to adopt the drawings filed in the provisional specification as a part of the complete specification, it will be sufficient if the applicant merely refers to them in the complete specification.<sup>66</sup> There is no need to reproduce the same drawings in the complete specification.

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<sup>61</sup> Section 10(5), Patents Act, 1970.

<sup>62</sup> Section 64(1)(i), Patents Act, 1970.

<sup>63</sup> Rule 13(5), Patents Rules, 2003.

<sup>64</sup> Rule 15(1), Patents Rules, 2003.

<sup>65</sup> Section 10(2), Patents Act, 1970.

<sup>66</sup> Rule 13(4), Patents Rules, 2003.

## **F. Models or Samples**

Models or samples shall be supplied only when required by the Controller.<sup>67</sup> The function of the model or sample is to illustrate the invention, especially where the invention involves moving parts. Models or samples are considered as supplements to the application and shall be furnished before the application is found in order for grant of a patent. Unlike drawings, models or samples shall not be deemed to form part of the specification. How far disclosure of models or samples would constitute anticipation will depend on the extent of information disclosed that would enable an average person skilled in the art to perform the invention.

## **G. Additional Requirements**

Apart from the above requirements, a specification should also be accompanied with a declaration as to the inventorship in a manner set out in Form 5. Such a declaration may also be filed at any time before the expiration of one month from the date of filing the complete specification.<sup>68</sup>

## **IV. PRIORITY DATES**

Every claim of a complete specification shall have a priority date.<sup>69</sup> The priority date is the date from which exclusive right in the patent will accrue on the patentee.<sup>70</sup> In every case, the priority date takes retrospective effect as it takes considerable time for the Patent Office to grant the patent. Once a patent is granted, the exclusive rights that can be exercised by the patentee under section 48 will accrue from the date of priority. In the same specification, different claims may have different priority dates.

### **A. Purpose of Priority Dates**

Priority date serves many purposes. First, it helps one to ascertain the date on which the rights in the patent came into force for the purpose of ascertaining infringement and prior art. Secondly, it helps the patentee to file multiple patent applications in different jurisdiction citing an earlier priority date under the PCT. The filing date of an application under s 7(1A)

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<sup>67</sup> Rule 16, Patents Rules, 2003.

<sup>68</sup> Rule 13(6), Patents Rules, 2003.

<sup>69</sup> Section 11, Patents Act, 1970.

<sup>70</sup> Section 2(1)(w), Patents Act, 1970.

and its complete specification processed by the Patent Office as designated office or elected office shall be the international filing date accorded under the PCT.<sup>71</sup>

## **B. Determination of Priority Dates**

Every claim should have a priority date.<sup>72</sup> As a rule, the date of priority of a claim shall be the date of filing of the complete specification.<sup>73</sup> This rule is, however, subject to certain conditions stipulated in the Act.<sup>74</sup> Section 11 explains certain situations, which are listed below, where the determination of priority date does not follow the above rule. The priority date of the claim in a complete specification shall be the date of filing of the provisional specification, provided the claim is fairly based on the matter disclosed in the provisional specification.<sup>75</sup>

### **i. 'Fairly Based' or 'Fair Basis'**

For the purpose of determining priority of a complete specification based on a provisional specification the issue of whether the complete specification is 'fairly based' on the provisional specification or what is disclosed in the provisional specification affords a 'fair basis' for the complete specification has to be ascertained. The doctrine of fair basis requires that the complete specification should be fairly based on the provisional specification. The issue of fair basis will depend on the contents and language of the relevant documents. What is required to be fair is not the applicant's claim to priority, but the basis which one document affords for a claim in the other.

Any claim in the complete specification relating to any such development or addition is entitled to a priority date as of the date of the relevant application for protection in the convention country if the claim is fairly based on the matter disclosed in the application for protection in the convention country. Any claim in the complete specification in respect of any development or addition which is not fairly based on the matter disclosed in the application for protection of the invention in the convention country will be entitled to priority only as of the date of the complete specification.

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<sup>71</sup> Section 7(1B), Patents Act, 1970.

<sup>72</sup> Section 11(1), Patents Act, 1970.

<sup>73</sup> Section 11(6), Patents Act, 1970.

<sup>74</sup> Section 11(2), 11(3), 11(3A), 11(4), 11(5) and 137, Patents Act, 1970.

<sup>75</sup> Section 11(2), Patents Act, 1970.



### **a) Test of 'Fair-Basis'**

The concept of 'fair basis' was introduced to ensure that the court or the tribunal should hold the balance fairly as between the patentee and the public. The courts have developed three tests in determining fair basis, which are summarised as follows:<sup>76</sup>

- 1) whether the patentee is entitled to a fair and reasonable monopoly having regard to the disclosure made without causing prejudice to the public;
- 2) whether the result in the complete specification necessarily flows from the constitution of the materials disclosed in the provisional specification thereby justifying the priority date attributed to the provisional specification; and
- 3) whether the feature in question as to which the provisional is silent is one which does not necessarily result from the embodiment of the other features which it does mention.

### **ii. Priority of Applications**

Section 11 of the Patents Act deals with priority of applications and specifically provides for determining the priority in the case of single application, multiple application, previous application and division application. Rules 19(4) and 21 of Patents Rules, 2003 deal with filing of priority documents.

### **a) Single Applications**

Ordinarily, a complete specification is filed within 12 to 15 months from the date of filing of the provisional specification. If the complete specification is not filed within the stipulated time the application shall be treated as abandoned. Where a complete specification is filed in pursuance of a single application which is accompanied by a provisional specification or a specification treated as a provisional specification under section 9(3), the priority date of the claim shall be the date of filing of the provisional specification. For the complete specification to get the benefit of the priority date of the provisional specification, the claim in the complete specification should be fairly based on the matter disclosed in the provisional specification.

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<sup>76</sup> Letraset Ltd v. Rexel Ltd., [1973] FSR 302.

### **b) Multiple Applications**

A claim has to be based on an earlier provisional specification so as to get the benefit of the earlier priority date. The key ingredient is determining the date of priority is the disclosure of matter in the specification. Any subsequent claim of a complete specification which seeks to get the benefit of an earlier priority date should be fairly based on the matter disclosed in the earlier provisional specification. In a case where the complete specification is filed pursuant to two or more applications containing provisional specifications, and the claim is fairly based on the matter disclosed in one of the provisional specifications, the priority date of the claim shall be the date of filing of the application along with such provisional specification. The crucial aspect for determining the priority is to ascertain the document in which the matter was completely and fully disclosed. In cases where matter is disclosed partly in one provisional specification and partly in another, the priority date of the claim shall be the date of filing of the latter provisional specification.

### **c) Previous Applications**

If the complete specification is based on a previously filed application in India and has been filed within 12 months from the date of that application, the priority date of the claim in the complete specification shall be the date of the previously filed application in which the matter was first disclosed, provided that the claim in the complete specification be fairly based on the matter disclosed in the previously filed application.

### **d) Divisional Applications**

An applicant may file a further application in respect of an invention disclosed in the provisional or complete specification already filed requiring the division of the earlier application. Such further application may be filed by the applicant, on its own volition or with a view to correct the objection raised by the Controller that the claim of the complete specification relates to more than one invention.<sup>77</sup> The priority date of the claim in respect of the complete specification filed in pursuance of such further application shall be the date of filing of the specification in which the matter was first disclosed.

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<sup>77</sup> Section 16, Patents Act, 1970.

### **C. Post-dating of Applications**

An application can be post-dated at the request of the applicant. In cases where a complete specification is filed following a provisional specification or where a complete specification is filed after the specification purporting to be a complete specification is treated as a provisional specification under sub-section (3) of section 9, the Controller may upon the request of the applicant, at any time before the grant of the patent, cancel the provisional specification, and post-date the application to the date of filing of such complete specification.<sup>78</sup> A reference to the date of filing or of the complete specification in section 11 shall be a reference to the date so post-dated or ante-dated.<sup>79</sup>

Post-dating can affect the priority date of applications. Where a complete specification is found not to be fairly based on its provisional application, the Patent Office may require the application to be post-dated. But on applying the fair basis test, if it is determined that the disclosure in the specification as originally filed would have provided a fair basis for the amended claim, then the amended claim would be allowed without post-dating.

### **D. Claim Splitting**

The Patents Act states that where any claim of a complete specification would have two or more priority dates, the priority date of that claim shall be the earlier or earliest date.<sup>80</sup> A claim in complete specification shall not be invalid by reason of the publication or use of the invention on or after the date of priority or the grant of another patent which claims the invention, so far as claimed in the first-mentioned claim, in a claim of the same or a later priority date.<sup>81</sup>

### **E. Cognate Inventions**

The Act does not explain the criterion for determining cognate inventions. It is for the Controller to decide whether the applications with regard to two or more inventions are cognate so as to constitute a single invention. As per section 9(2), where provisional specifications are filed with regard to two or more applications in respect of inventions which are cognate or of which one is a modification of another, the Controller may treat such applications as one single invention, and allow one complete specification to be filed in

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<sup>78</sup> Section 9(4), Patents Act, 1970.

<sup>79</sup> Section 11(7), Patents Act, 1970.

<sup>80</sup> Section 11(5), Patents Act, 1970.

<sup>81</sup> Section 11(8), Patents Act, 1970.

respect of all the provisional specifications. Similarly, a single convention application may be filed with regard to two or more inventions which are cognate where applications for protection have been made in one or more convention countries.<sup>82</sup>

#### **F. Convention Applications**

The priority date of a claim in a convention application is the date of making the basic application in the convention country.<sup>83</sup> Convention applications have to be filed along with a complete specification as there is no provision for filing a provisional specification.<sup>84</sup> As per section 135(1) of the Act, where a person has made an application for a patent in a convention country (basic application) and that person makes an application for the same invention under the Act within 12 months from the date on which the basic application was made, the priority date of a claim in the complete specification which is based on matter disclosed in the basic application, will be the date of making the basic application. The priority date of a claim of the complete specification, if the claim is based on matter disclosed in the basic application, is the date of making of the basic application. Where an application is filed under the PCT designating India and claiming priority from a previously filed application in India, the priority date of the claim of the complete specification shall be the date of making of the previous application, if the claim is based on the matter disclosed in the previous application.<sup>85</sup>

‘Matter disclosed’ in a priority document means the information concerning the invention disclosed in that document. Section 137(3) explains the instances when a matter shall be deemed to have been disclosed in a basic application. A matter shall be deemed to have been disclosed in a basic application for protection in a convention country if it was claimed or disclosed (otherwise than by way of disclaimer or acknowledgement of a prior art) in that application, or any documents submitted by the applicant for protection in support of, and at the same time as that application. However, no account shall be taken of any disclosure effected by any such document, unless a copy of the document is filed at the Patent Office with the convention application or within the prescribed period.

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<sup>82</sup> Section 135(2), Patents Act, 1970.

<sup>83</sup> Section 135(1), Patents Act, 1970.

<sup>84</sup> Section 136(1)(a), Patents Act, 1970.

<sup>85</sup> Section 135(3), Patents Act, 1970.

### **i. Multiple Priorities**

In the case of multiple applications filed in one or more convention countries for inventions which are closely related so as to constitute one invention, one application may be made within 12 months from the date on which the first application was made in respect of the inventions disclosed in the specifications which accompanied the basic applications.<sup>86</sup> Where the complete specification is based on matter disclosed in more than one application made in one or more convention countries, the priority date of the claim of such specification is the date on which the matter was first disclosed.<sup>87</sup>

A matter shall be deemed to have been disclosed in a basic application for protection in a convention country if it was claimed or disclosed in that application or any documents submitted in support of that application. However, such disclosure will not include matters disclosed by way of a disclaimer or acknowledgement of a prior art. In the case of disclosure by documents, the disclosure will be effective only if a copy of the document is filed at the Patent Office with the convention application.<sup>88</sup>

## **V. CLAIM INTERPRETATION**

The interpretation of a patent claim assumes vital significance in patent law because of the nature of a patent specification as legal documents detailing intangible rights which protect commercially valuable products of the human intellect and labour. Though the law accords property status to patents, in that the rules of law applicable to the ownership and devolution of moveable property shall apply in relation to patents,<sup>89</sup> the rights detailed in a patent specification, being intangible by nature, raise peculiar issues with regard to determination of the scope of the protection claimed.

Similar to the schedule to a landed property which marks and delimits its boundaries on all sides, the claims in a complete specification delimit the scope of the monopoly claimed by the invention. But unlike landed property, where the boundaries marked on the document can be measured and verified at the location where the property is situated, the intangible nature of patent rights imposes certain difficulties in determining the real boundary. The property

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<sup>86</sup> Section 137(1), Patents Act, 1970.

<sup>87</sup> Section 137(2), Patents Act, 1970.

<sup>88</sup> Section 137(3), Patents Act, 1970.

<sup>89</sup> Section 50(5), Patents Act 1970.

status of patents accrues from two character-defining traits-the law which confers a trespassory claim against intrusions into its enjoyment and its capability to be assigned.

The interpretation of a patent is the process by which the scope of the protection claimed by the patent is determined. The Patents Act confines the protection afforded to an invention to the scope of the claims defined by the inventor in the complete specification. By definition, patents are granted for inventions that are new and hitherto unknown. What should be the meaning given to the words chosen by the patentee to disclose information about his new and hitherto unknown invention? The need for detailed rules of interpretation arises from the fact that the meaning of words used by the patentee are not understood in accordance with what the patentee intends them to mean, but in accordance with what a person skilled in the art would have understood the patentee to mean. Due to the special nature of patent specifications and the disclosure requirements required by law for its grant, courts have recognised the fact that the information in a specification could be new, pertaining to something that has not existed before and in some cases, devoid of a generally accepted definition.<sup>90</sup>

In response to this standard, patent law has developed rules of interpretation for determining the scope of claims in a complete specification. The definition of the scope is relevant to determine the rights of a patentee detailed in section 48 of the Patents Act. It is as much relevant in answering specific questions on novelty or obviousness of an invention. Determining patent infringement differs significantly from cases of infringement of other intellectual property rights. It comprises of a two-fold approach of first determining the scope of the protection claimed for the invention in the complete specification and then ascertaining whether the act of the alleged infringer fell within that scope.

#### **A. Relevant Provisions under Patents Act, 1970**

The words ‘invention’ and ‘patent’ are defined in section 2(1) (j) and (m) of the Patents Act. These provisions of the Patents Act throw light on the manner in which a patent should be interpreted. Section 10 of the Patents Act deals with the contents of specifications and this provision shall also be used for interpretation. Further, the rights that accrue to a patentee are detailed in section 48 of the Patents Act.

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<sup>90</sup> Kirin-Amgen Inc v. Hoechst Marion Roussel Ltd., (2005) RPC 9, para 34.

The Patents Act also requires the scope of a claim to be definite and section 64(1) (i) of the Patents Act provides for the revocation of a patent on the ground: ‘(i) that the scope of any claim of the complete specification is not sufficiently or clearly defined’.

## **B. Relevant Provisions under UK and EU Patents Law**

Though the rules of interpretation of patents were exclusively developed by judicial decisions in United Kingdom under the UK Patents Act 1949, the introduction of section 125 of the UK Patents Act 1977 has codified the principles relating to interpretation. Further, section 125, UK Patents Act, 1977 and article 69 of the European Patent Convention (EPC) deals with extent of invention and extent of protection respectively. Thereafter, the Protocol on the Interpretation of article 69 of the EPC, which is equally applicable for interpreting section 125 of the UK Patents Act 1977, shall also be used for interpretation of the claims.

Article 69 should not be interpreted in the sense that the extent of the protection conferred by a European patent is to be understood as that defined by the strict, literal meaning of the wording used in the claims, the description and drawings being employed only for the purpose of resolving an ambiguity found in the claims. It should not be interpreted in the sense that the claims serve only as a guideline and that the actual protection conferred may extend to what, from a consideration of the description and drawings by a person skilled in the art, the patentee has contemplated. On the contrary, it is to be interpreted as defining a position between these extremes which combines a fair protection for the patentee with a reasonable degree of certainty for third parties.

## **C. General Principles of Interpretation**

Patents should be interpreted purposefully, balancing the fair protection for the patentee with a reasonable degree of certainty for third parties. The general principles applicable for the interpretation of patents have been comprehensively discussed in *Glaverbel SA v. British Coal Corporation*, a decision granted under the UK Patents Act, 1949 where Staughton LJ summarised the following principles:<sup>91</sup>

### **i. Interpretation of a Patent is Question of Law**

A patent specification contains both technical as well as legal information about an invention. While the technical aspects ‘describe’ the invention the legal aspects ‘demarcate’ the

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<sup>91</sup> (1995) RPC 255, pp 268-270.

invention. The interpretation of patents involves a unique situation where the language of science is tested by the language of law. It entails an exercise of giving meaning to the words used by the patentee judged from the standard of a person skilled in the art. As a legal document it contains a unilateral expression of intention of the inventor. Courts have reiterated the legal nature of a patent specification by stipulating that it should be interpreted like any other legal document, in accordance with the recognised canons of interpretation, and not by their strict literal meaning.<sup>92</sup> Despite their special nature, patents are predominantly legal documents and its interpretation is for the court alone.

The court should interpret the specification from the standpoint of a person skilled in the art having regard to the nature of the invention, to the nature and size of the industry concerned, the way it is organised for the purposes of conducting research into, and of producing and marketing, its products. It is well settled that evidence is only admissible for the purpose of explaining words or symbols of art, other technical matters and for informing the court of relevant surrounding circumstances. Such evidence may be given by an expert to explain the working of the invention or to point out the state of the art at the time of the specification among those to whom the teaching in the specification is addressed. In any case, the court has the final say with regard to what evidence may be accepted and is not obliged to accept the interpretation placed on the words by either of the parties.

## **ii. Principles Similar to Interpretation of Contracts**

Like any other written instrument, the patent will be interpreted as a whole. The principles for the interpretation of patents are similar to that developed for interpretation of contracts. The interpretation of documents is a question of law that does not change from case to case. The courts may rely on earlier judicial interpretation of a patent. The canons of interpretation are used more as general guidelines than rules of law to interpret a contract in a way to make it valid and give effect to all its parts. The same approach will apply to the interpretation of patents. In certain circumstances, similar to filling the gaps in a contract by the process of interpretation, the court may fill a gap or depart from the precise terms of the patent, if the court is satisfied that the same can be done as a matter of interpretation.

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<sup>92</sup> *Catnic Components Ltd v. Hill & Smith Ltd.*, (1982) RPC 183, p 243.



### **iii. Common Principles for Validity and Infringement**

The principles applied in the interpretation of patents are the same in determining cases of revocation (invalidity) and infringement. The extent of protection offered by the patent is important for both proceedings. Of course, it would have been desirable, had it been permissible, from the view point of a patentee, to interpret the scope of the patent broadly in cases of infringement and narrow down its scope where the validity of the patent is questioned in revocation proceedings. Such liberties are not available to the patentee. The scope and ambit of a patent claim must be interpreted without reference to the prior art; it must be the same regardless of the case pleaded against the patent. As issues of validity and infringement are likely to arise in the same proceedings, the standards of interpretation must necessarily be the same in revocation and infringement proceedings.

### **iv. Relevant Date for Interpreting the Specification**

The courts have deliberated, with differing opinions, on what should be the relevant date for interpreting a specification. The relevant date for determining insufficiency has been held to be the date of filing the application, the date of acceptance of specification, the date of filing of complete specification and the date of publication. Generally, a specification is interpreted with reference to the state of the art at the time it is published.

### **v. Patents are intended to be read by Persons Skilled in the Art**

The phrase ‘person skilled in the art’ is not defined under the Patents Act, though it is mentioned in section 2(1) (ja) in the context of determining obviousness. The person skilled in the art is also known as a notional skilled addressee to whom the patent is deemed to have been addressed. As a hypothetical construct, the addressee is taken to be an unimaginative person who lacks inventive capacity but at the same time is deemed to have common general knowledge of the subject matter of the invention. A patent is supposed to teach people how to perform the invention. If necessary information is not present in the patent, then the skilled person must be given a clear unambiguous direction on where to get it. He cannot be expected to find such a direction buried in acknowledgements of the prior art.<sup>93</sup>

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<sup>93</sup> Halliburton Energy Services Inc v. Smith International (North Sea) Ltd., [2006] EWCA Civ 1715, para 67 (CA).

**a) Determining the Person Skilled in the Art**

In determining the person skilled in the art, the court ‘has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question.’<sup>94</sup> The notional skilled addressee will vary with the facts and circumstances of each case, depending on the subject matter of the invention. The subject matter will be crucial in determining the addressee of the patent. The addressee will be expected to have ‘a practical interest in the subject matter’ of the invention having ‘practical knowledge and experience of the kind of work in which the invention is intended to be used’.<sup>95</sup> His interest in the subject will enable him to read a document assiduously, regardless of how immensely boring it is.<sup>96</sup> In certain cases, the skilled person will be required to exercise a high degree of skill in meticulous and detailed operations that may be time-consuming.<sup>97</sup>

**b) Common General Knowledge**

Common general knowledge is a part of the mental requirement of a person skilled in the art. It is the mental tools of the trade of a person skilled in the art. It is the technical background of the notional man in the art against which the prior art must be considered. The proof of common knowledge is given by expert witnesses. In interpreting patents, the court will have to put itself in the position of a skilled addressee at the time the specification was published and look at the patent from the standards of the common general knowledge of such person. Common general knowledge refers to the ‘common knowledge in art and science to which the alleged invention relates, so as to be known to duly qualified persons engaged in that art or science’. It is not limited to the material the person skilled in the art has memorised and has at the front of his mind. It also includes ‘all that material in the field he is working in, which he knows exists, which he would refer to as a matter of course if he cannot remember it, and which he understands is generally regarded as sufficiently reliable to use as a foundation for further work or to help understand the pleaded prior art’. The knowledge should be of a general nature. It will not suffice to show that a matter was known to some but not to others, and in particular, it will not be good enough to show that knowledge, or even a prejudice ‘was confined to one or a limited class of suggested exemplars of the skilled man’.

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<sup>94</sup> *Windsurfing International Inc v. Tabur Marine (Great Britain) Ltd* (1985) RPC 59, pp 73-74 per Oliver LJ.

<sup>95</sup> *Supra* note 62, p. 242.

<sup>96</sup> *Technip France SA’s Patent*, (2004) RPC 46, para 79 (CA).

<sup>97</sup> *Genentech Inc’s (Human Growth Hormone) Patent*, (1989) RPC 613, p 619.

A concept that is well-known to some will not be a part of the common general knowledge if it was not known to the bulk of those skilled in the art. The person skilled in the art cannot be expected to find such knowledge ‘buried in acknowledgements of the prior art’.

**vi. Interpretation of a Patent may require Expert Evidence on Technical Terms**

Common general knowledge or general public knowledge must be proved by witnesses in a general way and if necessary, there can be references to well-known works as to the state of general public knowledge at the relevant time. Usually, the expert witnesses who give evidence in patent cases tend to be over-skilled and have been referred to as ‘persons steeped in the art’. The eminence and technical qualification of the expert witness summoned by the parties can be a critical factor. The court is likely to go by the testimony of the expert whose field of expertise is directly in line with that of a person skilled in the art. As the primary duty of the expert is to educate the court in the technology, it will not really matter whether such witnesses did or did not approximate to the person skilled in the art. The court will not be bound to follow the opinion of the expert.

The context of the words used in the claims may be understood from its usage in the body of the specification, by reading the specification as a whole. The court may require evidence on the technical expressions used in the claims and specification, if it feels that any such expressions require an explanation. Where the words used in the claims are not technical words having a special trade meaning, the opinion of expert witnesses on the meaning of such words will not be admissible. It will be for the court to decipher and interpret the meaning of such words. The court is entitled to admit evidence on the meaning of technical terms, and must decide the meaning of these terms from the context in which they are used.<sup>98</sup>

**vii. Patent Specification and the Claims should be read as a whole**

Like any other legal document, a patent should be interpreted as a whole, i.e., the title, claims and drawings should be read together as a single document. The claims in a specification are analogous to the operative part of a deed. It follows that the claims must be interpreted as a part of the whole document. The claim and the specification should be looked at and interpreted together expecting one to be consistent with the other. This principle reflects a

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<sup>98</sup> Hoechst Celanese Corp v. BP Chemicals Ltd., [1999] FSR 319, pp 326-27.

statutory requirement under the Patents Act, as inconsistency of a claim with matter disclosed in the specification can be a ground for the revocation of the patent.<sup>99</sup>

The claims and the specification should be read in the light of the language employed. Where the language of the claim is clear and unambiguous, it will not be proper to extend or cut down the clear meaning of the claim by reference to the specification. This should be the case in infringement actions where ‘the main function of the court is to interpret the claims which are alleged to have been infringed, without reference to the body of the specification, and to refer to the body of the specification only if there is any ambiguity or difficulty in the interpretation of the claims in question’. In other words, if the claims have a plain meaning in themselves, then advantage cannot be taken of the language used in the body of the specification to make them mean something different.

#### **viii. Patents must be given a purposive interpretation**

A purposive interpretation as the phrase implies gives effect to the purpose of the inventor. The application of a purposive interpretation will aim at giving a sensible meaning and avoiding any absurd result, which the patentee could not have intended. Depending upon the context, a purposive interpretation may narrow or widen the claims from the contextual meaning. According to the principle of purposive interpretation, words must be interpreted having regard to the inventor's purpose as disclosed in the specification. The intention of the author of a contract or a patent specification in using the language is to make a communication for a practical purpose. Any rule of interpretation that gives his language a meaning different from the way it would have been understood by the people to whom it was actually addressed may defeat his intentions. The purposive rule of interpretation gives effect to this principle. The rule of purposive interpretation stated by the decision of the House of Lords in *Catnic* was statutorily incorporated in s. 125 of the UK Patents Act, 1977.

##### **a) Law before *Catnic***

The development of the rule of purposive interpretation can be traced back to a string of landmark cases, each confirming the earlier position and explaining further the details of the rule. The decision in *Catnic Components Ltd v. Hill & Smith Ltd.* was the first case where the rule of purposive interpretation of patents was applied. Before *Catnic* the issue of

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<sup>99</sup> Section 64(1)(i), Patents Act 1970.

infringement of patents was decided employing two techniques, i.e., the ‘textual infringement’ and the infringement of the ‘pith and marrow’ of the invention.

According to the textual infringement rule if the alleged infringement fell within the strict literal meaning of the claims and embodied every integer of the claim, a case for textual infringement was made out. This method followed the rule of literal interpretation. Allowance was made to this rule so as not to limit the scope of the patentee’s monopoly to the strict language used in the claim. The claims then came to be interpreted by its ‘pith and marrow’ to ensure that an infringer could not avoid infringement by making an ‘immaterial variation’ in the invention.

#### **b) Rule of Literal Interpretation**

The general principles of literal interpretation applied to the question of infringement have been summarised by the House of Lords in *Rodi and Wienenberger AG v. Henry Showell Limited*,<sup>100</sup> where Lord Upjohn stating that the first issue is to determine whether the relevant claim has been infringed, said:

*In considering the claim the court must ascertain what are the essential integers of the claim; this remains a question of construction and no general principles can be laid down (see my observations in Van der Lely v Bamfords [1961] RPC 296 at 313 approved on appeal to this House.)*

*Secondly the essential integers having been ascertained the infringing article must be considered. To constitute infringement the article must take each and every one of the essential integers of the claim. Non-essential integers may be omitted or replaced by mechanical equivalents; there will still be infringement. I believe that this states the whole substance of the ‘pith and marrow’ theory of infringement. Furthermore, where the invention, as in this case, resides in a new combination of known integers but also merely in a new arrangement and interaction of ordinary working parts it is not sufficient to show that the same result is reached; the working parts must act on one another in the way claimed in the claim of this patent.*

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<sup>100</sup> (1969) RPC 367 (HL).

### c) **Doctrine of Equivalents**

The doctrine of equivalents is applied to cover equivalents not expressly mentioned in the claims. It involves the extension the scope of a patent to cover something outside the literal wording of the claims. It is a well-settled principle that a specification should not be interpreted to mean a thing which was beyond the contemplation of the patentee. The extent of the protection shall be decided by the terms of the claims alone. There is no need to apply the doctrine of equivalents as the purposive interpretation of a claim would enable one to determine whether any technically trivial or minor difference between the element of claim and the corresponding element of the alleged infringement would fall within the meaning of the element.<sup>101</sup> In *Kirin-Amgen*, it was held that the doctrine of equivalents will not be applied by the courts in the United Kingdom.

The situation is similar in India, as protection is granted only for what is sufficiently and clearly defined in the claim. This is evident from a combined reading of section 64(1) (i) of the Patents Act, which requires the scope of any claim in the complete specification to be sufficiently and clearly defined, failing which it could be a ground for revocation and section 10(4) (c) of the Patents Act which confines the scope of protection to what is claimed. The doctrine of equivalents is unlikely to be applied in the interpretation of patents. Even at the policy level, the patent law in India has much in common to the law as it has developed in United Kingdom than its practice and application in the United States.

### ix. **Subsequent Conduct of the Patentee is not an Aid to Interpretation**

The interpretation of patents involves a unique situation where the court will try to interpret the words of the patentee with the understanding of a hypothetical skilled addressee. A patent, like any other written document, will be attributed the meaning as at the time when it was made. The courts will not alter or ascertain that meaning by placing reliance on how the patentee subsequently acted upon it or interpreted it.<sup>102</sup> This proposition proceeds from the general rule that extrinsic evidence is not admissible for the interpretation of a written contract and that the subsequent actions of a party to the contract shall not be taken into account for interpreting the same.

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<sup>101</sup> *Supra* note 66, para 41.

<sup>102</sup> *Supra* note 61, p. 94.

**x. Courts should discourage introduction of new requirements**

The purposive method of interpretation will not permit the introduction of any additional requirement over and above the ones stipulated by law. However, it is permissible for the court to introduce the requirements stated in section 10 of the Patents Act, the ingredients of which any complete specification must necessarily comply with. For instance, the court may introduce, by way of interpretation, the requirement that the claim must be fairly based on the matter disclosed in the specification.<sup>103</sup>

**xi. Courts shall not resolve any doubt in favour of or against the Patentee**

The requirement of disclosure to third parties is a vital part of a complete specification. The Patents Act requires every specification to fully and particularly describe the invention and its operation or use and the method by which it is to be performed.<sup>104</sup> The purposive interpretation will not allow the court to resolve a doubt in favour of the patentee or in favour of a strict or literal interpretation. Such an approach would result in rewarding opaque drafting. A specification must be interpreted impartially, in a neutral manner without ‘narrowing or widening the boundaries of the monopoly fixed by the plain words of a claim’. It follows that courts shall be reluctant to resolve difficulties in interpretation either in favour of the patentee or against the patentee.

**xii. Ambiguous claims should not be given a wide interpretation**

Lack of clarity is a ground for revocation of a patent under the Patents Act.<sup>105</sup> Similarly if the scope of any claim of the complete specification is not sufficiently or clearly defined, it could also be a ground for revocation.<sup>106</sup> But the mere fact that a word, phrase or other provision in a patent claim is not wholly clear will not automatically lead to the conclusion that the claim is objectionable, as this would set an unrealistic standard for drafting in any field. A claim needs to be as clear as the subject matter reasonably permits.

Claim in a specification will not be ambiguous merely because some part of it is capable of more than one interpretation or is difficult to interpret. In such cases, the court should prefer the sensible interpretation and would read the claim in such a manner so as to avoid an absurd result. As the patentee is free to use the language he likes to define his invention, ‘the court

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<sup>103</sup> Section 10(5), Patents Act, 1970.

<sup>104</sup> Section 10(4)(a), Patents Act, 1970.

<sup>105</sup> Section 64(1)(h), Patents Act, 1970.

<sup>106</sup> Section 64(1)(i), Patents Act, 1970.

has to guard against being impressed by the form and language of the claims rather than the substance of the patentee's alleged technical contribution'. Where the claims are prolix and opaque, the court should break free of the language and concern itself with what the claims really mean. An ambiguous claim can result in the patentee being unable to establish infringement. The courts may also impose costs for poor and ambiguous drafting. Ambiguous claims are drafted so that the patentee may claim the widest possible scope for the invention. The courts have cautioned not to interpret the claims so as to give a patentee the widest possible scope.



# PATENT APPLICATION

## I. INTRODUCTION

Before filing a patent application, the inventor must ascertain whether the invention is patentable under the Patents Act or not. Once a patentable invention is identified and before any disclosure is made, the crucial decision as to whether a patent application should be filed has to be taken. There would definitely be situations where it is not appropriate to make a patent application. For instance, if the objective of the inventor is not to get a monopoly and to exclude others from using the invention, the inventor may publish the invention immediately. This would not only give her the credit of the invention but will also prevent others from obtaining a patent for such an invention. Another instance involves inventions of such nature where it would be difficult to detect and prove infringement. Patenting such inventions would ultimately lead only to disclosure of vital information and prosecuting such infringements would be an arduous task. The inventor shall also take into account other alternatives, such as protecting the inventions as confidential information or through other forms of intellectual property rights.

The decision as to when a patent application has to be filed and where such an application is to be made depends on the patent strategy of the inventor. Where the invention is to be sold and used in more than one country, an international application (a convention application or a PCT application) would be the preferable route. Once an international application is made, it gives the invention priority from the date of the application. The patentee then has more than a year to file the individual applications in other countries. This would give the patentee enough time to test the commercial and inventive worthiness of the product. If a decision is made, within one year after filing the international application, that the invention is not worthy of being patented, the application can be abandoned. Alternatively, if the decision is to file patent applications in several other countries, the international application can be relied upon for the purpose of priority and the invention would have the priority date of the international application.

Like India, most jurisdictions encourage the patent application to be made as soon as the invention is identified. This is known as the first-to-file system for granting patents. An application for a patent can be made in anticipation of an invention. But it would be safer to test and try the invention before the first application is made. The Patents Act contains

various provisions for opposing and challenging a patent before and after its grant. Care should be taken to check whether the patent is capable of being worked and commercially exploited, as the patent can be challenged on these grounds.

It is important for the applicants not to publish their inventions before approaching the patent office, as publication of the invention, even by the inventor himself, will constitute a bar for patenting it in most cases. Even public use of the invention may be raised as an objection to the grant of a patent. The Patents Act, however, protects secret working of the invention for the purpose of research and trial. It is also important for the applicants not to wait till the inventions are fully developed for commercial working. As the Patent Office follows the first-to-file system, any delay in approaching the Patent Office may result in another inventor applying for a patent or increase the risk of inadvertent publication. The best recourse for the inventor will be to file a provisional specification as soon as practicable.

Every application for patent shall be made in Form 1 of Second Schedule to the Patents Rules, 2003 and shall relate to only one invention. Broadly, an application for the grant of a patent in India can be done in two ways; the application can either be made directly to the Indian Patent Office under the Patents Act or indirectly by filing an application under the Patent Cooperation Treaty (PCT).

## **II. PROVISIONS UNDER PATENTS ACT, 1970**

As per Chapter III of the Patents Act, this comprises of sections 6 to 11, dealing with applications for patents. The corresponding rules are contained in of the Patents Rules, 2003, rules 10 to 16. Chapter IV of the Patents Act, which comprises of sections 11A to 21, deals with publication and examination of applications. The corresponding rules are contained in rules 24 to 38. Chapter VII (sections 35 to 42) deals with the provisions for secrecy of certain inventions. Chapter IX (sections 54 to 56) deals with patents of addition. Chapter XXI, which comprises of sections 133 to 139, deals with Convention and PCT applications. Rules 17 to 23 deal with international applications under the PCT.

## **III. PERSONS WHO CAN APPLY**

An application for patent for an invention may be made, either alone or jointly with any other person, by any of the following persons:

- 1) any person claiming to be the true and first inventor of the invention; or

- 2) any person who may be the assignee of the true and first inventor; or
- 3) the legal representative of any deceased person who was entitled to make the application immediately before his death.<sup>107</sup>

An international application under the PCT can be filed before the Indian Patent Office.<sup>108</sup> The expression ‘applicant’ is defined in the PCT in a similar way to include the agent or other representative of the applicant.<sup>109</sup> The applicant must be a resident or a national of a Contracting State to the PCT.<sup>110</sup>

#### **A. ‘True and First’ Inventor**

The Patents Act does not define the expression ‘true and first inventor’. It merely excludes the first importer of an invention into India, and a person to whom an invention is first communicated from outside India, from the ambit of the expression.<sup>111</sup>

The Patents Act requires the true and first inventor to be a natural person. Many of the forms in second schedule to the Patents Rules require the disclosure of the name of the natural person who has signed them.<sup>112</sup> This requirement is equivalent to the disclosure of the name of the ‘true and first inventor’. Juristic entities like corporations, institutions and companies can, at best, be an assignee or a joint applicant along with the true and first inventor.

As the Patents Act follows the first-to-file system, in cases where two persons simultaneously make the same invention and neither of them uses or discloses the invention prior to making the application, the person who first applies for the patent will be considered as the ‘true and first inventor’ even if the other would have actually made the invention prior in time. The first-to-file system is based on the reasoning that the person who files the application first makes a contribution to the public by showing them how to practice the invention. Thus, a patent is granted under the Patents Act to a person who approaches the Patent Office first for a patent. The grant confers an exclusive right to monopolise the invention which is given in lieu of the disclosure of the invention. So, the disclosure made to the Patent Office is a condition that entitles one for a grant. This puts a person, who may have made the invention first but did not approach the Patent Office with an application for grant, in a position where

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<sup>107</sup> Section 6, Patents Act, 1970.

<sup>108</sup> Rule 18, Patents Rules, 2003.

<sup>109</sup> Rule 2.1, PCT Rules.

<sup>110</sup> Article 9(1), PCT.

<sup>111</sup> Section 2(1)(y), Patents Act, 1970.

<sup>112</sup> Forms 13 and 14, Patents Rules, 2003.

it would be difficult to prove himself as the 'true and first inventor', except in cases where the invention is wrongfully obtained from him.

For this reason, the patent is granted to the person who finds out 'something which has not been found out by other people'. The person to whom an idea occurred will not be the true and first inventor, unless he had also reduced the idea to a definite and practical shape. The name of the true and first inventor shall be disclosed in every application. Where the applicant is not the true and first inventor, the application shall contain a declaration that the applicant believes the person so named to be the true and first inventor.<sup>113</sup>

### **i. Identification of the Inventor**

On the issue of identifying the inventor, the British courts have held that it is essential to identify the inventive concept of the claims first and then to see who was responsible for it or who devised it. Inventive effort or intellectual contribution to the invention is the criterion for determining whether a person is a true and first inventor. Financial or material contribution, however, shall not entitle a person to be a true and first inventor. A partnership firm or a corporate entity, for this reason, cannot be the sole applicant claiming to be the inventor. But a firm or a company may be registered as a joint patentee along with the first and true inventor. A person making a suggestion, such as a claim limitation, having no substantial bearing on the inventive concept, will not be regarded as a joint inventor. Similarly, a person who adds common general knowledge of those in the art to the inventor's idea cannot be regarded as an inventor.

### **B. Assignee**

As the right to apply is an assignable right, the assignee of the true and first inventor may also apply for the patent.<sup>114</sup> There is no restriction as to who may be an assignee; even a foreigner can be an assignee.<sup>115</sup> An assignee can either be a natural person or a legal person such as a registered company, research organisation, educational institution or government. Though assignments are usually done in writing, the Patents Act or the Patents Rules do not preclude an oral assignment. No procedural formalities are stipulated under the Patents Act for an assignment to be valid. Where the application is made by an assignee of the true and first

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<sup>113</sup> Section 7(3), Patents Act, 1970.

<sup>114</sup> Section 2(1)(ab), Patents Act, 1970.

<sup>115</sup> But the applicant must be a national of India or of a convention country.

inventor, every application must contain a declaration by the applicant stating, among other things, the following:<sup>116</sup>

- 1) that the applicant is in possession of the invention;
- 2) that there is no lawful ground of objection to the grant of the patent to the applicant; and
- 3) that the applicant is the assignee or legal representative of the true and first inventor.

The assignee should also furnish the proof of the right to make the application either along with the application, or within a period of six months after the filing of such application.<sup>117</sup>

The above six-month period in case of an application corresponding to an international application designating India shall be calculated from the actual date on which the application is filed in India.<sup>118</sup> The assignee has to state the name of the true and first inventor. Any application made without making the true and first inventor a party is void. Such an omission cannot be cured by amendment.

A company or a firm may also apply for a patent as the assignee of the true and first inventor.<sup>119</sup> Though a body corporate does not have the capacity to invent, the rights of the true and first inventor may be assigned to it. As stated above, a person entitled to apply for a patent under the Patents Act includes the government.<sup>120</sup> But a member of an official commission or committee investigating into the patent cannot take out a patent for the results of an official investigation belonging absolutely to the state.

### **C. Legal Representative**

The right to apply for a patent is a continuing right which will pass on to the legal representatives of the any deceased person who was entitled to make such an application. A legal representative is a person who in law represents the estate of a deceased person.<sup>121</sup> The legal representative should file the death certificate and other documents as proof of right.

## **IV. MENTION OF INVENTOR**

An application should state that the person making the application is in possession of the invention and also mention the name of the inventor. The application for grant may be made

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<sup>116</sup> Form 1, Patents Rules, 2003.

<sup>117</sup> Section 7(2), Patents Act, 1970; Rule 10, Patents Rules, 2003.

<sup>118</sup> *Ibid.*

<sup>119</sup> *Shining Industries v. Shri Krishna Industries*, AIR 1975 All 231.

<sup>120</sup> Section 2(1)(s), Patents Act, 1970.

<sup>121</sup> Section 2(1)(k), Patents Act, 1970.

in the joint names of the employer and the employee; in such cases the employee may be entitled to compensation. Usually, the employer will apply for the grant of the patent in its own name. The employer (applicant) shall disclose the name of the true and first inventor and shall make a declaration that he believes the person so named to be the true and first inventor.<sup>122</sup>

Section 28 of the Patents Act provides for a mechanism by which the inventor may secure his right to be identified with the invention. If the Controller is satisfied, by a request or a claim made before him:

- 1) that the person in respect of or by whom the request or claim is made is the inventor of an invention in respect of which application for a patent has been made, or of a substantial part of that invention; and
- 2) that the application for the patent is a direct consequence of his being the inventor, the Controller shall cause such person to be mentioned as inventor in any patent granted in pursuance of the application in the complete specification and in the register of patent. However, such a mention of any person as the inventor shall not confer or derogate from any rights under the patent.

The Controller is empowered, upon a request or claim made to him, to cause the inventor's name to be mentioned in any patent granted as well as in the register of patents, in the manner mentioned in rule 70.<sup>123</sup> A request for the inventor's name to be mentioned shall be made in Form 8 either by the applicant (where the applicant is the inventor) or jointly by the applicant and the inventor (where the applicant is not the inventor). If any other person desires to be mentioned as the inventor, a claim shall be made to that effect in Form 8. Such a request or claim shall be made before the grant of the patent.<sup>124</sup>

When a request or a claim is made under section 28, the Controller shall give notice to every applicant and interested persons and give opportunity to hear the persons concerned before deciding the request or claim. The Controller shall follow the same procedure as in the case of opposition proceedings.<sup>125</sup> Section 28 provides for special powers for rectification of the register in cases where a person who ought not to have been mentioned as the inventor has been mentioned as one. Any person may apply to the Controller for a certification of

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<sup>122</sup> Section 7(3), Patents Act, 1970.

<sup>123</sup> Section 28(1), Patents Act, 1970.

<sup>124</sup> Section 28(4), Patents Act, 1970.

<sup>125</sup> Section 28(6), Patents Act, 1970; Rule 69, Patents Rules, 2003.

rectification, which may be granted after hearing the interested persons. Upon the issue of such a certificate, the specification and the register shall be rectified accordingly.<sup>126</sup> A proceeding under section 28 confers a special power on the Controller to rectify the register consequent to a request or a claim being made in accordance with that section. The general power of rectification of register vests with the Appellate Board.<sup>127</sup>

## **V. ENTITLEMENT DISPUTES**

As stated above, a proceeding under section 28 of the Patents Act will not confer or take away any rights under the patent. It merely acknowledges the right of an inventor to be identified with his invention. Disputes with regard to entitlement of a patent or a share or an interest in a patent shall be decided by a competent court.<sup>128</sup> Entitlement disputes with regard to a patent application which arises at any time before the patent is granted shall be decided by the Controller in accordance with section 20 of the Patents Act. The Controller also has powers to give directions to co-owners.<sup>129</sup>

### **A. Disputes before the grant of a patent**

Entitlement disputes which arise under the Patents Act at any time before the grant of a patent are decided by the Controller under section 20.

### **B. Disputes after the grant of a patent**

Disputes after the grant are dealt with by a combination of procedures. The Patents Act confers power on the Controller to take notice of a change in title to a patent.<sup>130</sup> But where there is any dispute with regard to the title or interest in a patent, the rights of the parties have to be decided by a competent court.<sup>131</sup> As the rules of law applicable to the ownership and devolution of moveable property shall apply in relation to patents,<sup>132</sup> disputes with regard to title or interest over patents may be settled by a suit for declaration under section 34 of the Specific Relief Act 1963.

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<sup>126</sup> Section 28(7), Patents Act, 1970.

<sup>127</sup> Section 71, Patents Act, 1970.

<sup>128</sup> Section 69(3), Patents Act, 1970.

<sup>129</sup> Section 51, Patents Act, 1970.

<sup>130</sup> Section 69, Patents Act, 1970.

<sup>131</sup> Section 69(3), Patents Act, 1970.

<sup>132</sup> Section 50(5), Patents Act, 1970.

### **i. Disputes between Employers and Employees**

Inventions are normally made by employees during the course of their employment with a company or an organisation. It is preferable for the inventor to clarify his rights with reference to his employers, co-workers, contractors and assistants who may be involved, in some manner, with the development of the invention, before filing the patent application. The common law on the point, pertaining to cases where there are no specific agreements clarifying the rights, indicates diverse findings as to who should be the owner of the invention. On the one hand, there are decisions which show that employees are not trustees of their employers and as such the inventor will be entitled to retain his interest in the invention as against the company. On the other hand, the courts have held that the contractual relationship will be decisive in determining to whom the invention belongs, even if not expressly provided for. An employer can bring in an action for declaration that the invention made by the employee during the period of employment belonged to the employer. If the employee has obtained the patent in his own name under circumstances that would render him a trustee, the employer is entitled for an order assigning the patent to him.

### **ii. Normal Duties of Employees**

An invention made by an employee in the course of his normal duties would belong to the employer if such an invention would have been reasonably expected from carrying out the duties. In interpreting the expression 'normal duties', the question that had to be considered was whether designing and inventing formed a part of the employee's duties. The expression 'normal duties' will also include subtle variations to the terms of the initial written contract of employment, as a contract can be expected to evolve in the course of time.

### **iii. Special Obligation**

In *Harris' Patent*,<sup>133</sup> the court also considered the second condition of section 39 of the UK Patents Act which pertains to special obligation. The section states that the invention should be made in the course of the duties of the employee and that such duties gave rise to a special obligation to further the interest of the employer. Justice Falconer, after considering Mr Harris's employment as a manager in Reiss Engineering, held:

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<sup>133</sup> (1985) RPC 19.



*It seems to me that, having regard to his status and the nature of his duties and responsibilities, as they were in fact under that status, the obligation which he had by reason of the nature of his duties and particular responsibilities arising therefrom was no more than to do the best he could to effect sales of the Wey valves which Reiss Engineering sold, valves made by Sistag or strictly to Sistag's drawings, and to ensure to customers after sales service of valves supplied. Beyond that obligation, in my judgment, he had no special obligation to further the interests of Reiss Engineering's valve business. Accordingly, I hold that Mr Harris's invention is not one falling within para (b) of s. 39(1).*

The legal provisions cited above and the judicial decisions on the subject would indicate that entitlement disputes pertain more to aspects of contract law than patent law. Needless to say, the Indian law with regard to entitlement disputes between the employer and employee is based on common law. Such codification will bring in certainty especially in this area where there are diverging, if not conflicting, decisions of the British courts.

#### **iv. Breach of Confidence**

A person who claims entitlement of another's patent application or a part of it must show that he is entitled to it by contract or by breach of confidence. It would be preferable to bring common proceedings for entitlement and breach of confidence. It has been observed that entitlement disputes, if fully fought, could lead to protracted, expensive and emotionally draining proceedings. A better course would be to settle such disputes by mediation or arbitration or by a combination of both.

#### **VI. REQUIREMENTS OF AN APPLICATION**

An application for a patent has to be filed in the appropriate patent office within whose territorial limits the applicant has his place of residence, domicile or business. In the case of a joint application, the whereabouts of the first mentioned applicant shall be taken into account in determining the appropriate patent office. An application can also be filed in the office within whose territorial limits the invention originated. If the applicant has no place of business or domicile in India, then the appropriate patent office will be the one within whose

territorial limits the address of service in India furnished by the applicant is situated.<sup>134</sup> An applicant may also furnish his patent agent's address as the address for service of documents.

An application for patent shall be made in duplicate, in Form 1, and by paying the prescribed fee. The application should be accompanied by the following documents, which are discussed below in detail:

- 1) Provisional or complete specification<sup>135</sup> and drawings, if any, in duplicate;<sup>136</sup>
- 2) Statement and undertaking regarding foreign filing details in respect of the same invention;<sup>137</sup>
- 3) Declaration as to inventorship;<sup>138</sup>
- 4) Priority document in the case of a convention application;<sup>139</sup>
- 5) Power of attorney where the application is made through a patent agent;<sup>140</sup>
- 6) Proof of right if the application is made by the assignee.<sup>141</sup>

#### **A. Specification**

The provisional specification is the document filed before the Patent Office which first discloses the patent. An applicant may choose to file a provisional specification when he feels that the invention has reached a presentable form. By preferring the provisional specification which describes the invention, the applicant gets priority over any other person who is likely to file an application with regard to the same invention. As the Patent Office follows the first-to-file system, the promptness in filing the provisional specification can be crucial in obtaining a patent. On the receipt of the provisional specification, the Patent Office accords a filing date for the application. From then on, the applicant has 12 months for filing the complete specification along with a declaration as to inventorship.<sup>142</sup>

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<sup>134</sup> Rule 4, Patents Rules, 2003.

<sup>135</sup> Section 9 and 10, Patents Act, 1970; Form 2, Patents Rules, 2003.

<sup>136</sup> Rules 13 and 15, Patents Rules, 2003.

<sup>137</sup> Section 8(1), Patents Act, 1970; Rule 12 and Form 3, Patents Rules, 2003.

<sup>138</sup> Form 5, Patents Rules, 2003.

<sup>139</sup> Section 138, Patents Act, 1970.

<sup>140</sup> Rule 135(1) and Form 26, Patents Rules, 2003.

<sup>141</sup> Section 7(2), Patents Act, 1970; Rule 10, Patents Rules, 2003.

<sup>142</sup> Form 5, Patents Rules, 2003.

## **B. Statement and Undertaking regarding Foreign Applications**

In cases where the applicant for a patent under the Patents Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file, along with his application, or within six months from the date of filing, a statement and an undertaking as prescribed in Form 3.<sup>143</sup> If there is no such foreign application, the applicant shall file a statement to that effect.

The statement shall set out the detailed particulars of such application including the name of the country, application number and status of such application. The undertaking given by the applicant shall state that, up to the date of the grant of his complete specification filed in India, the applicant would keep the Controller informed in writing, from time to time, the detailed particulars as required under clause (a) of section 8(1) of the Patents Act in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within six months of such filing.

At any time after an application for patent is filed in India and till the grant of patent or refusal to grant of patent is made, the Controller may also require the applicant to furnish details as may be prescribed relating to the processing of the application in a country outside India, and the applicant shall furnish information available to him to the Controller within six months from the date of receipt of the communication requiring such furnishing of information.<sup>144</sup> In case of delay in furnishing the details beyond six months, the applicant may seek for further extension of time by filing a petition under rule 138. When the Controller requires such information under section 8(2) of the Patents Act, the applicant shall furnish information pertaining to objections, if any, in respect of novelty and patentability of the invention and any other particulars as the Controller may require which may include claims of application allowed within six months from the date of such communication by the Controller.<sup>145</sup>

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<sup>143</sup> Section 8(1), Patents Act, 1970; Rule 12(1A), Patents Rules, 2003.

<sup>144</sup> Section 8(2), Patents Act, 1970; Rule 12(2), Patents Rules, 2003.

<sup>145</sup> Rule 12(3), Patents Rules, 2003.

### **C. Declaration as to Inventorship**

The applicant has to make a declaration as to inventorship in Form 5 showing the name, nationality and address of the true and first inventor. Such a declaration is not required in the case of an ordinary application filed along with the complete specification. However, a declaration is needed in case of a Convention application, a PCT National phase application and where the complete specification is filed after the provisional specification is made.<sup>146</sup>

### **D. Priority Document for Convention Applications**

The priority document for a convention application made in accordance with chapter XXII of the Patents Act refers to the copies of the specifications or corresponding documents filed or deposited by the applicant in the patent office of the convention country as referred to in section 133 of the Patents Act and verified to the satisfaction of the Controller.<sup>147</sup> The applicant shall furnish the above documents in addition to the complete specification. If the priority documents are in a foreign language, a translation in English verified by affidavit shall be furnished when required by the Controller.<sup>148</sup> The priority date shall be the date on which the application was made in the convention country.<sup>149</sup>

### **E. Representation through a Patent Agent**

The proof of representation by a patent agent or an advocate shall be by filing an authorisation under Form 26 or in the form of a power of attorney.<sup>150</sup>

### **F. Proof of Right**

Section 7(2) requires proof of right to file the application in cases where the application is made by virtue of an assignment of the right to apply. The applicant can produce the proof of right to apply either in the body of the application by means of an endorsement in Form 1 or by way of separate assignment deed. Where the applicants are the legal representatives of the deceased, the death certificate should be filed as proof of right. The time stipulated for filing the proof of right is six months from the date of application.<sup>151</sup>

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<sup>146</sup> Section 10(6), Patents Act, 1970; Rule 13(6), Patents Rules, 2003.

<sup>147</sup> Section 138(1), Patents Act, 1970.

<sup>148</sup> Section 138(2), Patents Act, 1970.

<sup>149</sup> Section 138(3), Patents Act, 1970.

<sup>150</sup> Sections 127 and 132, Patents Act, 1970; Rule 135(1), Patents Rules, 2003.

<sup>151</sup> Rule 10, Patents Rules, 2003.

## VII. TYPES OF PATENT APPLICATIONS

A patent application shall pertain to only one invention.<sup>152</sup> A complete specification shall relate either to a single invention or to a group of inventions linked so as to form a single inventive concept.<sup>153</sup> The expressions ‘single invention’ and ‘single inventive concept’ are not defined in the Patents Act. A single patent may be granted for cognate inventions, if the Controller is satisfied that there is a sufficiently close relationship between the inventions. With regard to chemical products, claims to intermediate and final chemical products have been held as not relating to a single inventive concept; but the same would be regarded as a single inventive concept if the intermediaries and the final products have a common structural element, providing the necessary technical interconnection for the existence of unity or if the intermediaries contribute to address a unitary overall problem.

The guidelines released by the Patent Office provide further clarification on how an application for single invention will be dealt with.<sup>154</sup> Where the subject matter of the application does not constitute one invention or a group of inventions so as to make a single invention, the application should be divided into separate applications. The Controller may also reject the application on the ground that the application pertained to more than one invention, if the applicant fails to amend the application.<sup>155</sup> But no person shall take any objection to a patent on the ground that it has been granted for more than one invention.<sup>156</sup> Nor shall the validity of a patent of addition be questioned on the ground that the invention ought to have been the subject matter of a separate patent.<sup>157</sup>

The different types of patent applications that can be made with regard to an Indian patent are as follows:

- 1) Ordinary application under section 7.
- 2) Convention application under section 135.
- 3) PCT international application under the PCT.
- 4) PCT national phase application under section 7(1)(A).
- 5) Application for patent of addition under section 54.
- 6) Divisional application under section 16.

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<sup>152</sup> Section 7(1), Patents Act, 1970.

<sup>153</sup> Section 10(5), Patents Act, 1970.

<sup>154</sup> Manual of Patent Practice and Procedure, Patent Office.

<sup>155</sup> Section 15, Patents Act, 1970.

<sup>156</sup> Section 46(2), Patents Act, 1970.

<sup>157</sup> Section 56(1), Patents Act, 1970.

The different types of applications are discussed below in detail.

**A. Ordinary Application: Section 7**

The first application for patent made in Patent Office without claiming any priority of application made in a convention country or without any reference to other application under process in the office is called an ordinary application. An application shall be made in Form 1 and filed in the Patent Office along with the prescribed fee.<sup>158</sup> Every application shall be made along with the provisional or complete specification, drawings, priority documents, statement and undertaking, power of attorney and declaration of inventorship.<sup>159</sup>

**B. Convention Application: Section 135**

Article 4 of the Paris Convention for the Protection of Industrial Property 1883 allows an applicant who has filed an application for a patent in one of the Convention countries a right to priority based on the basic application first filed in the convention country. An application filed before the Patent Office claiming a priority date based on the basic application is known as a convention application.<sup>160</sup> Application for a patent in India operates on the principle of reciprocity.<sup>161</sup> Countries which do not accord to Indian citizens the same rights in respect of the grant of patents and protection of patent rights as it accords to its own nationals, can be notified by the Central Government in the Official Gazette.<sup>162</sup> The nationals of such countries shall not be entitled, either solely or jointly, to apply for a grant of patent or to be registered as the proprietor. They are also precluded from being registered as an assignee or to apply or hold any licence.

Section 135 gives the applicant in India the benefit of priority by dating the claim of the applicant to the date when the applicant may have made an application in a convention country. To avail the benefit of convention priority, the applicant must satisfy the following conditions:

- 1) The applicant should have made an earlier application for a patent in a convention country (known as the basic application);
- 2) An application for the patent in India has to be made under the Patents Act;

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<sup>158</sup> Form 1, Patents Rules, 2003.

<sup>159</sup> *Ibid.*

<sup>160</sup> Sections 2(1)(c) and 135, Patents Act, 1970.

<sup>161</sup> Section 134, Patents Act, 1970.

<sup>162</sup> *Ibid.*

- 3) The application in India must be made within 12 months from the date of the basic application.

If the applicant fails to file the application in India within 12 months from the date of the basic application, the application can be opposed under section 25(1)(i) or section 25(2)(i). Moreover, if the basic application was filed in a country at a time when that country was not notified as a convention country for the purposes of the Patents Act, the application may be refused under section 15 of the Patents Act. This would be the case even if the three preconditions mentioned in section 135(1) of the Patents Act are fulfilled. The language of s 135 requires the basic application to be an ‘application for a patent in respect of an invention in a convention country’. This means that the basic application must be made to a country which is a convention country when the basic application is made in order to qualify the applicant for a priority claim under section 135 of the Patents Act. The fact that the application was made in a country which may subsequently be declared as a convention country will not suffice.

Every convention application shall:<sup>163</sup>

- 1) be accompanied by a complete specification; and
- 2) specify the date on which and the convention country in which the application for protection, or as the case may be, the first of such applications was made; and
- 3) state that no application for protection in respect of the invention had been made in a convention country before that date by the applicant or by any person from whom he derives title.

To claim the convention status, an applicant should file the convention application in the Patent Office within 12 months from the date of filing of a similar application in the convention country (basic application).<sup>164</sup> Where the applicant has made two or more applications in one or more convention countries and those inventions are related to constitute one invention, one application may be made by any or all of the persons mentioned in section 135(1) within 12 months from the date on which the earlier or earliest of those applications was made.<sup>165</sup> The applicant shall furnish, in addition to the complete specification, copies of the specifications or corresponding documents (priority documents)

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<sup>163</sup> Section 136(1), Patents Act, 1970.

<sup>164</sup> Section 135(1), Patents Act, 1970.

<sup>165</sup> Section 137(1), Patents Act, 1970.

filed or deposited by the applicant in the patent office of the convention country.<sup>166</sup> If the specification or the priority documents are in a foreign language, a translation in English of the same shall be furnished along with a verifying affidavit.<sup>167</sup> An applicant shall also furnish certified copies of the specification or the priority documents if required by the Controller.

### **C. PCT International Application**

The Patent Cooperation Treaty (PCT) is an international filing system which allows applicants to prefer applications in all the designated countries conferring late entry to the national offices without affecting the priority date. An international application is a patent application filed under the provisions of the PCT. An international application under the PCT can be filed only if at least one applicant is a national or a resident of India. It may be filed before the appropriate office in triplicate in English or Hindi.<sup>168</sup>

An international application under the Patents Act refers to an application for patent made in accordance with the Patent Cooperation Treaty.<sup>169</sup> Chapter III of the Patents Rules deals with international applications filed under the PCT. The Patent Office in India is a receiving office for international applications filed by nationals or residents of India.<sup>170</sup>

### **D. PCT - National Phase Application: Section 7(1A)**

An application corresponding to an international application under the PCT under s 7(1A), made in Form 1, claiming the priority of the international filing date is known as the PCT-National Phase Application.<sup>171</sup> Every international application under the PCT for a patent, as may be filed designating India, shall be deemed to be an application under the Patents Act provided a corresponding application (PCT National Phase Application) has also been filed before the Controller in India.<sup>172</sup> The filing date of an international application and its complete specification processed by the patent office as the designated office or elected office shall be the international filing date accorded under the PCT.<sup>173</sup> The Patent Office shall not commence processing of such an application before the expiry of 31 months from the

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<sup>166</sup> Section 138(1), Patents Act, 1970.

<sup>167</sup> Section 138(2), Patents Act, 1970.

<sup>168</sup> Rule 19(1), Patents Rules, 2003.

<sup>169</sup> Section 2(1)(ia), Patents Act, 1970.

<sup>170</sup> Article 10, PCT.

<sup>171</sup> Rule 20(1), Patents Rules, 2003.

<sup>172</sup> Section 7(1A), Patents Act, 1970.

<sup>173</sup> Section 7(1B), Patents Act, 1970.



international priority date.<sup>174</sup> This time-limit of 31 months from the date of international priority is the time-limit stipulated under the PCT.<sup>175</sup> However, the applicant may make an express request in Form 18 by paying the stipulated fees to process or examine the application at any time before 31 months.<sup>176</sup>

The title, description, drawings, abstract and claims filed with an international application designating India shall be taken as the complete specification for the purposes of the Patents Act. Though an ordinary application filed under the Patents Act treats the abstract as an accompaniment to the specification, the abstract filed with an international application shall be taken as the complete specification under section 10(4A) of the Patents Act. An applicant need not submit the documents while entering the national phase for filing the application in the designated or elected member countries, as the PCT provides for a mechanism to send those documents to the designated offices. But filing of such documents may speed up the processing.

Every international application designating India shall comply with the provisions of rule 20 and in case of any failure to comply with the said requirements, the application will be deemed to be withdrawn.<sup>177</sup> The provisions of chapter III of the Patents Rules which deal with international applications under the PCT shall be supplemental to the PCT and in case of any conflict with the provisions of the Treaty and the regulations and the administrative instructions made under the Treaty, the provisions of the Treaty shall prevail.<sup>178</sup>

#### **E. Application for Patent of Addition: Section 54**

A patent of addition is granted for an improvement or modification of an invention.<sup>179</sup> As the term implies, a patent of addition is granted as an addition to a pre-existing invention described or disclosed in the complete specification. The invention so described or disclosed is known as the 'main invention'. As a patent of addition can be granted only on the basis of an earlier application or in a granted patent, the grant of the patent of addition cannot precede the grant of the main invention.<sup>180</sup> For the same reason, the date of filing of the application

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<sup>174</sup> Rules 20(2) and 20(4)(i), Patents Rules, 2003.

<sup>175</sup> Article 2(xi), PCT.

<sup>176</sup> Rule 20(4)(ii), Patents Rules, 2003.

<sup>177</sup> Rule 22, Patents Rules, 2003.

<sup>178</sup> Rule 23, Patents Rules, 2003.

<sup>179</sup> Sections 2(1)(q) and 54, Patents Act, 1970.

<sup>180</sup> Section 54(4), Patents Act, 1970.

for a patent of addition should be the same as or later than the date of filing of the application of the main invention.<sup>181</sup>

The object to providing for patents of addition is to protect improvement and modification of an inventor which may be made in the course of working of his patent, which may, by itself, not be entitled for a separate patent. Such improvements and modifications are tagged along to the main invention and protected along with the main invention so long as the main invention exists. No additional renewal fee is required for such additions. However, the validity of a patent of addition is not affected by a revocation of the main invention.

A patent of addition may be granted in lieu of an independent patent for an improvement or a modification of another invention. Where an invention, which is an improvement in or modification of another invention, is the subject of an independent patent held by the patentee who also holds the patent for the main invention, the patentee may request the Controller to revoke the independent patent (the patent for the improvement or modification) and grant a patent of addition in lieu of it, bearing the same date as the date of the patent so revoked.<sup>182</sup> If the Controller is satisfied that the provisions under the Patents Act have not been met, he will be bound to make an order of revocation.

A specification in respect of a patent of addition under section 54 shall contain a specific reference to the number of the main patent, or the application for the main patent, as the case may be, and a definite statement that the invention comprises an improvement or modification over the invention claimed in the specification of the main patent granted or applied for.<sup>183</sup> A patent of addition may be combined with an earlier patent of addition and preferred in one application. An ordinary application may also be converted into an application for a patent of addition pursuant to an opposition proceeding.

#### **i. Requirements for a Patent of Addition**

Under section 54 of the Patents Act, an applicant must satisfy the following requirements:

- 1) the patent of addition must relate to an improvement in or modification of the main invention;

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<sup>181</sup> Section 54(3), Patents Act, 1970.

<sup>182</sup> Section 54(2), Patents Act, 1970.

<sup>183</sup> Rule 13(3), Patents Rules, 2003.

- 2) such improvement or modification should pertain to an invention described or disclosed in the complete specification of the main invention;
- 3) the patent of addition must show that the invention comes within the scope of an improvement or modification of the main invention, i.e., it should not pertain to an improvement or modification not covered in the main invention;
- 4) the complete specification of the patent of addition must be filed on the same date or after the filing of the complete specification of the main invention.

A patent of addition must relate to a single invention for which a patent has already been granted. It shall not be an addition to a series of invention for which separate patents subsist. A patent of addition must be fairly based on the main invention. In determining whether the patent of addition is fairly based on the main invention, the court has to look into the whole of the disclosure and not merely the claims.

#### **ii. 'Improvement' or 'Modification'**

In determining whether an improvement or modification has been made to the main invention, a proper comparison should be made between the novel contributions made by the two specifications to the art. It will be necessary to consider both what has been changed and what has been retained. The meaning of the expressions 'improvement' and 'modification' are well-understood. In *Elliott Brothers (London) Ltd's Application*, Lloyd-Jacob J said:<sup>184</sup>

*The meaning of the words 'modification' and 'improvement' is clear enough. A modification is an alternation which does not involve a radical transformation and an improvement is a variation, whether by addition, omission, or alteration to secure a better performance, whilst retaining some characteristic part... What seems to be abundantly clear is that the mere presence of a number of elements common to both inventions if common also in the known art, is not sufficient to make one invention an improvement or addition to the other*

#### **iii. 'Described' or 'Disclosed'**

It is important to note that section 54(1) of the Patents Act requires the improvement or modification to be described or disclosed in the complete specification of the main invention. It does not limit such improvement or modification to what is claimed in the earlier

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<sup>184</sup> [1966] FSR 334.

specification. In determining whether a patent of addition qualifies as an improvement or a modification the court has to looking into the whole of the disclosure made in the main invention and not merely to the claims. Thus the mere claiming in a later application of a subject matter contained in the earlier specification which is not claimed therein, cannot qualify for a patent of addition as the purpose of such a claim would only be to rectify an omission to claim at the first instance.

#### **iv. Improvements Qualifying for a Separate Patent**

The Patents Act allows for the making of an application for an improvement or modification independent of section 54. Under section 54, the improvement or modification of the invention described in the specification of the main invention which is required for qualifying for an application for a patent of addition need not be of such character as to qualify for an independent patent.<sup>185</sup> In other words, a patent of addition will be granted for an improvement or a modification of an earlier invention provided such an invention is described or disclosed in the complete specification of the main invention. The inventive step mentioned in the main invention (earlier patent) shall be taken into account in determining the inventive step of the improvement as the same is based on the earlier patent and any publication or use of the invention in the complete specification of the main invention or the patent of addition cannot be a ground for its refusal or revocation.<sup>186</sup> For this reason, section 56(1) makes it clear that the validity of patent of addition shall not be questioned on the ground that the invention ought to have been the subject of an independent patent.

The Patents Act also provides that a complete specification filed after a provisional specification may include claims in respect of developments or additions to the invention described in the provisional specification, if they are of such a nature that the applicant would be entitled to make a separate application for a patent under section 6 of the Patents Act.<sup>187</sup> It also provides for a similar provision for a convention application.<sup>188</sup>

The test to determine whether an improvement or a modification will qualify for a separate patent, as opposed to a patent of addition under section 54, will involve:

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<sup>185</sup> Justice N. Rajagopala Ayyangar, 'Report on the Revision of the Patent Laws', September 1959.

<sup>186</sup> Section 56, Patents Act, 1970.

<sup>187</sup> Section 10(7), Patents Act, 1970.

<sup>188</sup> Section 136(2), Patents Act, 1970.

- 1) identifying whether the improvement or modification relates to a single invention or to a group of invention linked to form a single inventive concept as disclosed in the specification of the main invention; and
- 2) determining whether the improvement or modification is fairly based on the matter disclosed in the specification of the main invention.

If the above two steps are answered in the negative, the improvement or modification may qualify for a separate patent if it satisfies the conditions of patentability under the Patents Act.

#### **v. Term**

A patent of addition does not extend the term of the main invention. A patent of addition is granted for a term equal to that of the main invention or to such extent of the term that has not expired. As the patent of addition is based on the main invention (earlier patent), it shall remain in force during the term of the main invention or until the main invention is revoked, whichever is shorter. If the patent for the main invention is revoked by the court or the Controller, the patentee may make a request in the prescribed manner for the patent of addition to be treated as an independent patent for the remainder of the term of the patent.

#### **vi. Renewal Fees**

The advantage of claiming an improvement or a modification of an invention as a patent of addition is that no renewal fee is payable in respect of the patent of addition. The renewal fee paid with regard to the main invention will suffice. But, if the main invention is revoked and the patent of addition becomes an independent patent, then the same fee as that of the main invention shall be paid on the same dates as that of the main invention had that been valid.<sup>189</sup>

#### **vii. Novelty and Obviousness**

A patent of addition is likely to raise contentious issues with regard to novelty and obviousness. The Patents Act states that the grant of a patent of addition shall not be refused or a patent of addition already granted shall not be revoked or invalidated on the ground only that the invention claimed in the complete specification does not involve any inventive step. In determining obviousness, the patent of addition shall not be regarded as obvious or lacking an inventive step by the fact of: (a) any publication or use of the main invention described in its complete specification; or (b) any publication or use of any improvement in or

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<sup>189</sup> Section 55(2), Patents Act, 1970.

modification of the main invention described in the complete specification of a patent of addition to the patent for the main invention or of an application for such a patent of addition. Such publication would include publication by the patentee as well as by third parties. The validity of a patent shall not be questioned on the ground that the invention ought to have been the subject of an independent patent.<sup>190</sup>

In determining the novelty of the invention claimed in the complete specification of the patent of addition, the complete specification of the main invention shall be considered.<sup>191</sup> In other words, the complete specification of the main invention may be cited for anticipation by publication. The claim in a patent of addition must disclose a novel matter not disclosed in the complete specification of the main invention, though it need not involve any inventive step.<sup>192</sup>

#### **F. Divisional Application: Section 16**

When an application is divided out of the original application, it is termed a divisional application. Divisional applications are filed to overcome objections on plurality of inventions, as the law allows only one application per invention.<sup>193</sup> The applicant may divide the invention into separate applications where the claims of the complete specification relate to more than one invention. The applicant may also, to meet the official objection raised by Controller, divide the application and file two or more applications as applicable for each of the inventions. Such divisional application shall be deemed to have been filed on the date on which the original application was made. This method of granting the same priority date to the divisional application as that of the original application is known as ante dating.

The divisional application shall be accompanied by a complete specification, which shall not include any matter not in substance disclosed in the original application.<sup>194</sup> In other words, no new matter shall be added in the divisional application. If new matter is found in the divisional application, it can be amended before the grant to exclude such matter. The complete specification of the original application or the divisional application may be amended, in such a manner, that neither of the specifications includes a claim for any matter

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<sup>190</sup> Section 56(1), Patents Act, 1970.

<sup>191</sup> Section 56(2), Patents Act, 1970.

<sup>192</sup> *Supra* note 155.

<sup>193</sup> Section 7(1), Patents Act, 1970.

<sup>194</sup> Section 16(2), Patents Act, 1970.

claimed in the other.<sup>195</sup> An amendment to divide the application into two new applications can be refused by the Patent Office on the ground that the patent had already been granted and that such procedures were available only before grant. There is no provision to file a divisional application after the grant to overcome a finding of plurality of invention. The Controller is bound to refuse a divisional application the disclosure of which extends beyond that of the main or parent application. A specification filed along with the divisional application shall contain a specific reference to the number of the original application.<sup>196</sup>

The purpose of a divisional application is to protect the rights of an applicant who has disclosed more than one invention in the parent application. It should not be allowed for merely claiming narrower or broader protection for the same invention. In cases where a divisional application is made along with a request for post-dating, the Patent Office will not be obliged to deal with the application after the normal period of acceptance has expired and which has not been renewed within the extended time. The Controller has complete discretion to allow ante-dating of a divisional application provided it does not ante-date it to a period earlier than the parent application.

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<sup>195</sup> Section 16(3), Patents Act, 1970.

<sup>196</sup> Rule 13(2), Patents Rules, 2003.

## PUBLICATION AND EXAMINATION

As soon as the Patent Office receives the application, it accords a number to it such that applications filed in a year will constitute a series identified by the year of such filing. PCT National phase applications shall constitute a different series.<sup>197</sup> Every application shall be screened to classify them into the respective field of technology and to find whether the invention disclosed in the application was relevant for defence purposes.

### I. PUBLICATION OF APPLICATIONS: SECTION 11A

Ordinarily, an application for patent shall not be open to public before the expiry of 18 months from the date of filing of application or the date of priority of the application whichever is earlier.<sup>198</sup> The applicant may make a request in Form 9, upon the payment of prescribed fee, for an early publication before the expiry of the 18-month period mentioned in section 11A(1) of the Patents Act.<sup>199</sup> Every application shall be published within one month from the date of expiry of the 18 month period or one month from the date of request for publication under rule 24A, except applications in respect of which there are secrecy directions or applications which are abandoned under section 9 or applications which are withdrawn three months before the expiry of 18 months.<sup>200</sup> In the case of applications in respect of which secrecy directions have been given under section 35, such applications shall be published after the expiry of 18 months or when the secrecy directions has ceased to operate, whichever is later.<sup>201</sup>

Every application published under section 11A shall include particulars with regard to the date of the application, number of the application, name and address of the applicant identifying the application and an abstract.<sup>202</sup> In the case of an application for an invention involving biological material, upon the publication of such application, the depository institution will make the biological material available to the public.<sup>203</sup> The Patent Office may make the application together with the complete and provisional specification, drawings and abstract available to the public on payment of the prescribed fees.<sup>204</sup> A request may be made

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<sup>197</sup> Rule 11, Patents Rules, 2003.

<sup>198</sup> Section 11A(1), Patents Act, 1970; Rule 24, Patents Rules, 2003.

<sup>199</sup> Section 11A(2), Patents Act, 1970; Rule 24A, Patents Rules, 2003.

<sup>200</sup> Section 11A(3), Patents Act, 1970.

<sup>201</sup> Section 11A(4), Patents Act, 1970.

<sup>202</sup> Section 11A(5), Patents Act, 1970.

<sup>203</sup> Section 11A(6)(a), Patents Act, 1970.

<sup>204</sup> Section 11A(6)(b), Patents Act, 1970; Rule 27, Patents Rules, 2003.



in writing on payment of the prescribed fees and copies of the said documents may be procured from the appropriate office.

**A. Rights of the Applicant**

Section 11A(7) of the Patents Act pertains to rights of an applicant. The said provision was introduced to accommodate the transitory hurdles that usually accompany a regime change. Prior to 1 January 2005, the Patents Act went through a 10-year transition period during which the patent office began to receive applications for product patents for pharmaceuticals and agro-chemicals. As the rights in a patent accrue retrospectively, there was a real possibility of the right holders proceeding against the competitors who were using the subject matter of invention prior to 1 January 2005. Section 11A(7) protects the rights of competitors and provides for reasonable royalty to the right holder.

The section provides that the applicant shall have like rights and privileges from the date of publication of the application for the patent till the date of grant of a patent, as if a patent for the invention had been granted on the date of publication of the application. However, section 11A(7) imposes the following restrictions:

- 1) the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted;
- 2) the rights of a patentee in respect of applications made under section 5(2) before 1 January 2005 shall accrue from the date of grant of the patent;
- 3) after a patent is granted in respect of applications made under section 5(2), the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to 1 January 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises.

The third restriction detailed above is likely to come under judicial scrutiny for many reasons. First, it restricts the right to institute a suit for infringement against an alleged infringer and confines the remedy to receiving royalty. Secondly, the clause does not give any guidance as to the authority that would determine the royalty and what amount would be reasonable. Ordinarily, it is the Controller who determines the royalty in the case of compulsory licences. Though the courts have evolved detailed guidelines for the award of royalty in the case of

licences, it remains to be seen whether the same principles would apply to compute the royalty paid under section 11A(7). Thirdly, the clause requires the enterprise (competitor) to produce and market the concerned product prior to 1 January 2005. This requirement may impose difficulties if the enterprise did not, on its own, market the concerned product. Fourthly, the requirement that the enterprise should 'continue to manufacture' the concerned product may cause problems where the enterprise is restrained by the right-holder by some other means, such as a temporary injunction procured pursuant to the grant of exclusive marketing rights under the Patents Act.

## **II. REQUEST FOR EXAMINATION: SECTION 11B**

An application will be taken up for examination if the applicant or any other interested person makes a request for examination, in Form 18 paying the prescribed fee, after the publication of application within 48 months from the date of priority of the application or from the date of filing of application, whichever is earlier.<sup>205</sup> Ordinarily, PCT National phase applications are processed or examined only after the expiry of 31 months from the priority date, but such application may be taken up for examination before the said period on the express request of the applicant filed in Form 18 along with the prescribed fees.<sup>206</sup>

In the case of application filed under section 5(2) of the Patents Act before 1 January 2005, a request for examination shall be made by the applicant or any other interested person within 48 months from the date of priority or from the date of filing of application.<sup>207</sup> The period for making a request for examination under section 11B for applications filed before 1 January 2005 shall be the period specified under section 11B before the commencement of the Patents (Amendment) Act, 2005 or the period specified under the Rules, whichever expires later.<sup>208</sup>

If the applicant or any other person interested does not make a request for examination of the application within 48 months under section 11B(1) or section 11B(3) or within six months from the date of revocation of the secrecy direction, whichever is later, the application will be treated as withdrawn by the applicant.<sup>209</sup> However, the applicant may, at any time after filing

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<sup>205</sup> Section 11B(1), Patents Act 1970; Rule 24B(1)(i), Patents Rules 2003.

<sup>206</sup> Rules 20(2), 20(4)(i) and 20(4)(ii), Patents Rules, 2003.

<sup>207</sup> Rule 24B(1)(ii), Patents Rules, 2003.

<sup>208</sup> Rule 24B(1)(v), Patents Rules, 2003.

<sup>209</sup> Section 11B(4), Patents Act, 1970; Rule 24B(1)(iii), Patents Rules, 2003.

the application but before the grant of patent, withdraw the application by making a request in writing.<sup>210</sup>

A request for examination under section 16(3) shall be made within 48 months from the date of filing of the application or from the date of priority of the first mentioned application or within six months from the date of filing of the further application, whichever is later.<sup>211</sup>

### **III. EXAMINATION OF APPLICATION: SECTION 12**

The applications filed under the Patents Act shall be taken up for examination as per the order in which the requests for examination are made.<sup>212</sup> Once a request for examination is made under section 11B, the application, specification and other documents shall be referred by the Controller to an examiner for making a report known as the First Examination Report.<sup>213</sup> The Controller shall refer the matter to the examiner ordinarily within one month from the date of its publication or from the date of the request for examination, whichever is later. The report shall be made to the Controller in respect of the following matters:<sup>214</sup>

- (a) whether the application and specification and other documents relating thereto are in accordance with the requirements of the Patent Act and the Patent Rules;
- (b) whether there is any lawful ground of objection to the grant of the patent under the Act in pursuance of the application;
- (c) the result of investigations made under section 13 of the Patents Act; and
- (d) any other matter which may be prescribed.

The examiner shall make the report ordinarily within one month but not exceeding three months from the date of reference of the application to him by the Controller.<sup>215</sup> The Controller shall dispose-off the report of the examiner within one month from the date of receipt of the report.<sup>216</sup> Where the applicant files a request for examination, the first examination report along with the application and specification shall be sent to the applicant within six months from the date of the request for examination or from the date of

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<sup>210</sup> Section 11B(4), Patents Act, 1970; Rule 26, Patents Rules, 2003.

<sup>211</sup> Rule 24B(1)(iv), Patents Rules, 2003.

<sup>212</sup> Rule 24B(2)(i), Patents Rules, 2003.

<sup>213</sup> Section 12(1), Patents Act, 1970.

<sup>214</sup> Section 12(1), Patents Act, 1970.

<sup>215</sup> Rule 24B(2)(ii), Patents Rules, 2003.

<sup>216</sup> Rule 24B(2)(iii), Patents Rules, 2003.

publication, whichever is later. Where the request for examination is filed by any other interested person, an intimation of such examination shall be sent to such person.<sup>217</sup>

The examination of an application for a patent by the examiner involves certain adjudicatory process. Section 12(1)(b) is broadly worded to include ‘any lawful ground of objection to the grant of the patent under the Act’. Clause (c) of section 12(1) requires the first examination report to contain the results of investigations made under section 13 of the Patents Act. In this way, section 12 had a direct nexus with section 13, which details the manner in which an examiner shall make investigations for the purpose of anticipation. Together, sections 12 and 13 constitute a code of examination for examiners. The examination and investigations done under sections 12, 13 of the Patents Act shall not be deemed to warrant the validity of any patent and no liability shall be incurred by the Central Government or any officer for such examination, investigation or report.<sup>218</sup> The reports of the examiners made to the Controller shall be treated as confidential and shall not be open to public inspection or be published by the Controller. Such reports shall not be liable to be produced or inspected in any legal proceedings unless the court certifies that the production or inspection is desirable in the interest of justice.<sup>219</sup>

The examiner may raise objections in the first examination report. The objections of the examiner shall be contained in a reasoned statement. The examiner has to act in a quasi-judicial manner and should give a reasoned order under section 12. In cases where a statement of objection is issued to the applicant to comply with the requirements therein, the applicant has to put the application in order for grant under section 21 within 12 months from the date on which the first statement of objection was issued.<sup>220</sup> Once the examiner issues his report, he will have no power to amend or delete anything that originally formed a part of the report.

#### **IV. SEARCH FOR ANTICIPATION: SECTION 13**

As an invention shall be regarded as new if it does not form a part of the state of the art, the examiner has to determine novelty of the invention by making a search for anticipation as mentioned in section 13. The fact that the examiner shall make an investigation under section 13 for the purpose of ascertaining novelty does not mean that the power of the examiner is

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<sup>217</sup> Rule 24B(3), Patents Rules, 2003.

<sup>218</sup> Section 13(4), Patents Act, 1970.

<sup>219</sup> Section 144, Patents Act, 1970.

<sup>220</sup> Rule 24B(4), Patents Rules, 2003.

confined to matters illustrated in that section, as the report of the examiner may deal with a wide array of matters detailed in section 12(1).

The standard of novelty required by the Patents Act is that of 'relative novelty'. But the introduction of the definition of 'new invention' in section 2(1)(l), which prescribes the standard of 'absolute novelty', raises doubts with regard to the standard of novelty followed under the Patents Act. For the purpose of determining anticipation by previous publication or previous claim, section 13 details the documents which the examiner shall take into consideration. It is pertinent to note that section 13 is confined to anticipation by prior publication as it restricts the search for anticipation to documents alone. It does not cover anticipation by prior use. It is sufficient to point out that anticipation by prior use is a ground for revocation under section 64(1)(e).

The examiner shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification:

- 1) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India on or after 1 January 1912;<sup>221</sup>
- 2) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming a priority date earlier than that date;<sup>222</sup> and
- 3) has been anticipated by publication in India or elsewhere in any other document, other than those mentioned in clause (1) and (2), before the date of filing of the applicant's complete specification.<sup>223</sup>

The first and the third clauses pertain to anticipation by prior publication whereas the second clause pertains to anticipation by prior claiming.

#### **V. REPORT OF EXAMINER: SECTION 14**

If the First Examination Report received by the Controller is adverse to the applicant or requires any amendment of the application, specification or other document to ensure

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<sup>221</sup> Section 13(1)(a), Patents Act, 1970.

<sup>222</sup> Section 13(1)(b), Patents Act, 1970.

<sup>223</sup> Section 13(2), Patents Act, 1970.

compliance with the provisions of the Patents Act or the Patent Rules, the Controller shall communicate as expeditiously as possible the gist of the objections to the applicant. The Patents Rules, 2003 envisages different procedures in cases of anticipation by prior publication and anticipation by prior claiming.

**A. Anticipation by Prior Publication**

If the investigations by the examiner reveal that the invention claimed in the complete specification is anticipated under sections 13(1)(a) or 13(2), the Controller shall communicate the gist of the specific objections to the applicant and afford an opportunity to the applicant to amend his specification.<sup>224</sup> If the applicant contests any of the objections raised in the report or if he files again his specification along with his observations as to whether or not the specification is to be amended, the applicant shall be given an opportunity of being heard, provided he makes a request for hearing 10 days before the final date of the period referred to under section 21(1) of the Patents Act or within such shorter period as the Controller may allow.<sup>225</sup>

As per Rule 28 of the Patents Rules, 2003, which governs the procedure where the applicant contests any of the objections communicated to him by the Controller. If the applicant requests for a hearing within one month from the date of communication of the gist of objections or the Controller grants a hearing whether or not the applicant re-filed his application, the Controller shall fix a date and time for hearing having regard to the period remaining for putting the application in order, or other circumstances of the case.<sup>226</sup> The applicant shall be given 10 days' notice of such hearing or such shorter notice as the Controller deems fit and the applicant shall notify the Controller whether he will be attending the hearing. After hearing the applicant or without hearing the applicant if he does not want to be heard, the Controller may specify or permit such amendment to the specification as he thinks fit and may refuse to grant the patent unless the amendment so specified or permitted is made within such period as he may fix.<sup>227</sup>

If it appears to the Controller that the invention claimed in the complete specification has been anticipated under sections 13(1)(a) or 13(2), he may refuse the application. However, the Controller may not refuse the application, if the applicant shows to the satisfaction of the

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<sup>224</sup> Rule 28(1), Patents Rules, 2003.

<sup>225</sup> Section 14, Patents Act, 1970; Rule 28(2), Patents Rules, 2003.

<sup>226</sup> Rule 28(3), Patents Rules, 2003.

<sup>227</sup> Section 15, Patents Act, 1970; Rule 28(5), Patents Rules, 2003.

Controller that the priority date of the claim of his complete specification is not later than the date on which the relevant document was published or if the applicant amends his complete specification to the satisfaction of the Controller.<sup>228</sup> If the Controller is satisfied that the invention is anticipated by prior publication under section 13(1)(a) and the other complete specification was published on or after the priority date of the applicant's claim, he may require a reference to be made to the other specification following the procedure under section 18(2), unless the applicant is able to show that the priority date of the applicant's claim is not later than the priority date of that specification.<sup>229</sup>

### **B. Anticipation by Prior Claiming**

If it is found that the invention claimed in the complete specification is anticipated under section 13(1)(b) of the Patents Act, the applicant shall be informed about the same and an opportunity shall be afforded to amend his specification. If the applicant's specification is found to be in order for grant except for an objection raised under section 13(1)(b), the Controller may postpone the grant of the patent and allow a period of two months to the applicant to remove the objection.<sup>230</sup>

If the applicant makes any amendment consequent to the objections, the amended specification shall be examined and investigated in like manner as the original specification.<sup>231</sup> There may be as many correspondences as necessary between the applicant and the Controller after the first examination report is issued, but the time for meeting the objections and putting the application in order shall be done within 12 months from the date of issue of the first examination report.<sup>232</sup> If the applicant fails to put the application in order within such time, the application will be treated as abandoned.

If the Controller is satisfied that the invention is anticipated by prior claiming in another patent, he may direct that a reference to that patent be made in the applicant's complete specification. Before such a reference is made, the Controller shall inform the applicant and shall give him an opportunity to amend his specification.<sup>233</sup>

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<sup>228</sup> Section 18(1), Patents Act, 1970.

<sup>229</sup> Section 18(3), Patents Act, 1970.

<sup>230</sup> Rule 29(2), Patents Rules, 2003.

<sup>231</sup> Section 13(3), Patents Act, 1970.

<sup>232</sup> Section 21, Patents Act, 1970; Rule 24B(4), Patents Rules, 2003.

<sup>233</sup> Rule 29(1), Patents Rules, 2003.

## **VI.    SECRECY OF INVENTIONS**

The Central Government may notify a class of inventions which are relevant for defence purposes. If the Controller is of the opinion that an application for patent belongs to the notified class or the invention appears to be so relevant, he may give directions for prohibiting or restricting the publication of information with respect to the invention.<sup>234</sup> The Controller shall give notice of the application and such direction to the Central Government, on the receipt of which the Central Government shall consider whether the publication of the invention would be prejudicial to the defence of India. If the Central Government feels that the publication of the invention would not prejudice the defence of India, it shall give notice to the Controller to that effect, who shall revoke the directions and notify the applicant about the same.<sup>235</sup>

If the Central Government is of the opinion that the invention is relevant for defence purposes and finds that the Controller has not given any directions under section 35(1), it may, at any time, before the grant of the patent notify the Controller about the same. The Central Government's notice to the Controller shall have the same effect as if the invention were one of the classes notified by the Central Government under section 35(1). The Controller shall give notice of the directions issued by him to the Central Government.<sup>236</sup>

### **A.       Periodic Review**

The Central Government shall review the secrecy directions every six months or upon the request of the applicant. It shall determine whether the invention in respect of which secrecy directions were given continues to be relevant for defence purposes. If upon reconsideration, the Central Government is of the opinion that the invention would be no longer prejudicial to the defence of India or in the case of an application filed by a foreign applicant the invention is found to be published outside India, the Central Government may give notice to the Controller to revoke such directions. The result of every such reconsideration shall be communicated to the applicant within 15 days of the receipt of the notice of the Controller.<sup>237</sup>

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<sup>234</sup> Section 35(1), Patents Act, 1970.

<sup>235</sup> Section 35(2), Patents Act, 1970.

<sup>236</sup> Section 35(3), Patents Act, 1970.

<sup>237</sup> Rule 72(1), Patents Rules, 2003.



## **B. Effect of Secrecy Directions**

The effect of secrecy directions passed under section 35 is that so long as such directions are in force, the Controller shall not pass an order refusing to grant an application in respect of which the directions are passed. Similarly, no appeal shall lie from any order of the Controller passed under section 35. However, the application in respect of which secrecy directions are passed may proceed up to the stage of grant of the patent but the application or the specification shall not be published and no patent shall be granted on that application.<sup>238</sup>

Where a complete specification is found to be in order for the grant of the patent during the continuance in force of the directions, if any use of the invention is made by the Central Government, the provisions of sections 100, 101 and 103 shall apply in relation to such use as if the patent had been granted for the invention.<sup>239</sup> Where a complete specification is found to be in order for the grant of the patent during the continuance in force of the directions, if it appears to the Central Government that the applicant for the patent has suffered hardship on account of the continuance of such direction, the Central Government may pay him reasonable compensation having regard to the novelty and utility of the invention and other factors.<sup>240</sup> No renewal fee shall be payable for the period during which secrecy directions were in force in respect of a patent which was subject to directions under section 35.<sup>241</sup>

## **C. Extension of Time**

The Controller may extend the time for doing anything required or authorised to be done by or under the Patents Act in connection to an application with regard to which secrecy directions issued under section 35 is revoked, whether or not the stipulated time has already expired.<sup>242</sup> Such extension shall not exceed the period for which directions given by the Central Government under section 35(1) were in force.<sup>243</sup>

## **D. Restriction of Foreign Applications**

Section 39 of the Patents Act, restricts persons residing in India from making any application outside India for the grant of a patent for an invention. A resident may make an application outside India under the authority of a written permit sought for in Form 25 and granted by the

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<sup>238</sup> Section 37(1), Patents Act, 1970.

<sup>239</sup> Section 37(2)(a), Patents Act, 1970.

<sup>240</sup> Section 37(2)(b), Patents Act, 1970.

<sup>241</sup> Section 37(3), Patents Act, 1970.

<sup>242</sup> Section 38, Patents Act, 1970.

<sup>243</sup> Rule 72(2), Patents Rules, 2003.

Controller if two conditions are satisfied, i.e., (1) an application for a patent for the same invention has been made in India, not less than six weeks before the application outside India; and (2) either no direction has been given under sub-section (1) of section 35 in relation to the application in India, or all such directions have been revoked.<sup>244</sup>

The Controller shall dispose of every such application within 21 days, except in the case of inventions relating to defence and atomic energy applications.<sup>245</sup> In case the invention is relevant for defence purpose or atomic energy, the Controller shall not grant permit without the prior consent of the Central Government. Section 39 shall not apply in relation to an invention for which an application for protection has first been filed in a country outside India by a person resident outside India.

#### **E.        Contravention of Section 35 and 39**

In the case of an application for a patent, any person who contravenes a direction as to secrecy given by the Controller under section 35 or makes an application for grant of a patent outside India in contravention of section 39, the application for patent under the Patents Act shall be deemed to have been abandoned and if the patent is granted it shall be liable for revocation under section 64(1)(n).<sup>246</sup>

The directions given and orders passed under chapter VII are not appealable. All orders of the Controller giving directions as to secrecy as well as all orders of the Central Government shall be final and shall not be called in question in any court on any ground.<sup>247</sup> Nothing in the Patents Act shall prevent the Controller from making disclosures to the Central Government for the purposes of chapter VII.<sup>248</sup>

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<sup>244</sup> Rule 71(1), Patents Rules, 2003.

<sup>245</sup> Section 39(2), Patents Act, 1970; Rule 71(2), Patents Rules, 2003.

<sup>246</sup> Section 40, Patents Act, 1970.

<sup>247</sup> Section 41, Patents Act, 1970.

<sup>248</sup> Section 42, Patents Act, 1970.

## ANTICIPATION

Anticipation means the invention for which, claim is made, has been published before the date of filing of the application in a specification. The application for patent can be refused if there is anticipation. The Patents Act provides certain circumstances, in which the publication, public use or reading of a paper containing the information in respect of the invention which is to be protected before learned society, before filing an application for patent for the said invention, will not lose its novelty. The circumstances are contained in Sections 29 to 34 of the Act. These are explained below.

### I. ANTICIPATION BY PREVIOUS PUBLICATION: SECTION 29

An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that the invention is published in a specification filed in pursuance of an application for patent made in India and dated before the 1st day of January 1912. An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that the invention was published before the priority date of the relevant claim of the specification, if the patentee or the applicant for patent proves:

- 1) that the matter published was obtained from him or (where he is not himself the true and first inventor) from any person from whom he derives title, and published without his consent or the consent of any such person; and
- 2) where the patentee or the applicant for patent or any person from whom he derives title learned of the publication before the date of the application for patent or in the case of a Convention application, before the date of the application for protection in a convention country, that the application or the application in Convention country, as the case may be, was made as soon as reasonably practicable thereafter.<sup>249</sup>

This is subject to the provision that it shall not apply if the invention was, before the priority date of the claim, commercially worked in India, otherwise than for the purposes of reasonable trial either by the patentee or the applicant for the patent or any person from whom he derives title or by any other person with the consent of the patentee or the applicant for the patent or any other person from whom he derives title.<sup>250</sup>

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<sup>249</sup> Section 29(2), Patents Act, 1970.

<sup>250</sup> *Ibid*, Proviso.

Where a complete specification is filed in pursuance of an application for patent made by a person being the true and first inventor or deriving title from him, an invention claimed in that specification shall not be deemed to have been anticipated by reason only of any other application for patent in respect of the same invention made in contravention of the rights of that person, or by reason only that after the date of filing of that application, the invention was used or published, without the consent of that person, by the applicant in respect of that other application, or by any other person in consequence of any disclosure of any invention by that applicant.<sup>251</sup>

## **II. ANTICIPATION BY PREVIOUS COMMUNICATION TO GOVERNMENT: SECTION 30**

An invention shall not be deemed to have been anticipated by reason only of the communication of the invention to the government or to any person authorised by the government to investigate the invention or its merits, or of anything done in consequence of such communication, for the purpose of the investigation.

## **III. ANTICIPATION BY PUBLIC DISPLAY: SECTION 31**

An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only of:

- (a) the display of the invention with the consent of the true and first inventor or a person deriving title from him at an industrial or other exhibition to which the provisions of Section 31 of the Act have been extended by the Central Government by notification in the Official Gazette or the use thereof with his consent for the purpose of such an exhibition in the place where it is held
- (b) the publication of any description of the invention in consequence of the display or use of the invention at any such exhibition as afore said;
- (c) the use of the invention after it has been displayed or used at any such exhibition as aforesaid and during the period of the exhibition by any person without the consent of the true and first inventor or a person deriving title from him; or

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<sup>251</sup> Section 29(3), Patents Act, 1970.

(d) the description of the invention in a paper read by the true and first inventor before a learned society or published with his consent in the transactions of such a society,

if the application for patent is made by the true and first inventor or a person deriving title from him not later than twelve months after the opening of the exhibition or the reading or publication of the paper, as the case may be.<sup>252</sup>

It is to be noted that if the application for patent is filed after the expiry of the twelve months period stipulated, after the opening of the exhibition or the reading or publication of the paper, as the case may be, the invention would be construed as having lost its novelty and subsequently securing patent protection may not be possible.

#### **A. Action to be taken for deriving benefits of Section 31**

For deriving benefit of the Section 31 of the Act, if an invention is to be displayed in an exhibition, it is very essential to get a notification in the Official Gazette (not the Patent Office Journal) issued by the Central Government before the date of commencement of the exhibition stating that the provisions of Section 31 of the Act is extended to the exhibition. Such notification, in addition to the Gazette of India, can include the Patent Office Journal also. The notification should contain all the information such as the authorities who is organising the exhibition, the date of opening and the duration off the exhibition, the place, etc.

Such notification should appear before the date of commencement of the exhibition. Therefore, while considering display of an invention in an exhibition it is to be confirmed that such a notification has been issued before the inauguration of the exhibition. If such a notification has not been issued in the above said manner and the invention is displayed in that exhibition, subsequently it may not be possible to avail the benefit of provision contained in Section 31 as the exhibit of the invention in the such an exhibition would be construed as public display and consequently the novelty of the invention would be treated as having lost.

#### **B. Learned Society under the Act**

Again what constitutes a learned society as mentioned in Section 31 has not been stipulated or defined in the Act or the Rules framed thereunder. Therefore, it is left to the discretion of the Controller. One Controller may consider one society, committee, seminar, as a learned

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<sup>252</sup> Section 31, Patents Act, 1970.

society and may extend the provision of Section 31 but some other Controller may not do so. There are also no specific and/or definite guidelines issued by the Patent Office. Therefore, by reading a paper before filing the application, the applicant may be taking a risk as such reading may result in losing the novelty of the invention.

Hence it would be advisable to file the application first at least accompanied with a provisional specification, before reading a paper before any Seminar, Meeting, Society, etc.

If filing of the application accompanied with a complete specification disclosing all the details of the invention is not possible at least the application accompanied with a provisional specification describing the nature of the invention should be filed before such reading. It is pointed out that filing of the application accompanied with complete specification will be advisable.

#### **IV. ANTICIPATION BY PUBLIC WORKING: SECTION 32**

An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only that at any time within one year before the priority date of the relevant claim of the specification, the invention was publicly worked in India:

- (a) by the patentee or applicant for the patent or any person from whom he derives title or;
- (b) by any other person with the consent of the patentee or applicant for the patent or any person from whom he derives title.

If the working was effected for the purpose of reasonable trial only and it was reasonably necessary, having regard to the nature of the invention, that he working for that purpose should be effected in public.<sup>253</sup>

#### **V. ANTICIPATION BY USE AND PUBLICATION AFTER FILING APPLICATION ACCOMPANIED WITHIN PROVISIONAL SPECIFICATION: SECTION 33**

Where a complete specification is filed or proceeded with in pursuance of an application which was accompanied by a provisional specification or where a complete specification filed with an application is treated by virtue of a direction under sub-section (3) of Section 9 of the Act, the Controller shall not refuse to grant the patent and the patent shall not be

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<sup>253</sup> Section 32, Patents Act, 1970.

revoked or invalidated by reason only that any matter described in the provisional specification or in the specification treated as aforesaid as provisional specification, was used in India or published in India or elsewhere at any time after the date of the filing of that specification.<sup>254</sup>

Where a complete specification is filed in pursuance of a Convention application, then, notwithstanding anything contained in the Act, the Controller shall not refuse to grant the patent and the patent shall not be revoked or invalidated by reason only that any matter disclosed in any application for protection in a Convention country upon which the Convention application is filed was used in India or published in India or elsewhere at any time after the date of that application for protection.<sup>255</sup>

#### **VI. NO ANTICIPATION IF CIRCUMSTANCES WERE ONLY AS DESCRIBED IN SECTIONS 29, 30 & 31: SECTION 34**

The Controller shall also not refuse to grant a patent and a patent shall not be revoked or invalidated by reason only of any circumstances which, by virtue of Section 29 or 30 or 31 or 32 do not constitute an anticipation of the invention claimed in the specification.<sup>256</sup>

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<sup>254</sup> Section 33(1), Patents Act, 1970.

<sup>255</sup> Section 33(2), Patents Act, 1970.

<sup>256</sup> Section 34, Patents Act, 1970.



தமிழ்நாடு டாக்டர் அம்பேத்கர் சட்டப் பல்கலைக்கழகம்  
The Tamilnadu Dr. Ambedkar Law University



# **COURSE MATERIAL – PART III**

## **ONLINE CERTIFICATE COURSE ON PATENT LAW: POLICY AND GOVERNANCE**

**COMPILED BY:**

**ORGANISING COMMITTEE**

**TAMIL NADU Dr. AMBEDKAR LAW UNIVERSITY**



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## **PCT PROCEDURE**

### **VI. INTRODUCTION**

Patent Cooperation Treaty (PCT) is an international convention was concluded in 1970, was brought into force on 14<sup>th</sup> January, 1978 and became operational on 1<sup>st</sup> June, 1978. In the beginning there were 18 Contracting States. PCT is open to States which are members of the Paris Convention and is administered by World Intellectual Property Organisation (WIPO). Instruments of ratification or accession must be deposited with the Director General of WIPO. It is the most significant advancement in International cooperation in this field since the adoption of Paris Convention. It is a treaty for rationalisation & cooperation of with regard to filing, searching and examination of patent applications and dissemination of scientific & technical information contained therein. It is to be noted that the PCT system does not provide for the grant of International Patents. In other words, the responsibility of granting patents remain exclusively with the patent office of the individual PCT member countries according to the law of the concerned countries which is for the time being in force at the point of time. Chapter III of the Patents Rules, 2003 enumerates the details of international applications under the PCT.

PCT is a special Treaty under the Paris Convention, open only to States which are members of the Paris Convention. PCT does not compete with but in fact, complements the Paris Convention. PCT serves the purpose of greatly simplifying the filing of patent applications around the world. The PCT helps an applicant in the following ways:

- i. to seek protection in several countries by filing a single International application without translation (can be filed in english)
- ii. seeking the protection availing the priority of the application in your country.
- iii. evaluating the invention for securing protection in foreign countries before incurring major costs.
- iv. for securing valid patents abroad.
- v. securing international search regarding the invention before incurring additional expenditure.
- vi. having the option of getting a preliminary examination report.
- vii. examination & further processing at the national patent offices after ascertaining the strength of the invention.

PCT is not a patent granting authority, but, if properly utilized, the system provides for, not only for filing the applications in the PCT member countries including India, but also conducting prior art searches and preliminary examination of the said application. Such a facility makes the system cost effective.

## **VII. INTERNATIONAL PHASE**

The International Phase is further classified into two, namely, PCT Chapter I & PCT Chapter II.

### **A. PCT Chapter I**

Under this Chapter, preliminaries like filing of the application is effected, the invention disclosed is published on the expiry of 18 months from the filing date or the priority date whichever is earlier and conducting the international search for ascertaining novelty of the invention disclosed. This Phase concludes with the issue of the search report. In this phase the applicant files the application (called the International application) at a single Patent Office (called the Receiving Office) in one language. Such a filing has the effect of filing in each of the PCT member countries which the application mentioned (designates) in the application. According to the present PCT Rules, the designation can be made to all the PCT member countries without any additional fees.

### **B. PCT Chapter II**

Under this chapter, if the applicants desires the preliminary examination of the application can be conducted and the examination report is issued. According to the amendment effected to the PCT Rule on 1<sup>st</sup> April 2004, making the request for examination has been made not a mandatory requirement. This means if the applicant so desires he need not resort to making the request for examination. He can directly enter the next phase, namely National phase.

## **VIII. NATIONAL PHASE**

As explained above, on the request made by the applicants at the conclusion of the Chapter I proceedings or after receiving the preliminary Examination in the Chapter II the applicants enters the National Phase. It is important to note that the entry to the National Phase should be made before the expiry of 30/31 months (as prescribed by the member countries) from the filing date or the priority date whichever is earlier, as prescribed by the PCT Rules. But in the following countries namely, Switzerland, Luxemburg, Sweden, Uganda, Zambia and United

Republic of Tanzania, the national phase has to be entered into before the expiry of 20 months from the filing date or the priority date whichever is earlier. This is because the above mentioned countries have not acceded to the modification effected to the PCT Rules in April 2004.

However, if a request for examination is filed before the expiry of the 19 month, then, the national phase entry can be made before the expiry of 30 month in the above mentioned countries. It is to be noted that no extension beyond the above mentioned dates under any circumstances. Therefore, the applicants have to be very carefully to note these important provisions in order to safeguard their interests in the applications and not lose the rights by default. In the case of India, the time limit for entering the National Phase is 31 months as prescribed under Rule 20(4) of the Patent Rules. No extension is possible. If such entry is not made, then, no applications in the desired national countries can be made as the novelty of the invention will be considered as lost due to the publication referred to above. Therefore, extreme care should be taken to enter into the national phase immediately after the completion of the proceedings under Chapters I or II of the International Phase.

In this connection, it is to be noted that for entering into the national phase and for processing the applications further, it is necessary to appoint a foreign attorney. This can be done either directly appointing an attorney in a foreign country like US, UK etc by the applicants themselves, which attorneys have working arrangements with other attorneys in various countries or one can appoint an Indian attorney who will have working arrangements with the foreign attorneys. Whichever way that may be adopted, it has to be decided well in advance so that an appropriate attorney can be appointed at an early stage itself.

#### **IX. ACTIONS TO BE TAKEN BY THE NATIONAL PATENT OFFICES OF THE INDIVIDUAL SELECTED COUNTRIES**

On receipt of the documents in respect of the application, the concerned national patent office(s) take up examination of the application according to the law of the respective countries independently of each other. Normally, the examination in the national patent offices would be based on the search and the preliminary examination reports issued under the International Phase. However, the Patent Offices of the individual national selected countries are at a liberty to examine in the manner prescribed under their patent law which is in force at the particular point of time. Therefore, in exceptional cases the examination can take place beyond the scope of the above reports. Accordingly, they can, if they so desire, ask

the applicants to furnish any other information or evidence to their satisfaction to substantiate the patentability criteria in line with their national law. In that case the applicants are duty bound to provide such information to their complete satisfaction. If the application satisfies all the requirements of the national law a patent will be granted which can be enforced in those countries.

## **X. INTERNATIONAL APPLICATION**

The application is filed in the designated PCT member countries where protection is desired. Such an application has the effect of filing in each individual PCT designated member countries with the establishment of the priority date if applicable. The filing date of the application (called as international filing date) will be the date of filing in the each designated states. The term of the patent which may be granted in the national countries will commence from the International filing date in each country.

### **A. Functions of Receiving Office**

Receiving Office receives the International Application from the applicant or from his authorized Agent. The Receiving Office verifies the International Application filed to ascertain as to whether the application satisfies all the prescribed requirements of PCT as to the form and content of International Applications. This verification is of a formal nature only and does not go into the substance of the invention. Therefore, it extends only to a certain number of elementary formal requirements specified in the Treaty as forming part of that verification. If the requirements of the PCT rules, namely, nationality/residence, language, format of the specification, fees etc. are fulfilled, then, the international application number is allotted on the date of receipt of the application. The receiving office accords, as the international filing date, the date of receipt of the international application, provided the application is in order in accordance the PCT Rules, at the time of receiving the application. If the receiving office finds that the international application did not, at the time of receipt, fulfill the requirements listed in paragraph (a) above, it will, as provided in the Rules, inform the applicant to effect the required correction(s). If the applicant complies with the requirements, the receiving office will accord, the international filing date, which is the date on which the corrected copy is submitted.

It is not required that all the requirements of the International Application are to be examined by the Receiving Office. For example, the Receiving Office does not examine the substantive questions such as (i) whether the disclosure of the invention in the application is sufficient and (ii) whether the requirement of unity of invention is complied with etc. It verifies only requirements which are formal in nature and which are essential for the purpose of confirming, that the application meets, reasonably, the requirements prescribed by PCT uniformly. When the above actions are completed, the Receiving Office transmits the record copy of the International Application to the International Bureau at Geneva and the search copy to the International Searching Authority. The Receiving Office keeps the third copy, as the home copy. The transmittals do not take place till proceedings pertaining to national security are completed. If the provision of national security applies the Receiving Office will, then, declare that national security provisions prevent the International Application from being treated as such.

#### **B. Functions of Designated Office**

These are the Patent Offices in the various contracting States (PCT member Countries) whose responsibilities are to grant patents according to the national laws of the country concerned when the international application enters the national phase of PCT.

#### **C. Functions of Elected Office**

In the demand for international preliminary examination, the applicant has to indicate for which of the contracting States designated in the international application he desires the examination is to be carried out. Such States are referred to as Elected States and the national or regional patent office acting for the elected state is called the Elected Office.

# AMENDMENT OF PATENT

## I. INTRODUCTION

'Amendment of a patent' is a broad expression which includes amendment of patent application, patent specification and other related documents. The purpose of an amendment is to validate a patent, whose validity is otherwise open to attack. Amendment plays a significant role in the grant of patents. Often, patents are not granted in the manner in which they are applied for. It is quite likely that during the course of prosecuting the patent application before the Patent Office, an application would be found not to comply with the requirements under the Patents Act and the Patents Rules. In such cases, the Controller may require the application, specification or the relevant document to be amended to his satisfaction.<sup>257</sup> Alternatively, the applicant or the patentee may file an application for amendment before the Controller or amend the specification in proceedings before the Appellate Board (or any authority notified by the appropriate authority) or the high court. The major purpose of a patent specification is to define the scope of the invention claimed so as to give public notice of the limits of the monopoly claimed. An amendment that is allowed will take retrospective effect from the date of filing of the complete specification. An amendment which would enlarge the limits of the scope of the invention claimed would make actionable, ex post facto, what, at the time when it was done, the doer had no reason to suppose that it amounted to an infringement of the patentee's rights. To remedy this, the Patents Act provides for publication of and opposition to the amendment and imposes certain restrictions on the scope of amendment.

Chapter X of the Patents Act, which comprises sections 57 to 59, deals with amendments of applications and specifications. The legislative history of chapter X is well-documented in the Ayyangar Committee Report.<sup>258</sup> There are also a host of other provisions in the Patents Act and the Patent Rules that come into play in the case of an amendment. The Patents Act provides for amendment at various stages of prosecution of the patent application, as well as after the grant of a patent. It also provides for restrictions to the amendments that can be made by the applicant or the patentee.

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<sup>257</sup> Section 15, Patents Act, 1970.

<sup>258</sup> Justice N Rajagopala Ayyangar, 'Report on the Revision of the Patent Laws', September 1959.



An amendment will also include an amendment to an amended specification. The right of an applicant or a patentee to make amendments shall not be called to question except on the ground of fraud.<sup>259</sup> In seeking an amendment, the applicant or the patentee has a heavy onus to discharge and to produce the full evidence to prove its case. An amendment made to a convention application before the international searching authority or preliminary examination authority shall be regarded as an amendment made before the patent office.<sup>260</sup> The particulars of all amendments shall be entered into the register of patents.<sup>261</sup>

## **II. PROVISIONS UNDER THE PATENT ACT, 1970**

The power of the Controller to require amendments at the application stage under chapter IV of the Patents Act is contained in section 15, 16(3), 18(1)(b), 18(2)(b) and 19(1)(b). Chapter X of the Patents Act deals with 'Amendment of Applications and Specifications'. Section 57 pertains to the amendments preferred before the Controller both before and after the grant. It also specifically deals with opposition of an amendment, though the provisions of sections 25 and 26 will also be relevant. Section 58 deals with amendments made before the Appellate Board or the high court in revocation proceedings. Section 59 describes the scope of amendment. Rules 81 to 83 describe the procedure of amendment. Rule 137 deals with residual power of the Controller to carry other amendments.

## **III. STAGES OF AMENDMENT**

An amendment may be made either before or after the grant of the patent. The clear use of the phrases 'application for the patent' and 'applicant for a patent' on the one hand, and 'patentee', 'complete specification' and 'complete specification as originally accepted', on the other, indicate that the Patents Act provides for amendments at both the stages. Section 57 deals with amendment of application and specification before the Controller. The provisions of section 57 are without prejudice to an applicant's right to amend the specification or any related document to comply with the directions of the Controller issued before the grant of the patent.<sup>262</sup> Section 58 deals with the amendment of specification before the Appellate Board or the high court. The scope of the amendment is dealt with in section 59.

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<sup>259</sup> Section 59(2)(c), Patents Act, 1970.

<sup>260</sup> Section 138(6), Patents Act, 1970.

<sup>261</sup> Section 67(1)(b), Patents Act, 1970.

<sup>262</sup> Section 57(6), Patents Act, 1970.

It is necessary to draw a distinction between the scope of amendment before and after the grant. The express language of sections 57 and 58 clearly indicates that the scope of the amendment under the said sections will be subject to the provisions of section 59 of the Patents Act. But a careful reading of section 57 will indicate that the Patents Act provides for the following two kinds of amendments before the grant: (a) Amendments before the grant under section 57(1); and (b) Amendments before the grant mentioned in section 57(6).

Amendments before the grant made under section 57(1) are discussed below in detail to show how they differ procedurally from the amendments after the grant. With regard to the amendments mentioned in section 57(6), it is clear that certain amendments before the grant, ie, amendments made in compliance with the direction of the Controller, will not come under the ambit of section 57 and consequently will not be bound by the mandate of section 59 with regard to the scope of such amendment. Thus amendments made pursuant to the direction of the Controller will not be regarded as an amendment under chapter X of the Patents Act and the scope of such amendments, it is submitted, need not be confined to the mandate of section 59.

#### **IV. AMENDMENTS BEFORE THE CONTROLLER**

Broadly, amendments before the Controller can be distinguished, by the stage in which they are introduced, as amendments before the grant of the patent and amendments after the grant of the patent. The amendments before the grant may be made only before the Controller. As for amendments after the grant, they may be made either before the Controller (section 57) or before the Appellate Board or the high court (section 58). Any amendment made under sections 57 and 58 must comply with the overarching requirements of section 59. The Patents Act provides for challenge of amendments allowed by the Controller. A decision or order passed by the Controller under section 57 is an appealable order under section 117A(2) of the Patents Act. The issue may also be brought up either before the Appellate Board or the high court in a proceeding for revocation of patent under section 58.

Minor amendments or corrections of irregularities need not follow the rigors mentioned under the Patents Act and the Patents Rules. The Patents Act does not require amendments which are not substantive in nature to be published.<sup>263</sup> Amendment of any other document for which no specific provision has been made in the Patents Act may be amended and any irregularity

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<sup>263</sup> Rule 81(3), Patent Rules, 2003.

in procedure may be obviated by the Controller, without detriment to the interests of any person.<sup>264</sup> For instance, the Controller has the power to amend the abstract for providing better information to third parties. Such correction or amendment may be carried out by the Controller in the manner he deems fit and upon such terms as he may direct.

#### **A. Amendments before the Grant**

The amendments before the grant of a patent can be made only before the Controller. The Patents Act provides for the following kinds of amendments before the grant: (a) Amendments pursuant to the direction of the Controller under chapter IV; (b) Amendments before the grant initiated by the applicant under section 57; and (c) Amendment of clerical errors before the grant under section 78. Section 57 deals with voluntary amendments made by the applicant or the patentee before the Controller. The said section provides for the amendment of the application of the patent as well as any documents filed therewith. Subsection (6) excludes from the ambit of section 57 the right of an applicant to amend his specification or any other document to comply with the directions of the Controller issued before the grant. This would include a direction to amend issued under Patents Act section 15. Thus, the amendments made before the grant may pertain to amendments made pursuant to the directions of the Controller passed under chapter IV as well as amendments made under section 57. The powers of the Controller under section 57 would exist without prejudice to his power of amendment under chapter IV. If a complete specification is amended under the provisions of the Patents Act before the grant of the patent, the same shall be examined and investigated (under sections 12 and 13) in the like manner as the original specification.<sup>265</sup> In an amendment made in the pre-grant stage, it will be immaterial whether such amendment resulted in widening or narrowing the scope of monopoly claimed. However, the amendment should not alter the claims in such a way as to claim a different invention from that which was disclosed in the application.

##### **i. Amendments under Chapter IV**

Amendments under chapter IV are made in compliance to the directions issued by the Controller. Unlike the amendments under section 57, they are not initiated by the applicant. These amendments are required to comply with the requirement under the Patents Act or the

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<sup>264</sup> Rule 137, Patent Rules, 2003; *See* Press Metal Corpn Ltd v. Noshir Sorabji Pochkhanawalla, AIR 1983 Bom 144.

<sup>265</sup> Section 13(3), Patents Act, 1970.

Patents Rules.<sup>266</sup> The amendments under chapter IV are usually done pursuant to the report of the examiner and after giving the applicant an opportunity of being heard.<sup>267</sup> Such amendments may also result as a consequence of an order in pre-grant opposition passed under section 15. Under chapter IV, the Controller has the power to require amendments in the following cases: (a) Amendments to comply with the requirements of the Patents Act and the Patents Rules under section 15;<sup>268</sup> (b) Amendments pursuant to division of application under section 16(3); (c) Amendments pursuant to objections on anticipation under sections 18(1)(b) and 18(2)(b);<sup>269</sup> (d) Amendments pursuant to objection on potential infringement under section 19(1)(b).

#### **a) Object and Nature of References**

A reference is made to earlier patents or specifications to overcome the objection of prior claim or prior publication. A reference restricts the scope of a claim and prevents the latter patentee from alleging a protection wider than what he is actually entitled to. The object of the reference, which is usually made in the interest of the public, is not to preserve or assist third party rights, but to protect the public from being misled in the absence of such a reference. If the Controller is satisfied that the governing idea or the basic principle of an invention for which an application is made, has already been claimed in an earlier patent, then a reference to that earlier patent should follow.

The reference inserted in a specification may be general or specific in nature. The Controller may insert a general reference 'for the purpose of preventing the later patentee from alleging his invention is wider than which he is entitled to claim, both in his own interests in order that his specification may not be invalidated by excessive width of claim and in the interests of the public, on the ground that the public are entitled to know what the patentee is entitled to claim and to have a fair description of the existing state of knowledge'. A specific reference may be inserted 'to warn the public and to call attention to the relationship existing between the invention described and claimed in the specification in which such reference appears and the invention described and claimed in the letters patent the subject of such specific reference'.

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<sup>266</sup> Section 15, Patents Act, 1970.

<sup>267</sup> Section 14, Patents Act, 1970.

<sup>268</sup> Rule 55(5), Patent Rules, 2003.

<sup>269</sup> Rules 28, 29 and 30, Patent Rules, 2003.

A specific reference serves the purpose of bringing out the relationship between the inventions disclosed in two specifications. Such a reference is made to make the specification clear and definite and to ensure safe use of the patents by the public by disclosing the existence of the prior patent. A specific reference should be inserted where 'its absence would lead to confusion with regard to the real nature of the invention and would put to risk the person reading the specification into believing that the discovery included or involved the discovery already protected by an undisclosed patent'.

#### **b) Reference made in case of Arbitration**

Under section 18(2) of the Patents Act, the Controller may, if it appears that the invention is anticipated by prior claiming, direct that a reference to the other specification shall be inserted by way of notice to the public. The applicant will be able to avert such an insertion being made in his specification if: (a) he can show that the priority date of his claim is not later than the priority date of the claim of the other specification; or (b) the complete specification is amended to the satisfaction of the Controller.

Where the invention in the former specification reveals a new departure from the prior art and the latter specification follows it, it will be necessary to record the departure from the new art and a reference to the former specification must be made in the latter specification. However, it will not be necessary for the Controller to make references to accurately describe the state of the art in the applicant's specification. A reference would be ordered if the real substance of the opponent's invention as described and claimed in its prior patent has been incorporated in the applicant's specification. Specific references should generally be made 'not only to patents which prevent the user of the patent in question, but also to the patent which might imperil the monopoly rights of the owners of the patent in question by virtue of their casting doubts upon the sufficiency, the novelty or the subject matter of their invention'.

#### **c) Reference made in Cases of Potential Infringement**

Under section 19(1), the Controller is empowered to make specific reference to another patent, where the applicant's patent cannot be performed without substantial risk of infringement of a claim in another patent. Specific references are made by citing the patent number of the earlier patent. The applicant may avoid such a reference being made in his specification if: (a) he is able to show to the satisfaction of the Controller that there are

reasonable grounds for contesting the validity of the said claim of the other patent; or (b) the complete specification is amended to the satisfaction of the Controller.

The fact that revocation proceedings are pending in respect of the prior patent will not bar a reference of the same in the applicant's patent. But if such proceedings result in the revocation of the prior patent, the Controller may delete the reference to such a patent from the applicant's application.<sup>270</sup> However, if the reference were inserted on the ground that the specification of the prior patent was a publication of closely related matter to which, in the public interest, attention ought to be directed, the revocation of the patent would have no bearing upon the necessity of the reference. It is not proper to order a specific reference to a revoked patent for the express purpose of introducing a reference to an American specification.

References may also be made in the form of disclaimers. In one case, where the specification of the earlier patent to which reference was made in the latter patent and was disclaimed, was so vague as to leave the reader in genuine doubt as to what it disclosed, the effect of such a disclaimer would be to render the earlier patent in suit ambiguous and invalid on that ground. Where a specific reference is inserted in a specification followed by a disclaimer, the disclaimer should state as clearly as possible the precise matter disclaimed.

#### **d) Amendment and Post-dating**

In the application stage, where an application or specification or any related document is amended under section 15, such amended document shall, if the Controller so directs, be deemed to have been made on the date on which the requirement is complied with or where such document is returned, the date on which it is re-filed after complying with the requirements. The general rule is that an amendment will be allowed with the earlier priority date. Thus, if the feature that was sought to be omitted by the amendment was not an essential feature of the invention, the amendment would be allowed without post-dating. But where the amendments have the effect of excluding an essential feature in the original claim or broadening the original claim, such amendments may not be allowed without post-dating the specification. Whether an amended application should be post-dated will depend on the 'fair basis' test. If, by applying the 'fair basis' test, it is found that the disclosure in the

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<sup>270</sup> Section 19(2), Patents Act, 1970.

specification as a whole as originally filed would have provided a fair basis for the amended claim, then the amended claim should be allowed to go forward without postdating.

In the case of a genuine mistake, the Controller may permit the amendment without post-dating. Thus, in the case of a convention application (United Kingdom), where the applicant was seeking to introduce new material by way of an amendment, and was able to show that the priority document (Japanese patent application) contained such material, the amendment would be allowed without post-dating.

#### **e) Time-limit for preferring an Amendment**

Under chapter IV, an application for a patent shall be deemed to have been abandoned if the applicant fails to comply with all the requirements imposed under the Patents Act within 12 months from the date on which the first statement of objection was issued to the applicant.<sup>271</sup> Any amendment of the application shall be done within the prescribed period. As the Patents Act stipulates a time-period for the conclusion of the examination process, the Controller will not accept amendments beyond the time prescribed in section 21.

#### **ii. Amendments before Grant – Section 57**

Under section 57, an application to amend may be preferred either before or after the grant. As the procedures for carrying out the amendments before and after the grant are different, they are dealt with separately. The following section pertains to the procedure followed for amendments before the grant. The amendments under section 57 are made voluntarily by the applicant or the patentee on an application made in Form 13.<sup>272</sup> The language used in section 57 indicates that the Controller has the discretion to allow or refuse an amendment.

#### **a) Leave to Amend**

Every application for amendment shall seek the leave of the Controller for carrying out the proposed amendment under section 57. The application shall state the nature of the proposed amendment and shall provide full particulars of the reasons for which the application is made. The applicant has to declare in the application that no action for infringement or for the revocation of patent in question is pending before the Appellate Board or the high court, as the Controller cannot entertain an amendment application pending infringement suits or

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<sup>271</sup> Section 21, Patents Act 1970; Rule 24B(4), Patent Rules, 2003,.

<sup>272</sup> Rule 81(1), Patent Rules, 2003.

revocation proceedings.<sup>273</sup> It is not necessary for the applicant seeking a leave to amend to establish good faith or reasonable skill and knowledge as an essential pre-requisite for the amendment. If the leave to amend the complete specification is obtained by fraud, the patent may be revoked under section 64(1)(o) of the Patents Act.

#### **b) Full Particulars of the Reasons**

The applicant has to give full particulars of the reasons for the amendment. As the leave to amend is a discretionary remedy, the applicant will have to establish sufficient reason for amending the specification, failing which leave to amend will not be granted. The onus is on the applicant to make a full disclosure of its case for amendment to the satisfaction of the Controller as a failure may lead to the refusal of the application. But a decision of the Controller not to order a discovery does not mean that the applicant has discharged the onus. The Controller has the power to require a party to voluntarily produce any document in its possession. The Controller may refuse the leave to amend if the applicant or patentee does not furnish the full particulars of the reasons for which the application to amend is made.

An application made under section 57 before the grant need not be published. Consequently, there is no scope for opposition of such amendments. In contrast, an application under section 57 after the grant must be published under section 57(3) and may be opposed under section 57(4). As any change made by such an application will eventually be published along with the patent, the desired effect of informing the public will be served when the patent is published at a later date. For amendments before the grant, the Controller will have the discretion to allow and stipulate conditions upon which such amendments will be allowed.<sup>274</sup>

For amendments before the grant, the Controller will have the discretion to allow and stipulate conditions upon which such amendments will be allowed.<sup>275</sup> The Controller is free to stipulate conditions to the amendment as he may deem fit. The Controller may take into account the extent to which an amendment could adversely affect the interests of other members of the public or applicants who had pending applications related to the same matter.

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<sup>273</sup> Section 57(1), Patent Act, 1970.

<sup>274</sup> Rule 81(2), Patent Rules, 2003.

<sup>275</sup> *Ibid.*



### **iii. Amendment of Clerical Errors before Grant**

The Controller may exercise his power under section 78 both before and after the grant of the patent. The power of the Controller under section 78 to correct clerical errors in any patent, specification or other documents is without prejudice to the provisions contained in sections 57 and 59, and is subject to section 44 of the Patents Act. This includes the power to correct entries made in the register of patents as well.<sup>276</sup> The Controller may exercise such powers either on a request in writing made by any person interested<sup>277</sup> or on his own motion.<sup>278</sup>

The Patents Act provides for a detailed procedure for carrying out such corrections. In cases where the Controller proposes to carry out a correction on his own motion, the Controller may give notice to the patentee, applicant or any interested person and give them an opportunity of being heard before making the correction.<sup>279</sup> If the request to carry out the correction is made by a person interested and the Controller is of the opinion that such a correction would materially alter the meaning and scope of the document, he may require notice to be issued to the person who may be affected, about the nature of the proposed correction, and the same may be published.<sup>280</sup> Any person interested in opposing the correction may give notice of opposition in Form 14 within three months from the date of the advertisement of the request for correction.<sup>281</sup> The Patents Act provides for an opposition as per the procedure laid down in the Act before the Controller decides the case.<sup>282</sup> The Controller shall notify the corrections so made.<sup>283</sup> An order of the Controller under section 78 may be the subject matter of an appeal to the Appellate Board.<sup>284</sup> The Controller may exercise his discretionary power to hear a party for the purposes of amendment.<sup>285</sup>

### **B. Amendment After the Grant**

The amendments after the grant may be made before the Controller [like amendments pursuant to opposition after the grant under section 25(4)] or before the Appellate Board or the high court in pending proceedings. Under section 57, the Controller cannot entertain an

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<sup>276</sup> Section 78(1), Patents Act, 1970.

<sup>277</sup> Rule 122, Patent Rules, 2003.

<sup>278</sup> Section 78(2), Patents Act, 1970.

<sup>279</sup> Section 78(3), Patents Act, 1970.

<sup>280</sup> Section 78(4), Patents Act, 1970; Rule 123, Patent Rules, 2003.

<sup>281</sup> Rule 124(1), Patent Rules, 2003.

<sup>282</sup> Rule 124(4), Patent Rules, 2003; See also Rules 58 to 63.

<sup>283</sup> Rule 125, Patent Rules, 2003.

<sup>284</sup> Rule 117A(2). Patent Rules, 2003.

<sup>285</sup> Section 80, Patents Act, 1970.

amendment application where revocation proceedings are pending. All amendments made after the grant shall be published.<sup>286</sup> The powers of the Controller to amend after the grant will include: (a) Amendments pursuant to post-grant opposition under section 25(4); (b) Amendments pursuant to an opposition proceeding on the ground of wrongful obtaining under section 26; (c) Amendments pursuant to the death of an applicant under section 44; (d) Amendments after the grant under section 57; (e) Amendments pursuant to a revocation of an invention relating to atomic energy under section 65; (f) Amendment of clerical errors after the grant under section 78.

**i. Amendments pursuant to opposition – Sections 25 and 26**

Such amendments may become necessary on an order passed by the Controller under section 25(4) of the Patents Act. Similarly, under section 26(1), the Controller may pass an order requiring amendment in cases where wrongful obtaining is established under section 25(2)(a). In post-grant opposition proceedings, the patentee may also, in exercise of the provisions of section 57, voluntarily make an application for amendment.

The Controller can order specific amendments in cases where the patentee has wrongfully obtained the invention or any part thereof from the opponent. The Controller has the power to direct a patent to be amended in the name of the opponent where the opponent has opposed the patent under section 25(2)(a) and consequent to which the patent was revoked.<sup>287</sup> Where only a part of the invention described in the complete specification has been wrongfully obtained from the opponent, the Controller may require that the specification be amended by the exclusion of that part of the invention.<sup>288</sup> The Controller may also effect an amendment with regard to the priority date of an invention.<sup>289</sup> In cases where the opponent has already preferred an application for a patent for an invention, before the order under section 26(1)(b) is made by the Controller, and such application is pending and includes the whole or a part of the invention wrongfully obtained, in so far as it relates to invention wrongfully obtained, it may be assigned the priority date of the earlier application disclosing the invention.<sup>290</sup>

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<sup>286</sup> Rule 83, Patent Rules, 2003.

<sup>287</sup> Section 26(1)(a), Patents Act, 1970.

<sup>288</sup> Section 26(1)(b), Patents Act, 1970.

<sup>289</sup> Section 57(5), Patents Act, 1970.

<sup>290</sup> Section 26(2), Patents Act, 1970.

The Controller is empowered to require an amendment, pursuant to opposition proceedings, in the light of the objection raised by the opponent. If the objections raised are of such a nature that they can be remedied by an amendment, the Controller may require such amendment to be made to his satisfaction. The Controller has a primary duty to avoid the grant of overlapping patents and where it is possible to avoid overlapping by a suitable amendment, the Controller must do so. In cases where it is difficult to establish overlapping of claims, the applicant/patentee must be given an opportunity to amend to avoid such overlapping. If the applicant/patentee does not make such an amendment, the Controller's only recourse would be to accept a reference, which should include a statement that the applicant/patentee was offered an opportunity to amend but did not avail it.

**ii. Amendments Pursuant to Death of Applicant – Section 44**

The amendment under section 44 is not a substantive amendment as the exercise involves a mere substitution or alteration of names. An application under section 44 for the amendment of a patent shall be made in Form 10 along with substantiating evidence and shall be accompanied by the patent.<sup>291</sup>

**iii. Amendments After Grant – Section 57**

An application to amend a complete specification or any related document may be preferred after the grant of the patent as well. The distinguishing feature of an amendment after the grant under section 57 lies in the procedure of publishing the amendment and providing for opposition of the amendment. Publication and opposition of the amendment are not done in the case of an amendment carried out before the grant under section 57. The amendments under section 57 are made voluntarily by the applicant or the patentee on an application made in Form 13.<sup>292</sup>

**a) Leave to Amend and Reasons for Amendment**

The provisions of section 57(2) with regard to 'leave to amend' and giving 'full particulars of the reasons' are common for amendments made both before as well as after the grant.

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<sup>291</sup> Rule 75, Patent Rules, 2003.

<sup>292</sup> Rule 81(1), Patent Rules, 2003.

### **b) Publication of Proposal Amendment**

Any application made under section 57 after the grant of a patent must be published. The publication of such application should disclose the nature of the proposed amendment. Amendments that are substantive in nature require publication.<sup>293</sup> However, publication will not be necessary where the amendment relates to an application for patent which has not been granted.

### **c) Opposition of Amendment**

When an application for amendment is published under section 57(3) of the Patents Act, any interested person will have a right to oppose the amendment. As with the general right to oppose a patent application, the right to oppose an amendment is also available to an interested person before the Controller.

Within three months from the date of publication, any interested person can give notice to the Controller opposing the amendment.<sup>294</sup> The period of notice will accrue from the actual date of publication. Upon receipt of the notice, the Controller shall notify the person (the applicant) who proposes the amendment and shall give the applicant and the opponent an opportunity to be heard.

Though section 57 does not expressly state the details of the opposition proceedings, by virtue of rule 81(3)(c) it can be implied that procedure of opposition will be the same as followed in the case of an opposition under sections 25 and 26 and its corresponding rules will apply with regard to opposition of amendment. Rule 81(3)(c) states that the procedure specified in rules 57 to 63 relating to the filing of written statement, reply statement, leading evidence, hearing and costs shall, so far as may be, apply to the hearing of the opposition under section 57 as they apply to the hearing of an opposition proceeding.

### **d) Scope of Opposition**

The opposition to the amendment must be confined to the grounds on which the amendment is sought for. It will not be open for the opponent to bring in issues of validity of the claims which are not related to the grounds of amendment. The procedure of amendment shall not be allowed to develop into a sort of roving inquiry on the validity of the patent. The patentee

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<sup>293</sup> Rule 81(3)(a), Patent Rules, 2003.

<sup>294</sup> Rule 81(3)(b), Patent Rules, 2003.

may require the opposition on the grounds of validity to be struck down in an amendment proceeding. Though substantive issues of lack of novelty and obviousness cannot be brought into amendment proceedings as the law provides for proper alternative forum to decide these issues, it will be open for an opponent to raise such issues in his pleadings with a view to persuade the Controller that he should refuse the amendment as it fails to cure an admitted defect. An opponent may be allowed to amend his grounds of opposition if it would cause no injustice to the patentee.

The opponent may bring to the notice of the Controller any covetousness and give evidence for the same. Covetous claims arise when the patentee knowingly or deliberately obtained or maintained claim of unjustified width. To raise the issue of covetousness, the opponent must 'set out the date and circumstances under which the patentee had knowledge of the prior art and the alleged action or inaction which give rise to a conclusion of the improper conduct alleged'.

Amendment to covetous claims imposes difficulties with regard to the extent to which the Controller should exercise his discretion to amend such claims. Where the claims as they were originally drawn were alleged to be covetous with the broadest unamended claim covering millions of compounds and an amendment was sought for to limit the claim to one compound of therapeutic value, the amendment was allowed on the ground that, in the absence of proof to the contrary, the patentee was right in making such a generalisation from their experimental data.

#### **e) Amendment Subject to Conditions**

The language used in section 57 indicates that the Controller has the discretion to allow or refuse an amendment. In allowing amendments under section 57, the Controller may impose conditions based on the opposition made before him. The Controller is free to stipulate conditions to the amendment as he may deem fit. The Controller may also take into account the extent to which the proposed amendments could adversely affect the interests of other members of the public or applicants who had pending patent applications related to the same matter. Since amendments can have retrospective effect, conditions may be imposed in an infringement action with regard to acts done by the opponent before the date of application of the leave to amend, which the patentee may be entitled to bring in the light of the amendment. In imposing conditions in the case of amendments after the grant, the Controller or the court may take into account the provisions of section 11A(7) of the Patents Act.

**iv. Amendment Pursuant to Central Government's Direction – Section 65**

At any time after the grant of a patent, under section 65(2) of the Patents Act, the Controller has the power to allow the patentee to amend the complete specification as he deems fit, instead of revoking the patent pursuant to a direction of the Central Government under section 65(1) in respect of an invention relating to atomic energy.

**v. Amendment of Clerical Errors After the Grant – Section 78**

The Controller may exercise his power under section 78 both before and after the grant of the patent.

**C. Power of Controller in respect of Pending Proceedings**

The applicant (in case of an application for a patent) or the patentee (in the case of a complete specification) may approach the Controller by filing an application for amendment. The power of the Controller under section 57(1) is restrained by the pendency of any infringement suit before a court or any proceeding before the high court for the revocation, irrespective of the fact whether the suit or proceeding commenced before or after the filing of an application. Though the proviso to section 57(1) does not specifically mention revocation proceeding before the Appellate Board, in the light of the amendment introduced to by the Patents (Amendment) Act 2005 section 58, it can be inferred that proceedings for the revocation of patents includes proceedings pending before the Appellate Board. The possible wisdom behind this provision is to ensure that the Controller does not exercise his power of amendment when the subject matter is before a higher authority, and more importantly, when such higher authority, which may be the Appellate Board or the high court, is empowered to order amendment of the specification under section 58.

**D. Procedure for Carrying out Amendments**

Rule 14 provides for the formalities to be complied with while amending the specification. Amendments to the specification shall not be done by slips pasted on or as footnotes or by writings in the margin. The amendments have to be in a separate page and the page incorporating such amendment shall be retyped and submitted to form a continuous document. The applicant shall submit in duplicate the copies of the pages retyped or added or of any drawing that has been added or substantially amended. A copy of the amended

application shall also be left at the Patent Office.<sup>295</sup> The amended documents shall be duly marked, cancelled or initialled by the applicant or his agent.

## **V. EFFECT OF AMENDMENT**

All amendments allowed after the grant of a patent shall be published expeditiously.<sup>296</sup> Once an amendment is allowed by the Controller or by the Appellate Board or the high court, it becomes final and the right of the patentee to make such an amendment cannot be called into question, except on the ground of fraud.<sup>297</sup> Such amendments shall be deemed to form a part of the specification along with other related documents. In construing the amended specification, reference may be made to the specification as originally accepted.<sup>298</sup> An amendment must be construed in the light of the specification, the prior art and the understanding of those concerned with the relative knowledge. It should not receive a different construction for the reason that it has been introduced by an amendment.

### **A. Amendment and Infringement Proceedings**

An amendment of a specification shall not entitle the patentee to any damages or accounts of profits in any proceeding in respect of use of the invention before the date of decision allowing the amendment, unless the court is satisfied the special conditions exist.<sup>299</sup> However, such an amendment will not have any effect on the power of the court to grant an injunction in any infringement suit.<sup>300</sup> After an amendment, the patentee will be expected to start a fresh action for infringement rather than enforce any relief he has obtained in a previous action, as there would be no judgment on infringement or validity of the amended patent.

### **B. Appeal**

The Patents Act provides for an appeal against the order of the Controller under sections 57 and 78 to the Appellate Board. Amendments which make the specification substantially different from the one considered in the decision of the Patent Office, will be allowed in appeal only in exceptional circumstances. The discretionary power to amend a patent will not

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<sup>295</sup> Rule 82, Patent Rules, 2003.

<sup>296</sup> Section 59(2)(a), Patents Act, 1970; Rule 83, Patent Rules, 2003.

<sup>297</sup> Section 59(2)(c), Patents Act, 1970.

<sup>298</sup> Section 59(3), Patents Act, 1970.

<sup>299</sup> Section 111(3), Patents Act, 1970.

<sup>300</sup> Section 111(4), Patents Act, 1970.

be interfered with in appeal unless it is clear that such discretion was exercised wrongly. The fact that the discretion is exercised differently shall not be a ground for interference in appeal.



# **PRE-GRANT AND POST-GRANT OPPOSITION**

## **I. INTRODUCTION**

Opposition to the grant of a patent signifies the first instance at which a challenge can be made to the grant of a patent under the Act. The characteristic feature of opposition proceedings available under the patent laws of various countries is the fact that it can be initiated before the authority which grants the patent, i.e., the Patent Office. Generally, opposition proceedings are regarded as administrative in nature as they happen within the Patent Office and not before a judicial authority. The opposition proceedings under the Act are unique, as they provide for opposition before the grant of a patent (pre-grant opposition) as well as for opposition after the grant (post-grant opposition).

### **A. Importance of Opposition Proceedings**

An opposition is instituted to challenge an application before its grant or to revoke a patent already granted on the grounds enumerated in section 25 of the Patents Act. The logic of opposition proceedings proceeds from the fact that a patent application will disclose technical information about the area in which the invention is claimed which may not be easily available to the Patent Office. By definition, an invention implies a thing not known or disclosed to the world at large. When the patent application is presented with new information, patent offices often face the problem of ascertaining the validity of the information. Despite being equipped with resources on technical and scientific information, patent offices throughout the world face difficulties in keeping pace with the rapid advancements made in all fields of technology. As the competitors of an inventor are likely to have more information about an invention, the law has devised a system of opposition where information with regard to an invention can be supplied by peers in the respective fields of technology. The information may pertain to an earlier invention or a disclosure that is more likely to come from the competitors who have expertise in that particular field of technology in which the invention is claimed. In sum, the device of opposition by competitors is a means to equip the Patent Office with information that may not be ordinarily available to it.

Opposition proceedings will be significant in determining the grant of patents for the applications pending before the Patent Office. In the field of pharmaceutical patents, opposition proceedings are likely to play an important role not only in the development of patent law but also in the future of the pharmaceutical industry considering the large number

of pharmaceutical patent applications pending before the Patent Office. During the ten-year transition period under the TRIPS, the Patent Office received a large number of applications through the mail-box, but reportedly there were only very few molecules invented during that period.<sup>301</sup> There could be many reasons for the disproportionate increase in the number of applications. Opposition is one of the methods by which the genuineness of these applications can be verified. In fact, the absence of opposition proceedings before the grant of EMR was regarded as the chief reason for the grant of monopoly rights to the EMR holders. Eventually, the EMR granted to Novartis' Gleevec and to Wockhardt's Nadoxin lapsed with the rejection of patent application by the Controller consequent to opposition proceedings initiated by its competitors.<sup>302</sup> Being the first instance of challenge to a patent application or a granted patent, opposition proceedings have certain distinct advantages over revocation proceedings available before a judicial authority. The merits of opposition proceedings are as follows:

**i. Challenge Before the Granting Authority**

Being an in-house mechanism, opposition proceeding gives the opponent an opportunity to challenge a patent application or a granted patent before the authority that grants it. There are distinct advantages with regard to familiarity of subject, proficiency in technical knowledge, availability of resources for patent search etc. that are available at the Patent Office.

**ii. Challenge by Peers**

More often the device of opposition is put into effect by peers in the same industry who have knowledge about the field of technology relating to the invention. Pre-grant opposition proceedings permit a patent application to be challenged by any person. Though 'any person' includes an unrestricted array of persons, the technical nature of patents will permit only persons who have knowledge about the invention to pose a substantial challenge to it. Post-grant opposition can be instituted only by an interested person as defined under the Patents Act.

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<sup>301</sup> See NR Madhava Menon, 'Indian Patent Law: Drawing on the Flexibility Offered by TRIPS', in Ajit Parulekar and Sarita D'Souza (eds), *Indian Patents Law-Legal and Business Implications*, 2006, p 11.

<sup>302</sup> *Novartis Application (1602/MAS/98) v, 2006 (32) PTC 261 (PO) (Mumbai)*.

### **iii. Time-bound Proceeding**

The Patents Act and the Patents Rules stipulate specific time-limits for completing the opposition process efficiently.<sup>303</sup> The underlying principle of opposition procedure is the early and complete presentation of the parties' cases as opposed to the piecemeal and tardy introduction of arguments and supporting evidence.<sup>4</sup>

### **iv. Cost Effective**

The comparatively straightforward procedure of opposition proceedings result in quick disposal on merits, thereby reducing the costs incurred in contesting the proceedings. Trial and appreciation of evidence in the traditional manner in which it happens in the courts of law do not occur in opposition proceedings. Additionally, there is no fee stipulated for filing a pre-grant opposition.

## **II. PROVISIONS UNDER THE PATENTS ACT, 1970**

Sections 25 to 28 of the Patents Act deal with opposition. Rules 55 to 70 of the Patents Rules explain the procedural details. The present provisions on opposition proceedings in section 25 were introduced by the Patents (Amendment) Act, 2005. Prior to its introduction, the chapter on opposition was titled 'Opposition to the Grant of Patents' and included grounds of opposition similar to those provided under section 25(1) of the Patents Act. The earlier provisions provided for opposition before the grant of a patent but were different from the pre-grant opposition proceedings introduced by the Patents (Amendment) Act 2005 as they required the opponent to give a notice of opposition to the Controller. Section 25 as it was before the Patents (Amendment) Act 2005 is still applicable to opposition proceedings instituted before the said amendment.<sup>304</sup> The said amendment introduced a device for opposition after the grant which did not exist earlier under the Patents Act.

Like many patent offices, the Indian Patent Office released a draft Manual of Patent Practice and Procedure initially in 2005 and recently in 2019 for providing guidelines for practice. It is stated therein that the contents of the Manual including the guidelines are for the purpose of illustration and not for legal purposes and in case of any conflict the Patents Act 1970 would prevail. Though guidelines stating the practice to be followed before the Patent Office would be desirable, it will not be legally binding in the absence of statutory backing. The experience

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<sup>303</sup> Section 25, Patents Act, 1970; Rule 55 to 62, Patent Rules, 2003.

<sup>304</sup> *Stoplik Services India Pvt Ltd v. Panacea Biotech Ltd* 2006 (32) PTC 811 (CPD)(Mumbai).

in the EPO illustrates the beneficial effect of such guidelines where the Guidelines have some salutary purpose. The Opposition Division of the EPO is likely to view the precedents as having considerable weight, and the practice calls for the Boards of Appeal to account to the President of the EPO if they deviate from earlier case law, and to the parties, if they deviate from the Guidelines.<sup>305</sup>

### **III. OPPOSITION PROCEEDINGS**

As stated above, opposition proceedings under the Patents Act provide the first instance at which a challenge can be instituted against a patent. The Act provides for a multiple challenge mechanism. The multiple challenge mechanism is in conformity with the mandate of the TRIPS Agreement which provides for two broad forms of challenges to a patent. Article 62.4 of the TRIPS Agreement provides for procedures *not inter partes* (administrative revocation) and procedures *inter partes* (opposition, revocation and cancellation) for the acquisition and maintenance of patents. Broadly, challenge proceedings under the Patents Act can be classified into the two categories, i.e.: (1) opposition proceedings and (2) revocation proceedings.

#### **B. Nature and Purpose of Opposition Proceedings**

The purpose and intention of opposition proceedings is to give a competitor the opportunity of opposing unjustified protective rights. The Act provides for opposition at various stages before a right or a claim vests with a person. Opposition proceedings can be instituted to oppose amendments, restoration of lapsed patents, surrender of patents, corrections of clerical errors and grant of compulsory licence. Opposition proceedings may also be instituted to challenge the grant of a patent, either before or after the grant.

##### **i. Opposition to the Grant of a Patent**

In a sense the opposition proceedings can also be regarded as revocation proceedings as one of the possible outcome of an opposition proceeding is revocation of the patent. Yet opposition proceedings should be distinguished from revocation proceedings under the Patents Act, though both the proceedings can be maintained on certain common grounds and can result in the revocation of the patent, as the Act treats them separately. The Patents Act

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<sup>305</sup> Article 15, Rules of Procedure of the Boards of Appeals, EPO.

provides for two kinds of opposition proceedings: (1) Opposition before the grant [section 25(1)], (2) Opposition after the grant [section 25(2)].

The first instance of challenge to a patent comes in the form of opposition to the patent application under section 25(1) of the Patents Act. As this form of challenge is made at the application stage, the opponent must prefer its challenge before the Patent Office. This is commonly known as the pre-grant opposition. The second instance of challenge can be made soon after the patent is granted by the Patent Office. This form of challenge is made before the Patent Office and is commonly known as the post-grant opposition. The consequences of pre-grant opposition and post-grant opposition are different. If successful, a pre-grant opposition will result in the refusal of the patent application,<sup>306</sup> whereas a successful post-grant opposition will result in the revocation of the patent granted, either in full or in part.<sup>307</sup>

A pre-grant opposition is initiated by filing a written representation for opposition before the appropriate office within the stipulated time. It is an opposition of a preliminary nature. Post-grant opposition is similar to revocation proceedings under section 64 in its outcome as both can have the effect of revoking the patent already granted. The significant difference being that the former is an option available at the Patent Office.

## **ii. Opposition Proceedings in General**

Apart from the above two provisions for opposing the grant of a patent, the Patents Act also provides for opposition procedure in general with regard to the following matters: (1) Opposition to an application for amendment under section 57 [section 57(4)]; (2) Opposition to an application for restoration of lapsed patents under section 60 [section 61(1)]; (3) Opposition to the surrender of a patent under section 63 [section 63(3)]; (4) Opposition to the correction of clerical errors under section 78 [section 78(5)]; (5) Opposition to an application for the grant of compulsory licence under section 84 [section 87(2)]; (6) Opposition to an application for revocation of a patent for non-working under section 85 [section 87(2)]; and (7) Opposition to an application for revision of terms and conditions of compulsory licence under section 88(4) [Rule 101(3)].

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<sup>306</sup> Section 15, Patents Act, 1970; Rule 55(5), Patent Rules, 2003.

<sup>307</sup> Section 25(4), Patents Act, 1970.

#### **IV. OPPOSITION BEFORE THE GRANT [PRE-GRANT OPPOSITION]**

Opposition before the grant or 'pre-grant opposition' proceedings have attained importance in India due to a variety of reasons. First, the large number of mail-box applications filed between 1999 and 2005 has stirred the curiosity of the pharmaceutical industry which has witnessed a comparatively low number of new molecules being developed during that period. Pre-grant opposition has emerged as the first instance to check the validity of these applications. Secondly, the relatively simple and cost-effective procedure of pre-grant opposition has attracted many to the Patent Office. Thirdly, challenging patents is a business strategy in itself which is bound to be employed in India, given the presence of a strong home-grown generic industry. Fourthly, the unrestricted status of an opponent is likely to attract more persons who have the expertise to question the validity of a patent.

##### **A. Nature of Pre-Grant Opposition**

Pre-grant opposition proceedings are summary in nature. The unique nature of pre-grant opposition has raised issues with regard to whether pre-grant proceeding is a procedure inter partes. The TRIPS Agreement provides for administrative revocation procedure which is not inter partes in nature. As pre-grant opposition under the Act is a form of administrative revocation, the procedure for opposition before the grant complies with and conforms to the TRIPS Agreement. The Patents Act and the Patents Rules clearly indicate that the opponent is not a party to the pre-grant opposition proceedings. To begin with, pre-grant opposition proceedings are entertained in the application stage where third parties cannot be regarded as essential parties to a proceeding. Again, the nature of representation is such that the parties opposing the application cannot be considered as parties to the proceedings. As the pre-grant opposition proceeding happens in the application stage, it is considered to be a part of the application procedure. But in the case of post-grant opposition, the opponents are parties to the proceedings who enter appearance by filing a notice of opposition in Form 7. Section 25(1) of the Patents Act, mentions that any person may give a written representation and request for a hearing, if the person so desires. Pre-grant opposition procedure is devised in such a manner so as to take into account the case presented by opponents who are not a party to the proceedings.

### **i. No Proceedings Inter-Partes**

Pre-grant opposition, though initiated by a third party, will be regarded as an extension of the application procedure as the opposition takes place before the grant of the application. For this reason, pre-grant opposition will be treated as a proceeding involving the Controller and the applicant. The role of the opponent is merely to supply grounds of opposition and the material to support the grounds. The Patent Act and the Patent Rules indicate that the opponent is not a proper and necessary party to the opposition proceedings. In fact, the power of the controller to revoke and amend an application conferred under section 15 may be exercised even without a pre-grant opposition. The opponent only presents information to the Controller in aiding him to decide the application in the light of the information presented. The outcome of the application can be the same even without an opposition, if the Controller exercises the powers vested in him in deciding an application.

A comparison between the procedures of pre-grant and post-grant opposition will give an unmistakable impression that the pre-grant opposition proceedings are not intended to be a proceeding between parties. In determining the nature of pre-grant opposition proceedings, the following factors will weigh in favour of a conclusion that pre-grant opposition proceeding is not a procedure inter partes:

#### **a) No Stipulated Procedure for Entering Appearance**

First, the opponent is not represented in any official capacity and is not regarded as a party. The Patents Act and the Patents Rules do not provide for a means by which the opponent can become a party to the proceedings. Unlike post-grant opposition where an opponent becomes a party by filing his notice of opposition in Form 7, pre-grant opposition requires only a written representation and as such there is no procedure by which the opponent can officially enter into the proceedings. The Schedule to the Patents Rules does not mention any particular form in which the representation is to be made. Similarly, there is no stipulated fee for filing a pre-grant opposition.

#### **b) No Procedure for Hearing the Opponent**

Secondly, the opponent's right to be heard accrues only after the Controller is satisfied with the merit of the opposition. In contrast, the opponent in a post-grant opposition can proceed with the case irrespective of the merit of the notice of opposition. A pre-grant opponent has to make a request for hearing and the rules do not detail how a hearing is to be conducted. The

rules are not clear whether the opponent will be heard in the presence of the applicant. Rule 129 of the Patents Rules states that the discretionary power of the Controller under the Patents Act or Patents Rules shall not be exercised without giving the applicant for a patent or a party to a proceeding, who is likely to be affected by such exercise of discretion, an opportunity of being heard. It will be interesting to see whether the above rule will oblige the Controller to give an opportunity to an opponent before deciding the opposition.

#### **c) Opposition subject to the Discretion of Controller**

Thirdly, the representation made by the opponent in pre-grant opposition will not become a part of the proceedings upon the fact of it being made before the Controller. The opposition is entertained only 'if the Controller is of the opinion that application for patent shall be refused or the complete specification requires amendment'.<sup>308</sup> Hence, the applicant will be informed about the opposition only if the Controller, in his opinion, is satisfied about the merits of the opposition. A pre-grant opposition is conducted as a part of the application stage and the proceedings are between the Controller and the applicant. In contrast, the filing of notice of opposition gives the opponent the right to initiate the opposition proceedings and a copy of the same will be served on the patentee regardless of its merit or the opinion of the Controller about the same.<sup>309</sup>

#### **d) No Right to Know the Applicant's Defence**

Fourthly, the Patents Act and the Patents Rules are silent with regard to whether the defence of the applicant should be disclosed to the opponent. As the chief purpose of opposition is to help the Controller get a more informed view about the invention seeking patent, non-disclosure of the applicant's defence to the opponent and thus denying the opponent an opportunity to reply to the same, will only defeat the object of opposition proceedings. Whether such an act of non-disclosure of documents by the Controller will amount to a violation of the principles of natural justice and fair hearing justifying the invocation of writ jurisdiction, is a matter the courts will have to decide. The opponent may also invoke other remedies which may be available for obtaining information from public officials.<sup>310</sup>

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<sup>308</sup> Rule 55(3), Patent Rules, 2003.

<sup>309</sup> Rule 57, Patent Rules, 2003.

<sup>310</sup> Section 153, Patents Act, 1970.



### **e) No provision for Appeal and Costs for the Opponent**

Though an applicant can appeal from the order of the Controller in pre-grant opposition proceedings to the Appellate Board, there is no provision under which an opponent can make such an appeal. Where, pursuant to pre-grant opposition the Controller grants a patent, the opponent will have no right of appeal to the Appellate Board. It is submitted that the filing of a writ petition against the order of grant of patent, rejecting the opposition, will not be appropriate as the Act provides for a scheme to challenge patents. The remedy will be either to initiate post-grant opposition proceedings before the Controller or file a petition for revocation before the Appellate Board. The absence of appellate remedy further emphasises the fact that the opponent is not a party to the pre-grant opposition proceedings. There is no specific provision similar to rule 63 of the Patents by which an opponent can be eligible for costs of opposition, though the Controller has a general power to order costs in proceedings before him.<sup>311</sup>

### **ii. Res Judicata and Pre-Grant Opposition**

The fact that pre-grant opposition was instituted by an opponent and was decided on merits, will not bar the same opponent from initiating post-grant opposition or revocation proceedings. The opponent in pre-grant opposition proceedings is not a party to the proceedings and does not have a right to appeal against the order passed by the Controller pursuant to his opposition. The Act provides for a multiple challenge mechanism and the exhaustion of one proceeding will not amount to res judicata for the purposes of further proceedings. The Act treats the various challenge proceedings as independent and does not bar revocation proceedings where opposition proceedings are exhausted. The principles of res judicata are well-settled by the courts in India. In any case, as the opponent is not a party to the pre-grant opposition proceedings, the principles of res judicata will not operate as a bar for further proceedings, either post-grant proceedings or revocation proceedings, where the opponent would be an actual party in those proceedings. The principle of res judicata in relation to suits detailed in section 11 of the Code of Civil Procedure 1908 requires both the former and latter suits to be between the same parties.

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<sup>311</sup> Section 77(2), Patents Act, 1970; Rule 136, Patent Rules, 2003.

## **B. Status of Opponent**

One important distinction between pre-grant opposition and post-grant opposition lies in the status of the opponent. In a pre-grant opposition, the opponent need not be a 'person interested' as defined in s 2(1)(t) of the Patents Act. Section 25(1) of the Patents Act states that 'any person' may make a representation to oppose the application of a patent, but for the Controller to consider such representation, a request for the examination of the application should be filed by a 'person interested', if the same is not done by the applicant.<sup>312</sup> This leads to a situation where the opponent's interest in the application will be material, though not in a mandatory sense, even for pre-grant opposition.

A 'person interested' is defined as one who is 'engaged in, or in promoting, research in the same field as that to which the invention relates'.<sup>313</sup> Such a requirement, as stated above, is not necessary for initiating a pre-grant opposition. However in practice, due to the technical nature of patents, the device of opposition is most likely to be employed by persons in the same industry who have knowledge about the field of technology relating to the invention. But there have been instances where NGOs representing patient groups have opposed patents relating to live-saving drugs. The term 'any person' is likely to be given a wide interpretation to include natural persons, legal persons, associations, corporations and NGOs. Association of pharmaceutical companies may also initiate pre-grant opposition proceedings. Opposition proceedings may be instituted by foreign parties who neither reside nor carry on business in India.<sup>314</sup>

### **i. Identification of Opponent**

The Act has designed pre-grant opposition procedure as a legal remedy in public interest and has made it open for any person to file an opposition. In this aspect, the position under the EPC is similar as a patent may be opposed by any person. In such circumstances, where any person can file an opposition, a question arises whether parties can conceal their identity and file an opposition in the name of another person. In the EPO, opposition on behalf of another undisclosed person will be admissible. The same should be the case under the Patents Act as the purpose of opposition is to provide information not available to the Patent Office. It should not matter who provides such information to the Patent Office.

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<sup>312</sup> Section 11B, Patents Act, 1970; Rule 55(2), Patent Rules, 2003.

<sup>313</sup> Section 2(1)(t), Patents Act, 1970.

<sup>314</sup> Section 150, Patents Act, 1970.

### **a) 'Straw Man'**

The use of 'straw man' or an indirect representative will be irrelevant in pre-grant opposition as the law permits an opposition to be filed by 'any person' without any qualification with regard to his interest or motive. Moreover, as the nature of pre-grant opposition detailed in rule 55 of the Patents Rules does not treat the opponent as a party to the proceeding, the issue of an indirect representation for another will not be relevant.

### **b) Technical Competence**

By its very nature, pre-grant opposition of patent applications relating to pharmaceuticals will involve a great degree of technical information which may not be commonly available. The words 'any person' do not require the opponents to state any particular interest or competence so as to qualify them as opponents. Generally the motive or competence of the opponent is irrelevant. Section 25(1) of the Patents Act refers to 'any person' as opposed to the reference of 'any person interested' in section 25(2). For this reason, the lack of interest in opposing a patent cannot be considered as a ground of inadmissibility.

### **ii. Sham Opposition**

The phrase 'any person' has led to some controversy with regard to whether an applicant of a patent could oppose his own patent. Though the phrase 'any person' is wide enough to include the public at large, it will not include the applicant of the patent. Self-opposition of one's own application is not permissible as the same would be against public policy. If the Controller is of the opinion that the proceedings are false or vexatious, he may award compensatory costs.<sup>315</sup>

### **iii. Representation in Pre-Grant Opposition**

Any person desirous of appearing before the Controller in a pre-grant opposition proceeding may do so through a patent agent who is entitled to practice before the Controller.<sup>316</sup> An applicant for a patent may also appear or act before the Controller in person.<sup>317</sup> The Act also entitles an advocate who is not a patent agent to take part in any hearing before the Controller on behalf of a party who is taking part in any proceeding under the Act.<sup>318</sup> Any person who

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<sup>315</sup> Rule 136(2), Patent Rules, 2003.

<sup>316</sup> Rule 127(a), Patent Rules, 2003.

<sup>317</sup> Section 132(a), Patents Act, 1970.

<sup>318</sup> Section 132(b), Patents Act, 1970.

acts as an agent of another should file his or her authorisation in Form 26 or in the form of a power of attorney.<sup>319</sup>

### **C. Grounds of Pre-Grant Opposition**

Section 25 of the Patents Act contains an exhaustive list of grounds on which an application can be challenged before the grant. The words 'but on no other ground' in the sub-section gives no room for any further ground other than the ones stated therein.

### **D. Admissibility of Pre-Grant Opposition**

The scope of challenging the maintainability of the pre-grant opposition is very narrow. An opposition does not become inadmissible purely because the person named as opponent is acting on behalf of a third party. However, such an opposition would become inadmissible if the involvement of the opponent is to be regarded as circumventing the law by abuse of process. In the EPO, an opposition by a third party will be inadmissible in the following cases: (1) where the opponent is acting on behalf of the patent proprietor and (2) where the opponent is acting on behalf of a client, in his professional capacity, without possessing the relevant qualification.

### **E. Procedure of Pre-Grant Opposition**

The procedure with regard to the conduct of pre-grant opposition is contained in section 25(1) of the Patents Act and rule 55 of the Patents Rules. Unlike post-grant opposition, the rules do not detail the manner in which pre-grant opposition is to be conducted. However, under s 159(2)(v) the Central Government may make rules for the manner in which and the period within which the Controller shall consider and dispose a representation of pre-grant opposition. The fact that there are no detailed rules governing the pre-grant opposition proceedings gives enough scope for developing the rules in practice. Moreover, the simplified procedure indicates the summary nature of pre-grant opposition. Compared to post-grant opposition, the procedure laid down for pre-grant opposition is much less rigorous. The capacity of a pre-grant opponent under the Patents Act is unclear as the procedure does not require the filing of a notice of opposition in Form 7.

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<sup>319</sup> Rule 135(1), Patent Rules, 2003.

### **i. Written Representation**

A pre-grant opposition proceeding may be instituted with the opponent filing a written representation before the Controller. The rules require that the written representation shall normally include the following:<sup>320</sup> (1) a statement detailing the opposition; (2) evidence, if any, to prove the opposition; and (3) request for hearing, if desired by the opponent.

The representation for pre-grant opposition shall be considered by the Controller only when a request for examination of the application has been filed.<sup>321</sup> A request for examination may be filed either by the applicant or by any other interested person. It is to be noted that though pre-grant opposition proceedings can be instituted by 'any person', only a 'person interested' can file a request for examination under the Act. The Controller shall consider the representation and if he is of the opinion that the application for patent has to be refused or that the complete specification requires amendment, he shall give notice to the applicant stating the same.<sup>322</sup>

Within three months from the date of receipt of the notice, the applicant shall file his statement detailing the reasons why the application should not be refused on the grounds mentioned in the statement of opposition. The applicant shall also file any evidence in support of his statement within the stipulated time.

### **ii. Hearing**

As stated above, the opponent's right to be heard accrues only after the Controller is satisfied with the merit of the opposition. If the opponent desires to be heard, he may make a request for hearing. The Patents Rules do not detail how a hearing (oral proceeding) is to be conducted or whether the opponent will be heard in the presence of the applicant. The Controller can hold the hearing in public, but the public may be excluded during the discussion of confidential and sensitive commercial information.<sup>323</sup>

### **iii. Evidence**

Under section 77 of the Patents Act, the Controller shall have the powers of a civil court with regard to proceedings before him in certain matters. The Controller has the power to summon

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<sup>320</sup> Rule 55(1), Patent Rules, 2003.

<sup>321</sup> Rule 55(2), Patent Rules, 2003.

<sup>322</sup> Rule 55(3), Patent Rules, 2003.

<sup>323</sup> Rule 139, Patent Rules, 2003.

and enforce the attendance of any person and examine him on oath. He may require the discovery and production of any document. The Controller may also receive evidence on affidavits. He may issue commissions for the examination of witnesses or documents. Proceedings before the Controller are largely decided on documentary evidence, though the Controller has the power to receive, and rely on, oral evidence.

#### **a) Request for Documents**

As the proceedings in pre-grant opposition are not proceedings inter partes, there is uncertainty with regard to whether the opponent is entitled to the documents filed by the applicant. The officers of the Patent Office are not obliged to furnish information except as stipulated under the Patents Act.<sup>324</sup> But the TRIPS Agreement expressly provides for member countries to accord its judicial authorities the authority to make preliminary and final determinations, including the complaint or the allegation presented by the party adversely affected by the denial of access to information, after hearing the parties on the allegations or evidence.<sup>48</sup> There will be cases where the opponent is not served with a copy of the statement and evidence filed by the applicant in response to the written representation of the opponent. In such cases, the opponent may make a request to the Controller to be served with a copy of the statement and evidence filed by the applicant under the Rule 55 of Patents Rules. The Controller should allow copies of the applicant's documents to be served on the opponent in order to allow the opponent a chance to reply to the statement and evidence of the applicant. This would not only help the Controller to form a fair opinion but also be in the interest of justice as the applicant is anyway entitled under the rules for a copy of the representation filed by the opponent. If the Controller fails to serve a copy of the statement and evidence of the applicant, the opponent may explore the option of moving the writ court for directing the Controller to serve a copy of the same. Due caution is to be exercised here as issues on the nature of pre-grant opposition, such as, whether the opponent is a party to the pre-grant proceedings are likely to crop up. If the opponent succeeds in procuring a copy of the statement and the evidence of the applicant, it would certainly be useful to the opponent in further proceedings. As mentioned earlier, the opponent may invoke other remedies which are available for obtaining information from public officials. The opponent may also seek recourse to rule 127 of the Patent Rules, which gives a party to the opposition a right to get the copies of exhibits filed in an opposition.

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<sup>324</sup> Section 76, Patents Act, 1970.

It would be in the interest of the applicant not to disclose the defence taken up by him in response to the grounds of opposition. As the grounds of opposition are similar to the grounds of revocation, disclosure of the defence by the applicant would expose details about the invention in the application stage which may be used by the opponent in subsequent proceedings like post-grant opposition and revocation proceedings.

#### **b) Late Submission of Documents**

Late submission of documents which introduce facts, evidence and related arguments that go beyond the indication of the facts, evidence and arguments already presented will be admitted only in exceptional circumstances. For the admittance of such facts it has to be shown that there are prima facie reasons to suspect that such late-filed material would prejudice the maintenance of the patent. Such documents may be allowed in public interest. A more practicable view with regard to admissibility of documents submitted late would be to look into the substance of the document, regardless of when the same is produced, and draw a conclusion whether it would be a cause for not granting a patent. The procedure of opposition is not an end in itself. The patent can still be revoked through revocation proceedings on the basis of the same documents. As stringent time-limits are fixed for every stage of the opposition procedure, the Controller or the Appellate Board may be justified in rejecting the documents that are submitted late or beyond the stipulated time period. The admissibility of a late-filed document should be determined on the relevance or evidential weight of the document in question and in relation to other documents already filed in the case.

#### **iv. Scope of Opposition**

An application of a patent may be opposed in its entirety or in part. Usually opponents oppose the patent in its entirety. If an opponent limits the extent to which a patent is opposed to certain subject-matters, the remaining subject-matters will not be treated as a subject of opposition. Where an opposition targets the subject-matter of an independent claim, it would include all the subject-matters covered by dependent claims.

#### **v. Fresh Grounds of Opposition**

A fresh ground for opposition should be allowed by the Controller at any time before the grant, as it would be open for 'any person' to bring in such a ground if the opponent is not allowed to do so. There is nothing in the Patents Act or the Patents Rules that bars multiple oppositions. Similarly, as there is no stipulation with regard to class action or representative

action, opponents can sustain parallel opposition proceedings before the Controller for the same application.

A fresh ground for opposition should be allowed by the Controller at any time before the grant, as it would be open for 'any person' to bring in such a ground if the opponent is not allowed to do so. There is nothing in the Patents Act or the Patents Rules that bars multiple oppositions. Similarly, as there is no stipulation with regard to class action or representative action, opponents can sustain parallel opposition proceedings before the Controller for the same application.

It would not be proper to admit a matter which not only goes beyond the bounds of the opponent's evidence but also introduces a new ground of opposition. But if the new ground of opposition is of such a nature that the public interest and justice demand that it should be admitted, the opponents may be allowed to include it. Opposition proceedings should be conducted expeditiously strictly adhering to the time-frame under the Patents Act and the Patents Rules. New material filed in support of existing grounds and the introduction of new grounds should not unnecessarily delay the proceedings.

#### **vi. Burden of Proof in Pre-Grant Opposition**

Normally the burden of proving a fact will be upon the person who seeks to rely on it. When a person is bound to prove the existence of any fact, the burden of proof lies on that person. The onus is on a person who asserts a proposition or fact which is not self-evident. The burden of proof in a proceeding lies on that person who would fail if no evidence at all were given on either side.<sup>325</sup> In pre-grant opposition proceedings, the role of the opponent is to oppose the grant of a patent on the grounds mentioned in the Patents Act section 25(1) by supplying information to the Controller.

It is not clear whether the burden of proving that the application can be refused on the grounds mentioned in section 25(1) of the Patents Act, would lie on the opponent. The uncertainty arises first, from the nature of pre-grant opposition which does not treat the opponent as a party to the proceedings and secondly, from the fact that pre-grant opposition will be treated as an extension of the application procedure. Though a pre-grant opposition can be made on the grounds mentioned in section 25(1), the decision of the Controller on a pre-grant opposition will be passed as an order under section 15. For an application to

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<sup>325</sup> Section 102, Patents Act, 1970.



materialise into a grant, the applicant has to prove, to the satisfaction of the Controller, that the application fully complies with the Patents Act and the Patents Rules. The role of the opponent is only to facilitate the Controller in making a decision on the application. It will be difficult to impose the burden of proving the opposition on the opponent, in circumstances where the Controller has the power to go beyond the opponent's case and reject the application independent of the opposition.

#### **vii. Representative Action**

The Patents Act and the Patents Rules do not provide for representative action. The provisions of the Code of Civil Procedure 1908 with regard to representative action will not apply for proceedings before the Controller. Opposition proceedings initiated by one opponent should be treated as an independent proceeding without reference to other oppositions, and separate orders should be passed even if all the oppositions are preferred on common grounds.

#### **viii. Withdrawal of the Opposition**

As pre-grant opposition is a part of the application procedure, it will be for the Controller to determine the effect of withdrawal of opposition. With the filing of the written representation, the opponent would have disclosed all the grounds and the material evidence on which the application can be refused. It is for the Controller to decide whether it should continue the opposition procedure on its own motion even after the withdrawal of the opposition. Even upon the receipt of notice to withdraw the opposition, the Controller may consider continuing the proceeding in the public interest. The Controller may impose costs on the opponent if the withdrawal was pursuant to a false or vexatious proceeding.<sup>326</sup>

#### **ix. Transfer of Opposition**

There is no provision under the Patents Act for the transfer of opposition proceedings from one party to another. As an opposition can be preferred by any person, it becomes immaterial whether the status of an opponent can be transferred to another. Though a company which was the subsidiary of the opponent when the opposition was filed and which carried on business related to the opposed patent cannot acquire the status as opponent if all its shares are assigned to another company, it has been held that an opposition pending before the EPO

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<sup>326</sup> Rule 136(2), Patent Rules, 2003.

may be transferred or assigned to a third party as part of the opponent's business assets together with the assets in the interest of which the opposition was filed.

#### **x. Time-bound Procedure**

The Patents Act provides for a summary, time-bound pre-grant opposition. The representation for pre-grant opposition has to be made before the grant of the patent. Once a patent is granted, a challenge to the patent can be made by way of post-grant opposition or revocation.

##### **a) Time Limit for Preferring an Opposition**

A pre-grant opposition may be instituted at any time after the application is published but before the patent is granted. Irrespective of the fact whether a representation for opposition is made, no patent shall be granted before the expiry of a period of six months from the date of publication of application under section 11A of the Patents Act.<sup>327</sup> This gives the opponent a period of at least six months to file a written representation of opposition. The period may extend up to the date of the grant.

##### **b) Time Limit for Disposing Opposition**

Upon the receipt of representation, if the Controller is satisfied that the application should be refused or the complete specification requires amendment, the Controller may send a notice to that effect to the applicant along with a copy of the representation. On receiving such notice, the applicant shall file its statement and evidence in reply to the representation within three months. After considering the representations made before him, the Controller shall either reject or grant the patent within one month from the completion of opposition proceedings.<sup>328</sup> The Controller may, after considering the representation and submission made by the parties to the opposition proceedings, either refuse or grant the application for patent within one month from the completion of the opposition proceedings. An appeal against the order of the Controller may be preferred by the applicant within three months to the Appellate Board.

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<sup>327</sup> Rule 55(1A), Patent Rules, 2003.

<sup>328</sup> Rule 55(6), Patent Rules, 2003.

### **c) Extension of Time**

Though the Controller is empowered to extend the time for doing any act for which a time is stipulated under the Patents Act or the Patents Rules, the time-limit specified under rule 55(4) is specifically excluded.<sup>329</sup> No extension of time is contemplated for the applicant to file its reply to the opposition.

### **F. Fees**

The Patents Act or the Patents Rules do not stipulate any fee for instituting pre-grant opposition proceedings.

### **G. Decision of Controller**

Upon considering the material placed before him, the Controller may either refuse to grant a patent on the application or require the complete specification to be amended to his satisfaction before granting the patent. If the Controller so finds that the grounds of opposition are not established and that there is no need for any amendment, he may proceed to grant the patent on the application in the manner it was preferred. The rejection of representation made by the opponent results in the grant of the patent. In case the Controller finds merit in the representation, he may accept the representation and refuse the grant of patent on that application within a similar period.

The decision of the Controller in refusing to grant a patent on the application clearly illustrates the state at which the opposition is preferred. There is no grant at this stage to be revoked. The power to refuse the application proceeds from section 15 of the Patents Act. The finding of the Controller in the pre-grant opposition of the Novartis Application clearly illustrates this position:

In view of the above findings and all the circumstances of the case, I hereby refuse to proceed with the application for Patent No 1602/MAS/1998.

The decision of the Controller refusing the application or amending the same can be appealed to the Appellate Board.<sup>330</sup> An application for review can also be made to the Controller for the review of his decision within the stipulated time.<sup>331</sup>

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<sup>329</sup> Rule 138, Patent Rules, 2003.

<sup>330</sup> Section 117A, Patents Act, 1970.

<sup>331</sup> Section 77(1)(f), Patents Act, 1970; Rule 130, Patent Rules, 2003.

## **H. Costs**

As the opponent is not a party to the pre-grant opposition in the strict sense, the opponent will not be entitled to costs of the proceedings. The fact that the opponent does not incur any fees in initiating the opposition further strengthens this view. But the Controller may award compensatory costs in any proceeding, if he is of the opinion that it is false and vexatious.<sup>332</sup>

## **V. OPPOSITION AFTER THE GRANT [POST-GRANT OPPOSITION]**

Opposition after the grant or 'post-grant opposition' may be made at any time after the grant of patent but before the expiry of one year from the date of publication of grant of a patent in the Official Journal.<sup>333</sup> This form of opposition is akin to the opposition proceedings under the EPO in that the opposition is made after the grant. Post-grant opposition can be initiated by an interested person alone. Any interested person may give notice of opposition in Form 7 to the Controller, paying the prescribed fee, for any of the grounds mentioned in section 25(2). The initial examination shall be conducted by an Opposition Board. The findings made by the Opposition Board are then submitted to the Controller. The findings of the Opposition Board are recommendatory and not binding on the Controller.

### **A. Nature of Post-Grant Opposition**

The Patents Act and the Patents Rules clearly indicate that post-grant opposition is a proceeding between the patentee and the opponent. Though the role of the opponent is similar to the one in pre-grant opposition, the opponent is treated as a party to the proceedings with all the rights and privileges that normally accrue in an inter partes procedure. Unlike pre-grant opposition which is regarded as an extension of the application stage, a post-grant opposition is initiated after the grant of the patent and the Controller decides the case based on the submissions made by the parties.

#### **i. Proceedings Inter Partes**

Various provisions of the Patents Act and the Patents Rules point towards the contentious nature of post-grant opposition. First, a procedure is provided for the opponent to become a party by filing his notice of opposition in Form 7 and paying the stipulated fee. Secondly, the Patents Rules provide for detailed procedure and for the manner in which the hearing is to be

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<sup>332</sup> Rule 136(2), Patent Rules, 2003.

<sup>333</sup> Section 145, Patents Act, 1970.

conducted. Thirdly, the representation made by the opponent in post-grant opposition will become a part of the proceedings. The filing of notice of opposition gives the opponent the right to initiate opposition proceedings and a copy of the same will be served on the patentee regardless of its merit or the opinion of the Controller about the same.<sup>334</sup> Fourthly, unlike pre-grant opposition proceedings, an opponent has the right to file an appeal against the decision of the Controller in a post-grant opposition proceeding. The opponent will also be eligible for costs.<sup>335</sup>

## **ii. Res Judicata and Post-Grant Opposition**

Can a decision rendered pursuant to opposition proceedings bar further revocation proceedings? A novel plea was raised before the EPO that a decision in the European opposition proceedings could give rise to an objection of res judicata in subsequent national revocation proceedings. The plea sees the involvement of a 'straw man' in the opposition proceedings as prejudicial to the patentee, who can plead res judicata against the opposing party in revocation proceedings. As the plea of res judicata can be raised only if the parties are identical, the use of 'straw man' in opposition proceedings and the exposure of the same at the opposition proceedings will be important.

The plea of res judicata will not only be confined to the issues which the court is actually asked to decide, but would also cover issues or facts which are so clearly part of the subject matter of the litigation and could have been raised, that it would be an abuse of the process of the court to allow a new proceeding to be started in respect of them. In such cases, the plaintiff would be estopped from disputing the finding of the earlier court. Thus the plea of res judicata would apply to every issue which properly belonged to the subject of litigation and which the parties exercising reasonable diligence might have brought forward at that time.

The application of the principle of res judicata for proceedings before the Controller is unclear, as under of the Code section 11 of Civil Procedure 1908, the plea of res judicata can be applied only in the case of suits, and the proceedings before the Controller are not subject to the Code of Civil Procedure 1908. In any case, the issue of res judicata would arise only in the subsequent proceedings, i.e., the revocation proceedings and not before the Controller. Yet, the argument of res judicata can be used before the Controller to expose a straw man

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<sup>334</sup> Rule 57, Patent Rules, 2003.

<sup>335</sup> Rule 63, Patent Rules, 2003.

opposition. The high court or the Appellate Board in revocation proceedings should consider whether the person filing for revocation has incited a straw man to lodge a post-opposition before the Controller as the authority in revocation proceeding, which judges the matter later in time, will have the full overview of the circumstances, issues and parties involved in opposition and revocation proceedings. No issue of estoppel by reason of res judicata would arise in any revocation proceedings on an issue that might have happened previously in opposition proceedings.

Under section 11 of the Austrian Law Introducing Patent Treaties, a decision in European opposition proceedings may lead to an objection of res judicata in subsequent national revocation proceedings if the parties and issues involved are identical. There is no similar legislative provision in Indian law. But the decision of the Controller in an opposition proceeding will not act as res judicata in revocation proceeding before the high court. This is due to the reason that the grounds of opposition are not coterminous with the grounds of revocation.<sup>336</sup> A person who unsuccessfully opposes a patent under section 25 will be entitled to file a petition for revocation under section 64.

### **B. Status of Opponent**

The status of an opponent in pre-grant opposition proceedings is unrestricted as the Patents Act permits 'any person' to oppose an application under section 25(1). But under section 25(2), only a 'person interested' in the patent can oppose it after the grant. Where it is felt that the opponent has concealed his identity, the applicant may seek confirmation that the opponent was acting entirely on his own behalf and not for an unnamed third party. In the context of medicine and drugs, the phrase 'person interested' is likely to include person engaged or promoting research in medicines and drugs. There could be cases where a person not entitled to oppose a patent may file a post-grant opposition through another. The Act allows opposition proceedings to be instituted by foreign parties who neither reside nor carry on business in India. Where the notice of opposition is given by a party who neither resides nor carries business in India, the Controller may require him to give security for the costs of the proceedings and may treat the failure to furnish security as an abandonment of the opposition.<sup>337</sup>

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<sup>336</sup> Surajmal Rambux v. Laxminarayan Raghunath, AIR 1951 Nag 284.

<sup>337</sup> Section 150, Patents Act, 1970.

**i. 'Person Interested'**

The Patents Act defines a 'person interested' as including a person engaged in, or in promoting, research in the same field as that to which the invention relates. Interest should mean an interest in the invalidation of the patent. Opposition should be a simple, speedily-conducted procedure in which, on the one hand, relevant objections to patentability are given appropriate consideration, and on the other hand, a decision on the validity of the patent is reached as quickly as possible, in the interests of both parties. In this respect, investigating a straw man challenge would mean that more matters in dispute would have to be considered, which could delay the proceedings. The Controller is empowered to ascertain the identity of straw man under section 77. The reference to 'any person interested' introduces the issue of locus standi with regard to third parties. The Controller can decide upon the eligibility of the parties to participate in opposition proceedings.

**a) 'Straw Man'**

'Straw man' refers to an indirect representative. 'Straw man' opposition refers to opposition proceedings conducted by a person without revealing its actual identity. The use of a 'straw man' in Japanese oppositions was extremely common where an opponent wished to remain anonymous, and this practice was permissible under art. 55 of the Japanese Patent Law which allowed 'any person may file opposition to the grant of a patent'. The issue of whether straw man oppositions will be permissible under the EPO was raised in a case where a request was made to the Board to seek confirmation that the opponent was acting entirely on his own behalf and not for an unnamed third party. The Enlarged Board of Appeal of the EPO considered this issue and held that the opposition would be inadmissible if the involvement of the opponent is to be regarded as circumventing the law by abuse of process.

The use of 'straw man' will be relevant in post-grant opposition proceedings as the proceedings are contentious in nature. The use of a 'straw man' will be important to defeat any effect of res judicata on the challenge proceedings. The principles of res judicata can be applied only if the parties in the former and latter proceedings are the same. Where the opponent was erroneously designated by its trading name as opposed to its corporate name, the opponent may carry out the correction in the notice of opposition as such an error will be treated as a mistake and not as a deliberate concealment.

### **b) Technical Competence**

The opposition of patents relating to pharmaceuticals will involve technical information not commonly available to the public at large and will require persons with technical competence to impose the challenge. The phrase 'person interested' implies an interest or competence to oppose a patent. The motive of the opponent will be relevant in post-grant opposition and the lack of 'interest' in opposing a patent can be raised as a ground for questioning the admissibility of opposition.

### **c) Locus Standi of the Opposition**

Though it would be difficult to question the locus standi of an opponent in pre-grant opposition proceedings, as the Patents Act entitles any person to prefer an opposition before the grant, the capacity of an opponent in post-grant opposition provides enough scope to question the locus standi of the opponent. The issue of the locus standi of the opponent is usually taken up as a preliminary issue which can question the maintainability of the opposition. It will be for the Controller and the courts to determine the nature of interest of an opponent as a question of fact.

### **d) Holding Company and its Subsidiaries**

As a general rule the status of an opponent is not freely transferable. But a holding company which has a controlling interest or a shareholding interest will be entitled to oppose on behalf of its subsidiary company, if the subsidiary company qualifies for a person interested under the Patents Act. With regard to the transfer of the status of an opponent consequent to the takeover of business, there are two views. While the EPO has held that the status of an opponent may be transferred or assigned to a third party as part of the opponent's business assets together with the assets in the interest of which the opposition was filed, an early decision under the UK Patents Act 1949 excluded a company from acquiring an interest of an opponent subsequent to the opposition.

### **e) Interest of an Opponent**

The phrase 'person interested' implies that the opponent has some form of interest in the patent. In United Kingdom, this phrase was given a threefold interpretation to include (1) any person who was in possession of patents (holders of patents) (2) a manufacturing interest and (3) a trading interest. The phrase will have a broader connotation in India as the definition of



a person interested under the Patents Act includes a person with a research interest in the same field as that of the invention. The phrase 'person interested' may also include public interest. The interest of an opponent will vary from case to case. The approach of the courts in determining a 'person interested' is well-summarised by the Delhi High Court in *Ajay Industrial Corpn v Shiro Kanao*:<sup>338</sup>

*We do not wish to say that a person who is not manufacturing or dealing in a patented machinery but is merely suing it can never be said to be 'interested' in it so as to be entitled to seek its revocation. We only wish to say that whether a user has an interest, for this purpose, will depend upon the facts and circumstances of each case and it cannot be laid down as a general proposition or an invariable rule that every person, merely because he uses certain machinery, will be entitled as of right to seek revocation of the patent obtained by the manufacturer in regard to such machinery. To lay down any such rule will make it impossible for such a patentee to enjoy his patent rights; mere users of his machinery or that of his competitors in different parts of the country can be set up to file applications in different courts seeking its revocation...In our opinion, a 'person interested' within the meaning of section 64 must be a person who has a direct, present and tangible commercial interest or public interest which is injured or affected by the continuance of the patent on the register.*

In determining the locus standi of a person the following principles may be considered:

(1) The circumstances of each case must be considered, and it is wrong to lay down any hard and fast rule as to the precise nature or extent of the interest which justifies locus. (2) The onus of establishing locus lies on the opponent or applicant for revocation. (3) If the opponent or applicant for revocation can show that he has some genuine interest which will be prejudiced and if the opposition or application to revoke is not frivolous, vexatious or blackmailing, then locus should be granted even if the patentee can throw some doubt on the exact extent of the opponent's interest. The interest in the opposition of patents must be a genuine interest. The Controller or the court should see that there must be the existence or likelihood of a real prejudice. Once the Controller or the Court is satisfied that the opposition is not frivolous, vexatious or a piece of blackmail, the interest shown will be sufficient to enable the opposition or application to proceed. The onus of establishing interest is on the opponent. The

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<sup>338</sup> AIR 1983 Del 496.

opponent should establish an existing interest at the date on which he gives the notice of opposition. It will be an arduous task to define who will be a person interested for the purpose of opposing a patent, as it is quite possible for the interest to vary at the stage of opposition and at the stage of revocation. As stated above, the courts have not enumerated any distinct test for determining a person interested. It will be a matter which has to be decided on the facts and circumstances of each case. The kinds of interest detailed below are only enumerative and not exhaustive

**a. Interest in the Possession of an Invention or Patent**

Any person who is in possession of a patent will be regarded as having an interest in a patent. Once a person assigns his patent to another, he ceases to have any interest in that patent. It has been held under the UK Patents Act 1949 that a person who has assigned his interest in the patent, by way of a deed of reassignment, ceases to be person interested within the meaning of that Act. The interest of a person will also manifest in cases where an application or a patent is opposed on the ground that applicant/ patentee had wrongfully obtained the invention from the opponent. Where the validity of a cited patent is contested by the applicant, the opponent will have the locus standi for the purposes of considering a reference under section 9 of the UK Patents Act 1949.

**b. Interest in Manufacture**

Any person who is interested in manufacturing or carrying on the manufacture of an article which is the subject matter of a patent will be a person who has an interest in the manufacture of that article. An existing manufacturer whose livelihood may be threatened by a patent could bring an action of opposition to ensure that 'the proposed monopoly is confined within proper limits and rests upon an adequate description in the specification'. An opposition may also be instituted by an organisation which represents a number of individuals who have sufficient manufacturing or trading interest for the purpose of opposition proceedings. A manufacturing interest will include the interest of the manufacturer of raw materials related to the product of an invention, and also extends to a holding company which has controlling interest in such a manufacturer.

**c. Interest in Trade**

It will be open for any person to qualify as a person interested, if he can show bona fide and satisfactory reasons to oppose the patent. Such a person can oppose if it can be shown that the

grant of patent rights to the applicant would be 'immediately or directly prejudicial to the interest of the opponents'. To come within the ambit of a person interested, it would be sufficient for a person to show that he has a genuine trading interest which may be prejudiced. Any person, who makes a bona fide attempt to carry out the invention and apprehends that he may be affected by the application, will be entitled to be heard as an opponent. Even a person with a trading interest but who is outside the jurisdiction may qualify as a person interested. But sole selling agents in Europe for goods manufactured by an American company were not entitled to oppose as they did not have a manufacturing or trading interest in the subject matter of the specification. The financial interest of a holding company whose subsidiary qualifies for a person interested will be sufficient for the holding company to oppose the grant of a patent.

**d. Interest in Research**

Section 2(1)(t) defines a person interested as including a person engaged in or in promoting research in the same field as that to which the invention relates. The fact that a person is involved in research should entitle that person to initiate an opposition.

**e. Interest in Public Health**

As the Patents Act and the TRIPS Agreement recognises the importance of public health in the field of patents for drugs and medicines, and in the light of the proactive role played by civil society in challenging patents for essential drugs, the meaning of the expression 'interest' may also include an interest in public health.

**ii. Sham Opposition**

Unlike pre-grant opposition which can be instituted by 'any person', the phrase 'person interested' imposes restrictions as to the persons who can institute a post-grant opposition. Even in the case of post-grant opposition, self-opposition of one's own patent will not be permissible as the same would be against public policy. Since there is scope for the patentee to raise the issue of res judicata in subsequent proceedings, exposure of a sham opposition will be important. If the Controller is of the opinion that the proceedings are false or vexatious, he may award compensatory costs.

### **iii. Intervention by Third Parties**

As post-grant opposition proceedings can take place while infringing proceedings are pending, the issue of whether third parties against whom infringement proceedings are pending can intervene in opposition proceedings will be relevant. Though the Patents Act does not provide for intervention by third parties pending opposition, any person interested will be able to institute opposition proceedings within the stipulated time. Needless to say, infringement proceedings will be against persons interested in the invention. Article 105 of the EPC provides for intervention by a third party who proves that infringement proceedings have been instituted against him. Where the law expressly provides for intervention, an intervention by the alleged infringer would be admissible during pending appeal proceedings and such intervention may be based on any ground for opposition available to an opponent. But if the opposition fails and none of the parties to the opposition proceedings have filed an appeal, then, the opposition proceedings stand terminated and any notice of intervention filed during the appeal period will not be entertained.

### **iv. Representation in Post-Grant Opposition**

Any person desirous of appearing before the Controller in a post-grant opposition proceeding may do so through a patent agent who is entitled to practice before the Controller.<sup>339</sup> An applicant for a patent or the patentee may also appear or act before the Controller in person.<sup>340</sup> The Patents Act also entitles an advocate who is not a patent agent to take part in any hearing before the Controller on behalf of a party in any proceeding under the Act.<sup>341</sup> Any person who acts as an agent of another should file his or her authorisation in Form 26 or in the form of a power of attorney.<sup>342</sup>

### **C. Grounds of Post-Grant Opposition**

Section 25(2) of the Patents Act deals with the grounds of post-grant opposition which are same as the grounds for pre-grant opposition. The only difference is with regard to the time at which these grounds are employed, i.e., before or after the grant. The grounds of opposition are exhaustive and deal with the legal issues that can be raised during opposition proceedings.

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<sup>339</sup> Section 127(a), Patents Act, 1970.

<sup>340</sup> Section 132(a), Patents Act, 1970.

<sup>341</sup> Section 132(b), Patents Act, 1970.

<sup>342</sup> Rule 135(1), Patent Rules, 2003.

#### **D. Admissibility of Post-Grant Opposition**

The patentee may challenge an opposition proceeding on the ground that it is not maintainable. As section 25(2) requires a post-grant opposition to be instituted by a 'person interested', the patentee can question the capacity of the person instituting the opposition. An opposition is not inadmissible purely because the person named as opponent is acting on behalf of a third party. However, such an opposition would become inadmissible if the involvement of the opponent is to be regarded as circumventing the law by abuse of process. As in the case of pre-grant opposition, an opposition by a third party will be inadmissible where the opponent is acting on behalf of the patent proprietor.

The admissibility of an opposition on grounds relating to the identity of an opponent may be challenged during the course of the appeal, even if no such challenge had been raised at the first instance. The burden of proof is on the person alleging that the opposition is inadmissible. The burden should be discharged either by the patentee or the Controller, depending on who had raised the issue of admissibility of opposition. If an opposition is found to be inadmissible, then it cannot be examined on substantive grounds and is likely to be rejected. The issue of admissibility can be raised at any stage in the opposition or appeal proceedings. Thus, the issue of admissibility has the potential to crop up at any stage in the proceeding. Hence it is vital to make an admissible case of opposition at the first instance. Mere sending of communication to the patentee does not mean that the opposition has been admitted.

#### **E. Procedure of Post-Grant Opposition**

An opposition after the grant is initiated by filing a notice of opposition as prescribed in Form 7 and upon the payment of the stipulated fee. Upon receiving the notice of opposition, the Controller shall constitute a Board known as the Opposition Board consisting of officers from the Patent Office and refer the notice of opposition and the related documents to the Board for examination. The examination under section 25(3)(b) of the Patents Act is different from the routine examination conducted under section 12 of the Act. The opponent shall then file its written statement of opposition and evidence. The patentee shall file a reply statement in response to the opponent's statement along with its evidence. The opponent may also file its evidence in reply to the patentee's evidence. Once the evidence is presented in full by both the sides, the Controller shall hear both the parties before deciding the case.

### **i. Notice of Opposition**

Any interested person may give notice of opposition to the Controller. The notice of opposition should be a detailed statement containing all the grounds and details on which the patent is opposed. All material facts on which the opponent intends to rely upon should be mentioned in the notice of opposition. The admissibility of the notice containing vague and unclear grounds has been considered by the EPO in a number of cases. Similarly, the position of adducing further material incongruous to the grounds mentioned in the notice of opposition has also been given due consideration. In short, the notice of opposition should be complete with all the grounds on which the opponent intends to rely. No piecemeal introduction of grounds will be appreciated by the Patent Office. Upon receipt of the notice of opposition, the Controller shall inform the patentee about such notice.

#### **a) Filing of Notice**

The process of post-grant opposition is initiated by filing a notice of opposition as per the prescribed form. The notice of opposition shall be sent to the Controller in duplicate.

#### **b) Publication not Mentioned in Notice**

Rule 62(4) of the Patents Rules provides for introduction of new material not mentioned in the notice of opposition. Any publication not mentioned in the notice, statement or evidence shall be introduced after giving five days' notice to the other party and to the Controller. The details of the publication shall also be furnished.

#### **c) Requirement of Notice**

It is preferable that the notice of opposition contains all the grounds of opposition to avoid technical objections at a later point of time. It should be seen whether the objection to a patent can be framed in the form of a ground of opposition. An opponent might be aggrieved by a very broadly termed patent for which there is no ground of opposition available. It has to be determined whether invention disclosed in the specification is an invention within the meaning of the Patents Act and whether it sufficiently discloses the subject matter of the patent. In this manner, the scope of the grounds of opposition may be broadened. On its part, the patentee may prepare a list of grounds which cannot be framed as grounds of opposition and should object to the same.

The opponent should mention in the notice of opposition all the relevant evidence prior to filing of the notice. Where the patent is opposed on the ground of prior art, the notice of opposition should be accompanied by documents in support of it and should identify the passages relied on in the prior art documents. Where the opponent fails to present the full case along with the notice of opposition, it can expose the opposition to the risk of inadmissibility. Moreover, there could also be a refusal to admit the documents that are submitted late.

Where the opponent relies on prior art as a ground for opposition, the notice of opposition must give sufficient indication of the relevant facts, evidence and argument so that the reasoning and merits of the opponent's case are properly understood by the Controller and the patentee. With regard to proving prior use, the notice of opposition should provide enough material for the average skilled person to: (1) verify the point or period of time of public prior use with a view to determining whether there was any use prior to the decisive point in time; (2) identify the object of the use precisely enough to be able to verify that it is the same as the object of the contested patent; (3) verify the circumstances of the use for purposes of establishing the manifest nature of the objects used.

#### **d) Sufficiency of Notice**

Sufficiency of the notice of opposition must be assessed objectively from the point of view of a person skilled in the art. The contents of a communication sent after the notice of opposition do not constitute a decision and cannot be the subject matter of an appeal. The sufficiency of notice of opposition must be distinguished from the strength of the opponent's case, as the former pertains to a procedural requirement, whereas the latter deals with a substantive requirement.

#### **e) Power to Amend Notice of Opposition**

A notice of opposition under section 25(2) should ideally contain all the grounds on which the patent is opposed and all the materials for proving the case. If all the materials are not presented along with the notice of opposition, the Controller may grant leave to amend the notice so that justice may be done. The Controller has a public duty to consider relevant matter brought to his attention at a late stage in an opposition.<sup>343</sup> The notice of opposition may be amended to introduce a fresh ground of opposition. But the delayed introduction of new grounds of opposition will not be appreciated. The Controller shall not allow the delayed

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<sup>343</sup> Rule 137, Patent Rules, 2003.

amendment of notice of opposition. The Controller should take care to ensure that the grant of a patent is not delayed as a result of frivolous oppositions. Where a late amendment is sought for, it would be desirable to require a declaration to be sworn explaining the reasons for the delay. A late amendment which does not follow this procedure may be held invalid.

#### **ii. Written Statement of Opposition**

The opponent shall present his case by filing a written statement of opposition along with the notice of opposition and shall deliver to the patentee a copy of the statement and the evidence. The opponent shall file a written statement in duplicate setting out the nature of opponent's interest, the facts upon which the opponent bases his case, the relief sought and the evidence relied upon. The nature of opponent's interest should be within the definition of 'person interested' under the Patents Act. The opponent should show that it is 'engaged in, or in promoting, research in the same field as that to which the invention relates'.

The opponent shall file the following documents in post-grant opposition proceedings: (1) Notice of opposition; (2) Written statement in duplicate detailing the opponent's interest, the facts upon which the opposition is based and the relief sought; and (3) Evidence in support of its case. The notice of opposition shall be complete with all the grounds of opposition along with the evidence on which the opponent intends to rely upon. A copy of the written statement and the evidence shall be sent to the patentee.

#### **iii. Reply Statement of the Patentee**

In response, the patentee, if it desires to contest the opposition, shall leave with the Patent Office a copy of the following documents: (1) Reply statement setting out the full grounds on which the opposition is objected; and (2) Evidence in support of its case. The reply statement and the evidence in support of it shall be filed within two months from the date of receipt of the copy of the written statement and opponent's evidence.

#### **iv. Evidence in Reply of the Opponent**

Within one month from the date of delivery of the reply statement of the patentee along with evidence supporting it, the opponent shall file evidence in reply strictly confining the same to matters in the patentee's evidence with the Patent Office, serving a copy of the same to the patentee. Any further evidence can be introduced only after procuring the leave of the Controller. Such leave should be prayed for before the Controller has fixed the hearing under rule 62 of the Patents Rules. Copies of all the documents referred to in support of the



opposition, duly authenticated to the satisfaction of the Controller, shall be filed in duplicate. Any document referred in the opposition which is not in English language shall contain an attested English translation of the same in duplicate.<sup>344</sup>

#### **v. Hearing**

Once the presentation of evidence is complete from both sides to the opposition and upon receiving the recommendation of the Opposition Board, the Controller shall fix a date and time for the hearing (oral proceeding) of the opposition. The Controller can exercise his discretion in fixing the date and time of the hearing. The Controller shall give at least 10 days' notice to the parties and may require the members of the Opposition Board to be present in the hearing. The party who desires to be heard shall inform the Controller by notice and pay the fee as stated in Entry 10 of First Schedule. The Controller may refuse to hear a party who has not given notice.<sup>345</sup> The Controller may also order public hearing in certain cases.<sup>346</sup>

It is not open for the parties, after the withdrawal of opposition, to give notice that they desire to be heard. No party to the opposition proceeding shall request for a hearing once the opposition is withdrawn as a result of a settlement. The phrase 'desirous of being heard' does not allow either party to change his mind after he has precluded himself by an agreement which in law and in equity is binding upon him.<sup>347</sup> It is not necessary to name the witnesses in the notice of opposition and the same may be determined at the time of hearing.

#### **vi. Scope of Opposition**

A patent may be opposed in its entirety or in parts. Usually oppositions target the patent in its entirety. In post-grant opposition, the scope of the opposition depends on the action taken by the opponent. If an opponent limits the extent to which a patent is opposed to certain subject-matters, the remaining subject-matters will not be treated as a subject of any opposition. An opposition targeting the subject-matter of an independent claim will include all the subject-matters covered by dependent claims.

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<sup>344</sup> Rule 61(2), Patent Rules, 2003.

<sup>345</sup> Rule 62(3), Patent Rules, 2003.

<sup>346</sup> Rule 139, Patent Rules, 2003.

<sup>347</sup> Rule 62(5), Patent Rules, 2003.

### **vii. Fresh Grounds of Opposition**

The Controller should allow a fresh ground for opposition at any time during the pendency of proceedings before him. As there is nothing in the Patents Act or the Patents Rules that bars multiple oppositions, it would be possible to introduce parallel oppositions within the stipulated time. The late introduction of new grounds may be allowed only in exceptional circumstances.

A fresh ground for opposition may not be introduced into the appeal proceedings without the agreement of the patentee. The introduction of a fresh ground without any indication of the fresh facts, evidence and argument supporting it would be inadmissible, whether within or after expiry of the opposition period. Fresh ground need not necessarily mean that it refers to a ground of opposition not covered by the statement. Rather, fresh ground could mean a ground of opposition relied on for the first time during the appeal proceedings. When a fresh ground is introduced at the appeal proceedings, the case may be remitted to the Controller.

Normally it would not be proper to admit a matter which not only goes beyond the bounds of the opponent's evidence but also introduces a new ground of opposition. But if the new ground of opposition is of such a nature that public interest and justice demands that it should be admitted, the opponents may be allowed to amend their notice of opposition to include it. Opposition proceedings should be conducted expeditiously, strictly adhering to the time-frame under the Patents Act and the Patents Rules. New material filed in support of existing grounds and the introduction of new grounds should not unnecessarily delay the proceedings.

### **viii. Representative Action**

The Patents Act and the Patents Rules do not provide for representative action. The provisions of the Code of Civil Procedure 1908 with regard to representative action will not apply for proceedings before the Controller. Opposition proceeding initiated by one opponent should be treated as an independent proceeding without reference to other oppositions and separate orders should be passed even if all the oppositions are preferred on common grounds.

### **ix. Evidence and Trial**

In any proceeding before the Controller, evidence shall be given by affidavit. Written evidence by way of affidavit is normally preferred, though the Controller has power to take

oral evidence in certain cases.<sup>348</sup> Oral evidence may be taken instead of, or in addition to, an affidavit. The Controller may allow any person to be cross-examined on the contents of the person's affidavit. However, the parties to the opposition cannot insist on oral evidence as a matter of right. Oral evidence is seldom used except in cases where the invention was 'wrongfully obtained'. Evidence once given cannot be backtracked. Once the Controller has refused to cross-examine a witness, the high court should not interfere unless there are strong grounds to do so.<sup>349</sup>

Under section 77 of the Patents Act, the Controller has powers similar to that of a civil court with regard to certain matters. The Act empowers the Controller to take evidence in the following manner: (a) hearing the parties; (b) making requests for information; (c) production of documents; (d) hearing the witnesses; (e) opinions by experts; (f) inspection; and (g) sworn statements in writing.

#### **x. Burden of Proof in Post-Grant Opposition**

Anyone who desires any court to give judgment as to any legal right or liability dependent on the existence of facts which he asserts, must prove that those facts exist. In other words, the party asserting the affirmative must prove it. When a person is bound to prove the existence of any fact, the burden of proof lies on that person. The burden of proof in a proceeding lies on that person who would fail if no evidence at all were given on either side. Onus is on a person who asserts a proposition or fact which is not self-evident.

As post-grant opposition proceedings follow the grant of a patent, it can be reasonably assumed that the patentee would have satisfied the Controller the necessary conditions for the grant of a patent under the Patents Act. The opponent has to prove that the ground of opposition exists for revocation of the patent. The opponent cannot ask the patentee to prove novelty as such a demand would be an inversion of the legal burden. The opposition authority should not decide grounds which have not been alleged in the notice of opposition. The grounds of opposition that are not properly supported are likely to be rejected as inadmissible. The burden of proof is to be borne by the person alleging that the opposition is inadmissible. Onus of proving the case is on the opponent.<sup>350</sup>

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<sup>348</sup> Section 79, Patents Act, 1970.

<sup>349</sup> *Guest Keen Williams v. Controller of Patents*, AIR 1985 Cal 334.

<sup>350</sup> *Poysha Industries Co Ltd v. Controller of Patents and Designs*, AIR 1975 Cal 178.

The burden may shift from time to time. Where the opponent raised prior use as a ground for revocation of patent, the patentee may produce proof to show that the prior use was secret. In the case of a process patent, the invention shall be deemed to have been publicly used in India before the priority date if the product made by that process has already been imported into India before that date.<sup>351</sup> The opponent need not produce any further proof to demonstrate public use. If prior use is established, but secrecy of that prior use is not raised in the case as a defence, the burden is discharged by opponent and he cannot be required to prove that the prior use was not a secret. Where the claims are too broad, the onus of establishing anything in the nature of an invention in the subsidiary claim would shift to the applicant/patentee, and his failure to assist by evidence or argument may affect the chances of amending the application/patent.

#### **xi. Standard of Proof in Opposition**

The standard of proof in opposition proceedings is tested on the balance of probabilities. The burden lies on the opponent to prove that the patent should be revoked but, if the balance of probability is met, the burden shifts to the patentee to prove that the patent should be maintained. The standard of proof required to discharge the legal burden is the civil standard and not the criminal standard. The standard of proof required to establish an issue on the balance of probabilities is not an absolute standard. The degree of probability required is that which is 'commensurate with the occasion' and 'proportionate to the subject-matter'.

The standard of proof in opposition proceedings is higher than the normal standard, as a high degree of certainty is required in refusing an application or revoking a granted patent in limine. The standard of proof in opposition differs from the standard of proof in infringement cases as there is no examination of witness, discovery etc. in opposition. Similarly, the issue of estoppel by reason of res judicata would not arise in any revocation proceedings on anything that might have happened previously in opposition proceedings.

#### **xii. Introduction of Late Argument**

There is no mention in the Patents Act or the Patents Rules with regard to the introduction of late arguments. A party may introduce any publication at the time of hearing after the presentation of evidence is completed. Any party will normally have the right to comment on

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<sup>351</sup> Section 25(2)(d), Patents Act, 1970.

facts introduced late by the other side. There would not be any need to notify new arguments to the other side if it does not involve the introduction of a new ground.

### **xiii. Withdrawal of the Opposition**

The Controller shall decide whether the opposition procedure should continue on its own motion even after the withdrawal of the opposition. Even upon the receipt of notice to withdraw the opposition, the Controller may consider continuing the proceeding in the public interest. The Controller may impose costs on the opponent if the withdrawal was pursuant to a false or vexatious proceeding.<sup>352</sup>

In appeal proceedings, the Appellate Board plays a limited role of reviewing the correctness of the decision of the Controller. Hence, the position is rather different at the appeal stage and depends on whether the appeal or the opposition is being withdrawn. Where the appellant withdraws the appeal, the appeal proceedings stand terminated. The fact that the opposition is withdrawn does not entitle an appellant before an appellate authority to have the decision of the Controller reversed. It is the duty of the Controller, as far as he can, especially when it is brought to his notice by an opposition, to not allow a patent to go forth to the public for an invention which has been substantially included in previous patents.

### **xiv. Transfer of Opposition**

The Patents Act and the Patents Rules do not provide for the transfer of opposition proceedings from one party to another. The status of an opponent cannot be freely transferred. The cases decided by the EPO provide some guidance in this regard. A company which was the subsidiary of the opponent when the opposition was filed and which carried on the business related to the opposed patent cannot acquire the status as opponent if all its shares are assigned to another company. However, an opposition pending before the EPO may be transferred or assigned to a third party as part of the opponent's business assets together with the assets in the interest of which the opposition was filed.

### **xv. Non-appearance of Party**

If a party fails to attend the hearing, it may be liable for costs as the Controller has general powers to award costs. Where neither party desires to be heard, the Controller may proceed to notify his decision without a hearing. The hearing of disputes shall usually be in public but the

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<sup>352</sup> Rule 136(2), Patent Rules, 2003.

Controller has the power to order otherwise.<sup>353</sup> However, a decision against a party who has been duly summoned but who fails to appear at oral proceedings (hearing) may not be based on facts put forward for the first time in those oral proceedings.

#### **xvi. Time-bound Procedure**

The Patents Act provides for a time-bound procedure for post-grant opposition. The notice of opposition may be filed at any time after the grant of the patent but before the expiry of a period of one year from the date of publication of grant of a patent.

##### **a) Time Limit for Preferring an Opposition**

The opposition has to be made within one year from the date of publication of grant of a patent. On the receipt of the notice of opposition, the Controller shall constitute an Opposition Board which shall tender its recommendations within three months from the date on which the documents are forwarded to them.<sup>354</sup> If the patentee desires to contest the opposition, it has to file a reply statement within two months from the date of receipt of copy of the opponent's statement.<sup>355</sup> The opponent may reply to the patentee's reply statement within one month.<sup>356</sup>

##### **b) Time Limit for Disposing Opposition**

Unlike pre-grant opposition where the Controller has to render his decision within one month from the completion of the opposition proceedings, there is no time limit for passing a decision pursuant to post-grant opposition.

##### **c) Extension of Time**

The Controller is empowered to extend the time for doing any act for which time is stipulated under the Patents Act or the Patents Rules. The Controller is not obliged to give notice or hear the party who seeks to oppose the extension. No appeal shall lie from any order of the Controller granting such extension.

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<sup>353</sup> Rule 139, Patent Rules, 2003.

<sup>354</sup> Rule 56(4), Patent Rules, 2003.

<sup>355</sup> Rule 58(1), Patent Rules, 2003.

<sup>356</sup> Rule 59, Patent Rules, 2003.

### **xvii. Amendment of Wrongfully Obtained Patent**

Under section 25(2)(a) of the Patents Act, a patent can be opposed on the ground that the patentee or the person through whom he claims, wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims. If, during opposition proceedings, it is found out that the patent was wrongfully obtained from the opponent as stated in section 25(2)(a) and the patent is revoked on that ground, the Controller may, upon request made by the opponent, direct the patent to be amended in the name of the opponent. Such request shall be made on Form 12 with three months from the date of order of the Controller and shall be accompanied by a statement of facts relied upon by the opponent, and the relief claimed by him.<sup>357</sup>

### **xviii. Opposition Proceedings and Infringement Action**

The Patents Act treats opposition and revocation proceedings as separate and distinct actions. An opposition is a remedy available before the Controller whereas a revocation proceeding is instituted before the Appellate Board or the high court. Revocation of a patent before the high court can be done only in response to an infringement action. The Patents Act allows the defendant in an infringement suit to raise any of the grounds of revocation available under section 64 as a counter-claim in an infringement suit.<sup>358</sup> The fact that infringement proceedings have been instituted against the defendant should not be a reason to stall opposition proceedings pending before the Controller. Unlike revocation proceedings, opposition proceedings cannot be maintained during the life of the patent. The focus should be on expediting opposition proceedings where an infringement action is pending.

The experience of the UK courts may throw some guidance on how parallel proceedings may be handled. In a case involving two patents relating to an apparatus for drying a paper web, the Court of Appeal acknowledged the reality of parallel proceeding both in the national courts and before the EPO as 'inevitable' as there was scope for amendment in both the national courts and as well as the EPO. This overlap meant that there could be parallel proceedings in UK and the EPO with the potential for conflict. Suggesting that it would be desirable to avoid such conflicts, the Court of Appeal observed that the Patents Court will stay the English proceedings pending a final resolution of the European proceedings, if they can be resolved quickly and where a stay will not inflict injustice on a party or be against the public

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<sup>357</sup> Rule 63A, Patent Rules, 2003.

<sup>358</sup> Section 104 and 107, Patents Act, 1970.

interest. In holding both the patents in issue as invalid, the Court of Appeal held that the existence of parallel opposition proceedings will not curtail the jurisdiction of Patents Court to revoke an invalid patent.

#### **xix. Decision**

The decision of the Controller may result in the revocation of the patent or in the complete or partial maintenance of the patent. The Controller shall give reasons for his decision. In the case of partial maintenance, amendment is carried out to the satisfaction of the Controller. The Controller may also require a reference to be made in the patent. In cases where the patent is intended to be maintained in amended form, an interlocutory decision requiring the amendment may be issued by the Controller. Such a decision may be the subject matter of a separate appeal as it would enable the particular amendment to be appealed without the requirement for publishing the entire patent. An application for review can be made to the Controller for the review of his decision within the time stipulated for the same.<sup>359</sup>

In the event of the patentee failing to file a reply statement within the stipulated time or not contesting the opposition, the patent shall be deemed to have been revoked.<sup>360</sup> If no request for hearing is made, the Controller shall, after considering the recommendation of the Opposition Board, decide the opposition.

The Controller must notify his decision to the parties giving reasons for the decision. The parties must have had an opportunity to comment on grounds and evidence on which the decision is based as the Patents Rules provide that the discretionary power of the Controller shall be exercised only after giving a party to a proceeding an opportunity to be heard.<sup>361</sup>

#### **xx. Costs**

Where the patentee withdraws the patent after notice of opposition is given, the opponent may be entitled for costs as decided by the Controller.<sup>362</sup> The Controller has the power to award costs in an opposition proceeding.<sup>363</sup> The award on costs should however be reasonable. The matters in respect of which cost can be awarded and the limit of such costs are detailed in the

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<sup>359</sup> Section 77(1)(f), Patents Act, 1970; Rule 130, Patent Rules, 2003.

<sup>360</sup> Rule 58(2), Patent Rules, 2003.

<sup>361</sup> Rule 129, Patent Rules, 2003.

<sup>362</sup> Rule 63, Patent Rules, 2003.

<sup>363</sup> Section 77(1)(e), Patents Act, 1970.



Fourth Schedule.<sup>364</sup> An order for costs awarded by the Controller shall be executable as a decree of a civil court.<sup>365</sup> The Controller may also award compensatory costs in opposition proceedings if he is of the opinion that the proceeding was false and vexatious.<sup>366</sup> A review of the award of costs can be requested by the relevant party although the apportionment of costs of opposition proceedings cannot be the sole subject of an appeal.

#### F. DIFFERENCES BETWEEN PRE-GRANT AND POST-GRANT OPPOSITION

S. No.	Description	Pre-Grant Opposition	Post-Grant Opposition
1.	Initiation of Proceedings	Written representation in no particular Form	Notice of Opposition in Form 7
2.	Infringement proceedings	Cannot be instituted during pre-grant opposition as the patent is still in the application stage	Can be instituted as the post-grant proceedings after the grant of the patent
3.	Who can be an opponent	Any person may be an opponent	Any person interested as defined in s 2(1)(t) may be an opponent
4.	Status of opponent	Not a party to the proceeding	Party to the proceeding
5.	Deciding authority	Controller	Controller on the recommendation of the Opposition Board
6.	Time for preferring opposition	Any time before the grant of patent. Preferably within six months as stated in r 55(1A)	Within one year after the grant of the patent
7.	Hearing	No procedure for hearing	Procedure detailed in r 62
8.	Relief	Rejection of application	Revocation of patent
9.	Appeal	Opponent has no right of appeal under the Act	Opponent may prefer an appeal to the Appellate Board
10.	Procedure	Not clearly detailed in the Act or the Rules	Comparatively detailed provisions on procedure

<sup>364</sup> See *Stoplik Services India Pvt Ltd v. Panacea Biotech Ltd* 2006 (32) PTC 811 (Asst Controller).

<sup>365</sup> Section 77(2), Patents Act, 1970.

<sup>366</sup> Rule 136(2), Patent Rules, 2003.

## REVOCATION AND SURRENDER OF PATENTS

### I. INTRODUCTION

A patent can come to end by lapse of term of the patent, by surrender or by revocation. When the patentee surrenders the patent, the Controller may pass an order revoking the patent. Where an order of revocation is passed pursuant to an offer to surrender or in culmination of a revocation proceeding, such revocation shall be entered into the register of patents kept at the Patent Office.<sup>367</sup>

#### A. Surrender of Patents

The Patents Act allows a patentee to surrender his patent by giving notice to the Controller. When the patentee makes an offer to surrender the patent, the Controller shall publish the offer and notify every person whose name appears in the register as having an interest in the patent.<sup>368</sup>

##### i. Opposition to Surrender

Any person interested may file an opposition to the surrender of a patent within three months from the date of publication of notice by giving notice of opposition to the Controller in Form 14.<sup>369</sup> The Controller shall inform the patentee of such notice on receipt of the same. The procedure for filing of written statement, reply statement, leaving evidence, hearing and costs shall be the same as that of an opposition to the grant of a patent detailed under Rules 57 to 63. On hearing both the parties, if the Controller is satisfied that the patent may be surrendered, he may accept the offer and pass an order revoking the patent. If the Controller accepts the offer to surrender the patent, he may direct the patentee to return the patent. Upon the receipt of such patent, the Controller shall by order revoke the patent and publish the revocation.<sup>370</sup> The patent will cease to have effect from the date of publication of the Controller's acceptance of the offer to surrender the patent. An appeal from an order revoking the patent consequent to the surrender will lie to the Appellate Board.

An application to surrender shall not be employed to revoke a patent application for an invention which was the subject matter of an earlier patent, as the same can be revoked on a

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<sup>367</sup> Section 67(1)(b), Patents Act, 1970; Rule 88(2), Patent Rules, 2003.

<sup>368</sup> Section 63(2), Patents Act, 1970.

<sup>369</sup> Rule 87(2), Patent Rules, 2003.

<sup>370</sup> Rule 87(4), Patent Rules, 2003.

separate ground under section 64 of the Patents Act. It will be open for the patentee to surrender its patent during the pendency of revocation proceedings, as the very object of providing for a patentee-initiated revocation in the form of an offer to surrender is to enable the patentee to avoid, if he so desires, revocation proceedings and its consequent costs. When an offer to surrender is made during the pendency of revocation proceedings, it is unlikely that the Controller will accept the same, as surrender proceedings and revocation proceedings have different consequences. A patent revoked pursuant to a revocation proceeding will be void ab initio. But a patent surrendered will take effect only from the date of acceptance of the offer of surrender by the Controller. In such proceedings, the Controller shall look into the conduct of the patentee and the grounds of revocation before accepting the patentee's offer to surrender the patent. The Controller may also stay the application to surrender before him pending the outcome of a revocation.

## **B. Revocation of Patents**

Revocation is a process by which a patent may be put to an end before the expiry of the ordinary term of the patent. Upon revocation, all the rights and privileges offered by a patent will cease to have any effect. An order for revocation has the effect of rendering the patent void ab initio. A proceeding for revocation can be initiated only on specific grounds in specific circumstances. In addition, a proceeding for revocation can be instituted by certain persons before the authorities specified in the Patents Act. The revocation of every patent shall be entered into the register of patents kept at the Patent Office.<sup>371</sup>

### **i. Revocation in Context**

The topic of revocation may be approached from the following three inter-related perspectives: (1) Proceedings which lead to revocation of a patent; (2) Persons entitled to seek the revocation of a patent; and (3) Authorities who can revoke a patent.

The Patents Act provides for various mechanisms by which a granted patent may be revoked. Other than the most common proceeding of revocation detailed in section 64, a patent may be revoked consequent to an opposition proceeding<sup>3</sup> [a post-grant opposition under section 25(4) of the Patents Act] or a surrender proceeding (a voluntary surrender of a patent by the patentee under section 63 of the Patents Act).

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<sup>371</sup> Section 67(1)(b), Patents Act, 1970.

### **a) Revocation and Opposition**

An opposition proceeding can also be regarded as a revocation proceeding since one of the possible results of an opposition proceeding is revocation of the patent. But the treatment of both the proceedings have been different in the Patents Act and the same will be followed here, though both the proceedings can be maintained on certain common grounds and can result in revocation. The most important distinction is that opposition proceedings are time-bound procedures which have to be preferred within a time period stipulated under the Patents Act, whereas revocation proceedings may be instituted at any time after the grant of the patent, while the patent is in force. The decision of the Controller in an opposition proceeding will not act as *res judicata* in revocation proceeding before the high court. The right to oppose under section 25 and the right to revoke under section 64 exist independent of each other under the Patents Act. The grounds of opposition are not coterminous with the grounds of revocation. A person who unsuccessfully opposes a patent under section 25 shall be entitled to file a petition for revocation under section 64.

### **b) Revocation and Invalidity**

Revocation and invalidity, though employed in similar context, have different meanings. As a patent has to be valid to be in force, the validity of a patent can be questioned at any time during the term of patent. In fact, the Patents Act provides for instances in which a patent will not be regarded as invalid, and allows for the validity of the patent to be put in issue without petitioning for its revocation.<sup>372</sup> The Patents Act also provides for proceedings in which the validity of a patent shall not be called into question.<sup>373</sup> But there will not be any difficulty to revoke a patent that is invalid (i.e., expired). When the validity of a patent (or a claim in the specification of a patent) is questioned it may lead to two consequences, i.e., the patent may be revoked or the patent may be amended.<sup>374</sup> Thus invalidity of a patent can lead to its revocation or to an amendment. The invalidity of a patent can be a cause for its revocation, but need not always result in revocation.<sup>375</sup>

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<sup>372</sup> Section 103(2)(b), Patents Act, 1970.

<sup>373</sup> Section 105(4), Patents Act, 1970.

<sup>374</sup> Section 58(1), Patents Act, 1970.

<sup>375</sup> Section 113(1), Patents Act, 1970.

## **ii. Who May Seek Revocation**

Under section 64 of the Patents Act, a petition for revocation may be filed by any person interested or by the Central Government before the Appellate Board. Under s 64, any interested person or the Central Government may file a petition to the high court to revoke a patent. The procedure for such a petition will be governed by the Code of Civil Procedure 1908 and the relevant high court rules, whichever may be applicable. Where a suit for infringement of patent is pending before the high court, revocation of the patent may be sought for as a counter-claim by any person interested or by the Central Government. In cases where infringement suits are pending, it will be open for an alleged infringer who is a party to the suit to seek revocation. The position under the Patents Act which requires the person seeking revocation to be a 'person interested' is different from the position in the United Kingdom, where 'any person' can revoke a patent.

### **C. Revocation by Controller**

The Controller is the authority which grants the patent under the Patents Act. The Controller is also empowered to revoke a patent in certain circumstances. The Controller may revoke a patent as a culmination of proceedings before him, as in the case of a post-grant opposition. Where the revocation is consequent to some direction or act, like the direction issued by the Central Government under section 65 or an offer to surrender the patent by the patentee, the power of the Controller to revoke the patent is contingent upon such direction or act. Where the patent is revoked by an order made by an authority other than the Controller, like the Appellate Board or the high court, the Patents Act provides for such orders to be transmitted to the Controller who shall record the same in the register of patents. The general procedure to be followed in the case of revocation before the Controller, unless a specific procedure is prescribed, are those detailed in rules 57 to 63 of the Patents Rules 2003.

#### **i. Revocation of Patents relating to Atomic Energy – Section 65**

Inventions relating to atomic energy cannot be a subject matter of patent under section 4 of the Patents Act. Section 20(1) of the Atomic Energy Act 1962 specifically excludes patents for atomic energy inventions. Under section 65 of the Patents Act, any patent granted for atomic energy inventions can be revoked at any time after the grant. Thus, an application for an invention concerning 'imaging systems' was refused after the Central Government expressed its opinion under s 20(6) of the Atomic Energy Act 1962, that the invention was not

patentable.<sup>376</sup> The invention pertained to an imaging system suitable for use with radiation characterised by the high energy particles, particularly high energy photons such as in gamma radiation.

#### **ii. Revocation of Patent for Nonworking – Section 85**

The Controller may revoke a patent in respect of which a compulsory licence has already been granted on the ground that it is not worked in India, or that the reasonable requirements of the public with regard to the invention has not been satisfied or that the invention is not available to the public at a reasonably affordable price.

#### **iii. Revocation Consequent to Other Proceedings – Section 25(4), 54(2) and 63(4)**

The Controller may revoke a patent consequent to the outcome of other proceedings, such as a revocation of a patent for improvement or modification under section 54(2), an offer of surrender of patent by the patentee under section 63(4), or a post-grant opposition under section 25(4).

#### **D. Revocation by Appellate Board**

Section 64(1) of the Patents Act allows any interested person or the Central Government to institute revocation proceedings on the common grounds in two different fora, i.e., the Appellate Board and the high court. Despite the identical grounds, the two proceedings of revocation must be distinguished. The distinction between the two proceedings arise from the ability to initiate the revocation proceedings. In the case of proceedings before the Appellate Board, any interested person may initiate the process by filing an application for revocation under section 117D. In the light of the Patents (Amendment) Act 2005, which empowers the Appellate Board to entertain a petition for revocation, it would appear that revocation proceedings before the high court can only be taken in the form of a counter-claim in a pending infringement suit, and hence an interested person will not be able to initiate the revocation proceedings before the high court. Under section 64, any interested person or the Central Government may file a petition for revocation to the high court. Such a petition will be governed by the Code of Civil Procedure 1908 and the relevant high court rules, whichever

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<sup>376</sup> Raytheon Company v. Controller of Patents and Designs AIR 1974 Cal 336.

may be applicable. However, the right to revoke a patent before the high court on a counter-claim will be restricted to parties who are arrayed as infringers in the suit.

### **E. Revocation by High Court**

The high court may revoke a patent on any of the grounds mentioned in section 64(1), if the same is raised as a counter-claim in an infringement suit. The high court may also revoke the patent if the patentee has failed to comply with the request for government use.<sup>377</sup> The two forms of revocation are discussed below.

#### **i. Revocation by a Petition or by a Counter-claim – Section 64(1)**

The grounds of revocation may be taken as a defence in an infringement suit.<sup>378</sup> A suit for infringement can be filed either in the district court or the high court. In a case where the infringement suit is filed before the district court and the defendant has raised a counter-claim of revocation, the suit along with the counter-claim shall be transferred to the high court.<sup>379</sup>

#### **ii. Revocation for failure to comply with Section 99 – Section 64(4)**

Under of the Patents Acts 103, the high court has the power to decide disputes between the Central Government and any person as to terms of use of an invention for the purposes of the government. The high court also has the power to revoke a patent on the petition of the Central Government, if it is satisfied that the patentee has, without reasonable cause, failed to comply with the request of the Central Government to make, use or exercise the patented invention for the purposes of government within the meaning of section 99 upon reasonable terms. A notice of the petition for revocation under section 64(4) shall be served on all persons whose names appear in the register as proprietors or interested person. There is no need to serve a notice on any other person.

### **F. Revocation by Central Government**

Every patent under the Patents Act is granted by the Patent Office which is a part of the Central Government. The Central Government is the authority which establishes the Patent Office and regulates the matters pertaining to grant and maintenance of patents. It is vested

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<sup>377</sup> Section 64(4), Patents Act, 1970.

<sup>378</sup> Section 107, Patents Act, 1970.

<sup>379</sup> Section 104, Patents Act, 1970.

with rule making powers for carrying out the purposes of the Patents Act.<sup>380</sup> Despite its role in the grant, all patents shall have the same effect against the government as it has against any other person.<sup>381</sup> But the government has special powers to sell or use any articles forfeited under the law.<sup>382</sup> The Central Government is vested with the power to revoke patents in the following cases:

**i. Revocation of Patent Prejudicial to State or Public – Section 66**

The Central Government may revoke a patent that affects the state or is prejudicial to the public. Where the Central Government is of the opinion that a patent or the mode in which it is exercised is mischievous to the state or generally prejudicial to the public, it may, after giving the patentee an opportunity to be heard, make a declaration to that effect in the Official Gazette. The patent shall be deemed to be revoked once such declaration is made.

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<sup>380</sup> Section 159, Patents Act, 1970.

<sup>381</sup> Section 156, Patents Act, 1970.

<sup>382</sup> Section 157, Patents Act, 1970.





தமிழ்நாடு டாக்டர் அம்பேத்கர் சட்டப் பல்கலைக்கழகம்  
**The Tamilnadu Dr. Ambedkar Law University**



# **COURSE MATERIAL – PART IV**

## **ONLINE CERTIFICATE COURSE ON PATENT LAW: POLICY AND GOVERNANCE**

**COMPILED BY:**

**ORGANISING COMMITTEE**

**TAMIL NADU Dr. AMBEDKAR LAW UNIVERSITY**

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9.	Merrill Lynch Inc's Application	(1989) RPC 561 (CA)
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17.	T424/03 Microsoft/Clipboard formats I	[2006] EPOR 39
18.	T1173/97 IBM/Computer-related invention	[1987] EPOR 74
19.	Ferid Allani v. Union of India	2019 SCC Online Del 11867
20.	Halliburton Energy Services Inc v. Smith International (North Sea) Ltd	(2006) RPC 2
21.	Dimminaco AG v. Controller of Patents and Designs	(2002) IPLR 255
22.	Polar Industries Ltd v. Jay Engineering Works Ltd	1989 PTC (Supp) (2) 310 (Cal).

# INFRINGEMENT AND DEFENCES

## I. INTRODUCTION

The law of patents is all about stopping people from doing things. Though the expression 'infringement' is not defined under the Patents Act, it is understood to mean any intrusion into the 'scope of the invention for which protection is claimed'.<sup>383</sup> Infringement of a patent refers to any of those acts which violate the rights of a patentee, against which the patentee has a remedy.<sup>384</sup> The infringement of a patent is an action founded on tort. As the scope of the protection offered to an invention is confined to what is claimed, there can be no infringement with regard to what is not claimed. This would give any person the freedom to work around the invention claimed.

Infringement is in effect the violation of the exclusive right of a patentee granted under the Patents Act. The form of patent in the Third Schedule to the Patents Rules 2003, as it was before the Patents (Amendment) Rules 2006, clearly enumerated the right granted to the patentee and the conditions in which they would remain in force.

The above form has now been replaced with a simple form which states that the patent described by its title as disclosed in its application is granted to the patentee for a period of 20 years from the date of application in accordance with the Patents Act.<sup>385</sup> Thus, in considering the issue of infringement under the Patents Act, one has to take into account the scope of monopoly rights conferred on the patentee; the conditions subject to which a patent is granted, and the exceptions to infringement.<sup>386</sup>

## II. PROVISIONS UNDER THE PATENT ACT

The Patents Act defines infringement indirectly. A combined reading of sections 10(4)(c) and 48 will detail the scope of the monopoly rights of the patentee for which protection can Patents Act be claimed. Any intrusion into these rights will amount to an infringement. A patent is granted under the Patents Act subject to certain conditions detailed in section 47. Any action within the purview of section 47 will not amount to an infringement. The Patents Act also specifically excludes certain acts from being considered as an infringement; these are detailed in sections 49 and 107A. Under section 107, a person against whom an

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<sup>383</sup> Section 10(4)(c), Patents Act, 1970.

<sup>384</sup> Section 48, Patents Act, 1970.

<sup>385</sup> Third Schedule, Patent Rules, 2003.

<sup>386</sup> Sections 49 & 107A, Patents Act, 1970.

infringement action is instituted may take up as a defence any ground on which a patent may be revoked under section 64.

### **III. DETERMINING INFRINGEMENT**

An infringement is an attack on the invention for which protection is claimed. The Patents Act defines an invention as a new product or process involving an inventive step and capable of industrial application. The subject matter of protection is contained in the claim of a specification which defines the scope of the invention. Thus, to determine infringement, one has to ascertain whether the alleged act came within the scope of the specification and the claims. This will involve construction of the patent. An act amounts to infringement only if it falls within the scope of the claims. If the alleged process or product did not fall within the scope of the claim, there can be no infringement.

In order to determine whether there has been an infringement of a product or a process granted under the Patents Act, the following questions have to be considered:

- 1) Whether the alleged act fell within the scope of the invention as defined in the claims.
- 2) Whether the alleged act violated any right of the patentee as defined under the Patents Act.
- 3) Who is liable for the alleged act?
- 4) Whether the alleged act fell within the acts which do not amount to infringement under the Patents Act or under any other valid exception.

#### **i. Act within the scope of Invention**

The first step in determining whether there has been an infringement of a patent would be to determine the scope of protection offered to the invention. This is done by constructing the patent using the principles evolved by the courts. As patents are granted for inventions patentable under the Patents Act, infringement has to be determined with regard to what is claimed as an invention under the Patents Act. A patent protects the invention which is claimed in the claim. The scope of the claim has to be determined by construing the specification as a whole.<sup>387</sup> As issues of validity and infringement are likely to arise in the same proceedings, the standards of construction must necessarily be the same in revocation and infringement proceedings.

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<sup>387</sup> Lallubhai Chakubhai Jariwala v. Chimanlal Chunilal & Co, AIR 1936 Bom 99.

In an infringement action the 'main function of the court is to construe the claims which are alleged to have been infringed, without reference to the body of the specification, and to refer to the body of the specification only if there is any ambiguity or difficulty in the construction of the claims in question'.<sup>388</sup> To constitute infringement, the infringing process or product should fall within the claim, as constructed by the court. As whatever is not claimed is treated as being disclaimed, any person will be free to employ a process or a product which does not fall within the claims of a patent.

Once the scope of the protection offered to the invention is determined by applying the principles of construction, the court will have to determine whether the alleged act fell within the scope of the protection claimed by the patent.

## **ii. Act Violates the Rights of the Patentee**

The second step involves a determination whether the alleged act violated any right of the patentee under section 48 of the Patents Act. Section 48 details the rights of a patentee in respect of a product patent and a process patent. But the rights of a patentee under section 48 can be enforced only during the term of the patent. Thus, before determining the rights of a patentee, it must be ensured that the patent in respect of which infringement is alleged is valid and subsisting.

### **a) Infringements during term of patent**

Only infringements that occur during the term of a patent are actionable. The right to take action on infringement accrues only after the grant of a patent, that too in respect of acts committed after the date of publication of the application.<sup>389</sup> Section 11A(7) considers an application 'as published' as well as a patent 'as granted'. The effect of the said section is to confer on the patentee for the period during the publication and the grant, the same rights as if the patent were granted at the beginning of the said period, i.e., date of publication. The alleged act should have infringed the patent as granted and the claims in the application as it were before they were published. An infringement action would lie only if there is infringement of the claims as published and as granted. In ascertaining the rights of a patentee to sue, both the scope of the claim as published and as granted have to be determined.

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<sup>388</sup> Raj Prakash v. Mangat Ram Choudhury, AIR 1978 Del 1.

<sup>389</sup> Section 45(3), Patents Act, 1970.

The issues of infringement and validity of a patent are inter-related. An act of infringement can be done only with regard to a valid patent: an invalid patent cannot be infringed even if the alleged act fell within its language. There cannot be an infringement of an invalid patent. For a patent to be valid, the conditions stipulated under the Patents Act have to be followed. The rights of a patentee can be enforced only during the term of a patent. The term of a patent may come to an end due to any of the circumstances mentioned in the Patents Act, like expiry of term, non-payment of renewal fees, surrender or revocation.

### **b) Rights of a Patentee protected against Infringements**

The acts that constitute infringement are essentially the acts which violate the right of a patentee under the Patents Act. The rights of a patentee are detailed in section 48 of the Patents Act include:

Section 48: Rights of Patentees - Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted under this Act shall confer upon the patentee:

- 1) where the subject matter of the patent is a product, the exclusive right to prevent third parties, who do not have his consent, from the act of making, using, offering for sale, selling or importing for those purposes that product in India;
- 2) where the subject matter of the patent is a process, the exclusive right to prevent third parties, who do not have his consent, from the act of using that process, and from the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India.

#### **i. Without Consent**

An act which violates the right of a patentee must be done without the consent of the patentee. In other words, only an act done without the consent of the patentee will amount to an infringement. Where the act is done under an assignment or a licence, it cannot be said that such an act is done without consent. Following the instructions given by the patentee in the form of directions to do what is claimed in the patent will amount to infringement. But where the patentee gave no instructions to the defendant to do a specific act, the defendant's act of repairing the product of the patentee will amount to infringement.

Restrictive conditions imposed by the patentee will indicate that the patentee has not given consent for carrying out certain acts with respect to the patent. It is settled law that 'where the patentee supplies his product and at the time of the supply informs the person supplied (normally via the contract) that there are limitations as to what may be done with the product supplied then, provided those terms are brought home first to the person originally supplied and, second, to subsequent dealers in the product, no licence to carry out or do any act outside the terms of the licence runs with the goods'.

A restriction rests upon a purchaser of goods which are covered by a grant of patent, and which have come into the possession of a purchaser in the full knowledge of the restrictions imposed by the patentee upon their disposal. Where a person has sufficient notice of the existence of a restrictive condition, like a condition restraining export, with regard to such goods, any act done in respect of those goods in breach of the restrictive conditions will amount to infringement. It is for the patentee to prove that the defendants had the restrictive condition brought to his notice when he acquired the goods.

## **ii. In India**

Section 48 of the Patents Act states that the rights of a patentee shall pertain to acts done in India. The exclusive right of the patentee to prevent third parties is limited to acts of infringement committed within India, as the operation of the Patents Act is territorial in nature. The jurisdiction will be determined according to the place where the tortious act of infringement is performed. Section 107A excludes from the scope of infringement certain acts which may amount to indirect infringement.

## **c) Infringement of Products and Processes**

Patents Act clearly distinguishes the rights in process patents and product patents. The alleged act could infringe a patent which pertains to a product or a process.

### **i. Infringement of a product**

Where the subject matter of the patent is a product, any act by a third party, of making, using, offering for sale, selling or importing for those purposes, such product in India, without the consent of the patentee, will amount to infringement.



**a) 'Making'**

Making of a patented product without the consent of the patentee will amount to infringement. Similarly, making and selling separate parts of a patented instrument, whose parts can be put together without any difficulty by any ordinary skilled workman, will constitute an infringement of the patented product. The person who manufactures the parts and the customers who assemble will be liable as joint tortfeasors. However, the making of an article which per se does not infringe a patent, but may be used for infringing a patent, will not amount to infringement of the patent.

Section 140(4)(c) of the Patents Act makes provisions for repair of a patented article. Repair involves the replacement or renewal of part or parts of an article. By definition, a repair of a patented article is an act which does not amount to the making of it. What amounts to a repair is a question of degree. Repairing a patented product will come under the ambit of the term 'making' if such repair is only a guise for making the product. Replacement of a product (toner cartridge) which is the subject matter of a copyright protection will not amount to a repair. A repair of a patented article has been compared with an implied licence, such that 'any purchaser of such an article, whether from the patentee or from a licensee of the patentee or from a purchaser from the patentee or such a licensee or purchaser, is impliedly licensed to carry it out or to contract with someone else to carry it out for him'.<sup>390</sup> The House of Lords has distinguished the above proposition, where it was held that in the light of an allegation that the defendant had infringed a patent, the concept of implied licence will have no role to play.<sup>391</sup>

**b) 'Using'**

Possession with the intention of 'using' the articles for trade purposes and for the securing of a profit would amount to an infringement. But possession by a carrier or a warehouseman, who innocently carried or stored the infringing goods for a consignor or consignee, will not amount to an infringement. An injunction, in respect of a patented product, may be granted even if there is no actual infringement by the user of the product. Even if there is no actual use, an injunction may be granted where there is a threat of potential use. Application to the regulatory authority for approval to market the product will not however come under the

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<sup>390</sup> Solar Thompson Engineering Co Ltd v. Barton, (1977) RPC 537.

<sup>391</sup> United Wire Ltd v. Screen Repair Services (Scotland) Ltd., (2001) RPC 24.

ambit of use. It will be difficult to include mere use of the information with regard to the product under this provision.

**c) 'Offering for Sale'**

'Offering for sale' would include an advertisement or a pre-contractual negotiation to supply a patented product. If, pursuant to the offer, the supply of the product happens during the term of the patent, it would certainly amount to infringement. An injunction may be obtained to restrain such acts. But negotiations during the term of a patent to supply after the expiry of the patent will not amount to infringement.

**d) 'Selling'**

The expression 'selling' or 'sale' would include any form of commercialisation. The sale has to take place within the territory of India. If the conclusion of sale was done abroad, it will not come under the ambit of 'selling' or 'vending'. There can be no infringement if the property is passed on to a purchaser in a foreign country.

If the patentee sells the article without any clear and express limitation, the buyer will be entitled to do as he pleases. In the case of patented products sold by a licence, the extent to which the article is released from the patentee's patent rights will depend on the extent of the authority conferred by the licence. If the patentee has assigned his rights in the patent, the patentee will not be allowed to manufacture the product abroad and import them to sell the same in a country where the said patent has already been assigned. Though export of an article will not come under the ambit of 'selling', the acts that precede an export will usually be accompanied by infringing acts like 'importing with a view of selling in export market', 'purchase and possession with a view to sale', etc. An injunction may be granted to restrain the defendants from exporting the allegedly infringing goods.

**e) 'Importing'**

'Importing' should be understood in the context in which it is used in section 48(a) of the Patents Act. What is covered under the said sub-section is the import for the purposes of 'making, using, offering for sale or selling' a product in India without the consent of the patentee. Where the subject matter that is imported is covered by a patent, for the purpose of distributing and selling them in a country, it would amount to infringement of that patent.

Both the vendor and the purchaser will be liable for infringement. Regardless of the person in whom the property in the goods vested, they would be jointly implicated in a transaction the effect of which was to infringe the patent law of the country, and they will both be liable as principals in the transaction. In determining an importer, the court shall have regard to the person who has possession to the title of the goods.

The act of importing a patented product for uses relating to the development and submission of information required under any law in India or abroad that regulates the import of any product will not amount to an infringement. Similarly, the importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product will also not amount to an infringement of such a product.

## **ii. Infringement of a Process**

Where the subject matter of the patent is a process, any act by a third party, of using that process and the act of using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India, without the consent of the patentee will amount to an infringement.

### **a) Use of the Process**

The use of a patented process can amount to an infringement of that process. The use of the process is different from use of information relating to the process.

### **b) Product obtained directly from that process**

Section 48(b) also covers the act of 'using, offering for sale, selling or importing' for the above purposes the product obtained directly by a patented process in India. The expressions 'using', 'offering for sale', 'selling' and 'importing' will take the same meaning as in section 48(a). The expression 'obtained directly' will mean obtained without an intermediary. It would signify products which are the direct and immediate result of applying the process. The product will be considered to have been 'obtained directly' even if the product is subject to further processing such that it does not lose its identity and retained its essential characteristics. But if the output of a patented process was transformed by further processing into an inseparable component of a composite object, it can no longer be regarded as a product directly obtained by a process. The requirement of 'obtained directly' appears to have

altered the earlier position of law, as decided by the courts in the United Kingdom, where infringement can be established if an imported product has been directly or indirectly obtained from a patented process, provided always that substantial use had been made of it.<sup>392</sup>

#### **IV. LIABILITY FOR THE ACT OF INFRINGEMENT**

Any third party who commits the acts mentioned in section 48 of the Patents Act without the consent of the patentee will be liable for infringement. A person who infringes through an agent will also be liable for infringement. Patent infringement has been treated as a tortious act. Where two persons are liable as joint tortfeasors, an act by one will hold the other liable.

##### **i. Acts by the Infringer**

The language used in section 48 refers to an infringer as a third party who violates the rights of a patentee without his consent.

##### **a) Infringement by Agency**

A principal will be liable for the acts committed by his agents and servants. Where the employees commit infringement while in employment, the employer will be vicariously liable for the acts of his employees. A workman who aids in the infringement innocently and who is not the actual infringer, shall not be liable for infringement.

##### **b) Infringement by the Joint Tortfeasors**

As in the case of other torts, joint tortfeasors will be liable for acts of infringement done in furtherance of a common design. To be liable as joint tortfeasors, the persons should have acted in concert in the commission of the tort. The person must have conspired with the tortfeasor or procured or induced his commission of the tort. In other words, there must be a common design to do an act. Such common design should result in an act committed in furtherance of such design.

Facilitating an act of infringement is different from procuring the doing of an act of infringement. Mere assistance, like the one rendered by a warehouseman or a carrier, will not make a person a joint tortfeasor. A person involved in the sale of goods, which may be used

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<sup>392</sup> Beecham Group Ltd v. Bristol Laboratories Ltd., [1977] FSR 215 & Saccharin Corp Ltd v. Anglo-Continental Chemical Works, (1978) RPC 153.

by the purchaser in a wrong way, will not make the seller liable as a joint tortfeasor. This would be the case even if the seller knew that the goods would be used for infringing a patent. The conduct of a person that makes him liable as a joint tortfeasor will depend on the facts and circumstances of each case. It will not amount to an abuse of process if the parent foreign company is made a joint tortfeasor in an infringement suit for obtaining a discovery of documents relevant to the claims.

### **c) Corporate Entities**

A director of the defendant company may be joined as a party to an infringement suit if common design can be shown with regard to the acts committed by the defendants. A director shall not be made liable for an act of infringement unless his involvement in the infringement would make him liable as a joint tortfeasor if the company had not existed. The fact that the director gave instructions for an act which turned out to be tortious would not be sufficient to establish liability. Under the Patents Act, the directors and other officers of a company may be made liable for offences committed by that company.<sup>393</sup>

#### **ii. Knowledge of the Invention is Irrelevant**

In most cases, the knowledge or the intention of the defendant to commit the act of infringement is not relevant. Even if the defendant came up with the invention on his own effort, without copying the patentee's invention, he would still be liable for infringement. The patentee is not obliged to bring to notice the act of infringement committed by a defendant. The fact that the patentee did not give notice to the defendant 'cannot reasonably be taken as any representation that what they were doing was not an infringement'. To show that the plaintiff had acquiesced it is necessary for the defendants to 'establish that the plaintiff stood by and knowingly allowed the defendants to proceed and to expend money in ignorance of the fact that he had rights and meant to assert such rights'.

The patentee may seek an injunction to restrain the defendant without giving notice to the defendant. But where the patentee acquiesced, by his conduct, from taking any action on the infringement, he will be denied the relief of injunction. However, a defendant will be not be

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<sup>393</sup> Section 124, Patents Act, 1970.

liable for damages or an account of profits if he proves that at the date of the infringement he was not aware or had no reasonable grounds to believe that the patent existed.<sup>394</sup>

Similarly, the intention of the defendant to copy or infringe will be irrelevant. Instances where the defendant intends to work around or design around the invention without infringing it would amount to infringement regardless of the defendant's intention. The issue of infringement is decided objectively without regard to whether the defendant designed the infringing product with an eye on the patented product. The fact that the infringing article is an exact replica of the patented article, and that the infringing article was made to look like the patented article will not be relevant in determining infringement. However, the intention of a defendant to infringe will be relevant when the court seeks to restrain future acts of infringement.

A defendant cannot seek refuge that alleged infringement was caused inadvertently. It will not be a defence for the defendant to show that the infringement was short-term and unintended, and did not fall within the scope of the claim which required the parameters to be 'maintained'. The liability in an action for infringement is absolute and does not depend on the alleged infringer's state of mind. It is not necessary for the patentee to show that it has suffered damage or commercial loss as a result of the infringement.

### **iii. Proof of Infringement**

Infringement involves a mixed question of fact and law. The burden of proving infringement is on the patentee who files the suit for infringement. As the standard of proof for establishing infringement is based on the balance of probabilities, the plaintiff has to produce such evidence before the court. The burden of proof with regard to an article manufactured abroad will lie on the patentee. This holds true in the case of process as well as product patents. The defendant is not expected to show proof of non-infringement, but the court may draw an adverse inference if material which could throw light on infringement was disposed of.

In the case of process patents, if the patentee is able to demonstrate that all the processes of making that article were patented by the patentee and there was no other known way of manufacturing the article, it would be upon the defendant to show that the articles were made

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<sup>394</sup> Section 111(1), Patents Act, 1970.

by a different method than that of the patentee's. The Patents Act makes an exception in the case of process patents involving new products.<sup>395</sup>

Section 104A of the Patents Act was introduced by Patents (Amendment) Act 2002. The said section shifts the burden on the defendant. The above section will apply only in case of processes that result in new products. The obligation on the defendant is to show that the product was not produced by a patented process. Section 104A states that the burden of proving that the process by which the defendant prepared the substance in issue will be on the defendant as the knowledge about this would specifically be with the defendant.

After the Patents (Amendment) Act 2005 introduced product patents for pharmaceuticals, the provision makes little sense as patentees would go in for a stronger product protection for their new products. Where the defendant is obliged to disclose his process, certain leeway may be made where the process involves confidential information like manufacturing or commercial secrets. In such cases, the court may order controlled disclosure as consistent with the protection of trade secrets and as may be necessary to prove infringement.

## **V. ACT MUST NOT BE AN EXCLUDED ACT**

The Patents Act excludes certain acts from amounting to infringement states that a patent is granted under the Patents Act. Section 47 subject to the four conditions mentioned therein. The performance of any of them will not amount to an infringement of a patent. Section 49 protects patents used in a foreign vessel, aircraft or vehicle from infringement under the Patents Act. Section 107 states that the grounds of revocation under section 64 may be raised as a defence in a suit for infringement. Section 107A details certain acts which are not considered as infringement. Under section 140(3), it will be a defence against infringement to prove that at the time of infringement, there was in force a contract containing a restrictive condition declared void under section 140.

### **i. Government Use – Section 47(1) & (2)**

A patent is granted subject to the condition that the government may employ it for its own use. Any process or product which is the subject matter of a patent may be imported or made by the government for its own use. The government may also use any process which is a

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<sup>395</sup> Section 104A, Patents Act, 1970.

subject matter of a patent for its own use. These acts shall not amount to an infringement of a patent.

**ii. Experiment and Research – Section 47(3)**

A patent is granted subject to the condition that any person may make or use any patented product or a product made by a patented process or use a patented process for the purpose of experiment or research. Imparting instructions to pupils is expressly covered under the sub-section. The ambit of the expression 'experiment' will be understood better when one reads it along with the expression 'research' as it appears in the sub-section. The kinds of experiment contemplated in this exception are the ones that lead to finding out something that is unknown.

Experiment and research should be of such nature that the act must be done in relation to the subject matter of the invention found in the claims of the patent alleged to be infringed. It should have a real and direct connection to the claimed subject matter of the patent in suit. But if an infringing product is sold for use in experiments, the vendor will be liable for infringement. Similarly, if a pirated article is purchased and put to use for instructing pupils who 'pull them to pieces or experiment with them', such use was not mere experimental use but an infringement.

The provisions of section 47(3) should be read in the light of section 107A(a) which allows experiments or research to be conducted 'for uses reasonably related to the development and submission of information required under any law'.

**iii. Import of Medicine or Drug – Section 47(4)**

A patent in respect of any medicine or drug is granted subject to the condition that the government may import such medicine or drug for its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the government or any other dispensary, hospital or other medical institution which the Central Government, having regard to the public service rendered by such institution, may specify in the Official Gazette.

**iv. Patents in Foreign Vessels, Aircrafts and Vehicles – Section 49**

The acts mentioned in section 49 of the Patents Act will not amount to an infringement. The section deals with inventions that may be a part of a vessel, an aircraft or a land vehicle that



comes into India temporarily or accidentally. The rights conferred by a patent for an invention shall not be deemed to be infringed by the use of the invention in the body of the vessel or in the construction or working of the aircraft or land vehicle. The provision protects ships involved in inter-state passage. The expression 'temporarily' refers to entry that is transient or for a limited period of time. The fact that the same journey is repeated over and over again into the territorial waters, does not alter the temporary nature of the entry. The section works on the principle of reciprocity.

**v. Defences to Infringement – Section 107**

In a suit for infringement, every ground on which a patent may be revoked under section 64 shall be available as a ground for defence. The reasoning behind this provision is that there could be an infringement only with regard to a valid patent. If the patent is shown to be invalid and revoked on any of the grounds mentioned in section 64, the case of infringement would necessarily fail. The making, using, importation or distribution in accordance with any one or more of the conditions in section 47 shall also be a ground for defence in an infringement suit.

**vi. Bolar Exemptions and Parallel Importation – Section 107A**

Section 107A introduced provisions relating to 'Bolar exemptions' and 'Parallel imports' into the Patents Act. Though the provisions of section 107A are worded in general terms to apply to all inventions in all fields of technology, it is more likely to affect pharmaceuticals.

Section 107A(a) exempts certain acts done for procuring regulatory approval with regard to patented products during the life of the patent. It incorporates what is commonly known as the 'Bolar exemptions'. Bolar exemptions are found in the laws of other countries as well. Even countries which do not have an express legislative provision have allowed for clinical trials of a patented drug during the patent term and have refused to hold such use as infringement on the basis that such trials would come within the purview of experimentation privilege. Section 107A(a) allows generic companies to make preparations during the lifetime of a patent for commercial exploitation upon its expiry. The above provision aids generic companies to bring cheaper generic versions of a patented product into the market soon after the expiry of the patent. It enables generic companies to undertake activities prior to the patent expiry which would otherwise amount to infringement. All kinds of pharmaceutical research will be covered by the above provision.

Section 107A(b) deals with international exhaustion of patent rights. The above provision is based on the principle of 'exhaustion of rights' which states that when patented goods are sold by the patentee, the patentee shall have no further control over them. It follows that once there is international exhaustion of patent rights, importation of the same should be allowed. 'Parallel importation' refers to the importation of patented products from a country in which the products are legally on the market. Article 6 of the TRIPS Agreement specifically states that the dispute settlement mechanism under the TRIPS Agreement shall not be used to address the issue of exhaustion of intellectual property rights. This gives the WTO member countries the liberty to incorporate international exhaustion into their national law and the same cannot be objected to by other members by invoking the dispute settlement mechanism. The only way in which a provision on international exhaustion can be challenged invoking the TRIPS Agreement, would be on the ground that international exhaustion is selectively applied to pharmaceuticals by violating the mandate of article 27 of the TRIPS Agreement. The general language in which section 107A(b) is worded would make it impossible to challenge the provision on the ground that it selectively discriminates pharmaceuticals from other fields of technology. Thus the provision enables the importation of patented products by any person from a person who is duly authorised under the law to produce and sell or distribute the product. Such an act of importation will not amount to infringement.

## **VI. INFRINGEMENT PROCEEDINGS**

Infringement proceedings form the back-bone of patent law. Law regards infringement of a patent as a wrong done to the property of another. Any intrusion into the rights of a patentee protected under the Patents Act , for which the patentee has a remedy, will amount to an infringement of a patent. To protect the rights a patentee has in a patent, he will have to institute a suit for infringement against any person who infringes his rights. For protecting a patented invention, law does not, by itself, restrain others from using the invention. It is left to the patentee to initiate an infringement action against the infringer in the courts to protect its rights. A suit for infringement can be filed only after the grant of a patent,<sup>396</sup> and that too in respect of an infringement committed after the date of publication of the application.<sup>397</sup> Under the Patents Act , a suit for infringement may be instituted in a district court or a high court.

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<sup>396</sup> Section 11A(7), Patents Act, 1970.

<sup>397</sup> Section 45(3), Patents Act, 1970.

Chapter XVIII of the Patents Act deals with suits for infringement. Section 104 deals with the jurisdiction for filing a suit for infringement and a suit under sections 105 and 106 of the Patents Act. Section 104A deals with burden of proof in infringement suits. Section 105 deals with the power of the court to make a declaration as to non-infringement. Section 106 deals with the power of the court to grant relief in cases of threat of infringement proceedings. Section 107 deals with the kinds of defence available in a suit for infringement. Section 107A details certain acts which shall not be considered as infringement. Section 108 details the relief available to a plaintiff in an infringement suit. The right of an exclusive licensee and a licensee under section 84 to sue for infringement is detailed in sections 109 and 110 respectively. Section 111 imposes certain restrictions on the power of the court to award damages or an account of profits in a suit for infringement. Section 113 deals with the power of the court to issue a certification of validity. Section 114 deals with the relief that may be granted in the case of a partially valid specification. Section 115 deals with the power of the court to appoint scientific advisers.

## **VII. JURISDICTION**

The jurisdiction to entertain an action for infringement vests with the civil courts, i.e., with the district courts and the high courts. Neither the Controller, nor the Appellate Board has the power to decide issues pertaining to infringement of patents. The specific provision in section 104 of the Patents Act, which will determine the jurisdiction of the court to try an infringement suit. But the provisions of the Patents Act are not as detailed as the provisions of the Code of Civil Procedure 1908 which determine the jurisdiction of the civil courts.

In practice, there is a tendency to institute the infringement suit in the high court instead of filing the same before the district court. This is due to the proviso of section 104 which provides for the transfer of an infringement suit pending before the district court to the high court where a counter-claim for revocation is raised by the defendant. In most cases, the defendant would raise the defence of revocation as a counter-claim which would result in the transfer of the suit. Hence, it would not be practicable for the plaintiff, who, in most cases would press on interim relief, to have the case transferred to the high court.

## **DEFENCES**

The defendant shall raise in its written statement all matters regarding the maintainability of the suit and all the grounds of defence on which he relies.<sup>398</sup> The ground of defence must be stated so as to not take the opposite party by surprise. The defendant must specifically plead, in his defence, those facts which do not arise out of the plaint, such as those relating to fraud, limitation, facts showing illegality, etc.

The defendant may question the title of the plaintiff to the patent. The defendant may deny that the plaintiff is the patentee or the exclusive licensee and thereby its capacity to maintain the infringement suit. The plaintiff must show its title to the patent by means of some evidence. Entry in register is prima facie evidence of title but such evidence is of a rebuttable nature. If the plaintiff derives its title through assignment or licence, it must produce evidence to that effect and also show that the grantor had the necessary title to make the grant. The plaintiff will not be entitled to maintain an infringement action as an exclusive licensee, if it fails to show title as on the date of the action.

A licence issued by the patentee may be raised as a defence in respect of the acts covered by the licence. If the defendant claims to be a licensee of the plaintiff, it should produce evidence to that effect.

### **i. Innocent Infringement – Section 111(1)**

A defendant who proves that on the date of the infringement he was not aware of the patent and that he had no reasonable grounds for believing that the patent existed, will not be liable for damages or an account of profit. The above defence should be specifically pleaded and proved by the defendant.

### **ii. Non-renewal of Patent – Section 111(2)**

A defendant will not be liable for damages or an account of profit in case of any infringement committed after a failure to pay any renewal fee within the prescribed period and before any extension of that period. The defendant has to specifically plead that the renewal fee was not paid during this period and that the alleged act was done during the said period.

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<sup>398</sup> Order VIII, Rule 2, CPC, 1908.

### **iii. Amendments after Publication – Section 111(3)**

Where an amendment is allowed after the publication of the specification, a defendant will not be liable for damages or an account of profit in respect of use of the invention before the date of the decision allowing the amendment, unless the court is satisfied that the specification as originally published, was framed in good faith and with reasonable skill and knowledge.

### **iv. Right to Continue Manufacture – Section 11A(7)**

A patent-holder cannot institute an infringement suit against a person who had made significant investment in respect of a pharmaceutical product under the circumstances mentioned in section 11A(7) of the Patents Act. If an infringement suit is filed against such a manufacturer, the only relief the patent-holder will be entitled to will be one of reasonable royalty. Section 11A(7) provides that in the case of a patent granted in respect of applications made under section 5(2), the defendant against whom an infringement suit is filed, may continue to manufacture the product on payment of reasonable royalty to the patent-holder, if it is shown that the defendant had made significant investment and was producing and marketing the concerned product prior to 1 January 2005, and continued to manufacture the product covered by the patent on the date of grant of the patent.

### **v. Acquiescence, Laches and Estoppel**

Res judicata is treated as a part of the principle of estoppel. The doctrine of res judicata contained in section 11 of the Code of Civil Procedure 1908 corresponds to the English doctrine of estoppel by judgment and the same applies to patent infringement suits as well. The question of the validity of the patent which is raised as a defence in an infringement suit was res judicata between the parties to the suit, if the issue of validity was decided earlier between the parties. Thus, judgment in an earlier action on the validity of a patent estopped the defendant from denying the validity of the patent in a subsequent action. But the defendant will be allowed to question the validity of the patent on fresh grounds not raised in the earlier proceedings. A person who unsuccessfully opposes a patent under section 25 shall not be estopped from filing a petition for revocation under section 64.<sup>399</sup>

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<sup>399</sup> Surajmal Rambux v. Laxminarayan Raghunath, AIR 1951 Nag 284.

Order II, Rule 2 of the Code of Civil Procedure, 1908 requires the plaintiff to include the whole of the claim which the plaintiff is entitled to make in respect of the cause of action. The plaintiff may also relinquish any portion of his claim in order to bring the suit within the jurisdiction of any court. If the plaintiff omits to sue or intentionally relinquishes any portion of his claim, he shall be estopped from suing in respect of the portion so omitted or relinquished, except where he has procured the leave of the court to sue at a future point in time. Order II, Rule 2 of the Code of Civil Procedure, 1908 protects the defendant from being vexed twice for the same cause of action.

Order II, Rule 2 prohibits a plaintiff from raising a matter in a subsequent suit which he ought to have raised in the earlier proceeding. However, O II, Rule 2 does not bar a defence in respect of the same cause of action.

**vi. Infringement not Novel**

The defendant may take a plea that the alleged infringement was not novel at the relevant date. An invalid patent cannot be infringed. If the defendant could show that a patent was granted in respect of a matter which was not entitled to a patent, i.e., the subject matter of the patent was invalid, it could be a valid defence against infringement. Where the defendant can produce a prior document which discloses the invention, it could be relied for destroying the novelty of the invention. This is popularly known as the 'Gillette defence'. The Gillette defence is in effect an attack on the validity of a patent.

# SOFTWARE PATENTS

## I. INTRODUCTION

A mathematical or business method or a computer program per se or algorithms is not patentable under the Patents Act . In India, patent protection is not afforded to business methods and computer programs though article 27 of the TRIPS Agreement does not exclude them from patentability. Computer programs are excluded from patent protection as they are protected as a literary work under the Copyright Act, 1957 . Though patent for a computer program per se is not patentable, a claim expressed as a computer arranged to produce a particular result, and computer programmes which have the effect of controlling computers to operate in a particular way may be the subject matter of a patent. The prevailing view is that where the subject matter as claimed makes a technical contribution to the known art, the patentability should not be denied merely on the ground that a computer program was involved in its implementation.

## II. DIFFERENT APPROACHES TO COMPUTER PROGRAMS

In the United Kingdom, the courts have relied on different approaches in deciding whether computer programs will qualify for a patent. An illustrative summary of the different approaches followed in granting patents for computer programs, which is an excluded matter under section 1(2) of the UK Patents Act and article 52(2) of the EPC, is given by the Court of Appeal in:<sup>400</sup>

*Our summary of the various approaches which have been adopted is as follows:*

1) *The contribution approach*

*Ask whether the inventive step resides only in the contribution of excluded matter--if yes, Art 52(2) applies. This approach was supported by Falconer J in Merrill Lynch<sup>401</sup>, but expressly rejected by this Court.*

2) *The technical effect approach*

*Ask whether the invention as defined in the claim makes a technical contribution to the known art-if no, Art 52(2) applies. A possible*

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<sup>400</sup> Aerotel Ltd. v. Telco Holdings, [2006] EWCA Civ 1371.

<sup>401</sup> Merrill Lynch Inc's Application (1989) RPC 561 (CA).

clarification (at least by way of exclusion) of this approach is to add the rider that novel or inventive, purely excluded matter does not count as a 'technical contribution'. This is the approach (with the rider) adopted by this Court in *Merrill Lynch*. It has been followed in the subsequent decisions of this Court, *Gale*<sup>402</sup> and *Fujitsu*<sup>403</sup>. The approach (without the rider as an express caution) was that first adopted by the EPO Boards of Appeal, see *Vicom*<sup>404</sup>, *IBM/Text processing*<sup>405</sup> and *IBM/Data processor network*<sup>406</sup>.

3) The 'any hardware' approach

Ask whether the claim involves the use of or is to a piece of physical hardware, however mundane (whether a computer or a pencil and paper). If yes, Art 52(2) does not apply. This approach was adopted in three cases, *Pension Benefits*<sup>407</sup>, *Hitachi*<sup>408</sup> and *Microsoft/Data transfer*<sup>409</sup> (the 'trio'). It was specifically rejected by this Court in *Gale*. However there are variants of the 'any hardware' approach:

- i. Where a claim is to a method which consists of an excluded category, it is excluded by Art 52(2) even if hardware is used to carry out the method. But a claim to the apparatus itself, being 'concrete' is not so excluded. The apparatus claim is nonetheless bad for obviousness because the notional skilled man must be taken to know about the improved, excluded, method. This is the *Pension Benefits* approach.
- ii. A claim to hardware necessarily is not caught by Art 52(2). A claim to a method of using that hardware is likewise not excluded even if that method as such is excluded matter. Either type of claim is nonetheless bad for obviousness for the same reason as above. This is *Hitachi*, expressly disagreeing with *Pensions Benefits* about method claims

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<sup>402</sup> *Gale's Application* (1991) RPC 305 (CA).

<sup>403</sup> *Fujitsu Ltd's Application* (1997) RPC 608 (CA).

<sup>404</sup> T208/84 *VICOM/Computer-related invention* [1987] EPOR 74.

<sup>405</sup> T38/86 *IBM/Text clarity processing* [1990] EPOR 606.

<sup>406</sup> T6/83 *IBM/Data processor network* [1990] EPOR 91.

<sup>407</sup> T931/95 *R v PBS Partnership/Controlling pension benefits system* [2002] EPOR 52.

<sup>408</sup> T258/03 *Hitachi/Auction method* [2004] EPOR 55.

<sup>409</sup> T424/03 *Microsoft/Clipboard formats I* [2006] EPOR 39.



- iii. *Simply ask whether there is a claim to something 'concrete' e.g., an apparatus. If yes, Art 52(2) does not apply. Then examine for patentability on conventional grounds - do not treat the notional skilled man as knowing about any improved excluded method. This is Microsoft/Data transfer.*

In the above case, the Court of Appeal went on to accept the 'technical effect approach' with the rider rejecting all other approaches. It detailed the said approach as follows:

The approach is in 4 steps: (1) properly construe the claim; (2) identify the actual contribution; (3) ask whether it falls solely within the excluded subject matter; (4) check whether the actual or alleged contribution is actually technical in nature.

The above approach followed by the Court of Appeal is the one likely to be followed under the Patents Act. It is likely that the Patent Office would allow patents for computer programs which provide a technical advancement over the existing knowledge.<sup>410</sup> The applicant will be required to show the technical contribution to the prior art where the invention involves a computer program.

An invention which would be patentable in accordance with conventional patentability criteria should not be excluded from protection by the mere fact that computer programs are used for its implementation.<sup>411</sup> However, any objection to patentability will be considered if the actual protection was offered to the patenting of a mental act in the guise of a computer program. In most cases involving computer programs, the claims would be directed both to a method of using a piece of hardware, in the form of a programmed computer, and to the piece of hardware programmed to carry out the method.<sup>412</sup>

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<sup>410</sup> Section 2(1)(ja), Patents Act, 1970 & Manual of Patent Practice and Procedure, Patent Office; Ferid Allani v. Union of India, 2019 SCC Online Del 11867.

<sup>411</sup> T1173/97 IBM/Computer-related invention [1987] EPOR 74 .

<sup>412</sup> Halliburton Energy Services Inc v. Smith International (North Sea) Ltd (2006) RPC 2.

# BIOTECHNOLOGY PATENTS

## I. INTRODUCTION

Biotechnology is the science of developing techniques for the application of biological processes and organisms to the production of materials of use in medicine and industry. Traditionally, biotechnology pertained to the production of useful products (like antibiotics, cheese, etc.) by employing living micro-organisms (like fungi, bacteria, etc.). The modern meaning of the term signifies the use of genetic engineering to modify bacterial cells to synthesise completely new substances (like the use of hybridoma technology in fusing different types of immune cells to form a hybrid cell line producing monoclonal antibodies) or to introduce novel traits in plants and animals (like the use of recombinant DNA technology to introduce genetic material from an external source into a cell to cause the production of a desired protein by the cell). Broadly, biotechnology can be classified into two: industrial biotechnology and agricultural biotechnology. Industrial biotechnology refers to chemical and pharmaceutical substances derived from or processes pertaining to the plant and animal kingdom. Agricultural biotechnology involves the use of genetic engineering to develop new plants and animal varieties.

As biotechnology inventions synthesised through recombinant DNA technology usually involved large investments in R&D, it triggered the need to protect these inventions through the grant of patents. Due to various factors pertaining to ethics, morality and access to technology, there was no unanimity on the issue of patenting biotechnological inventions between the WTO member countries during the Uruguay Round of negotiations. As a result, art 27.3(b) of the TRIPS Agreement reflects the minimum agreement which the WTO members agreed to revisit within four years after the TRIPS Agreement came into force.

Biotechnological inventions raise peculiar challenges as it imports issues relating to ethics, morality and access to technology into patent law. These challenges are complicated by the rapid advancements made in science and technology, which often requires the criteria for patentability of biotechnological inventions to be redefined. The exclusion of plants and animals from patentability and the permissibility of patenting gene sequences are some of the issues that have an impact on the patentability of these inventions. Apart from these special issues, the patent for a biotechnological invention revolves around the criteria of patentability, as is the case with inventions from any other field of technology. Biotechnological inventions

have to satisfy the three prerequisites of novelty, inventive step and industrial application. They must also not be excluded under the exceptions to patentability in sections 3 and 4 of the Patents Act.

Patenting of biotechnological inventions can give rise to tremendous challenges in patent law. For instance, determining the novelty of a biotechnological invention can be difficult as most such inventions are based on naturally existing material. The most likely ground of challenge for a biotechnological invention will be on the ground that it lacks novelty. But a novelty destroying disclosure should be of an enabling nature to constitute anticipation, as demonstrated in cases involving biotechnological inventions. A biotechnological invention may also be challenged on the ground that it is not an invention within the meaning of the Patents Act and that it is a mere discovery. An objection may also be raised on the ground that the use or commercial exploitation of the invention would be against public order or morality.

The grant of patents for biotechnological inventions is a matter of policy. The Patent Office has made a detailed expression of the policy it would follow in its Manual of Patent Practice and Procedure. Annexure I of the said Manual contains guidelines for examination of biotechnological inventions. Though only the draft version of the Manual has been released, it adequately reflects the policy that the Patent Office would follow in granting or refusing patents for biotechnological invention.

## **II. PROVISIONS UNDER PATENTS ACT**

The special provisions which pertain to the patentability of biotechnological inventions are contained in section 3 of the Patents Act, the relevant clauses are reproduced below:

*3. What are not inventions - The following are not inventions within the meaning of this Act:*

*(b) an invention the primary or intended use or commercial exploitation of which would be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment;*

*(c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature; ...*

*(j) Plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.*

The equivalent provision of clause (b), which is similar to art 27.2 of the TRIPS Agreement, has been employed to challenge biotechnological inventions in various jurisdictions on the ground that they are contrary to public order or morality. Clause (c) of section 3 prohibits the discovery of anything or substance that occurs naturally. Clause (j), which is similar to art 27.3(b) of the TRIPS Agreement.

### **III. PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS**

In the field of biotechnology, inventions may be made with respect to the following:

- (a) living entity of natural origin (like animal, plant, human beings including parts thereof);
- (b) living entity of artificial origin (like micro-organism, vaccines, transgenic animals and plants etc);
- (c) biological materials (like DNA, plasmids, genes, vector, tissues, cells, replicons etc); and
- (d) biological processes (like process relating to living entities, process relating to biological material, methods of treatment of human or animal body, essentially biological process).

As in the case of an invention in any other field of technology, the three prerequisites of patentability, i.e., novelty, inventive step and industrial application, have to be satisfied for the grant of a patent for a biotechnological invention. The application of these standards has lead to differing practices between countries. It is essential to have detailed guidelines for the grant of patents for biotechnological inventions.

According to section 3(j), patents shall not be granted for 'plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals'. The above section is modelled on article 27.3(b) of the TRIPS Agreement. Section 3(j) of the

Patents Act deals with the following three broad classes which are discussed in detail: 'micro-organisms', 'essentially biological processes' and 'plants and animals'.

### **i. Micro-organisms**

Section 3(j) of the Patents Act allows for patents for micro-organisms. It is worded in the form of an exception to an exception. The permissibility of patenting micro-organisms was considered in *Dimminaco AG v. Controller of Patents and Designs*, a case which involved an invention relating to a process for preparation of infectious Bursitis vaccine for protecting poultry. The Assistant Controller of Patents and Designs rejected the application on the ground that it did not constitute an invention under section 2(1)(j) of the Patents Act holding that the process of preparing the vaccine which contains a living virus cannot be considered as 'manufacture' under the old definition of invention. The Assistant Controller further held that the vaccine with living organisms cannot be considered a substance. An inanimate object can be described as a thing or item but not as a living one. Micro-organisms cannot be considered an inanimate substance as it cannot be converted physically or chemically to any other product. On an appeal preferred under section 116 of the Patents Act to the Calcutta High Court the court took into account the practice of the Patent Office in granting patents for end-products containing living virus and quashed the order of the Controller and directed the reconsideration of the patent application.

The above case was decided under the provisions of the Patents Act before the Patents (Amendment) Act 2002 came into force. The said Amendment introduces s 3(j) which allows patents for micro-organisms. The decision in *Dimminaco* considers the practice of the Patent Office in granting patents for end-products containing living virus and arrives at its conclusion to allow patents for micro-organisms on the basis of such practice.<sup>413</sup>

The controversial question pertains to how micro-organisms are to be defined. By a broader definition, it will include any microscopic organism. A narrower definition of the word would limit the definition to only unicellular organisms. The narrow definition of micro-organism confines the application of the definition to organisms such as viruses, algae, bacteria, fungi and protozoa. It would exclude cell lines, genes and gene sequences.

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<sup>413</sup> *Dimminaco AG v. Controller of Patents and Designs*, (2002) IPLR 255.

The language of art 27.3(b) of the TRIPS Agreement adopts the wordings of the equivalent provision in the EPC. But it does not follow that the practice in EPO should be followed. EPO adopts a broader definition for micro-organisms to include cells and cell parts. Since the TRIPS Agreement approves patents for micro-organism, member countries of the WTO have shown a tendency to expand the scope of the micro-organism and microbiological process to include genetic material and plants and animals. But the TRIPS Agreement does not define the term 'micro-organisms', leaving the member countries the necessary flexibility to decide the kinds of micro-organisms that will be entitled to protection. The Patent Office is unlikely to grant protection for micro-organisms which are living entities of natural origin.

Microbiological processes are processes in which micro-organisms or their parts are used to make or to modify products. Though art 27.3(b) of the TRIPS Agreement provides for exclusion of 'non-biological and microbiological processes', section 3(j) does not expressly exclude such processes from patentability. Unlike section 1(3)(b) of the UK Patents Act, which uses the expression 'microbiological process or the product of such a process', the Patents Act does not refer to microbiological processes at all. It refers only to the product, i.e., micro-organism. Patents for the micro-organisms as a product are likely to include 'microbiological processes' or the products of such processes

The Patent Office is likely to grant patents for processes relating to micro-organisms or producing chemical substances using such micro-organisms. The specific exclusion of 'essentially biological processes', together with the permissibility of patenting micro-organisms, indicates an inclination towards grant of patents for microbiological processes. The EPO Technical Board of Appeal in Plant Genetic Systems has interpreted the phrase 'microbiological processes or the products thereof' to refer to products which are made or modified by micro-organisms as well as new micro-organisms.

## **ii. Essentially Biological Process**

The Patent Office is likely to hold that 'essentially biological processes' for the production of plants and animals such as methods of crossing or breeding, etc, are not patentable. The phrase 'essentially biological processes' has not been defined in the TRIPS Agreement and has left many avenues open, though the Agreement does exclude 'non-biological and microbiological processes' from the exclusion under art 27.3(b).

It has been argued that the phrase 'essentially biological process' must be read in a restricted sense. First, it only applies to processes and hence has no application to a product-by-process claim. Secondly, the exclusion applies only where the process is for the production or propagation of plants and animals. It may not apply if the process results in the death or termination of animals or plants. Thirdly, the exclusion will apply only if the process is 'essentially biological'. This raises the issue of the degree of technical or human intervention required for the process to fall outside the exclusion. It would thus be safe to assume that where there is no technical or human intervention, the process will be regarded as 'essentially biological'. Even in cases where the extent of human intervention is trivial or minimal, it has been observed that human interventions may only mean that the process is not a 'purely biological' process; it could still be 'essentially' biological and hence may still be excluded. For instance, process of conventional breeding will be regarded as essentially biological and hence will not be patentable.

The expression 'essentially biological processes' was considered by the Technical Board of Appeal of the EPO in the Plant Genetic Systems case, where it was held that a process will not be regarded as essentially biological if it consisted of a technical step requiring human intervention which had an impact on the final result.

### **iii. Plants and Animals**

The Patent Office will not grant patents for living entities of natural origin such as animals, plants, in whole or any parts thereof, plant varieties, seeds, species, genes and micro-organism. Any process of manufacture or production relating to such living entities will not be entitled for patent protection. Any method of treatment such as medicinal, surgical, curative, prophylactic, diagnostic and therapeutic of human beings or animals or other treatments of similar nature, being specifically excluded under the Patents Act, will not be patentable. Any living entity of artificial origin such as transgenic animals and plants or any part thereof shall not be entitled to a patent. However, a living entity of artificial origin such as micro-organisms or vaccines may be the subject matter of patent protection.

#### **a) Seeds**

The Patent Office is unlikely to grant patents for seeds as it is expressly excluded under s 3(j) of the Patents Act.

### **b) Plant Varieties**

Under art 27.3(b) of the TRIPS Agreement, member countries are required to provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. India opted for the sui generis system of protection in introducing the Protection of Plant Varieties and Farmers' Right Act 2001 for protecting plant varieties. Plant varieties have been interpreted by the EPO to mean the lowest rank plant groupings. Plant varieties, however, will not include plant cells.

### **c) Animal Varieties**

Section 3(j) of the Patents Act expressly excludes animal varieties and species. The phrase 'animal varieties' was interpreted narrowly by the EPO to limit the phrase to a variety and as not extending to animals per Section 3(j) of the Patents Act will not permit such an interpretation as it includes 'animals in whole or any part thereof'.

### **d) Biological Material**

The Patent Office shall not grant patents for any biological material and method of making the same which is capable of causing serious prejudice to human, animal or plant lives or health or to the environment, including the use of those which would be contrary to public order and morality, in the light of the exceptions contained in section 3(b) of the Patents Act. The exclusion in the above section will cover terminator gene technology. Biological materials such as organs, tissues, cells, etc and process of preparing thereof shall not be patentable under section 3(j) of the Patents Act as being a 'part' of plants and animals. However, the Patent Office may grant patents for biological material such as recombinant DNA, plasmids and processes of manufacturing provided they are produced by substantive human intervention. But the Patent Office is unlikely to grant patents for gene sequences, DNA sequences which do not disclose their functions, if they lack inventive step and industrial application.

Section 10(4) of the Patents Act requires the applicant, where a biological material is mentioned in the specification which is not described as per clauses (a) and (b) of section 10(4), to deposit the biological material in any International Depository Authority (IDA) recognised under the Budapest Treaty on or before the filing of the application in order to



supplement the description for sufficiency of disclosure of the invention. The applicant also has to disclose the source and geographical origin of the biological material in the specification.

**e) Cloning**

The Patent Office is unlikely to grant patents for processes for cloning human beings or animals, processes for modifying the germ line, genetic identity of human beings or animals, uses of human or animal embryos for any purpose on the ground that they are against public order and morality.

**f) Traditional Knowledge**

A biotechnological invention which is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known components, cannot be the subject matter of a patent under section 3(p) of the Patents Act.

# **PHARMACEUTICAL PATENTS AND COMPULSORY LICENSING**

## **I. INTRODUCTION**

Though the mandate of the TRIPS Agreement requires patents to be made available for any invention in all fields of technology, patent laws throughout the world recognise patents for pharmaceuticals as a special branch which raises issues not common to other fields of technology. Pharmaceuticals came to be inevitably considered as a part of public health, leading many countries to provide special regulations for them. Like India, many countries showed initial reluctance to grant product patents for pharmaceuticals, and thus allowed only process patents. This reluctance has been one of the factors that contributed to the growth of the generic pharmaceutical industry in India. The concessions in the Patents Act enabled local companies to manufacture drugs that enjoyed a product patent protection elsewhere by employing a non-infringing process.

The situation changed after the TRIPS Agreement, which required member countries to grant product patents for pharmaceuticals. The TRIPS Agreement contained special transitional arrangements for developing countries to enable their compliance with the TRIPS mandate. The insurmountable problems caused by these arrangements is well-illustrated by the introduction of exclusive marketing rights in India, and the consequences that ensued. The special accommodation for pharmaceuticals can also be seen in the provisions of article 31 of the TRIPS Agreement which provides for use without authorisation of the right holder. These provisions are more likely to be used in the case of pharmaceuticals. The Doha Declaration on Public Health emphasises the special relationship between pharmaceuticals and public health, in that it affirms that the 'Agreement can and should be interpreted and implemented in a manner supportive of WTO Members right to protect public health and, in particular, to promote the access to medicines for all'.

The technology also imposes certain problems in determining the patentability of pharmaceutical substances. Pharmaceutical substances are nothing but chemicals used for the treatment of diseases. The issues that normally arise in patenting chemical substances will be relevant for pharmaceutical substances. This chapter deals with the legislative provisions in the Patents Act on the patentability of pharmaceutical substances. The peculiar issues on

patentability of pharmaceutical substances like the permissibility of selection patents and Swiss-type of patents are also discussed here in detail. The constitutional validity of section 3(d) of the Patents Act was recently challenged on the primary ground that the provision is not in compliance with the TRIPS Agreement. The concluding part of this chapter discusses this issue in detail.

## II. PROVISIONS UNDER THE ACT

The special provisions which pertain to the patentability of pharmaceutical and chemical inventions are contained in section 3 of the Patents Act, the relevant clauses are reproduced below:

*3. What are not inventions: The following are not inventions within the meaning of this Act:*

*... (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.*

*Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.*

*(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;*

*(i) any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.*

### III. PATENTABILITY OF PHARMACEUTICALS

Like any other invention, a pharmaceutical invention should satisfy the three tests of novelty, inventive step and industrial application for it to be patentable. In addition, the invention should not fall under the exceptions laid down in sections 3 and 4.

#### i. Exceptions to Patentability

The history of patent law is replete with exceptions to patentability. The exceptions to certain product patents were made usually on grounds of public policy. The exceptions to certain processes were made either because they were deemed not to be inventions or even if inventions, were deemed to be non-patentable as they did not otherwise satisfy the criteria of patentability. Though every country has made exceptions to patentability, the following instances will show that the exceptions to patentability need not be exhaustive or confined to the ones mentioned in the TRIPS Agreement.

The TRIPS Agreement, being a minimum-standard setting agreement, provides for the following exceptions to patentability in clause (2) and (3) of article 27:

*Article 27: Patentable Subject Matter:*

*... (2) Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*

*(3) Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.*

## **ii. TRIPS Exceptions not Exhaustive**

The exceptions to patentability contained in arts 27.2 and 27.3 of the TRIPS Agreement are not exhaustive. Member countries are permitted to provide for exceptions in addition to the ones mentioned in art 27 so far as 'patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'. In fact, a survey of the patent laws of various WTO member countries will show the exceptions to patentability provided for in their domestic legislations go much beyond the exceptions provided in arts 27.2 and 27.3 of the TRIPS Agreement. Various countries exclude 'business method', 'presentation of information', 'computer programs', 'aesthetic creation' from patentability, though the exceptions in arts 27.2 and 27.3 do not contemplate such exceptions.

Thus, the TRIPS Agreement does not contemplate an exhaustive list of exceptions leaving member countries the flexibility to introduce further exceptions on grounds of policy. Section 3(d) of the Patents Act may be viewed as one such exception.

## **iii. Exception on the ground of Public Health**

Section 3(d) may also be viewed as an exception under the ambit of article 27.2. Article 27.2 of the TRIPS Agreement provides for exceptions to patentability made on the ground of health. The said provision gives enough room for member countries to carve out exceptions on the ground of public health. Such measure may also extend to pharmaceuticals as patents for pharmaceuticals can have a direct impact on human health. The Doha Declaration on public health further reiterates that the provision of the TRIPS Agreement must be interpreted and implemented in a manner supportive of WTO members' right to protect public health and to promote access to medicines for all. As we shall see in detail, the effect of section 3(d) is to limit the grant of fresh patents for known substances and known processes. The impact of such a provision on pharmaceuticals can certainly be viewed as a measure to protect public health and promote access to medicines.

## **IV. APPLICATION OF SECTION 3(d)**

On the face of it, section 3(d) will be read as an exception to patentability which should be applied before the three tests of patentability in section 2(1)(j) are satisfied. Section 3(d),

though worded in the form of an exception to patentability, does provide for conditions in which such exceptions may become patentable. In effect, section 3(d) may be applied at two stages, i.e., before and after determining the three prerequisites of patentability, section 3(d) may be applied before determining the three prerequisites of patentability, i.e., novelty, inventive step and industrial application.

A patent may be granted for a pharmaceutical process or a product which is new, involves an inventive step and is capable of industrial application. Section 3(d) may also become applicable, depending upon the particular circumstances, after the individual ingredients of patentability, i.e., novelty, inventive step, and industrial application are determined. This is so because section 3(d) encompasses elements of novelty ('new' form, 'new' property, 'new' use, 'new' product and 'new' reactant) inventive step or obviousness ('known' substance, 'known' efficacy and 'known' process) and industrial application ('efficacy', 'use' of known substance or process).

#### **i. The Ingredients of Section 3(d)**

Section 3(d) comprises three parts and one explanation. For the sake of clarity, the parts of section 3(d) are detailed separately. The section states that the following are not inventions within the meaning of the Patents Act:

(1) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance; or

(2) the mere discovery (i) of any new property or new use for a known substance; or (ii) of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

The three parts are dealt with below separately and referred to individually as the first part, second part and third part of section 3(d). The common element in all the three parts, 'mere discovery' is discussed below followed by the three situations contained in the three parts.

#### **a) Mere Discovery**

While mere discoveries have been excluded from patentability in United Kingdom, the practical application of a discovery may be the subject matter of a patent. Under the Patents

Act a discovery to be patentable will be subject to the conditions imposed by section 3(d). The first part of section 3(d) and the explanation create a rebuttable presumption that the discovery of a new form of a known substance will be regarded as the same substance, unless the applicant is able to show that the new form differs significantly in properties with regard to efficacy. In this regard, the criterion of enhanced efficacy, which may be regarded as a component of utility or usefulness, will be similar to the requirement of 'practical application of a discovery' as recognised by the British patent law.

A discovery, an invention or an identification of a new form of a known substance implies finding a different form of an already known substance. The law with regard to patentability of discoveries, as practised by various WTO member countries, show a varying range of positions, which is yet another indication that member countries can derogate from the exceptions mentioned in the TRIPS to expand further the exceptions to patentability. On the one hand, we have the US law which states that all discoveries are patentable.

On the other hand, we have many countries like Argentina, Austria, Brazil, Chile, China, Finland, Malaysia, the Philippines, Russia and South Africa which impose a blanket ban on discoveries. All the above countries fully exclude discoveries from patentability.

Viewed in the light of the above two extreme positions on patentability of discoveries, section 3(d) may be seen as a middle-path which allows for patentability of discoveries of a new form of a known substance which result in the enhancement of the known efficacy of that substance. The criterion of enhanced efficacy is a condition imposed by the Patents Act to qualify a discovery of a new form of a known substance as patentable.

#### **b) New Form of a Known Substance**

The first part of s 3(d) incredibly imports the three prerequisites of patentability in a single clause. The first part states that a 'new' (implying novelty) form of a 'known' (implying obviousness) substance which does not result in the enhancement of known 'efficacy' (implying industrial application), shall not be regarded as an invention under the Patents Act . The effect of the first part is that it allows for the discovery of a new form of a known substance to be treated as an invention if there is an enhancement of its known efficacy. It is the discovery which leads to the claiming of the particular result in the form of a patentable invention. The first part of section 3(d) states that such mere discoveries cannot amount to an

invention under the Patents Act. It follows that the properties pursuant to such discovery, which are devoid of any inventive step, will not be allowed to be the subject matter of a patent.

If the Patents Act were to allow for a new form of a known substance without the conditional clause on efficacy, it would mean that the novelty of the invention will lie in its form. Such a provision can have an uncertain effect in the case of chemicals and pharmaceuticals, a field in which obtaining new forms of a substance is possible and sometimes can be achieved with consummate ease. Thus, the requirement of the invention to have novelty of effect, i.e., increase in known efficacy, may be viewed as a reasonable requirement.

The full impact of the first part of section 3(d) cannot be understood without considering the second part of section 3(d). This is because while the first part requires a new form of a known substance to differ significantly in 'properties' with regard to efficacy, the second part comprehensively bans any new 'property' of a known substance. It might appear that the second part of section 3(d) subsumes the first part of section 3(d), as both deals with properties of known substances. This might raise an issue whether, in such a case, the effect of the first part is nugatory. That is not so. A careful reading of the first part will reveal that new form of a known substance will qualify for an invention if there is an enhancement of a 'known property', i.e., efficacy of the substance. As the first part pertains only to an increase or enhancement of a 'known property', it is submitted that the first part will not be affected by the second part which bans a 'new property'. But if the enhancement of a known property is to be regarded as a new property, then the second part may be applicable.

### **c) Known Efficacy**

The intention of the legislators will become more apparent when the use of the word efficacy is understood. Efficacy means the effectiveness of substance. The term efficacy is a well-understood in the pharmaceutical field. Efficacy of a drug involves a degree of potency as a drug. Bioavailability of a drug is one of the characteristics that affect the efficacy of a drug. It is also possible that 'known efficacy' may mean clinical efficacy in cases where the clinical efficacy of the known substance is already determined. Clinical efficacy is a regulatory requirement under the Drugs and Cosmetics Rules 1945, and as such importing the concept



of clinical efficacy, which will require phase III trials to be conducted, may impose an unreasonable restriction on patentability.<sup>414</sup>

In the case of a pharmaceutical, the reference to a 'property' of a known substance means the physicochemical properties of the drug such as the solubility of the drug in aqueous and other media, the stability of the drug in solution, bioavailability, interactions between the drug and excipients (inert substances) etc. The first part of section 3(d) uses the term 'efficacy' to describe the property of a drug. Thus, the first part deals with an increase or improvement of a 'known property' of a known substance, whereas the second part concerns with a 'new property' of a known substance.

The importance of two factors should not be misplaced in determining the scope of the first part of section 3(d). First, the fact that said clause deals with known substances. It cannot be argued that the patent is for a new substance. Whether a new form of an old and known substance could itself qualify it as a new substance for the purpose of novelty and obviousness is an issue on which there is no consensus. One only needs to look into the practice followed by various countries in the case of selection patents to understand the lack of agreement with regard to granting patents for known substances. Secondly, the first part of section 3(d) regards as an invention, any improvement (enhancement) on the known property (efficacy) of a known substance. Thus, when read in the light of the second part of section 3(d), it would emerge that the only way the first part can be read is to cover patents for improvements. This brings us to the provisions under the Patents Act for the grant of patents for improvements.

## **ii. Patents for Improvements**

The Patents Act provides for patents for improvements. Whether a particular invention will qualify for an improvement will depend on facts and circumstances of each case having regard to the technical advancement over the earlier invention. Similarly, 'enhancement of the known efficacy' should also be determined having regard to the known efficacy and the significant difference made through the enhancement. A new product or a process could also mean a new improvement over an existing product or a process. Every improvement cannot qualify for a patent, but improvements on the prior art so long as it satisfies the prerequisites

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<sup>414</sup> Schedule Y, Drugs and Cosmetics Rules, 1945.

of patentability, can qualify as a patentable invention. Mere workshop (laboratory) improvements, devoid of ingenuity, will not qualify for a patent.<sup>415</sup>

The requirement of 'enhancement of the known efficacy' is not a requirement unknown to law. In plain terms, 'enhancement of the known efficacy' means an improvement on what is already known. It is a well-established principle in patent law that improvements are patentable. To qualify for a patent, an improvement must by itself satisfy the test of patentability. An improvement or modification of an earlier patent may qualify for a patent as a patent of addition.<sup>416</sup>

### **iii. Determining 'Enhancement of Efficacy'**

The enhancement of known efficacy has to be determined by the Controller. The standard of efficacy applied for determining the patentability of an invention has to be developed by the Patent Office and the courts, and applied on a case to case basis. The spirit of the provisions in the Patents Act does indicate that the threshold of efficacy is likely to be high. The bar against selection patents and Swiss form of claims under section 3(d) of the Patents Act would further strengthen the requirement of a higher standard of efficacy.

The first part of section 3(d) will be relevant in determining novelty of a known substance. It has an in-built guideline as it refers to two comparative concepts, i.e., 'known efficacy' and 'enhanced efficacy' for determining patentability of new forms of known substance. The first part states that the 'enhanced efficacy' has to be determined vis-à-vis the 'known efficacy'. As the first part of section 3(d) pertains to known substances, it is quite reasonable to assume that the efficacy or effectiveness of the substance will also be known. Thus, with the 'known efficacy' as the benchmark, the Controller has to look at the 'enhanced efficacy', and decide whether there has been a significant difference in the efficacy of the new form compared to the existing form. This would reiterate the proposition that the first part of 3(d) provides for patents for improvements. The law with regard to improvements is well-settled and the Patents Act statutorily provides for the same.

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<sup>415</sup> Polar Industries Ltd v. Jay Engineering Works Ltd, 1989 PTC (Supp) (2) 310 (Cal).

<sup>416</sup> Section 54-56, Patents Act, 1970.

#### iv. New Property

The second part states that the discovery of any new property of a known substance shall not be regarded an invention for the purposes of the Patents Act. This provision pertains to the prohibition on selection patents.

Selection patents constitute a problematic area for patent law. Selection patents are patents which claim particular compounds to be individually new, but as falling within an earlier disclosure of a broader group of compounds for which protection is already claimed. Selection patents are inventions based on a selection of a particular compound or a relatively small group of compounds from a larger group previously disclosed in broad terms. Selection patents were developed in response to a particular problem that arose in certain fields like chemistry, where the researcher may discover that a particular combination of molecules may produce a particular result. Once a particular result is identified, the researcher extrapolates from the initial discovery to assert that the same qualities will be produced by a range of variants or homologues. This is regarded as a generic disclosure, where the researcher would disclose a very broad range or class of compounds.

When later discoveries show that the some of the compounds outlined in the generic disclosure have particular advantages or uses other than what was originally discovered, the issue arises whether such discoveries could qualify for a separate patent. Logically, the earlier generic disclosure would prevent any subsequent claim to be made on any of the individual member or members of the group. But the problem imposed by this situation was that if the earlier generic disclosure is to be regarded as anticipating the latter discovery, it would be a disincentive for further research to be carried out on the materials already disclosed. Thus, the following question arises in the case of selection patents: whether a prior generic disclosure anticipates subsequent inventions in the same field and if so, to what extent.

The rules that apply to selection patents do not differ from the general rules of patent law. Some specific rules have been devised with regard to selection patents as laid down in some decisions by the UK courts. In *IG Farbenindustrie AG's Patents*, Maugham J elucidated that the following conditions must be shown, which are by no means exhaustive, for a selection patent to be valid: (1) the selection must be based on some substantial advantage to be secured by the use of the selected members; (2) the whole of the selected members must

possess the advantage in question; and (3) the selection must be in respect of a quality of a special character which can fairly be said to be peculiar to the selected group.

The above rules have been approved and followed in a number of decisions. Though selection patents will have a significant impact on pharmaceuticals, the above rules were framed in a case involving textile dyes. The patent for a process of manufacturing certain azo and aromatic amine dyestuffs claimed by IG Farbenindustrie was challenged by a revocation application on the ground of lack of novelty that the prior disclosure in an expired patent revealed the invention. The patentees took a defence that though the disclosure made in the earlier patent revealed millions of combinations of dyes, the particular group of dyes selected by the patentee had certain beneficial properties not previously known. Applying the above rules, the court came to the conclusion that the patent was invalid.

Section 3(d) encompasses the situations stated in the preceding paragraph. In the case of selection patents claiming a new property or a new use, the second part of section 3(d) of the Patents Act will act as a bar for patenting such inventions. A selection patent may be allowed if it satisfies the conditions stipulated in the first part of section 3(d) of the Patents Act. The selection patent should show that a new form of a known substance results in the enhancement of known efficacy.

#### **v. New Use**

The Patents Act requires novelty per se. It does not allow for novelty of use. The Patents Act does not contain any provision which allows for novelty of use. This is a distinguishing feature of the Patents Act which has remained the same over the years, whereas countries like UK have relaxed the novelty requirement to allow novelty of use.

There has been a move towards relaxing the novelty standard for pharmaceuticals. In the recent years, the pharmaceutical industry has witnessed a marked reduction in the possibility of discovering new things. This shifted the focus of research to the discovery of new uses or purposes of old substances in old ways. Patent law traditionally refused to recognise the discovery of a new advantage of an old thing used in an old way as being novel. This was because patent law recognised the particular use of a product as a part of a claim for the product itself. The product would thus lack novelty even if it was previously employed to a different use.

An issue then arises whether the new use of a known substance is patentable under article 27(1) of the TRIPS Agreement. This forms a part of the larger issue of the standard of novelty prescribed by the TRIPS. The TRIPS Agreement requires the novelty of product or of process for which a patent is claimed. It requires the product or the process to be new. In other words, the TRIPS Agreement mandates novelty per se. It may be argued that since patents for new uses of known substances are drafted in the form of a process claim (Swiss claim), it would come under the ambit of a new process, within the existing mandate of TRIPS. But there is no express provision conferring novelty of use akin to the provisions found in the EPC and the UK Patents Act. The TRIPS is silent about novelty of purpose or use. The silences within the TRIPS further reiterate the proposition that the TRIPS is a minimum-standard setting agreement.

India continues to follow the traditional position of not allowing new uses for known substances. The second part of section 3(d) comprehensively prohibits patents for new uses of known substances. In enacting the second part of, the Patents Act section 3(d) has embodied an age-old principle of not recognising novelty of use or purpose. Novelty, in the manner in which the concept is understood under the Patents Act and the TRIPS Agreement, is confined to novel products and processes. It does not envisage novelty of use or purpose of an already known substance. It would be illogical to grant new patents for already known substances as the earlier grant will cover all forms of uses and purposes to which the invention can be applied. Moreover, to relax the standard of novelty for pharmaceuticals alone may violate the general mandate in article 27.1 that patents shall be available for any inventions in all fields of technology.

#### **vi. 'Swiss' Form of Claims**

A 'Swiss' form of claim ('Swiss claim') is a claim to the use of a known pharmaceutically active compound for the manufacture of pharmaceutical compositions in which the compound exhibits previously unknown therapeutic activity. The claim is so drafted so as to cover the discovery of a subsequent medical use of a known substance. The commonly cited example involves the well-known analgesic 'aspirin'. Aspirin was introduced as a pain-killer but somewhere down the line, research established that aspirin had blood-thinning properties which could be used for preventing blood clots, and thereby reducing the incidence of stroke.

A Swiss form of claim is in effect a claim for a process. Section 3(d) of the Patents Act does not allow patents for any new property or new use for a known substance. Even in the absence of section 3(d), Swiss claims will not be allowed under section 3(i) of the Patents Act. If patents in the form of a Swiss claim were to be granted, they will stand the risk of being revoked under section 64(1)(l) if the invention was used earlier in India.

#### **vii. Explanation to Section 3(d)**

A known substance is defined in the explanation as substances having similar properties with regard to efficacy. It is made clear that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy. What would be a significant difference in efficacy, will vary from case to case and from substance to substance, there being no universally applicable guidelines for the same. The Patent Office has issued guidelines for examination of applications pertaining to chemical and pharmaceutical inventions detailing the manner in which the above explanation will be applied.

#### **viii. Bioavailability of Drugs**

Drugs are not invented in the manner in which it is finally available to the market. Lead compounds are invented which may ultimately result in the drug. The lead drug is a compound which has a number of attractive properties like desired biological or pharmacological activity, but may also have a host of undesirable properties like high toxicity, adsorption difficulties (bioavailability), insolubility or metabolism problems. One of the important characteristics of any drug is its bioavailability. Bioavailability determines the extent to which, and rate at which, a drug appears in the bloodstream after administration in dosage form. Where the bioavailability of one drug is the same as another drug (or the bioavailability of two different formulations of the same drug are the same) they are said to be bioequivalent.

It is a common practice to modify the structure of the lead compound to amplify the desired properties and to suppress or eliminate the unwanted properties. The resultant drug is known as the drug candidate, which is a compound worthy of extensive biological, pharmacological

and animal studies. The drug candidate is then developed into a clinical drug, which is a compound ready for clinical trials.

The preparation of a drug will normally involve the pre-formulation stage and the testing stage. In the pre-formulation stage, the formulator will be given an appropriate specification which would, for instance, define the drug dosage to be incorporated and whether the formulations should provide for the immediate release of the drug or a more controlled release. The formulator will also have basic information about the physicochemical properties of the drug, including information about the solubility of the drug in aqueous and other media, the stability of the drug in solution; and interactions between the drug and excipients that might be required in preparation of the dosage form. In the testing stage, the formulator would perform dissolution studies in order to ascertain the dissolution rate of the drug which would give an indication of the likely bioavailability of the drug. Where the drug had a slow dissolution rate, the formulator would know that it was likely to have poor bioavailability. If the drug had a slow dissolution rate, the formulator would know techniques to improve it, such as reduction of particle size and using excipients (inert substances) to ensure that the dosage form is wetted easily, and quickly breaks up to release the drug into the surrounding fluids.

## COMPULSORY LICENSING

### I. INTRODUCTION

The grant of a patent confers limited monopoly on the patentee to the exclusion of others. Though the law permits this, it also takes into account the fact that the monopoly granted through a patent may be abused and hence, provides for certain restrictions to its enjoyment.<sup>417</sup> The grant of compulsory licence is one such restriction imposed on the absolute exploitation of a patent. Restrictions on the monopoly existed even in the early days, as is evident from the Statute of Monopolies which made a patent void if the grant was prejudicial or inconvenient to the King's subjects and provided for revocation of a patent on the ground that the patentee neglected to work the patent. In India, the provisions on compulsory licensing were introduced into the Patents Act pursuant to the recommendations made by the Ayyangar Committee.

### II. PROVISIONS UNDER THE ACT

The provisions on compulsory licences are detailed in chapter XVI of the Patents Act. This chapter was substantially amended by the Patents (Amendment) Act 2002. Before the said amendment, the chapter consisted of sections 82 to 98 and included provisions on 'Licences of right'. The Patents (Amendment) Act 2002 omitted the provisions on 'Licences of right' and resultantly the chapter and the Patents Act now remains devoid of sections 95 to 98. Presently, sections 82 to 94 deal with working of patents, compulsory licences and revocation for non-working. A brief statement of law before the Patents (Amendment) Act 2002, which came into effect from 20 May 2003, will be helpful in understanding the changes brought about by the said amendment which are largely in compliance with the provisions of the TRIPS Agreement.

The Patents (Amendment) Act 2002 brought about substantial changes to the earlier provisions of chapter XVI. Section 83 deals with the general principles applicable to the working of patented inventions. Before the said amendment, the said section had only two clauses, i.e., clause (a) and (b). The Patents (Amendment) Act 2002 introduced clause (c) to (g). Section 84 as it existed before the amendment provided for the applicant to pray 'for the grant of a compulsory licence to work the patented invention'. The present provision refers to

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<sup>417</sup> Section 140 & 141, Patents Act, 1970.



'grant of compulsory licence on patent'. Section 85 of the Patents Act, as it was before the amendment, now figures as section 84(6). The earlier provision was devoid of clause (iv). Sections 86, 87 and 88 of the Patents Act, in its original form, dealt with 'Licences of right'. The provisions on 'Licences of right' were completely removed by the Patents (Amendment) Act 2002. Section 89 of the original Act now exists as s 85 with appropriate modifications removing the provisions on 'Licences of right'.

Section 90 of the Patents Act, in its original form, dealt with situations where the reasonable requirements of the public were deemed not to have been satisfied. The said section as it was before the amendment, now figures as section 84(7) with some modifications. Section 84(7) now contains clause (c), which deals with conditions imposed by the patentee 'to provide exclusive grant back, prevention to challenges to the validity of patent or coercive package licensing'. Importantly, the Patents Act no longer contains the provision on importation which existed as section 90(d) of the Act before the amendment.

### **III. PROVISIONS UNDER TRIPS AGREEMENT**

Article 27(1) of the TRIPS Agreement provides that 'patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced'. As a part of the principle of national treatment enshrined in the WTO Agreement as well as the TRIPS Agreement, the compulsory licensing provisions have to be applied equally without any discrimination between persons who choose to import and persons who choose to manufacture domestically.

Article 31 of the TRIPS Agreement provides for certain conditions to be taken into account where the law permits certain kinds of uses without the authorisation of the right holder, which includes the grant of compulsory licences. Article 40 of the TRIPS Agreement allows member countries to take measures on those acts of the right holder which may restrain competition. The member countries may specify in their legislation such licensing practices or conditions pertaining to intellectual property rights which may have adverse effect on trade, and may impede the transfer and dissemination of technology. The member may adopt measures to prevent or control such practices which may include exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that member.

#### IV. GENERAL PRINCIPLES ON WORKING OF PATENT

Under chapter XVI of the Patents Act, any person can make an application to the Controller for grant of compulsory licence on patent on the ground that the patented invention is not worked in the territory of India. Working of the patent in India is different from the requirement of utility. An invention may be of perfect utility, but the patentee may choose not to work the invention in India to stifle competition. For the purpose of chapter XVI, the working of a patent is linked with the grant of compulsory licence on the patent.

In exercising the powers under chapter XVI on matters pertaining to compulsory licensing, the following general considerations shall be taken into account:<sup>418</sup>

- (1) Patents are granted for the general object of encouraging inventions and to secure that the inventions are worked within India on a commercial scale. The working of the patent is important if the patent is to remain effective. The expression that patents are to be worked 'to the fullest extent that is reasonably practicable without undue delay' will include manufacture of the patented article domestically.
- (2) Patents are granted for working the patented invention in India. They are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.
- (3) The protection and enforcement of patent rights contributes to the promotion of technological innovation and to the transfer and dissemination of technology.
- (4) The grant of patents should not impede protection of public health and nutrition. Patents should act as instruments to promote public interest, especially in areas of vital importance for socio-economic and technological development in India.
- (5) The grant of patents does not prohibit the Central Government in taking measures to protect public health. The Doha Declaration on TRIPS and public health further reiterates this point.
- (6) The patent right should not be abused and practices which unreasonably restrain trade or adversely affect the transfer of technology should not be resorted to.
- (7) Patents are granted to make the benefit of patented invention available at reasonably affordable prices to the public.

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<sup>418</sup> Section 83, Patents Act, 1970.

## V. APPLICATION FOR GRANT OF COMPULSORY LICENSES

Any person interested shall make an application for the grant of compulsory licence to the Controller in Form 17.

Chapter XVI provides for the grant of compulsory licences in different circumstances. The procedure followed in granting the licences and the grounds on which an application can be made differ significantly. The procedures and grounds for the grant of compulsory licences are in the following sections. An application for compulsory licence may be made under the following provisions: (1) Application under section 84; (2) Application under section 91; (3) Application under section 92; (4) Application under section 92A.

The applicant must establish a prima facie case for the grant of a compulsory licence in its favour.<sup>419</sup> The procedure laid down in section 87 requires the Controller to be satisfied 'that a prima facie case has been made out for the making of an order'. Section 87 is applicable for applications made under sections 84, 85 (application for revocation of patent), 91 and 92(1). However, section 92(3) expressly excludes the procedure laid down in section 87 and hence, a prima facie case need not be made out in the case of an application considered under section 92(3). Similarly, an application under section 92A need not make out a prima facie case. The Controller shall grant a compulsory licence if the situations stated in section 92A(1) are present.

If upon the consideration of evidence, the Controller feels that no prima facie case has been made out by the applicant, he shall notify the applicant. Within one month from the date of such notification, the applicant shall request for a hearing. If no request for hearing is made, the Controller shall refuse the application. Thus, if no prima facie case is made out, the application would be dismissed. If the applicant makes request for hearing, the Controller shall give the applicant an opportunity of being heard, and then determine whether to proceed with the application or to refuse it. To establish a prima facie case the applicant is only required to produce sufficient evidence to substantiate his case, it is immaterial whether such evidence is the best evidence.

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<sup>419</sup> Rule 97, Patent Rules, 2003.

### **i. Who Can Apply?**

Any person who has an interest in the patented article is eligible to make an application for compulsory licence. A person who is currently the holder of a licence under the patent may also prefer an application for compulsory licence. The licence holder shall not be estopped from alleging the grounds under the Patents Act by the reason of any admission made by the licence holder in such a licence or otherwise. The applicant need not admit the validity of the patent and is entitled to challenge the patent separately. However, such challenge may delay the application for compulsory licence as the grant of licence will be subject to the outcome of the challenge. Even the fact that the licence holder has accepted such a licence will not be a ground to prevent the licence holder from applying for a compulsory licence on the grounds mentioned in section 84(1).

Every application, save the one made by the Central Government, shall set out the nature of applicant's interest, and the terms and conditions of the licence which the applicant is willing to accept.<sup>420</sup> The application shall contain a statement setting out the nature of the applicant's interest along with the necessary particulars and facts. In determining who is an interested person, the Controller shall take into account, if the applicant is an existing licensee, the measures already taken by the licensee to make full use of the invention. The ability of the interested person to work the invention to the public advantage and his capacity to take the risk in providing capital and in working the invention shall also be relevant.

The applicants should show that they have the ability to work the inventions and that 'the applicants are likely to have available to them the various resources, including technical expertise and know-how, which would be necessary to put the inventions into practice in a way which would benefit the public'. It is not necessary for the applicant to show a definite intention to work the licence, but a genuine interest is necessary to found an application. The mere fact that other manufacturers could more satisfactorily exploit the invention than the applicant cannot be a ground for refusal so long as such other manufacturers failed to apply for a compulsory licence. If, on evidence, it is shown that the applicant could properly exploit the invention, the compulsory licence should be granted.

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<sup>420</sup> Rule 96, Patent Rules, 2003.

## ii. Procedure

In an application made under section 84 or section 85 of the Patents Act, if the Controller is satisfied that the time which has elapsed since the grant of patent has not been sufficient to work the invention on a commercial scale or to enable the invention to be worked to the fullest extent, the Controller may by order adjourn further hearing of the application for a period aggregating to not more than 12 months. This provision ensures that sufficient time is given to work an invention. The elapse of time is to be computed from the date of 'grant of the patent' and not from the date of 'sealing of patent', as mentioned in section 86(1).

If the inability to work the patented invention is due to a restriction imposed by a Central or state Act, rule or regulation or order of Government, then the period of adjournment shall be computed from the date on which such restriction expires. An adjournment shall not be ordered if the Controller is satisfied that the patentee has not taken adequate steps to start working the invention in India on a commercial scale. When an application is made to the Controller and the Controller is satisfied that a prima facie case for making a grant has been made out, he shall direct the applicant to serve copies of the application upon the patentee and other interested persons. The Controller shall publish the application in the Official Journal. If necessary, the Controller may require the applicant to file a draft licence along with the application.

The patentee or any interested persons intending to oppose the application, may, within the time stipulated, give notice of opposition to the Controller containing the statement setting out the grounds of opposition. An exclusive licensee may also oppose an application. Upon receipt of the notice, the Controller shall notify the applicant and shall give the applicant and the opponent an opportunity to be heard.<sup>421</sup>

Notice of opposition shall be given in Form 14 and shall be sent to the Controller within two months from the date of publication of the application in the Official Journal. Where the opponent is the patentee, the notice may include the terms and conditions of the licence which the patentee is prepared to grant. The notice shall be accompanied by evidence supporting the opposition. The opponent shall serve a copy on the applicant and shall notify

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<sup>421</sup> Section 87(4), Patents Act, 1970.

the Controller of such service. The Controller shall fix a date for the hearing of the opposition, which will be conducted like a post-grant opposition hearing.<sup>422</sup>

### **iii. Factors to be considered for Grant**

Sub-section (6) of section 84 of the Patents Act contains a list of factors that have to be taken into account in considering an application filed for the grant of a compulsory licence. The Controller shall consider the following: (1) the nature of the invention and the time that has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention; (2) the ability of the applicant to work the invention to the public advantage; (3) the capacity of the applicant to undertake the risk in providing capital and working the invention after the licence is granted; (4) whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts were not successful within a reasonable period not ordinarily exceeding six months.

The fourth factor mentioned above shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practice adopted by the patentee. The Controller need not take into account matters subsequent to the making of application.<sup>423</sup>

### **iv. Burden of Proof**

The burden of proof is on the applicant to show that the grounds for the grant of compulsory licence exist. In fact, applications made under sections 84, 85 (application for revocation of patent), 91 and 92(1) require the applicant to make out a prima facie case. The onus will be on the applicant to establish that the patented invention is not being worked to the fullest extent that is reasonably possible, i.e., at the rate of production which is practicable and necessary to meet the demand of the patented invention. In such cases, the onus is on the applicant to establish that the invention is not worked to the 'fullest extent that is reasonably practicable'. The applicant has 'to bring evidence to show what the demand for the invention might reasonably be expected to be, and how far short, if at all, production under the patent fails, as far as is practicable to supply it'.

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<sup>422</sup> Rule 62, Patent Rules, 2003.

<sup>423</sup> Section 84(6), Patents Act, 1970.

## **VI. GENERAL COMPULSORY LICENSES – SECTION 84 APPLICATION**

Section 84(1) of the Patents Act details three broad grounds, the existence of any of which may be a ground for an applicant to seek a grant of compulsory licence. The three grounds are:

- (a) the reasonable requirements of the public with respect to the patented invention have not been satisfied, or
- (b) the patented invention is not available to the public at a reasonably affordable price, or
- (c) the patented invention is not worked in the territory of India.

### **i. Reasonable Restrictions of Public**

Sub-section (7) of section 84 of the Patents Act mentions the situations in which the reasonable requirements of the public shall be deemed not to have been satisfied. The law attempts to include situations where anti-competitive practices can be countered by the grant of a compulsory licence.

A refusal implies that the applicant had made a request to the patentee and the patentee had refused to grant a licence on reasonable terms. The refusal of the patentee to grant licence under the above provision relates to licences that are different from the exclusive licences. Section 84(7)(a) details the instances where the refusal of the patentee to grant a licence on reasonable terms shall result in the reasonable requirements of the public not being satisfied, if it leads to the following four situations.

The Patents Act employs the expression 'prejudiced' without any qualifications in section 84(7). It employs the expression 'unfairly prejudiced' in section 89(b). Section 89 provides that the powers of the Controller in a section 84 application shall be exercised with a view to secure some general purposes, which includes unfair prejudice that may be caused to 'the interest of any person for the time being working or developing an invention in the territory of India under the protection of a patent'. The Patents Act also uses the expression 'unduly prejudiced' in the context of termination of compulsory licences.

For the purpose of section 84(7), any prejudice caused to the trade or industry in India will suffice. In any case, the difference between 'prejudiced' and 'unfairly prejudiced' is not

significant as it could be expected of the Controller to consider the public interest whether or not he was specifically directed to do so. The Controller will be required to take into account the ability of any person to whom a licence would be granted under the order to work the invention to the public advantage.

The reasonable requirements of the public will not be deemed to have been satisfied if the refusal of the patentee to grant a licence results in the demand for the patented article not being met to an adequate extent or on reasonable terms. A demand may be a demand for domestic consumption or for export. The patentee may take a plea that there is no demand for the patented article. In United Kingdom, the absence of any demand for the patented article in that country will not be a valid excuse. But where the technology of the invention was surpassed and it was not commercially viable to establish a manufacture of that invention in United Kingdom, the patentee's action of charging royalties on imported French cars containing the patented mechanism will be regarded as not meeting the demand. If, pursuant to an application made for a compulsory licence, the patentee starts manufacture in that country where it was previously meeting the demand for the patented article by importation, it will not be open for the patentee to contend that the demand for the patented article was met to an adequate extent.

Under the ground that the demand for a patented article has not been fully met, it should be shown that the demand must be an actual one and not merely one which an applicant hopes or expects to create. The conditions stated in section 84(7)(a)(ii) of the Patents Act require that the demand for the patented article must not have been met to an 'adequate extent' or on 'reasonable terms'. The latter expression introduces the element of affordability and in determining the demand for the patented article, the price stipulated for such an article will be relevant. Thus, if the price charged for the patented article made in a country is higher than that charged for the imported article, the bona fides of the price may be looked into. The Controller can consider whether the price is a bona fide one and is not a price adapted for the very purpose of checking and diminishing the demand for the home-manufactured article.

The reasonable requirements of the public will not be deemed to have been satisfied if the refusal of the patentee to grant a licence results in a situation where a market for export of the patented article manufactured in India is not being supplied or developed. The Patents Act provides for the grant of a compulsory licence for supply and development of a market for export of a patented article manufactured in India. In determining whether the demand for the



patented article has been met under section 84(7)(a)(ii), the condition under section 84(7)(d) that the patent is not being worked 'to the fullest extent that is reasonably practicable' shall also be considered.

The reasonable requirements of the public will not be deemed to have been satisfied if the refusal of the patentee to grant a licence prejudices the establishment or development of commercial activities in India. The foregoing explanation of the expression 'prejudiced' will be applicable to the above ground as well.

The reasonable requirements of the public will not be deemed to have been satisfied if the conditions imposed by the patentee upon the grant of licence under the patent or upon the purchase, hire or use of the patented article or process, prejudices: (1) the manufacture, use or sale of materials not protected by the patent; or (2) the establishment or development of any trade or industry in India.

The reasonable requirements of the public will not be deemed to have been satisfied if the patentee imposes a condition upon the grant of licences under the patent for: (a) exclusive grant back; or (b) prevention to challenges to the validity of patent; or (c) coercive package licensing. Coercive package licensing includes instances where the patentee may insist upon licensing a group of patents together and stipulate royalties on non-patented articles. In certain cases, the patentee may impose restrictive conditions for the grant of a licence in such a manner that it would defeat the very purpose of such grant. Such conditions will have the effect of not satisfying the reasonable requirements of the public.

The reasonable requirements of the public will not be deemed to have been satisfied if the patented invention is not being worked in India on a commercial scale to an adequate extent or if it is not being so worked to the fullest extent that is reasonably practicable. The Controller may require a patentee or licensee to furnish information as to the extent to which the patented invention has been commercially worked in India.<sup>424</sup> The patentee or the licensee may furnish a statement in Form 27 with regard to the extent to which the patented invention has been worked on a commercial scale in India.

A compulsory licence will be granted if the patented invention is not worked to the fullest extent that is reasonably practicable. An applicant making an application on the above ground

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<sup>424</sup> Section 146(1), Patents Act, 1970.

will have to establish the demand expected for the patented invention and the extent to which it has not been satisfied. As a defence to reject the application, the patentee has to show that the invention is being presently worked in the country on the date of the application for compulsory licence. Reliance on the fact that the invention was once worked and then discontinued will not be a sufficient defence.

### **ii. Invention not available at Affordable Price**

A compulsory licence on the patent may be granted if the patented invention is not available to the public at a reasonably affordable price. Section 84(1)(b) overlaps with section 84(1)(a) as one of the conditions where the reasonable requirement of the public shall be deemed to have been not satisfied includes instances where the demand of the article has not been met on reasonable terms.

In a case involving a licence of right, it was held that if the price was reasonable and demand at that price was being met, it will not be relevant to consider whether the demand would have been greater at a lower price. In determining whether the price is reasonable, the court shall take into account the fact that the patentees and licensees who are engaged in the research and development of drugs may exercise their monopoly during the term of the patent to recoup their research and development expenditure and make a profit. An undertaking from the dealers and licensees that the licensees shall not sell articles below a specified price which resulted in the article being sold at a higher price locally than abroad, will not make the price prohibitive or unreasonable in the absence of any evidence to that effect.

### **iii. Patented Invention not worked in India**

A compulsory licence on the patent may be granted if the patented invention is not worked in the territory of India. The above ground overlaps with section 84(1)(a) of the Patents Act as the conditions where the reasonable requirement of the public has not been satisfied includes the grounds under section 84(7)(d) and (e). Clauses (d) and (e) of section 84(7) explain the conditions where the patented invention is not worked in India. If the Controller is satisfied that the patentable invention does not satisfy the reasonable requirements of the public or is not worked in India or is not available at an affordable price, the Controller may grant the licence upon the terms that he deems fit. The Controller may also grant a compulsory licence where the working of the patented invention is prevented or hindered by the import of the

patented article from abroad. The fact that the patentable invention is not worked in India can be a separate ground in itself, distinct from the reasonable requirement of public, for the grant of a compulsory licence.

There may be many reasons as to why an invention may not be worked by the patentee or its licensee. Where the patentee takes a plea that it did not have enough time to exploit the invention commercially, the Controller shall determine the date of sealing (the date of grant under the Patents Act) of the patent before considering such a plea. If special tools or specially skilled labour have to be imported into a particular country to work a patented invention, it will be regarded that the patented invention is not capable of being worked in that country. Inventions which work under a licence in one country but do not work in another can lead to a situation where the patentee should explain the non-working. In some cases, the working of a patent would be prevented by threat of an infringement due to the existence of another patent, as such working may lead to infringement of the other patent.

#### **VII. LICENSING OF RELATED PATENTS – SECTION 91 APPLICATION**

At any time after the grant, any person who has the right to work any other patented invention either as patentee or licensee may apply to the Controller for the grant of licence of the first mentioned patent on the ground that he is prevented or hindered without such licence from working the other invention efficiently or to the best advantage possible. In order to procure a licence of related patents, the applicant will have to satisfy the following conditions: (a) that the applicant is able and willing to grant, or procure the grant from the patentee and his licensees if they so desire, a licence in respect of the other invention on reasonable terms; and (b) that the other invention has made a substantial contribution to the establishment or development of commercial or industrial activities in the territory of India.]

If the above conditions are satisfied, the Controller may make an order on such terms as he thinks fit granting a licence under the first mentioned patent and a similar order under the other patent if so requested by the proprietor of the first mentioned patent. A licence granted under the above section shall be non-assignable except with the assignment of the related patents. The provisions on the procedure (section 87), powers of Controller (section 88), general purposes (section 89) and terms and conditions (section 90) of the grant of licences of related patents under section 91 shall be the same as that of licences granted under section 84.

## **VIII. SPECIAL COMPULSORY LICENSES – SECTION 92 APPLICATION**

A compulsory licence may be granted to work an invention, if the Central Government is satisfied that certain special circumstances exist for such a grant. Section 92 of the Patents Act encompasses the principles contained in article 31(b) of the TRIPS Agreement. The Central Government may, by notification in the Official Gazette, make a declaration that it is necessary to grant compulsory licence in respect of any patent in force to work the invention in: (a) circumstances of national emergency; or (b) circumstances of extreme urgency; or (c) cases of public non-commercial use.

An application for compulsory licence under section 92(1) may be made at any time after the grant of the patent. Such an application can be made immediately after the grant of the patent. The applicant need not wait for the expiry of three years from the date of grant before making the application. But it can only be made after the Central Government makes the notification in the Official Gazette. The Controller shall, on an application made by any person interested, grant the applicant a licence under the patent on such terms and conditions as he thinks fit. In settling the terms and conditions of such a licence, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patents. The provisions on the general principles on working of patented inventions (section 83), procedure (section 87), powers of Controller (section 88), general purposes (section 89) and terms and conditions (section 90) of the grant of licences under section 92 shall be the same as that of licences granted under section 84.

Section 92(3) envisages a fast-track procedure. It empowers the Controller to circumvent the procedure laid down in section 87 in the case of an application made under section 92(1)(i). The Controller may use his discretion not to apply the procedure in section 87 for such an application. Section 87 deals with a common procedure for dealing with applications for compulsory licences made under sections 84, 91 and 92(1). The procedure stipulated in section 87 requires the following: (a) the applicant should make out a prima facie case; (b) the applicant shall serve copies of the application on the patentee; (c) the Controller shall publish the application in the official journal; (d) the patentee may oppose the application by giving notice of opposition; and (e) the Controller shall give the parties a hearing before deciding the case. Thus, in the case of an application considered under section 92(3), the applicant need not make out a prima facie case.

Section 92(3) deals with special circumstances like national emergency, extreme urgency or public non-commercial use which may arise. It expressly includes public health crises relating to Acquired Immuno Deficiency Syndrome (AIDS), Human Immuno-deficiency Virus (HIV), tuberculosis, malaria or other epidemics. The Controller shall however inform the concerned patentee, as soon as practicable, about the non-application of section 87.

## **IX. COMPULSORY LICENSE FOR EXPORT OF PHARMACEUTICALS – SECTION 92A APPLICATION**

The Patents (Amendment) Act 2005 introduced a new provision for the grant of compulsory licence for the export of patented pharmaceutical products. Section 92A reflects the principles contained in art 31(b) of the TRIPS Agreement. The above section defines 'pharmaceutical products' to mean 'any patented product, or product manufactured through a patented process, of the pharmaceutical sector, needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use'.

For the grant of a compulsory licence under section 92A, the following conditions need to be satisfied: (a) the compulsory licence shall be solely for manufacture and export of patented pharmaceutical products; (b) the export should be to a country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems; (c) a compulsory licence should have been granted by that country or that country should have, by notification or otherwise, allowed importation of patented pharmaceutical products from India. Unlike other provisions for the grant of compulsory licences, the grant under section 92A is not subject to the satisfaction of the Controller. Where the above conditions are satisfied, the grant should follow. As in the case of an application considered under section 92(3), the Controller need not apply the provisions of section 87 in granting a compulsory licence for export of patented pharmaceutical products. Thus, there is no requirement for the applicant to make out a prima facie case.

On the receipt of an application under section 92A, the Controller shall grant a compulsory licence solely for manufacture and export of the pharmaceutical product on such terms and conditions that the Controller may specify. The Controller shall publish such terms and conditions, thereby informing the patentee of his decision. Section 92A(3) clarifies that the provisions of section 92A shall be without prejudice to the extent to which pharmaceutical

products produced under a compulsory licence can be exported under the other provisions of the Patents Act.

## **X. TERMINATION OF COMPULSORY LICENSE**

An application may be made by the patentee or any interested person, under section 94, to the Controller for the termination of a compulsory licence granted under section 84 on the ground that the circumstances under which the licence was granted no longer exist and they are unlikely to recur. The holder of the compulsory licence shall have a right to object to such termination. In considering an application for termination, the Controller shall have regard to the fact that the interest of the person who had previously been granted a compulsory licence is not prejudiced. The above section reflects the principle contained in article 31(g) of the TRIPS Agreement.

An application for termination of compulsory licence granted under s 84 shall be made by the patentee or any other person as given in Form 21. The application shall be supported by the necessary evidence.<sup>425</sup> The applicant shall serve a copy of the application and evidence, on the holder of the compulsory licence and shall inform the Controller of the service. Within one month from the receipt of the application and evidence, the holder of compulsory licence may file his objection along with evidence to the Controller and serve a copy on the applicant.<sup>426</sup> Once the pleadings are complete from either side, the Controller may fix a date and time for hearing the case after giving notice to the parties. The procedure of such hearing shall be the same as that of post-grant opposition. If the Controller decides to terminate the compulsory licence, he shall issue an order giving the terms and conditions of such termination and shall serve copies on the parties.

## **XI. APPEALS**

Article 31(i) of the TRIPS Agreement provides for judicial review of decisions granting compulsory licences. Section 117B provides for an appeal from the decision of the Controller to the Appellate Board of orders passed under sections 84(1) to (5), 85, 88, 91, 92 and 94. It is submitted that the references to sub-sections (1) to (5) of section 84 are misleading as an order is passed only under section 84(4) which can be the subject matter of an appeal. The

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<sup>425</sup> Rule 102(1), Patent Rules, 2003.

<sup>426</sup> Rule 102(3), Patent Rules 2003.

Patents Act provides for an appeal from an order passed by the Controller in the following cases:

- (1) An order granting a licence under section 84(4);
- (2) An order revoking a patent under section 85(3);
- (3) An order granting licences to customers of the applicant under section 88(1);
- (4) An order cancelling or amending an existing licence under section 88(2);
- (5) An order reviewing the terms and conditions of a licence under section 88(4);
- (6) An order granting a licence of a related patent under section 91(3);
- (7) An order granting a licence under section 92(1)(i); and
- (8) An order of termination of compulsory licence under section 94(1).

It is important to note that an order passed by the Controller under section 92A cannot be the subject matter of an appeal under the Patents Act. Such orders can be judicially reviewed by exercising the writ jurisdiction of the high courts. The right to appeal from a decision of the Controller would exist regardless of whether the patentee opposed the application.

## ASSIGNMENT

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