

# Compulsory Licensing of Patents - A Comparative Analysis of Japanese and Indian Practices (\*)

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*The TRIPS agreement has brought a basic universal common denominator on various Intellectual Property segments among the member states of World Trade Organization. Yet in practice there are considerable differences among the Nation States and standpoints between Developed Nations and rest of the world. One of the issues is that of award of compulsory licenses and its impact on patent system. In Asian context, Japan and India both have compulsory licensing provisions based on public interest in their respective statutes. India awarded the first compulsory license in 2012 in the field of drugs and it had a widespread support for CL among civil society groups and academia in India to use CL as an effective tool to counter the issue of prices and access to its population. In contrast Japan has not so far issued and has its interpretation for a pro-patent regime reflected in its 2013 “Japan Revitalization Strategy” and the Japanese Cabinet approved the “Basic Policy Concerning Intellectual Property Policy” where the emphasis is on global acquisition and effective use of IPR. This research aims to study the divergent approaches towards Compulsory licenses of these two Asian countries- and to disseminate the reasons and logic of such approaches.*

## I Introduction

The evolution of Intellectual Property (IP) in different parts of the world in the last three centuries had its foundation based on diverse theoretical justifications. If one has to condense them to few broad aspects which has led to legislative efforts it can be listed as: a. to provide incentive to the creator/inventor for disclosure to the public b. to have a limited monopoly to recoup the investments in such efforts c. to allow the same to enter the public domain after a period of monopoly and d. to provide legal channels to challenge and overcome abuses using such monopoly and finally e. the right of the government to intervene to manage such rights for public interest. In modern times the Intellectual Property System has evolved as a complex regime where investments and trade has a huge stake as Institutional (public and private) players embark on research & development in case of inventions and technological platform based dissemination and distribution in case of other creative industries.

The research undertaken by the scholar would like to focus on the patent system among the other forms of Intellectual properties and specially that of the interface of patents and health to deal with concept and practice of ‘Compulsory License’ (CL) and its appropriate justifications in the landscape of the patent system. This paper proposes to look key issues of the public interest foundation of the patent system, the conditions for monopoly grants, abuse of monopolies, issues of access, legislative and judicial interventions based on public interest. This paper will analyze

the comparative policy and practice of India and Japan in terms of the legal framework of compulsory licensing mechanism and how in practice it has shaped in the recent times.

Indian Patent Act of 1970 under section 84<sup>1</sup> deals with compulsory licensing whereas the Japanese Patent Act of 1959 under article 93<sup>2</sup> under the (Award granting non-exclusive license for public interest). A comparative analysis throws the convergence in legislative provisions and yet divergence in practice which has various factors of the business aspects and socio-economic factors which forms the analysis and conclusion of this research paper.

## II Patents and Public Interest

The theoretical foundations for Intellectual Property laws are found in various loosely defined legal doctrines enunciated by scholars from the fields of law, economics and management. Such foundations are often grouped broad approaches of that of Natural Rights, Utilitarian, Person hood theories. The Natural Rights perspective of Locke<sup>3</sup> Utilitarian concept espoused by Jeremy Bentham<sup>4</sup> justified monopolies to encourage innovations aimed at benefit to the larger society revolves around two premises – firstly, the justification of monopolies to result in creating an ecosystem of innovations and creations and secondly such instruments are tools to benefit the public at large.

In United Kingdom in the year 1449 the grant of a

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(\*) This is a summary of the report published under the 2014FY Industrial Property Research Promotion Project (2014FY-2016FY) Entrusted by the Japan Patent Office.

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patent invention to John of Utynam with a monopoly for a period of 20 years for a glass making is quoted by various sources<sup>5</sup>. The later monopolies granted by the crown resulted in wide spread crisis and this resulted in the enactment of the 1624 Statute of Monopolies in UK. The French Patent Act in 1791- later amended in 1800 and 1844 matched the developments in the United Kingdom. A notable exclusion from patents was that of Medicines during that period. The German efforts started in the enactment of the Unified National Patent Act of 1877. Further legislations enacted undertook to revoke non-working patents after three years and the provision to revoke it is against that of public interest including the provision of compulsory licenses. United States passed its first Patent Act in 1790. However From its early legislation United States had the philosophy of compulsory licenses as an impediment to that of the innovation and equated individual efforts to innovation and protection as a social welfare principle. Japan passed the Patent Act of 1921 had the features of state compensation to revoke patents in public interest and at that point excluded Medicines, food and chemical product patents and allowed only processes, which changed with later developments in other nations. The later day entrants like India, China and other countries in Asia, Africa, Latin America and Canada have introduced intervention instruments in their Act on the issue of public interest. However the grounds and practice have variations by countries. The variations include public interest, non-use of patented inventions, national emergencies and insufficient capacity to work the patent. The issue of linking compulsory licenses is not explicit in many national IP regimes but has the potential to be interpreted.

The WIPO study in 2011 on legislative aspects relating to Compulsory Licenses interfacing anti-competitive practices revealed the divergent positions of the approaches to Compulsory License especially that of European Union (EU) and United States (US) the two dominant players in the space of Patents among the 38 respondents. The EU position indicated that the rights of the IP could be granted under the competition law, which is akin to that of the compulsory license if there an abuse of a dominant player is proved under the relevant laws under the ‘Essential Facilities Doctrine’<sup>6</sup> where as the United States took the interpretation that the competition law has no link with compulsory license and sought to address the issue of anti-competition by other outcomes such as voluntary license, injunction, civil penalties, relief by a federal court, cease and desist order and consumer redress by the approach of ‘Rule of Reason’<sup>7</sup>.

### **III International Perspectives of limitations on Patent Rights**

The evolution of Patent system among various Nation States also had parallel efforts in the realm of International Law. Starting with Paris Convention to that of the World

Trade Organization (WTO) led Trade Related Intellectual Property Rights (TRIPS) agreement, the attempts to harmonize with mutual and minimum standards for protection of global trade has a modest progress. The analysis of the ‘three instrumentalities’ from the view point of the researcher are discussed as – Paris Convention and Compulsory License, WTO-TRIPS and Compulsory License and Doha declaration and Compulsory License in this chapter.

Under Paris convention there are two schools of argument on the interpretation of Article 5 A of Paris Convention where there is an argument that it does not explicitly mention about ‘public interest’ and a counter argument that the Article 5A – paragraph two pointing out the freedom of the members of the Union to take measures to prevent abuses and failure to work is only one example of that.<sup>8</sup>

The second landmark harmonization effort of Patent System resulted in the form of TRIPS agreement as part of the WTO in 1995. The agreement reiterated the Paris convention provisions by B. Article 8<sup>9</sup>- The Doha declaration further reaffirmed and cleared the ambiguities of TRIPS provision where the provisions of TRIPS were clarified. The clarification had the following central aspects- a. allowing compulsory license by governments without the consent of the patent owner b. the CL to be mainly for the domestic market and not for export c. need for a negotiation with the patent owner before award of CL d. adequate compensation to the right holder in case of CL e. members free to decide the grounds for CL f. can bypass voluntary license in case of emergency or extreme urgency g. the patent owner’s right to a legal review of the granted CL h. to allow for making generic copies for export in case of inadequate capacity by the desiring member state.

### **IV Comparative Analysis of Japanese and Indian Practices**

The opening and adopting of the successful strategies of the European powers and the rising American power led Japan embrace Intellectual Property models of France and US as early as 1885 with the enactment of the Statute of Monopoly Patent. The law as in many other countries went through changes and resulted in the postwar Patent Law of 1959, which came into effect in 1960. The period between 1960-80 was more that of a catch-up game with the innovations happening in the western countries and applied successfully into finest manufacturing process in Japan.

The last decade saw a big push of IP in Japan’s policy arena and has been reiterated in 2013 with the “Japan Revitalization Strategy” and the Japanese Cabinet approved the “Basic Policy Concerning Intellectual Property Policy”. On the subject of Compulsory licenses, The Japanese Patent Act of 1959 as amended in 1990 under the Chapter IV- 1

Patent Rights – provision 93 provides for CL where if there is no agreement reached between the holder and the seeker of CL the Minister for International Trade and Industry is entitled for an arbitration decision to award a CL.

The Japan Patent Office (JPO) in its clause-by-clause explanation of Industrial Property Law states the official position of the implementation of this provision.<sup>10</sup> In the various interview conducted by the researcher with Prof. Shigeo Takakura<sup>11</sup> of the law School of Meiji University, Akiko Kato,<sup>12</sup> Associate Professor of the Graduate School of Intellectual Property at Nihon University and Officials of the Japanese Generic Medicines Association (JGMA)<sup>13</sup> in Tokyo on the issue of Compulsory licenses it emerged the concept of public interest is interpreted as a stable industrial development and its facilitation than that of the pricing and affordability issues. The issues of non-access to be met by other instrumentalities like universal insurance access rather than restricting and removing patent rights. Emphasis was on negotiated settlement and arbitration methods and only as a last resort the intervention by the Minister is envisaged which explains the non-issuance of CL in Japan so far.

In comparison an analysis of the Act LXXXII of 1950 in India, amended in 1952, the subsequent Indian Patent Act 1970 and the revised Patent (Amendment) Act of 2005 will reveal the strong policy perspective of compulsory license in the Indian patent landscape. This provision specifically was kept to address public health issues as a priority over the concept that Indian Pharma will come out with new drugs. It is in 2012 when the first CL was issued by the CG of the Indian Patent Office (IPO)<sup>14</sup> for NATCO Pharma against Bayer Corporation the judicial review came into the fore to test the legal validity of the provisions of section 82 of the Indian Patent Act. After the refusal of Bayer to negotiate for a voluntary license for its drug ‘Sorafenib’ (Carboxy Substituted Diphenyl Ureas) marketed as Nexavar for treating advance stage kidney and liver cancer, NATCO approached the Controller General of Patents in India to award a CL. The CG awarded the CL based on (a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or (b) that the patented invention is not available to the public at a reasonably affordable price, or (c) that the patented invention is not worked in the territory of India. The appeals in Intellectual Property Appellate Board, Bombay High Court and Supreme Court could not get relief for Bayer.

Following that case further applications of Compulsory Licensing by BDR Pharmaceuticals on Dasatinib, a cancer drug patented by Bristol-Myers Squibb<sup>15</sup> and Lee Pharma for anti-diabetes drug saxagliptin branded as Onglyza by Astra Zeneca<sup>16</sup> in August 2015 were rejected by the Indian Patent Office.

## V Conclusion

This research paper aimed at understanding and analyzing the concept of Compulsory Licensing based on Public Interest with a special reference to the comparative analysis of Japanese and Indian law and practices has thrown a mixed result of ‘convergence and divergence’ on the subject matter. The position of the International law since Paris Convention clearly establishes that patent is not an absolute right in itself but a granted right with the aim of incentivizing inventions and investment staked in such efforts. Such a right is an instrument to serve large public interest in various forms like health, communication, consumer goods, transportation and environmental solutions to list a few. The legal right granted by the State has the potential to defeat the purpose of public interest on inadvertent or deliberate commercial practices. Such an abuse intended or otherwise needs to be corrected by the same legal system, which has empowered it. This principle has continuously been part of the discourse of national and international law making.

However there is a divergence based on historical experiences and philosophical foundations. Such divergences has been the debate and dialogue in International and regional forums. The researcher wants to use the analogy of ‘Qualia’ a cognitive science concept, which is about subjective and conscious experience of how to view an object. In a sense Public Interest interpreted differently in societies is akin to the concept of Qualia and there cannot be common meeting ground. In case of IP and its benefits the proof is in the pudding. The past history has shown that countries have tailored and shaped the IP practice based on their development stage. Further when it comes to the issue of medicines and health care it requires enlarging public interest from national perspective to that of international perspective. This is advocated by other bodies like World Health Organization and UNHCR to deal issues beyond borders like the issue of environment. The researcher is of the opinion and conclusion that Patent system world over need to devise a duality of approaches in dealing with health as a fundamental right and other areas of technology as consumption of choice and comfort.

<sup>1</sup> [http://ipindia.nic.in/IPActs\\_Rules/updated\\_Version/sections/ps84.html](http://ipindia.nic.in/IPActs_Rules/updated_Version/sections/ps84.html) -visited on 12/15/2015

<sup>2</sup> <http://www.japaneselawtranslation.go.jp/law/detail/?id=42&vm=04&re=01&new=1>

<sup>3</sup> John Locke, *Two Treatises of Government* (P. Laslett, ed., Cambridge: Cambridge University Press, 1970), *Second Treatise*, Sec. 27.

<sup>4</sup> Bentham, Jeremy (January 2009). *An Introduction to the Principles of Morals and Legislation* (Dover Philosophical Classics). Dover Publications Inc. p. 1. ISBN 978-0486454528.

<sup>5</sup> <http://ip-science.thomsonreuters.com/support/patents/patinf/patentfaqs/history/>

<http://www.uh.edu/engines/epi2002.htm>

<http://www.reuters.com/article/us-moments-patent-idUSKBN0IN1Y>

- <sup>6</sup> [http://www.wipo.int/edocs/mdocs/mdocs/en/cdip\\_4/cdip\\_4\\_4\\_rev\\_study\\_inf\\_5.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_5.pdf)p9
- <sup>7</sup> [http://www.wipo.int/edocs/mdocs/mdocs/en/cdip\\_4/cdip\\_4\\_4\\_rev\\_study\\_inf\\_5.pdf](http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_5.pdf)-p11
- <sup>8</sup> G.H.C. Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property, as Revised at Stockholm in 1967 Geneva: BIRPI, 1968, p. 71. He articulates that ‘The provisions in paragraph (2) ... do not deal with measures other than those whose purpose is to prevent the abuses referred to. The member States are therefore free to provide analogous or different measures, for example, compulsory licenses on conditions other than those indicated in paragraph (4) in other cases where the public interest is deemed to require such measures. This may be the case when patents concern vital interests of the country in the fields of military security or public health or in the case of so-called “dependent patents”
- <sup>9</sup> Ibid
- <sup>10</sup> Japan Patent office, Kogyo Shoyuken Ho Chikujō Kaisetu (Clause-by-Clause Explanation of Intellectual Property Law), (Japan Institute of Invention and Innovation, 16<sup>th</sup> Edition, 2001) translated by the Institute of Intellectual Property on October 9<sup>th</sup> 2015
- <sup>11</sup> Prof. Shigeo Takakura – Professor at the Meiji University was interviewed by the researcher on \_\_\_\_\_ and also submitted his written submissions on the questions raised by the researcher on CL and its application in context of Japan
- <sup>12</sup> Excerpts from Akiko Kato, Associate Professor, Graduate School of Intellectual Property, Nihon University was interviewed at IIP office on \_\_\_\_\_ by the researcher
- <sup>13</sup> The interview at the JGMA office had Takeshi Hishikura, Director, International affairs, JGMA, Naoko Iwasaki, Director, IP Dept. Legal & IP of Teva Pharma Japan Inc., Yoshihito Daimon, Patent Attorney, Director, Intellectual Property (Legal) of Mylan Seiyaku Ltd presenting their views.
- <sup>14</sup> [http://www.ipindia.nic.in/iponew/compulsory\\_license\\_12032012.pdf](http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf)
- <sup>15</sup> [http://ipindia.nic.in/iponew/Order\\_30October2013.pdf](http://ipindia.nic.in/iponew/Order_30October2013.pdf)
- <sup>16</sup> <http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/india-rejects-compulsory-license-application-of-lee-pharma-against-astrazenecas-saxagliptin/articleshow/50652935.cms>