<table>
<thead>
<tr>
<th>Topic</th>
<th>Authors</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Editorial Note</td>
<td>Ms. Megha Ojha, Senior Editor</td>
<td>03</td>
</tr>
<tr>
<td>Editorial: Evolving Data Protection Regime: The PDP Bill 2019</td>
<td>Sameer Avasarala, Founding Editor</td>
<td>05</td>
</tr>
<tr>
<td>Editorial Board</td>
<td></td>
<td>06</td>
</tr>
<tr>
<td>Compulsory Licensing and the Indian Pharmaceutical Sector</td>
<td>Nirmal Prasad, Eeshan Pandey</td>
<td>07</td>
</tr>
<tr>
<td>Adopting and Legitimatising Orphan Drugs in the Intellectual Property</td>
<td>Nimisha Priyadarshii, Tanisha Kaushal</td>
<td>19</td>
</tr>
<tr>
<td>regime of India: An Analysis of the concept of ‘Exclusivity’ for Orphan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘Google’ing the way out of Antitrust allegations</td>
<td>Bhaavi Agrawal</td>
<td>32</td>
</tr>
<tr>
<td>Patent Rights and Competition Law: Conflicts and need for harmonization</td>
<td>Saksham Malik</td>
<td>45</td>
</tr>
<tr>
<td>Thanking Note</td>
<td></td>
<td>62</td>
</tr>
<tr>
<td>Editorial Note</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Ms. Megha Ojha, Senior Editor

Patents are granted for the inventions/creations that mainly relate to process, products, apparatus and industrial applications. Through registration of a patent an exclusive right is granted to its inventor/creator, and after registration without consent of the patent holder their invention cannot be manufactured/used/distributed/sold commercially. Thus, protection of inventions through patent registration has a crucial importance for inventors/creators because it grants an exclusive right to them over their inventions/creations. In today’s digital economy, patent registration is important to gain financial benefits. Therefore, it is necessary for an individual as well as for companies to have strong IP strategies to recover the expenses which have been invested in the development of creations/inventions. As Intellectual Property (IP) is the biggest asset for any company, therefore, it is essential for inventors of the products to protect their IP assets, as without protection, others may own utilize their creation without authorization which can lead to unfair competition in the market. On the contrary, a stringent or excessive use of patent rights, especially pharmaceutical innovations, is creating a number of complex issues. Development and use of new medical products/drugs have foremost importance for public health to cure diseases. Many researches confirm that patent protection for pharmaceutical innovation has great importance for pharmaceutical companies as compared to any other industry because huge investment is required to develop many new drugs or health products. As the protection of patent can give appropriate benefits to inventors/developers of these new drugs; therefore, the market exclusivity, which can be established through effective patent protection, gives a fair return to them. Therefore, the use of patent rights in the health industry facilitates the company to cover expenses that occur on research and development.

Our current edition

The Journal of Innovation, Competition and Information Law is pleased to feature four articles in this issue. The article by Nirmal Prasad & Eeshan Pandey delves into compulsory licensing and highlights its value for pharmaceutical companies in India. In the article, theoretical models of competition and innovation, along with basic models of Intellectual Property Rights (IPRs) have been discussed in light of the importance of compulsory licensing in the field of pharmaceuticals. Authors of the article have attempted to highlight the importance of compulsory licensing in the pharmaceutical industry by providing data and experiences of compulsory licensing of German owned American Patents. By providing relevant data and information, authors have tried to show how granting of a compulsory licence was proved beneficial for the development of new innovations in America. In article relevancy of compulsory licence for pharmaceutical industries of India is highlighted through positive and negative effects of compulsory licensing.

Edition 5 | February 2020
The article by Nimisha Priyadarshi & Tanisha Kaushal is highlighting the significance and need for new IPR policies for the development of orphan drugs in India. It is suggested in the article to change the concept of ‘exclusivity’ specifically for orphan drugs by highlighting its worth for human well-being. It is evident that medicines for major diseases are accessible, which can cure several diseases, though, treatment for such medical conditions/diseases which are unusual, might not attract corporations to invest money for the development of medicines without expecting adequate financial incentives. Therefore, many countries have introduced public policies for the development of orphan drugs so that treatment may become accessible for the patients who are suffering due to rare diseases. It is understood that same development stages like other pharmaceutical drugs have to be followed to develop an orphan drug but to maintain development momentum of these drugs heavy statistical burdens blaze on developers because it is difficult to get an economic return which incurs in development of orphan drugs. A paper recommends modification in the concept of ‘exclusivity’ with the help of Compensatory Liability Model and suggesting effective IP protection strategies to encourage development of orphan drugs in India so that the rightful interest of the patients and the originators of the orphan drugs can be protected.

The article by Bhaavi Agarwal is on the subject of the use of dominance in digital word by Google Company, which violated the antitrust law of the European Union (EU). The paper highlights that the dominant position of Google that emerged through the maneuver and strategies of the Company is now disturbing selection of the customers, thus it is affecting free operations in the market. Google has a substantial (approx. 90%) hold on the internet in search related activities; therefore, such dominance was misused by the Company by breaking the antitrust law of the EU. Due to the dominance of Google, it has been alleged that search results of Google are not neutral; and therefore, it may affect choices/preferences in the contemporary digital economy.

The article by Saksham Malik is about patent rights and competition law. The paper is discussing the relationship between patent law and competition law, which are distinct spheres of law. Mainly, the focus of this article is in favour of an establishment of a harmonious relationship between these distinctive laws. The Author of the article tried to show the way to extend cooperation by preventing misuse of patent rights to developing fair market activities.

While we publish this issue, I would like to take a moment to thank all our contributors and readers for supporting the work of the JICIL. JICIL envisions being a true open access journal, committed to keeping its readers informed on the most vital issues in the field of innovation, competition and information law. I wish our readers a successful year ahead.
| Editorial: Evolving Data Protection Regime: The PDP Bill 2019

Sameer Avasarala, Founding Editor

The data protection regime in India is undergoing a transformative change with the introduction of the Personal Data Protection Bill, 2019 (Bill) in the Parliament and further public consultations to be held by the joint parliamentary committee (JPC) to which the Bill is referred. This Bill is largely reflective of the European Union’s General Data Protection Regulation and is a modified version of the 2018 draft (2018 Draft) annexed to the Report of the Committee of Experts headed by Justice (Retd.) B. N. Srikrishna (Report).

While many features of the Bill pose the onset of a robust data protection regime for India, its application to State and wide exemptions granted therein do not indicate a parallel ground. The regime put forth for application to private entities is worth perusing on some notable grounds. Firstly, the localization regime has been relaxed as opposed to the 2018 Draft requiring a copy of sensitive personal data to be in India while having a hard-localization requirement (with specified exemptions, which appear to be illusory) to critical personal data. Secondly, the requirement to share anonymized or non-personal data with the Government appears to be, both beyond the scope of a personal data legislation as well as too onerous in nature. Thirdly, the Bill, to its credit, does provide much needed comfort to search engine operations, entities involved in innovation and new technologies and business process outsourcing and the like, however, many onerous obligations are specified with vast powers left to the Data Protection Authority (DPA) to specify which may bring in significant standstill to its implementation and further cause uncertainty in compliance.

As the JPC moves towards making public consultations on the Bill, the JICIL’s editorial team would be interested in contributing towards the policy landscape on personal data protection in India. The Bill could prove to be the stellar data protection regime that India awaits which combines the positives of the GDPR and the PDP Act of Singapore while retaining elements required for developing economies like India. We anticipate that these finer balances would be refined by the JPC as part of its review.

Please contact the Editorial Board for the article on the detailed assessment of the PDP Bill.
| Editorial Board |

**Honorary Advisors**

1. Justice A. K Sikri, Former Judge, Supreme Court of India
2. Justice Pratibha Singh, Judge, Delhi High Court
3. Dr. Phansalkar Joshi, Judge, Bombay High Court
4. Justice Prabha Srideva, Former Judge, Madras High Court
5. Adv. Arvind Datar, Senior Advocate, Supreme Court of India
6. Dr. Ranbir Singh, Vice-Chancellor, NLU Delhi
7. Dr. R. Venkata Rao, Former Vice-Chancellor, NLSIU Bengaluru
8. Dr. Geeta Gouri, Former Member, Competition Commission of India
10. Dr. V. C. Vivekanandan, MHRD Chair Professor, NALSAR Hyderabad
15. Adv. Swathi Sukumar, Advocate-on-Record
16. Dr. Shashikala Gurpur, Director, Symbiosis Law School, Pune

**Students**

1. Anubhuti Maithani, Publishing Editor
2. Himani Singh, Deputy Publishing Editor
3. Ashna Chhabra, Editor-in-Chief
4. Anmol Malhotra, Deputy Editor-in-Chief
5. Ameya Foujdar, Senior Editor
6. Megha Ojha, Senior Editor
7. Aditi Duggal, Associate Editor
8. Akshita Das, Associate Editor
9. Nishant Pande, Editor
10. Chandrika Bothra, Editor
11. Abhishek Tripathy, Editor
12. Aadhyaa Kancharla, Editor
13. Nayanika Shukla, Editor
Compulsory Licensing and the Indian Pharmaceutical Sector

Nirmal Prasad, Eeshan Pandey*

Abstract

The objective of this paper is to analyse whether compulsory licensing would hinder innovation and reduce the returns from investment in research and development for pharmaceutical companies in India. The objectives are attained by studying theoretical models of competition and innovation along with basic models of Intellectual Property rights. Moreover, empirical data with regard to patents filed after the grant of compulsory licensing in the field of pharmaceuticals will also be analyzed. Lastly, Trading with the Enemy Act, 1917 will also be analyzed as it allowed for compulsory licensing of 4,706 German owned American patents. It was found that with regard to German owned American patents, after compulsory licensing was given, German inventors began to patent more in research fields that were being licensed while patenting in other fields stayed flat. Over the years, it has also been witnessed that compulsory licensing can promote innovation if governments commit to using it sparingly and in times of need. This research is highly relevant as in India, pharmaceutical companies are scared that their drugs would be compulsorily licensed. The paper would address their fears in light of the practical scenario. Empirical data and Indian judicial precedent with regard to compulsory licensing is limited. The paper aims to provide an insight into compulsory licensing from an Indian perspective. An analysis of the first case on compulsory licensing would help shed light on the effect it could have on companies. This paper aims to provide the readers with the history of compulsory licensing coming into force in India followed by the opinions of various committees, which bought Patent Act, 1970 into practice. Later, this papers contrasts between the positive and negative impact of the compulsory licensing. Lastly, it highlights the relevance and importance of compulsory licensing.

Keywords

compulsory licensing, intellectual property rights, IPR, patents, pharmaceutical sector

*Advocates, Delhi High Court.
BACKGROUND OF THE INDIAN PATENT REGIME

Indian patent legislation first came to light due to the recommendations of the Lord Macaulay Law Commission.\(^1\) The regime for patent administration was created under the Indian Patents and Designs Act, 1911.\(^2\) Under this new law, compulsory licensing could be granted in the case of misuse or abuse of patent rights. The application could only be made three years after the sealing of the patent. An interested person would have to apply to the Controller of Patents for the grant of compulsory license on the following grounds:

a) That the patented invention, capable of being commercially used in India, has not been commercially used therein or is not being so worked to the fullest extent that is reasonably practicable;\(^3\)

b) That a demand for the patented article in India is not being met to an adequate extent or on reasonable terms, or is being met to a substantial extent by importation of the patented article from other countries;\(^4\)

c) That by reason of the refusal of the patentee to grant a licence on reasonable terms, a market for the export of the patented article manufactured in India is not being supplied.\(^5\)

d) That by reason of conditions imposed by the patentee upon the grant of licences under the patent, or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent or the establishment or development of commercial or industrial activities in India is unfairly prejudiced.\(^6\)

TEK CHAND COMMITTEE REPORT

Accordingly, the Government of India constituted a committee under the Chairmanship of Justice (Dr.) Bakshi Tek Chand, a retired Judge of Lahore High Court, in 1949 to review the patent law in India in order to ensure that the patent system is conducive to the national interest. The terms of reference included:

a) To survey and report on the working of the patent system in India;

b) To examine the existing patent legislation in India and to make recommendations for improving it, particularly with reference to the provisions concerned with the prevention of abuse of patent rights;

---

\(^2\) Act No. 2 of 1911.
\(^3\) Indian Patents and Designs Act, 1911, §22(2)(a) [hereinafter ‘The Act’].
\(^4\) Id., at §22(2)(b).
\(^5\) The Act, supra note 3, at§22(2)(c).
\(^6\) The Act, supra note 3, at §22(2)(d).
c) To deliberate whether any special restrictions should be imposed on patent regarding food and medicine;

d) To advise steps for ensuring effective publicity to the patent system and to patent literature, particularly as regards patents obtained by Indian inventors;

e) To deliberate the necessity and feasibility of setting up a National Patents Trust;

f) To contemplate the desirability or otherwise of regulating the profession of patent agents

g) To observe the working of the Patent Office and the services rendered by it to the public and make suitable recommendations for improvement; and

h) To report generally on any improvement that the Committee thinks fit to recommend for enabling the Indian Patent System to be more conducive to national interest by encouraging invention and the commercial development and use of inventions.

The Committee was constituted to highlight and aimed at defending public interest with regard to the availability of food and medicine through an effective system of compulsory licensing for inventions related to food and medicine.7 The Committee believed that compulsory licensing would prove to be a useful way of making the necessary drugs accessible to the residents of India, as it is cost effective and available to use. The Committee further suggested that applications for compulsory licenses after three years of the grant of patent should include the following grounds:

a) Commerce/industry is being substantially affected;

b) Export of the patented item is absent;

c) Manufacture or market of other patented items is adversely affected.

Such changes were given effect through the 1950 amendment to the Patent Act, 1911 before the final report of the Committee was published. Thus, the grounds for compulsory licensing widened. These widened grounds included the condition of commercial activities being hampered and also situations where the interests of consumers or industrial development of the country were being affected. Another amendment that took place in 1952, where the insertion of §23CC provided that there would be an automatic authorisation of licensing to inventions with regard to food, medicine or drugs.8

AYYANGAR COMMITTEE REPORT

---

8 §23CC, Introduced by Act No. 70 of 1952.
In 1957, the Government of India appointed the Justice N. Rajagopala Ayyangar Committee to examine the question of revision of the Patent Law and advise the government accordingly. After Independence, it was felt that the Indian Patents & Designs Act, 1911 was not fulfilling its objective. It was found desirable to enact a comprehensive patent law owing to substantial changes in the political and economic conditions in the country.

This Committee observed that almost eighty percent of the patents in India were held by foreigners and the majority of said patents were not being worked in India adequately. The Committee submitted its interim report on 4th August, 1959 with recommendations for prevention of misuse or abuse of patent rights in India. It suggested amendments to sections 22, 23 & 23A of the Patents & Designs Act, 1911 on the lines of the United Kingdom’s Acts of 1919 and 1949.

The committee further observed that the Patents Act should contain clear indication to ensure that food and medicine and surgical and curative devices are made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee. This Act remained in force for about 24 years without any change until December 1994. An ordinance effecting certain changes in the Act was issued on 31st December 1994, which ceased to operate after six months. Subsequently, another ordinance was issued in 1999. This ordinance was replaced by the Patents (Amendment) Act, 1999 that was brought into force retrospectively from 1st January, 1995. The amended Act provided for filing of applications for product patents in the areas of drugs, pharmaceuticals and agro chemicals though such patents were not allowed. Furthermore, it was stated that provisions of compulsory licensing were “wholly inadequate to prevent the misuse or abuse of patent rights, particularly by foreigners”. The suggestions made with regard to compulsory licenses were incorporated in the Patents Act, 1970.

**THE PATENTS ACT, 1970**

The Act was amended in 1999, 2002, and 2005 to comply with The Agreement on Trade-Related Aspects of Intellectual Property Rights (‘TRIPS’). Under §82 to §94, the system of compulsory licensing is enumerated. The grounds for compulsory licensing include:

1. Abuse of patent rights, dealt with broadly under §84.
2. ‘Public Interest’, dealt with broadly under §92.
3. New Grounds introduced by the 2005 amendments –

---

a. Emphasis on Indigenous manufacturers

b. Both pre-grant and post-grant opposition avenues

(4) Other provisions on compulsory licensing such as §91, dealing with the licensing of related patents.

**GRANT OF COMPELLARY LICENSE**

Compulsory licensing has become relevant recently. In 2012, India granted its first compulsory license to NATCO Pharma Limited.\(^{13}\) In the same case, a compulsory license was granted on the basis of public interest as the Court found the patent was not being worked to a reasonable extent. Moreover, the price of the drug for which the patent had been originally was deemed to be at unreasonably high. Thus, the intention of granting a compulsory license was that the drug would be available at a cheaper price and be more affordable to consumers. However, in this particular case, the aspect of how this compulsory license affects the competition of the market was overlooked. There are multiple theories as to the effect compulsory licensing may have on the market. These will be explored further in the article.

**EFFECT OF COMPELLARY LICENSE ON INNOVATION**

In the pharmaceutical industry, developing nations around the world have always used compulsory licenses to improve access to drugs that have been patented in their nations without the consent of the patent owners, who are usually foreigners. Countries like Brazil, Malaysia, Zimbabwe, Mozambique, Zambia, Thailand and Ecuador have used compulsory licensing to allow for cheaper HIV drugs to be accessed by their domestic consumers.\(^{14}\)

**Model where Compulsory License negatively affects Innovation**

The system of intellectual property rights in countries may help raise the welfare by increasing access to patented drugs.\(^{15}\) However, the effects of compulsory licensing on innovation are not theoretically clear and evidence for the same is rare to come by. A patent regime that grants large amounts of patents may discourage innovation in the long-run as expected returns from research and development would be lowered. However, there is a general belief that compulsory licensing hampers the objectives of innovation and inventions it discourages people from inventing and seeking patent protection for their inventions.\(^{16}\)


\(^{15}\) Eric Bond & Kamal Saggi, *Compulsory Licensing, Price Controls, and Access to Patented Foreign Products*, 109(C) JOURNAL OF DEVELOPMENT ECONOMICS, 217-228 (2014).

Some of the reasons are as follows:

a) Compulsory licenses may raise safety concerns. As the simple dynamics of economics work – as and when a product in the market gains momentum and popularity, its counterfeit products find their way in the distribution too. Thus, buyers of such counterfeit products are exposed to risks as these products are neither medically approved and definitely lie below the approved quality.  

b) Ensuring Compulsory Licensing can bring the much needed medical help to third world countries wherein the type and mass of the epidemics that hit are much larger in scale due to the inability of such countries to tackle such epidemics in the absence of appropriate medical facilities. If patent protection is ensured in these countries, it would provide an incentive to multinationals to invest in the research to investigate these diseases which would otherwise remain incurable;

c) Be that as it may, the bottom-line still is that Pharmaceutical industry is still a Business and profit aiming scheme. In absence of a business friendly environment in countries wherein compulsory licensing provisions lack, it may result in discouraging these firms to invest. Thus for the betterment of medical health in the larger picture, it is imperative that nations succumb to business friendly ties with these firms that shall propel them to safeguard health of numerous citizens.

d) Use of compulsory license may cause trade friction with the countries that produce patented drugs.

e) Foreign Direct Investment is the need of the hour in the current scenario wherein nations depend on each other for all kinds of exports/imports and investments for boosting one’s economy. Thus, the decision of a government to grant compulsory licenses may lead to the loss of foreign direct investment. Therefore, by granting compulsory license, a country may lose out on Foreign Direct Investment coming in and give up on a potential source of economic growth.

f) Another principle that drives innovation in any field is ‘Incentive’. Incentive can be in any form, be it monetary, climatically driven or just to satisfy the sheer genius of the innovator. So in case that a country becomes less competitive in its intellectual property regime, particularly in granting compulsory licensing in the pharmaceutical sector, the talented scientists,


18 R. C. Bird, Developing nations and the Compulsory License: Maximizing access to essential medicines while minimizing investment side effects, 37 (2) JOURNAL OF LAW, MEDICINE & ETHICS, 210 (2009).


innovators and researchers might move out to better nations wherein their work is duly recognized and paid for.21

Models where Compulsory License positively affects innovation

There are theoretical models of competition that conclude that compulsory licenses can encourage rather than discourage innovation by increasing competition, consequently giving more incentive for the market to increase their market share.22 The theory behind this is that patents can create monopoly rights to the invention as the patent holder would have exclusive rights to their invention.23 In turn, such a patent holder would have little to no incentive to innovate as they would have almost no competition.24 Where competition levels are low, an increase in competition encourages invention as it encourages the market leaders to invest in research and development in order to escape the said competition.25 As the market leaders, it can be presumed that they would have superior funds for investment in research and development.

Therefore, where compulsory licensing is granted, competition is increased. An example can be taken from the Indian scenario where NATCO Pharma Limited has been granted a compulsory license for the drug from Bayer Corporation. In this case, before compulsory license was granted, they essentially had a monopoly with regard to a specific drug. Now that NATCO Pharma Limited has a license to produce their drug, which they would do so at a cheaper price than Bayer, competition has increased. Theoretically, this should motivate Bayer to invest more in their research and development so as to ward off their competition such as NATCO Pharma Limited.

ANALYSING THE INDIAN PATENT ACT, 1970 IN RESPECT OF TRADING WITH THE ENEMY ACT, 1917

For a more practical model, one can look at the effect of compulsory licenses under the Trading with the Enemy Act, 1917 which allowed the United States authorities to confiscate all American patents that had been created by German inventors.26 Additionally, the Act allowed for almost five thousand German owned American patents to be available for compulsory licensing. Non-exclusive licenses for almost a thousand patents were allowed “upon equal terms and a royalty basis, to any bona fide

22 A complementary view, reaching back to Schumpeter (1934 and 1942) argues that large firms, which are typically the owners of licensed patents, have greater incentives to innovate because they are better able to appropriate returns from investments in R&D. Goettler and Gordon (2011) confirm these predictions with estimates of a dynamic oligopoly model for the durable goods microprocessor industry.
24 Id.
American individual or corporation”. 27 A study on this Act, stated that the access to German patents helped the American industry. In the field of chemistry and pharmaceuticals where licensing was allowed, American patents by domestic inventors and investors increased by twenty percent after 1918. 28 Thus, this is an indicator that innovation had increased due to the access to a large number of patents. Moreover, a study reveals that while American inventors increased the number of patents they would receive, even the number of German inventors who would patent in USA increased significantly. 29 There was an increase by almost seventy percent after 1918 in the number of German firms who were revealed to be active in licensing. 30

**IMPACT ON COMPETITION**

In view of what has been said and discussed above, the next reasonable question that arises is whether the increase in patents actually affected the competition in the market. Data suggests that nearly forty percent of all patents after 1918 were secured by firms that did not have patents before 1918. 31 Also, firms that had not been active before 1918 were discovered to have created more patents than those firms which had been active in the market. 32 Thus, there was a large number of new entrants in the market for pharmaceuticals and industrial chemicals.

Therefore, such a finding is opposite to the basic model of patents. The basic model suggests that increased compulsory licensing would reduce the incentives for firms to invest in their research and development. The advocates of the above findings strongly believe that invention is promoted by encouraging competitors to enter into the field of licensing that, in turn, increases the competition and motivates them to invest.

Furthermore, the industries which are most affected by compulsory licensing are the ones that are concentrated – where the market is dominated by one firm or a small number of firms. Thus, pharmaceutical industry falls under this category. Despite the increase of compulsory licensing, firms such as Gilead and Bristol-Myers are recording sales around $3.1 billion while other drugs selling in substantially less numbers. 33

---

29 Id.
30 Supra note 28.
It is further suggested that compulsory licensing encourages invention and innovation in such industries. As mentioned earlier, when the German patents were being confiscated, it significantly increased the competition in industries where competition was not concentrated. However, competition would not increase to the same extent in industries that are already largely competitive.

**IMPORTANCE OF GOVERNMENT AND COMPULSORY LICENSES**

The underdeveloped and underprivileged countries often lack their own technical know-how and infrastructure that serves as a prerequisite for pharmaceutical patents. Thus awarding patents in such countries might lead to a dampening economy and in turn harming the country’s own population in the longer run. Thus, here comes in ‘non-voluntary licensing’, the threat of which may be helpful in negotiating a reasonable price of the needed drug acceptable to both the patent owner and the government.\(^{34}\)

It is a definite and settled principle that patent protection surely favours the developed and more advanced countries as compared to those that come low in the development-hierarchy charts that in turn gives a further push to the ever increasing menace of ‘neocolonialism’. If such is the case, then, compulsory licensing of pharmaceuticals, particularly, can be used to ease down the monopolistic stress that originates out of ‘neocolonialism’. In simpler words, pharmaceutical patents can make way to save and secure lives by ensuring regular availability of affordable drugs. Thus, governments of underdeveloped and developing countries can influence and command the patent holders by correctly effectuating and implementing a well-regulated compulsory licensing mechanism.\(^{35}\)

Not always is the original patentee the one who has the power to take the final decision when it comes to compulsory licensing. Sometimes, delay in development of important technology is caused due to serious standstill and difference of opinion between the improver and the original patentee. In order to combat this deadlock between the two aforementioned interested parties, Compulsory Licensing is the way forward.\(^{36}\) Compulsory Licensing, if used and implemented correctly can definitely help resolve the conflict of opinion between the aforementioned parties thus granting technical progress for everyone’s betterment.\(^{37}\)

Compulsory licensing might be necessary in situations where its refusal may prevent utilization of another important invention which can be significant for technological advancement or economic growth. Yes, there is no doubt that there are huge costs involved in the research and development of a

---

\(^{34}\) J. Kuanpoth, *supra* note 21.

\(^{35}\) J. Kuanpoth, *supra* note 21.


product and then to further get it patented. But, in the larger scheme of things, the cost incurred during the development of such drug is a negligible price to pay vis-à-vis the profits that it will earn in the near future from its sales in developed nations that have well-regulated patent laws.\textsuperscript{38}

Use of compulsory licensing to protect the public interest does not only have an economic feasibility in its favour but has definitely growing proponents for social justice grounds. In view of what has been stated herein above, it can be inferred that the benefits of Compulsory Licensing boil down to the creditability of national governments in how well the respective governments stringently enact the patents in their respective jurisdictions. Though the findings suggest that innovation may be promoted with compulsory licensing, an important point to consider is the effect of the governments itself.

A very important aspect of regularizing compulsory licensing is that the governments must display to firms that compulsory licensing will not be given frequently. It should only be given and provided in when need arises. The reasoning behind this argument is fairly simple – If firms are easily given out compulsory licenses for their products then the quality of products coming from the firms would naturally diminish and quantity is what the firms would then aim for. If there was such uncertainty with compulsory licenses given numerous times, firms would be discouraged in terms of providing quality products.\textsuperscript{39} Numbers would matter instead of quality products and the entire essence of Compulsory Licensing would move to shackles.

**RELEVANCE OF FINDINGS WITH REGARD TO INDIA’S PRESENT SCENARIO**

These findings are relevant to a small extent. After the first compulsory license was granted in India, pharmaceutical companies are scared that more drugs will also be given the same fate. However, no other compulsory license has been granted yet. Therefore, there has been no significant change in the industry as of now. A large number of new entrants have not entered the market so as to cause a huge change in competition.

However, it is important to note that the findings suggest that the Indian government is credible. They have only granted one compulsory license which was in fact in public interest. Thus, it shows that the authorities are exercising caution. This promotes certainty and confidence to the pharmaceutical companies. Additionally, such a model should convince the patent authorities that the grant of compulsory licenses in emergencies will not actually discourage market leaders in the pharmaceutical industries. It will encourage new players who will take advantage of the compulsory licensing but it

\textsuperscript{38}T. Jain, *Compulsory licenses under trips and its obligations for member countries*, 8 ICFAI Journal of Intellectual Property Rights 1, 44 (2009).

will also lead to investment in research and development by the market leaders of the pharmaceutical industry.

**CONCLUSION**

The patient versus patent issue is one of the most important problems now in the modern healthcare system. Although India has only passed one compulsory license yet, the number of compulsory licenses granted worldwide is on the rise. The underdeveloped and developing countries want to pass compulsory licenses, and the developed, and the big pharmaceutical companies do not want the compulsory licenses to be passed. The main reason the big pharmaceutical companies do not want compulsory licenses to be passed is that it takes a lot of money and effort to create the drugs, and even then, there is no certainty. They have to recoup the costs of innovation. Hence, the companies have to fix the cost of their patented module according to the economic status of the country if they want to protect their product from compulsory licensing.

India, in particular, faces a challenge, owing to the economic condition of the majority population. On one hand, it has to comply strictly with the international standards of patent protection and on the other hand, it has to safeguard public health. It can be said that compulsory licensing has now become the hope for financially challenged patients in underdeveloped countries, and compulsory licensing is now one of the most controversial topics in International Property matters. India as a low-cost producer of drugs has particular significance from the point of view of supplies to countries with no manufacturing capacities. Care has not been taken in the patent amendments to facilitate such exports. Patent amendments should be favored for the patent protection in India which will turn India into an ideal center for research and the domestic manufacturers will be benefited. However, the loopholes in it should be rectified for all-round development.

The grant of compulsory license to NATCO Pharma Limited has not yielded a great change in the Indian pharmaceutical sector. The license is with regard to only one cancer drug. Therefore, the revenue of Bayer Corporation may have decreased to a limited extent due to increased competition with NATCO Pharma Limited. However, while this will only be limited to one drug, there are certain implications. The grant of the compulsory license shows that the patent administration is ready to grant the compulsory license in case of public need and emergencies. This is a reasonable expectation. Moreover, the fact that the patent authorities have been careful in granting compulsory licenses shows other firms in the pharmaceutical market that their business operations will be stable as there will not be any frequent grants of compulsory licenses.

With regard to innovation in the industry, the effect of compulsory licensing is ambiguous. This is because the data with regard to the same is scarce. The effect of compulsory licensing with regard to German-owned patents under the Trading with Enemy Act could be studied due to the amount of data
that was available. Additionally, it has only been a few years since the first compulsory license was granted. Therefore, the effect of it may only be clear after more time. Furthermore, compulsory licensing can be used as a mechanism to promote innovation in the field of pharmaceuticals. Firstly, it is an industry that is dominated by a small number of firms. Thus, more compulsory licenses would allow for an increased number of entrants which in turn would increase competition. Increased competition should propel the market leaders to invest more in their research and development and increase the number of patents they get. The same may be possible in India as the patent authorities have shown that they are careful with granting compulsory licences, thus giving them credibility.
Adopting and Legitimatising Orphan Drugs in the Intellectual Property regime of India: An Analysis of the concept of ‘Exclusivity’ for Orphan Drugs

Nimisha Priyadarsh, Tanisha Kaushal

Abstract

Today, the world has advanced to such an extent that it has developed cures for the majority of the diseases possibly known to the human race. Keeping in pace with the discovery of medicines, intellectual property laws have also evolved to protect and incentivize the discoverers. However, development in the realm of orphan drugs has not been made—both legally and pharmaceutically. One of the major causes of this situation is that the target patient population is very insignificant in number whereas the development costs incurred in the research and production stage are huge; hence, the industry receives a low rate of return on the investment. Additionally, ‘orphan drugs’ are neither legally defined nor recognized in India. However, this is not the legal situation vis-à-vis orphan drugs in other developed countries. Unlike developed countries, India is insufficiently equipped with resources for the research and development of drugs hence there is a need to have a separate provision for orphan drugs. As a solution to the low-incentivizing market, this paper discusses the concept of ‘exclusivity’ as an attractive incentive to be given to the originator of the orphan drug in order to develop a sound economic model that caters to the development of orphan drugs in India. To supplement the proposed solution, the paper recommends a modification to the ‘exclusivity’ concept with the help of a Compensatory Liability Model. Further, it also recommends a ‘supplementary protection policy’ as one of the key strategies for the development of orphan drugs.

Keywords

orphan drugs, exclusivity, compensatory liability model, supplementary protection policy

* Year IV, B.A. LL.B. (Hons.), Rajiv Gandhi National University of Law (RGNUL), Punjab.
INTRODUCTION

The advancement of the medical sciences and the resultant discovery of life-saving drugs has not only increased the life expectancy of people around the world but has also improved the quality of their lifestyle. One cannot forget the end of the polio virus epidemic or very recently, the introduction of a cancer-treating drug, Gleevec that treats chronic myeloid leukemia (CML) by zeroing-in on a particular cancerous cell without causing unwanted side-effects to cancer patients.\(^{40}\) In order to incentivize innovators and to encourage them further, laws on protecting innovations have evolved to grant innovators exclusive rights over their innovations. In the words of Alfred Marshall, \"If inventions have increased man’s power over nature very much, then the real value of money is better measured for some purposes in labour than in commodities\",\(^{41}\) and in modern times, labour essentially includes the management and execution of knowledge. Thus, India’s tryst with intellectual property rights started in order to strengthen the hold on inventions in the production sector.

The regime of Intellectual Property Rights (\"IPR\") in India holds a crucial place in the development of innovations and technology as it facilitates the competitive edge of the innovators. These rights also aid in striking a balance between the monopoly rights of IPR holders and the unrestricted flow of knowledge in the public domain. Considerable development was also made in the pharmaceutical sector in the field of intellectual property. However, specifically, the development in the field of rare diseases has not gained much momentum in India owing to the fact that it is less profitable and low-incentivizing. The lack of specific provisions for dealing with rare diseases further discourages any development in this field. This has created a vicious cycle.

This paper attempts to scrutinize the relevance of legislative changes in the IPR regime to promote the development of orphan drugs in India. Part I delves into the concept of Orphan drugs, ‘exclusivity’, its adoption in other countries such as USA, Australia, Japan, EU and the need for orphan drugs in the Indian market; Part II proposes a balancing approach in the International and Indian approach towards exclusivity in orphan drugs with the help of ‘compensatory liability model’; Part III of the paper discusses the efficacy of a ‘supplementary protection policy’ as another parameter for protection of orphan drugs and how it adds value to the exclusivity model and Part IV concludes the paper by providing a roadmap for the future intellectual property regime.

MEANING OF ORPHAN DRUGS


\(^{41}\) ALFRED MARSHALL, PRINCIPLES OF ECONOMICS, 62 (1890).
Orphan diseases, as the name suggests, are those diseases that affect only a few in a global patient population. Further, they show a variety of characteristics in their symptoms and signs which range differently from disease to disease and even patient to patient of the same disease or disorder, hence, making their diagnosis more difficult. This raises the cost of research and development and since the target market is limited, it makes its production and development less lucrative and profitable. Therefore, there is not much development in drugs for these diseases. Though they affect a very small population, they show a variety of characteristics in symptoms and signs and range differently from disease to disease or patient to patient of the same disease or disorder.

Different countries and organizations have defined the term “orphan disease” differently. However, there are two common elements in these definitions – firstly, the prevalence of the disease and second, the non-availability of treatment for the disorder. The World Health Organization (“WHO”) defines orphan diseases as “rare diseases which affect 6.5–10 out of every 10,000 persons”. If a disease, though considered rare, has adequate therapeutic treatment and policies for the same, it would not be considered as orphan.

Orphan drugs are those that help in the treatment, prevention, and diagnosing of rare or orphan diseases. There is not only a deficiency of therapeutic treatment for orphan diseases but also limited knowledge of such diseases. Moreover, the market for orphan drugs is comparatively small and less viable. Hence, pharmaceutical companies are often reluctant to invest in these drugs as the return on investment would not help in recovering the huge cost incurred by them on research and development. Coupled with that, there are legal complexities that leave the right holders with minimal rights. The outcome of such deficiencies is that the harm caused to the patients is greater than it would have been had there been adequacy of research and production of orphan drugs. Therefore, such an issue could be solved by providing exclusivity to orphan drugs through IPR in order to incentivize and promote this industry. The starting point of any legislation is to provide comprehensive definitions so that rights and duties therein can be effectively recognized for different stakeholders. In India, because of less awareness of

---

43 INSTITUTE OF MEDICINE, BOARD ON HEALTH SCIENCES POLICY, COMMITTEE ON ACCELERATING RARE DISEASES RESEARCH AND ORPHAN PRODUCT DEVELOPMENT, RARE DISEASES AND ORPHAN PRODUCTS: ACCELERATING RESEARCH AND DEVELOPMENT, (MJ Field, TF Boat Eds., 2010)
47 Saurabh Agarwal, supra note 5.
the orphan disease, it is not legally defined. However, the Organization for Rare Diseases in India (ORDI) defines rare disease as one “that affects 1 in 5000 people or less”\(^{48}\) which is generally taken as a definition in common parlance in India. Hence, a legal definition of orphan drugs is the first step towards developing a legislative framework in this field.

**Exclusivity for Orphan Drugs**

The incentive of market exclusivity is a significant form of attraction for investment in orphan drugs. A pharmaceutical company before releasing its product in the market needs authorization from regulatory authorities for which it has to submit the data related to orphan drugs to such authorities.\(^{49}\) The concept of ‘exclusivity’ grants protection to the originator company against disclosure of the data to the third party by the regulatory authority for a fixed period of time. This principle gives assurance to the originator company that the extensive efforts and huge development costs that they have incurred in their research have not been put to unfair commercial use by third parties. This concept has been legally adopted for facilitating the development of orphan drugs by various countries across the world which have been further discussed below. The adoption of exclusivity in India is also deliberated upon in subsequent sections.

**International Position**

The importance of discussing the international position with respect to orphan drugs is to show that the developed countries of the world have realized the need for an intellectual property law that would strengthen the development of orphan drugs, which in fact, has proven to be successful. The idea is to draw inspiration for importing the ‘better-world’ concept of exclusivity in the Indian IPR regime vis-à-vis orphan drugs. In the following parts, exclusivity provisions in countries like the USA, Japan, Australia, and so on are discussed followed by a discussion over its need and adoption in India.

**United States of America**

Orphan diseases saw their first ray of light in 1983 in the USA when a young boy was diagnosed with Tourette syndrome.\(^{50}\) At that time, orphan diseases were known to a few, and therefore, a conceptual understanding of the same was not developed. However, the young boy’s deplorable condition caught the attention of the public and caused a hue and cry among the masses. The out-turn of the public pressure led to the formulation of the rules and guidelines for the orphan diseases in the form of the Orphan Drugs Act. Until then, pharmaceutical companies showed negligible interest in conducting trials

\(^{48}\) Saurabh Agarwal, *supra* note 5.


\(^{50}\) ABBEY S. MEYERS, A GLOBAL CRUSADE (Rob Tomaino Ed., 1st ed. 2017)
on orphan drugs due to the small market for the same and low rate of affected individuals coupled with the high cost of development.\textsuperscript{51} It was for the promotion and development of Orphan drugs that such regulations were introduced. Gradually, other countries too started shedding light and formulating policies in this grey area of the pharmaceutical industry.\textsuperscript{52}

The US Food and Drug Administration (“\textit{FDA}”) defines an orphan drug as a \textit{“drug or biological product intended for use in a rare disease or condition, where a rare disease or condition is one that affects less than 200,000 people in the USA.”}\textsuperscript{53}

Although passed in 1983 in the USA, various amendments were effected to bring the law in consonance with the needs of the society. FDA also created an intermediary i.e. the Office of Orphan Products Development (\textit{“OOPD”}) for managing and accelerating its regulatory functions and granting orphan drug designations. The USA is not only concerned with pharmaceutical and biological products, but also medical devices and dietary products that are used with orphan drugs. For the success of orphan drugs, USA provided various incentives and rights to the makers of these drugs such as exemption from application fee, fast-track procedure, tax credits and market exclusivity for a period of 7 years, thereby helping in overcoming the obstacles in the growth and development of the pharmaceutical industry.\textsuperscript{54}

The successful journey of this regulation can be witnessed from the data compiled by the FDA Orphan Drug Product designation database\textsuperscript{55} that shows that the number of Orphan Drug Designations per year has increased by leaps and bounds since 1984.

\textbf{Japan}

Japan, enacted a law similar to the FDA on 1\textsuperscript{st} October, 1993 with the Orphan Drug Amendment to the Pharmaceutical Laws.\textsuperscript{56} The rare diseases were defined as ‘\textit{intractable disease (Nambyo)’ until 1995 when the Ministry of Health and Welfare revised the definition within the legislation.\textsuperscript{57} The concept of orphan drugs in Japan is derived from Article 77-2 of the Pharma Law. It was defined as ‘\textit{a disease of

\begin{footnotesize}
\footnotesize{\textsuperscript{51} S Bell. & C. Smith, \textit{A comparison of interventional clinical trials in rare versus non-rare diseases: an analysis of ClinicalTrials.gov}, 9(1) ORPHANET JOURNAL OF RARE DISEASES, 1 (2014)}
\footnotesize{\textsuperscript{52} Saurabh Agarwal, \textit{supra} note 5.}
\footnotesize{\textsuperscript{53} Jaydip Sapariya & Dilip Maheshwari, \textit{An Insight On Orphan Drug Development Strategy In Us And Europe}, 6 JOURNAL OF GLOBAL TRENDS IN PHARMACEUTICAL SCIENCES, 2322 (2015) [hereinafter ‘Jaydip Sapariya’].}
\footnotesize{\textsuperscript{54} U.S. Department of Health and Human Services, \textit{Developing Products for Rare Diseases & Conditions}, U.S. FOOD AND DRUG ADMINISTRATION, available at http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm2005525.htm.}
\footnotesize{\textsuperscript{55} Jaydip Sapariya, \textit{supra} note 14.}
\footnotesize{\textsuperscript{56} Revised Orphan Drug Regulations (Amendment of the Pharmaceutical Affairs Act & Drug Fund for Adverse Reaction Relief& Research Promotion Act), 1993 (Japan).}
\footnotesize{\textsuperscript{57} Peipei Song, Jianjun Gao& Wei Tang, \textit{Rare diseases, orphan drugs, and their regulation in Asia: Current status and future perspectives}, 1(1) INTRACTABLE AND RARE DISEASES RESEARCH, 3 (2012), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4204590/}
\end{footnotesize}
unknown aetiology with no effective treatment, that presents a major financial and psychological burden and that is rare (fewer than 50,000 total patients)."\(^{58}\)

While the term market exclusivity is not used *per se*, the re-examination period is granted to the orphan drug for 10 years\(^{59}\) which bars the generic companies from using the data meant for the manufacturers of orphan drugs. Thus, in effect, market exclusivity is granted to orphan drugs for a period of 10 years.

**Australia**

Australia, too, tried to be on the same footing as that of the USA and Japan and introduced the regulation of orphan drugs in 1997. The authority to grant the status of an orphan drug is vested with the nodal agency, Australian Therapeutic Goods Administration ("TGA"). Requirements to fall under the category of an orphan drug are:\(^{60}\)

a) The target disease is found to be prevalent in 2,000 patients out of the total Australian population or a "maximum of 12 persons in 10,000 people".

b) It must fulfil the safety requirements as prescribed by the TGA and different agencies around the world such as US-FDA, the Medicines and Healthcare Products Regulatory Agency of the United Kingdom, the Therapeutic Products Directorate of Canada, the Medical Products Agency of Sweden, the Medicines Evaluation Board of the Netherlands, or the European Medicines Evaluation Agency ("EMEA").

Further, in order to provide incentives to the manufacturers, market exclusivity is granted by Article 25A of the Therapeutic Goods Act, 1989 wherein clause (1) states that "*When evaluating therapeutic goods for registration, the Secretary must not use information about other therapeutic goods that are protected information.*" Further, clause (2) states that the information is "protected information" if, according to sub-clause (e) "*5 years have not passed since the day the new goods became registered*."\(^{61}\)

Thus, market exclusivity is granted to orphan drugs for 5 years.

**European Union**

The European Union ("EU") also had its own version of rare diseases and orphan drugs. In the EU, rare diseases are defined as "*life-threatening or chronic debilitating conditions that affect less than 5 in 10,000 persons.*"\(^{62}\)

---

\(^{58}\) *Id.*

\(^{59}\) Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, 1960 (Japan), art.14-4.


\(^{61}\) Therapeutic Goods Act, 1989, art. 25A.

In the EU, the regulatory framework and the process of Orphan Drug Designation came into operation in 2000. Though adopted in 2000, the efforts of stakeholders such as the European Medicines Agency (EMA) and the European Commission (“EC”) were considered by the Parliament in 1999 which resulted in the framing of Orphan Drug regulations.63

The task of carrying out the scientific assessment of orphan drugs in the EU is assigned by the EMA to the Committee for Orphan Medicinal Products (COMP) which consists of individuals from member states, the EC and patient associations. There are various incentives provided by EU regulations to boost research and development in this field. These include protocol assistance, fee reduction, grants, market exclusivity for 10 years and other incentives. The exclusivity period provided for orphan drugs is not rigid and may be reduced after 5 years if it is deduced that the drug has earned sufficient profits and is no longer entitled to come within the ambit of an orphan drug for recovering the cost on research and development of the drug.64

A feature exclusive to the EU and its member states is that it has a centralized framework for orphan drug designation and market approval. Since the recognition of orphan drugs in the EU, there have been continuous efforts to improve the situation of Rare Disease patients in the world. The credit of recognizing February 28th or 29th as Rare Disease Day goes to EURORDIS, a non-governmental patient-driven alliance of patient organizations representing 869 rare disease patient organizations in 71 countries.65 In 2008, Europe launched this day for the first time by making it an annual event for spreading awareness amongst the general public and encouraging research and development of Orphan drugs.66

ADOPTING EXCLUSIVITY FOR ORPHAN DRUGS IN INDIA

After the enforcement of the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) at the international forum, the intellectual property law regime in India has witnessed a sea change. However, the pharmaceutical sector has not gained much momentum in India. Although there has been increasing awareness of the situation of orphan drugs and diseases, the Indian legislation on the same has not been given the due attention that it warrants. As of now, no proper definition has been proposed by any authority for orphan drugs or rare diseases which leaves a loophole as to the threshold of what would constitutes “orphan drugs”, and no legislation or national plans on the same have been

---

64 Commission of the European Communities Regulation No 141/2000 (Dec. 16, 1999).
laid down. To rub salt on the wound, there has been no provision to provide any sort of incentive, whether by market exclusivity or financial or non-financial incentives to the developers.

The most challenging stage that the inventors of orphan drugs face are clinical trials. At this stage, there are chances of leakage of data submitted to the authorities and also an administrative delay in obtaining clearance for public use. This increases the development cost for the inventors. It was estimated that USD 350-850 million are invested in introducing a new drug into the market. Further, testing the orphan drug at the end-point is another challenge faced by the producers.

Despite the huge investments made on the production of orphan drugs, there is a limited market scope since a very small population is affected by rare diseases in comparison to other generic diseases. The major problem which is faced is that even if a handful of pharmaceutical companies undertake the production of rare drugs, they are discouraged by the fear of their research and data being disclosed to other companies in the trial stage, which is why a provision of data exclusivity is necessary. An analysis by researchers highlights that the pharmaceutical sectors in India face an additional problem of preparing drugs for diseases that normally do not exist in developed countries. These researchers concur that “data exclusivity will make India an attractive destination and a huge pool for research and development work.” Exclusivity is also favoured by the originator company on the grounds that it will prevent unfair advantage accrued to the generic companies who sell the drugs at a low cost without making the huge investments that are inherent in orphan drugs production for market approval.

Orphan drugs maybe of academic interest but for a person suffering from a rare disease, it is a messiah that must be provided promptly at a lower cost. Exclusivity would delay the mass production of orphan drugs by generic companies. At the same time, it would grant monopoly rights to the originator company, thus, giving excessive power to the originator company to raise the market price indiscriminately and arbitrarily. Moreover, exclusivity may lead multi-national companies to delay the introduction of orphan drugs at a lower cost in developing countries. In such a situation, the ultimate

---

68 N. Azie & J. Vincent, Rare diseases: The Bane of Modern Society and the Quest for Cures, 92(2) CLINICAL PHARMACOLOGY & THERAPEUTICS, 135 (2012).
70 Saurabh Agarwal, supra note 5.
73 A. Sharma, Data Exclusivity with Regard to Clinical Data, 2 JOURNAL OF LAW AND TECHNOLOGY, 100 (2007).
losers are the patients suffering from the rare disease. Despite the shortcomings, the benefits outweigh the harms and thus exclusivity should be provided.

**BALANCING APPROACH TOWARDS EXCLUSIVITY: A COMPENSATORY LIABILITY MODEL**

While there is no specific provision dealing in exclusivity in terms of orphan drugs, exclusivity is given under the Drugs and Cosmetics Rules, 1945. Rule 53, when read with Rule 122E, requires that an inspector of Drug Regulator shall not disclose to a third party any data submitted or acquired during the course of duty without the sanction, in writing, of his official superiors for a period of four years. However, such data can be disclosed at any time by the permission of a superior authority under certain cases such as in the interest of public health. This puts a wide discretionary power on the superior authority which may be arbitrary for the originator party. Moreover, the originator company gains nothing from such disclosure. Such disclosure will result in a loss to the originator company who would be unable to cover the cost for its research and development. Thus, a specific provision dealing in exclusivity which specifically caters to orphan drugs must be provided under the statutory mandate.

While access to affordable medicines for rare diseases is imperative from the patient’s point of view, exclusivity is also important for incentivizing production from the originator firm’s point of view. Thus, in order to bring the conflicting interests in tangent to each other, a balancing approach needs to be adopted, especially in the Indian scenario. A compensatory liability model can serve this purpose by solving the dilemma. A compensatory liability model\(^4\) is one wherein the data is disclosed to a third party as a matter of right by the regulatory authority in consideration of ‘fair’ compensation to the originator of the data, without having to demonstrate the existence of grounds such as excessive pricing or that the invention did not satisfy the requirements of the public or any other grounds by the drug originator. Additionally, scholars such as Fellmeth interpret Article 39.3 of TRIPS, envisaging a compensatory liability model:

“...the purpose of the duties of confidentiality and of data exclusivity may be satisfied even when the data has been released to a competitor of the initial registrant, or a competitor has been permitted to rely on the data, or both. In these instances, the drug regulatory authority must ensure that adequate compensation renders the disclosure and use of the data economically ‘fair’.”

Further, Fellmeth discusses a ‘simple division royalties’ model\(^5\) in order to ascertain fair compensation. According to this system, the subsequent registrant would use the original data as long as they paid an “equal portion of the cost of [initial] testing” to the originator of the data.\(^6\) This approach is based on


\(^6\) G. Skillington, supra note 33.
a fixed-cost sharing approach wherein the originator has to ascertain the cost of approval so that it is divided among subsequent registrants. A very significant disadvantage of this model is that the generic company will have to pay huge clinical costs to the originator company which is not affordable by a generic company in a developing country.77

Improvising upon the ‘simple division royalty’ model,78 Fellmeth introduced the ‘re-adjustable royalties’ model. Under the new system, the subsequent registrants would pay the originator an amount that is proportionate to the benefit derived from using the original data. This system “should correlate the benefits of market access with the costs of obtaining such access.” Thus, initially, the originator company will receive a higher amount from the generic company since the benefit gained would be higher. Subsequently, the royalty would be reduced for subsequent companies since the benefit derived would be lesser due to the existence of a previous generic company.79 Therefore, according to this system, the originator company would recover around 80% of the costs incurred.80

This model, therefore, ensures that at least 80% of the cost is recovered by the originator company but not more than 100% of the real cost; hence, creating a balance between the right of the originator company to recover its costs and the need to provide access to the orphan drugs. Further, the flexibility in adjusting the royalties serves to regulate effective competition in the market since it takes into account the number of competitors and their ability to pay. At the same time, it “will disperse the cost of the clinical trials among all available competitors.”81 The Indian system can adopt the compensatory liability model while granting exclusivity to the orphan drugs.

SUPPLEMENTARY PROTECTION CERTIFICATE AS A SUPPLEMENT TO EXCLUSIVITY

One of the biggest challenges faced by patent protection is the time lag, which requires managing the life cycle of the patent.82 Patent regulation encourages preliminary filing, till the time an orphan drug comes to the market (after the clinical trials and the regulatory approval) majority of the patent protection period expires.83 Therefore, Patent term expansion was introduced by the European Union for restoring this lost life of the patent. This patent term expansion is known as a Supplementary Protection Certificate (“SPC”).84 Patent protection and SPC run parallel to orphan exclusivity which helps the developer to recoup the investment in research and development of the drug. SPC is the

77 Fellmeth, supra note 36, at 481-482.
78 Fellmeth, supra note 36.
79 Fellmeth, supra note 36.
80 Fellmeth, supra note 36.
81 Fellmeth, supra note 36.
82 Randall Morin, supra note 3.
84 Id.
augmentation of a patent right. It is an intellectual property right which provides additional patent rights after the end of the patent protection period. SPC is linked to a product and its patent.\textsuperscript{85}

SPC term comes into operation after the expiry of the standard patent period, that is, 20 years. In the EU, the maximum extension provided is up to 5 years depending upon the time taken in research and development and clinical trials. SPC is granted only on the product which is patented, validly authorised and the term between the patent filing and authorisation is not more than 5 years.

The objective behind the introduction of SPCs was to promote innovation and development in fields such as medicine where the effective part of the patent life is lost due to prolonged development and authorisation process.\textsuperscript{86} It is a form of attracting R&D investments in this field, thereby retaining innovation and ensuring sufficient protection to recuperate investments. SPC helps in increasing the availability of medicinal products in the market and preventing supply shortages. Supply shortages occur in the market due to various causes among which low-profit margins make the market more vulnerable to the shortage. In addition, if there is a generic entry in the market, it will lead to a decrease in prices leading to lowering the profit-margin, which ultimately gives rise to the risk of supply shortages. By providing SPC to a product, it delays the entry of generic competitors, thus alleviating the problem of supply shortages.\textsuperscript{87} It also helps in minimising the gap between the European market and the international market of the pharmaceutical industry. Currently, the patent restoration term in the EU, US and Japan for orphan products is up to 5 years, whereas Canada provides a term of up to 2 years. There is no such provision of SPC or patent term extension in India and China.\textsuperscript{88}

\textbf{RELATIONSHIP BETWEEN EXCLUSIVITY AND SUPPLEMENTARY PROTECTION CERTIFICATE}

It is an imperative task for a pharmaceutical company to protect the intellectual property of a new drug. This protection is provided by patent and orphan exclusivity, which furnishes time for a drug to recapture the market and get sufficient return on the investment in research and development. It also helps in the promotion and development of the drug which in turn results in advancement in the medical field.\textsuperscript{89}

Patent protection is provided to a product if it fulfils the criterion of novelty, non-obviousness and industrial applicability whereas, for a drug to get orphan exclusivity, it must involve scientific principle

\textsuperscript{85}\textit{COPENHAGEN ECONOMICS, STUDY ON THE ECONOMIC IMPACT OF SUPPLEMENTARY PROTECTION CERTIFICATES, PHARMACEUTICAL INCENTIVES AND REWARDS IN EUROPE, European Commission Doc.at 25-28 (2018) [hereinafter ‘Copenhagen Economics’].}

\textsuperscript{86} Id.

\textsuperscript{87} Copenhagen Economics, supra note 46.


and help in the treatment of a rare disease for which no adequate alternatives are available. Patent protection emphasizes on innovation and non-obviousness but such characteristics, in case of orphan exclusivity, are secondary. Orphan exclusivity is granted to that drug which receives market approval and market approval is granted only if the drug is new and is used for the treatment of rare diseases. The need for the introduction of exclusivity arose to promote development in the medical sector as the non-availability of patent protection in some cases coupled with a non-viable market for orphan diseases often discourages pharmaceutical companies from investing in research and development. It is not necessary that a drug should be patented to get orphan exclusivity, a non-patented product can also get exclusivity. However, a patented drug supplements the orphan exclusivity in numerous ways such as patent protection that extends to other uses of the same drug but Orphan drug exclusivity does not. This reduces the risk of ‘off-label’ use of the drug. Further, exclusivity is obtained after the completion of the clinical trials, but a patent is obtained after the discovery of the compound which helps in protecting the drug composition matter. Patents provide ancillary rights and have greater enforcement regulation.

Just like patent protection acts as an accessory to orphan exclusivity, exclusivity also fulfils the shortcomings of patent protection. While patent protection is obtained at the trial stage, the exclusivity period starts when the drug is on the market. Till the time the drug gets to the market, little time is left from the patent protection period. Therefore, exclusivity fits more with the life cycle of an orphan drug. To protect a drug from competitors, patent owners may indulge in infringement lawsuits which may be costly and uncertain whereas orphan exclusivity better protects the drug as it keeps competitors away from the market without the need for the owners to bring expensive and uncertain infringement lawsuits. Therefore, both patent protection and orphan exclusivity are complementary to each other and play a significant role in the development of an orphan drug in the market.

CONCLUSION

Exclusivity, by granting monopoly rights, may lead to higher prices and may prohibit drug access to the general public. Sometimes, it may violate the spirit behind the introduction of Orphan legislation and hence, forces the burden upon the patients who would ultimately be at loss. However, as stated above, exclusivity is the need of the hour to fill the gap created in the market for orphan drugs due to

---

92 Shannon Gibson, supra note 44.
93 Randall Morin, supra note 3.
95 REBECCA S. EISENBERG, PATENTS AND REGULATORY EXCLUSIVITY, 174-175 (P. Danzon and S. Nicholson eds., 2012).
lack of incentives and legislation protecting the IPR of the originators. Moreover, lack of a legislative framework for orphan drugs would have even stronger repercussions on the affected patients in India, which has one of the largest populations in the world. Therefore, the balance must be maintained by introducing a legal framework wherein the interests of both the patients and the originator of the orphan drugs are taken care of. Since there already exists a Drugs and Cosmetics Act dealing with pharmaceuticals, the Act can be amended to incorporate regulations pertaining to orphan drugs, wherever possible. While exclusivity for a fixed period is necessary, a rather flexible rule of allowing the disclosure of data in consideration of a ‘fair’ compensation along the lines of compensatory liability model can be adopted. Moreover, supplementary protection certificate must be granted to complement exclusivity in India.

Legislations of various countries and regions vary with regard to the regulatory framework and other IP and non-IP regimes relating to orphan drugs. A global approach should be followed by the regulatory authorities of different countries with an aim to incentivize the production of orphan drugs, to bring transparency and efficacy in administration. India should also learn from various countries where incentives like Supplementary Protection Certificate, tax benefits, and Orphan Drug Exclusivity are incorporated in their legal provisions. An efficient IP strategy will help in reducing the gap between India and the developed countries.
‘Google’ing the way out of Antitrust allegations

Bhaavi Agrawal*

Abstract

The age of digitalization has dawned upon humanity and it has vowed to change the structure of the market. The wheels started slowly turning when the internet bubble quietly took place on Wall Street. The giants like Microsoft, Google, Apple, and Amazon were just entering the market when the profits were slim and the capital was Lilliputian. However, along with well thought out marketing strategies and continuous innovation, these companies established themselves as a household name. The very basis of the functioning of the digital companies is based on the collection of data. The use of private data not only ropes in privacy concerns but also gives rise to competition law concerns. Data has become a major source of market power in the new age markets. However, the investigation authorities lack the required toolkit to analyse the matters. Search engines play a big role in conducting the hi-tech market. Since they provide the gateway for the internet of things; they have preliminary access to the search data. This data is often exposed to either third party analytics or the companies who generate target advertisements on the basis of the same. This effectively harms the competition and the consumer interest in an unparalleled manner. Google being the dominant search engine in the market has effectively refracted the competition. But is it just a part and parcel of the new age market or a clear case of abuse of dominance?

Keywords
digital economy, Google, abuse of dominant position, antitrust

---

*Year V, B.A. LL.B. (Hons.), Rajiv Gandhi National University of Law (RGNUL), Punjab.
INTRODUCTION

It is true that the Earth has shrunken and reduced to a global village now. Everything is connected in the massive web of internet, efficient and cheaper transportation, excellent telecommunication infrastructure and easily accessible worldwide market. The concept of nationality and economic patriotism are now diminishing and becoming steadily irrelevant as the diaspora across the world is on an all-time high and the borders hold no meaning anymore.

The driving factor of such rapid globalization can be single headedly accredited to the World Wide Web, or now very commonly known as the Internet. The economy grew by leaps and bounds when it was fuelled by the power of the internet. So much so, that digital economy has now become a separate aspect of the economy of the nations. The impact of the digital economy is so much that the government everywhere is trying to come up with rules and regulations to control the rapidness even when the full potential of the digital economy has not been achieved. Therefore, it becomes imperative to understand the meaning and scope of the digital economy.

DEFINITION

The digital economy, generally speaking, is the part of an economy that enables and conducts the trade of goods and services through electronic commerce on the Internet. The term “Digital Economy” was first used in the 1990s by the Canadian researcher and author Don Tapscott, inspired by the professor who coined the term in midst of a recession in Japan, while conducting his economic research. Traditionally, the digital economy consists of three components –

i. E-business infrastructure – It mainly includes the physical tangible products like hardware, telecom, software, networks, etc.;

ii. E-business – It consists of the gateways and methods of how business is conducted, any process that an organization conducts over computer-mediated networks;

iii. E-commerce – It consists of the actual economic and commercial transaction that takes place when e-business is conducted using the available e-business infrastructure like the transfer of goods, like goods being sold and purchased online.96

SHIFTING SCOPE

As observed from the definition, e-commerce as defined for the first time still had a physical tangible aspect to it. However, the main concern with digitalization is that it is an arduous task to keep up with the rapid technological advancement in this field. The boundaries set out in the definition to limit the

scope are constantly blurring and new complexities are being introduced. This takes place under the
garb of making the entire experience more smooth and user-friendly along with avoiding bugs so as to
prevent hacking. The innovative disruption is caused in various sectors and thereby making the global
economy a pinnacle of independence from the traditional geographic market. This leads to the formation
of the digital market.\textsuperscript{97}

**DIGITAL MARKET**

Digital Marketplace is an online platform that is used by organizations to find and buy cloud-based
services. Digital marketplace uses digital technologies, mainly on the Internet but also uses mobile
phones, and other digital mediums.\textsuperscript{98} The digital market consists of various aspects of the world
economy, impacting various sectors like retail, banking, education, health, cosmetics and beauty,
publishing, communication and transportation. The scope of the digital market is ever-broadening as it
makes everything one click away.

The model of the digital place is not a new facet of the market. However, the world was apprehensive
of the power of the internet and the extent of digitalization that the world would achieve in the next two
decades. Initially, only a few companies entered the arena of digitalization and took it upon themselves
to forward the need and cause of digitalization. Those companies have now achieved a global digital
dominance that controls most of the data uploaded and on the basis of that sell commercial digital goods,
recommend us, people, to build social relations with and even influence our political opinions. These
digitally dominant companies are none other than our daily interactive companies – Google (Alphabet),
Amazon, Facebook, Apple and Microsoft. These technological giant companies had very humble
beginnings in Silicon Valley and have now become essential to everyone’s life in one way or the other.
They are often referred to as G.A.F.A. These companies are now dominant in the stock market for the
first time, even more than they were at the time of the Internet bubble of 1990. These companies, though
dominant together in the tech-market; they still have dominance on a certain aspect of e-business and
constitute the most vital part of the e-commerce sector.

**E-COMMERCE MARKET**

As per Organisation for Economic Co-operation and Development (OECD), an e-commerce transaction
is the sale or purchase of goods or services, conducted over computer networks by methods specifically
designed for the purpose of receiving or placing orders. An e-commerce transaction can be between
enterprises, individuals, governments, and other public or private organizations. The type is defined by

----


the method of placing the order. To be excluded are orders made by telephone calls, facsimile or manually typed e-mail.99

Due to the broadening scope of e-commerce, global efforts are being made to reduce the gap between e-commerce and competition law. This is being done so that the consumers reap maximum advantage of a competitive business setting digitally. This, in turn, ensures that innovative developments do not lessen the consumer benefits.100

NATURE AND DEVELOPMENT OF E-COMMERCE

E-commerce is now the fastest growing and all-embracing marketplace. It has become even more pertinent to adapt to the changing technologies so as to effectively tackle the challenges put forth in the legal arena because of the new circumstances.

Technology and law cannot be left in two isolated boxes. The relationship between the two has to be dynamic, simultaneous and interactive. The dichotomy of the situation is such that every other day, better and new technology is introduced while the law takes time to brew. The process of making laws or amending the present laws is slow as compared to the technological development which leads to a gap between them and the absence of adequate legal protection. Initially, it poses a challenge as to the existence of the rights and liabilities of the parties concerned and the remedies to the occurrence of the violations. But at the same time, it also grabs the attention of the legislators and provides them with an opportunity to deeply analyse the ground reality and practicalities. This, in turn, would lead to the formation of a law that would effectively deal with all possible situations arising in the legal vis-à-vis digital arena.101

CONFLICT WITH THE TRADITIONAL MARKET

The rapid development and growth in the e-commerce sector has led to conflict between the physical brick and mortar market place and e-commerce market space due to predatory pricing and personalized pricing so as to expand the market share in the online market space. As the e-commerce market is new in India, the big foreign retail companies frequently offer discounted prices as they have big pockets and huge funding. The traditional market cannot keep up and offer the same reduced prices without suffering a loss. Though it is favourable to the consumers, it is harmful to the traditional market retailers who want to protect their earning margins as they have to pay for service and in-store competition. The players in the market justify the same by presenting the efficiency arguments which is generally based


on putting limitations on free riding, improvement in services, etc. This leads to a precarious situation causing misbalance, inefficiency, exclusivity and exclusion in other jurisdictions which will diffuse into Indian digital space as well.\textsuperscript{102}

**INTER-RELATIONSHIP OF COMPETITION LAW AND E-COMMERCE SECTOR**

The competition law concerns itself with the commercial market and the position of the players in the market so as to ensure that the consumer is not in a position of loss and neither is a market player in relation to another competing market player. The primary aim of competition law is to protect competition and not the competitors. The web commercial space exists in the purview of the antitrust or competition regulatory authorities as they are simply a way of selling the products using a different distribution method as an alternative to the brick and mortar marketplace. The online and offline markets are simply different facets of the distribution of the products therefore the target consumers are more or less the same. The gap between the offline and online markets, which was wide once is now blurring due to rapid telecommunication services becoming gradually accessible everywhere. The number of internet users is on a constant rise, which is a joint effort of the government who wants to make the internet accessible to everyone and the telecommunication giant private players who want to expand the revenue by expanding the consumer base.

Hence, the online market has become too massive to be ignored by the competition authorities around the globe. Through new rules and policy and through setting precedents, the authorities are trying to give a positive direction to the ever-growing and inherently dynamic e-commerce market.

**GOOGLE AND ANTITRUST CHARGES**

As ironic as the situation may be, Google cannot hide the antitrust violations that it has committed in 10 different manners over a period of 5 years.\textsuperscript{103} The company has been under the constant vigilance of the antitrust enforcement agencies but due to lacunas in the antitrust laws and the effective manipulation of the law by the company, the authorities were unable to proceed with any formal charges. However, on 30th November, 2010, the European Commission (‘EC’) was successful in opening a full-fledged investigation against the allegations of antitrust violation against Google Inc. that the Company has abused its dominant position in online search functions, in violation of the European Union Rules.\textsuperscript{104}


The legal basis of launching an investigation was provided under Article 11(6) of Council Regulation No 1/2003 and Article 2(1) of Commission Regulation No 773/2004.

**GROUNDS OF INVESTIGATION**

The grounds of investigation and the charges were as follows –

I. The more favourable treatment, within Google’s general web search results, of its own content and its own vertical search services.

II. *Scraping*: Use of third-party content by Google without prior consent of the owners, for the benefit of its own vertical search services.

III. *Advertising exclusivity*: exclusivity agreements between third-party web sites and Google to receive majority of the online search advertisements from the latter, therefore, successfully excluding the rivals from competing in the search advertising intermediation service market.

IV. Putting undue restrictions on the advertisers to transfer online search-advertising campaigns to its competitors.

The investigation by the EC set a chain reaction in order against Google Inc., United States of America and India were quick to catch up. Both the jurisdictions found the allegations as pressed by EC to be relevant and, therefore, took adequate measures to counter the same.

**MATRIMONY.COM v. GOOGLE INC.**

**Facts of the Case**

The informant in the case was Bharat matrimony who was aggrieved by the way business was being conducted by Google. The core issue was that search and advertising was conducted in a discriminatory

---


108 Specialized or vertical search sites are the search engines that let users search specifically in a particular domain. Vertical search services are specialised search engines which focus on specific topics such as *for example* restaurants, new or products.

109 Without any prior authorization, Google was found to be copying from the authentic content from the websites of its rivals such as user reviews.

manner which was causing harm to advertisers and then ultimately to the consumers. This effectively created an unfair advantage in favour of the services provided by Google and its partners. This was achieved by manipulating the search results of a search where the top results were links to YouTube, Google Maps and Google News which infamously are the vertical partners of the Google group. The results of search often show the search results from above-mentioned sites as a part of the organic result and not in the form of an advertisement or suggestion.

The Informant also stated that Google is acquiring various software products so as to complete the vertical integration and obtain an indirect monopolistic position and eventually eliminate any kind of competition in the market. On the basis of this, a CCI complaint was officially lodged as there was an abuse of dominant position. The relevant market claimed to be was online search and advertising market in India.

**Findings of CCI**

Based on the information submitted by the Informant, CCI launched an investigation and held that relevant market would be –

I. Online General Web Search Service in India;

II. Online Search Advertising in India.111

It was concluded that Google was a dominant player in the relevant market as established. And due to a lot of entry barriers present in the relevant market, it was asserted that Google maintained its position of dominance and strength.

**Search Bias Concern**

The Director-General was of the view that Google offers its own search software like Google News, Google Maps, Google reviews, etc. These system software are either acquired or created by Google itself. During the course of the investigation it was found out that Google integrates and blends its own search into the general web search services in the worldwide results that are provided using the mechanisms which do not essentially apply in an equivalent manner to non-Google web content. Such results are often provided as special features and given special ranks to catch the eye of a consumer and increases online visibility. This efficiently increases the deviation of the consumer to the Google services from the generally available results of the search conducted.

The search bias is visible in the three specialized result designs which are curated by Google:

---

111 *Id.*, at ¶19.
a) **Universal Results**

These are a group of results for a specific type of information. These are usually considered free results – like blue link results. These are displayed so as to increase relevance and usefulness. It is done in three ways –

a. The group results formulate the specific information category;

b. To increase the relevancy of the results in the category of information, results are selected within a group based on category-specific signals; and

c. They show results in formats tailored to the type of information at issue.\(^{112}\)

b) **One Boxes**

One Boxes are often sources as data feeds from the third-party content provider. Google has an agreement with the content providing party. They directly answer a query that has been searched for and are tailor-made for that specific search question. These are discriminatory in nature as these might not be the most relevant answer satisfying the search question but are shown to a consumer as if they are. This causes an information asymmetry. This happens because the information is presented in an authoritative manner.

c) **Commercial Units**

These are the result types that are set in a different manner than free search results. The distinction is observed from the free search results by putting tag – ‘Sponsored’ to the commercial units search. The Commercial Units are used only for shopping and air transportation purposes by Google in the Indian market. It as a common sight in the hotel searches before but it has been discontinued. The DG noted that Google treats Commercial Units in a “preferential” manner because they are as they are mostly mechanics-based and there is no application on the links to non-Google websites in a uniform manner. Google has effectively denied such conclusions and findings of the DG.\(^{113}\)

This creates an appreciable adverse effect on the competition in the relevant market. Resultantly, Google was found to be exhibiting anti-competitive behaviour, specifically abuse of dominant position in terms of Section 4(2)(a)(i), Section 4(2)(b)(ii), Section 4(2)(c) and Section 4(2)(e) of the Competition Act, 2002.\(^{114}\)

---

\(^{112}\) *Supra* note 15, at ¶209.

\(^{113}\) *Supra* note 15, at ¶232-233.

\(^{114}\) *Supra* note 15, at ¶21.
Trademark Concerns

It was also found that Google was abusing its dominant position by imposing unfair conditions upon the trademark owners as their trademarks were allowed to be bid as keywords by third parties in the online search. This practice also creates a significant risk of causing confusion and deception in the minds of the users thereby causing consumer harm. The uninformed consumers would easily believe that there exists a relation between the trademark owner and the rivals whose advertisements pop-up in response to the search. This may lead to the diversion of consumer traffic. Due to this, the trademark owners have no option but to participate and outbid competitors. This is done to make the trademark owners’ ads appear before its competitors, therefore swelling up their advertising budget.\(^{115}\)

Opinion on Digital Economy

The CCI while analyzing the dominant position in the online market held that due to lack of adequate antitrust checks and balances in place; players in the digital market are in a ‘virtual hegemony’. The situation is of winner takes all and the competition is forever tilted in that particular direction, therefore it becomes hard to fixate any level for all the players in the market. The dominant enterprise in the digital cyberspace carries a special responsibility. This is so because the abuse of the dominant practice would not only impact the market but also the entry and sustenance. As Google is in a dominant position because the majority of the internet users use Google as a gateway to access other websites therefore it carries a special responsibility to ensure fairness in the policies.

CCI was also aware that the digital landscape is still in the developing stage and any kind of hastiness in the formation of new policies is only going to stifle the innovation and deny the consumer the welfare that the digital market has to offer. The main allegations of the Informant are against the way search results are presented to a consumer on the Google Search Engine. This is done in a manner that some search results catch the attention of a normal prudent consumer as compared to various other search results. Therefore, Product Design plays a major role in the present case.

Order of the CCI

The final order passed by the commission mainly resonated with the views of the Informants. The fact that makes the discussion in this case very pertinent is the penalty that was imposed on Google. As the CCI is empowered with enormous discretionary powers, the CCI in the particular case decided to levy the penalty in proportion to the turnover of the Company. The penalty was set to be at 5% of the average turnover of the past three years. The financial records, as provided to CCI were:

\(^{115}\) Supra note 15, at ¶26.
Consequently, the CCI imposed a hefty penalty in the tune of INR 135.86 Crore for violation of the provisions of the Competition Act.

**European Perspective**

The European Commission (EC) found Google to be dominant in the general Internet search markets throughout the European Economic Area (EEA) that is consisting of 33 countries.\(^{116}\) It is generally agreed that the Commission was right in holding the Company to be dominant. The EC had a very interesting take on the search bias. It held that the search bias is a by-product of the algorithm that is being used to generate the relevant search results.

**Algorithm-based abuse**

Since the search bias has been alleged in various other jurisdictions as well, the algorithms used are to be blamed. Therefore, it becomes tricky to check the anti-competitiveness of the algorithms. They abuse newer positions like – data capture, extraction, and co-opetition (between super platforms and applications developers).\(^{117}\) However, the EC has observed that search algorithms and search engines by definition do not treat all information equally. The results produced from the search are ranked to increase the relevance using the methods to select and then index the information. Due to this, the advertisements of smaller companies or content provider are ranked lower after the integration of data and profiling. While the larger company gets a discriminatory advantage since they bring in more business. The consumers are also treated unequally by the search engines and the algorithms. Based on the previous behaviour of the users, the algorithms create a behavioural profile, personal risks profile, etc. which present them with different results compared to the others.\(^{118}\)

---


This leads to the conclusion that the behaviour is exclusionary in nature which might be tailored so as to improve the search result and interaction experience. The problem arising from algorithmic-based models of online platforms is an asymmetry of power between the institutions that accumulate data and the people who generate these data.119

In July 2016, the EC launched its third investigation against Google and this time the focus was primarily on the advertising practices of the Company that is – Google Search and Android. It was an estimation of the CCI that Google’s total market share in search advertising in Europe was approximately 80% in the past 10 years. In 2017, the EC gave the decision on the antitrust investigation launched in 2015. It was of the opinion that the Company has indulged in abusive practices, being in a dominant position. This has therefore resulted in stifling competition and comparison-shopping markets. The EC also levied a fine of 2.42 Billion Euros in regard to the comparison shopping services.

**IS SEARCH NEUTRALITY A SOLUTION?**

Google being the largest and the most widely used search engine is in a tricky position in the antitrust lens. In the past few years, legal scholars and the policymakers are considering a fair way out of the system until a definitive law is in place. This is “search neutrality” to counter the search bias. Neutrality in general means indifference. Search neutrality, a flexible term that is still not clearly explored and defined, usually means that search engines would not give preference to the content in the search results and they are to be presented in an objective manner. And only show its own content in a higher rank if it is of superior quality as compared to the search algorithms.120 So the principle, in essence, asks the search engines not to rank the websites in accordance with the algorithms but simply display the information and leave it to the consumer to sort and choose the information sought.

The theory was first suggested by the Federal Trade Commission (FTC) in the USA in its probe against Google. Some have suggested that Google’s search engine is a “gatekeeper” to the Internet121 and, therefore, an “essential facility” the control of which would impose some duty on Google to assist its competitors — websites with competing content.122 The essential facilities doctrine, however, is a poor fit in the context of search results,123 even if we disregard the United States Supreme Court’s recently expressed skepticism of the doctrine in *Verizon Communications, Inc. v. Law Offices of Curtis V.*

---

122 Id., at 1176.
Trinko. The essential facilities doctrine raises a valid concern that due to the introduction of compulsory dealings and price range fixing; it may cause a depreciation in the ongoing incentive for innovation and the investment. Fearing this consequence, the Courts have imposed strict conditions on its application and seldom rule in favour of the plaintiffs.

**Principles**

The search neutrality is based on 8 different doctrines. They are –

i. *Equality*: Search engines should not differentiate at all among websites.

ii. *Objectivity*: There are correct search results and incorrect ones, so search engines should return only the correct ones.

iii. *Bias*: Search engines should not distort the information landscape.

iv. *Traffic*: Websites that depend on a flow of visitors should not be cut off by search engines.

v. *Relevance*: Search engines should maximize users’ satisfaction with search results.

vi. *Self-interest*: Search engines should not trade on their own account.

vii. *Transparency*: Search engines should disclose the algorithms they use to rank web pages.

viii. *Manipulation*: Search engines should rank sites only according to general rules, rather than promoting and demoting sites on an individual basis.

**CONCLUSION**

A good search engine is more exquisitely sensitive to a user’s interests than any other communications technology. The search neutrality principle is a largely undeveloped concept and its broad application would only play detrimental to the consumer’s interest. But at the same time, a mechanism is required in place to hold the dominant search engines liable for interfering with the hits of the rivals in the search results. However, this liability has to be carefully drawn so as not to suffocate the developing arc of

---

124 Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko, 540 U.S. 398, 410–11 (2004) (describing the doctrine dismissively as having been “crafted by some lower courts” and refusing to recognize (or repudiate) it).
digital growth and innovation in the industry. Search neutrality may thus have a future, not as a general principle, but as the misfitting tag line on fact-specific findings of egregious abuses by dominant search engines.\textsuperscript{129}

However, Google Inc. is a popular and preferred search engine because of its ability to present the most relevant and accurate information in no span of time. This is possible because of certain quality and kind of information is given priority. The priority is given on the basis of the cookies that are used by a website to collect the data and predict future trends and needs of the same user. Because of the efficiency, an individual consumer is willing to let go of the privacy and data ownership.

Google is the most popular search engine in the market today and the reason it is so is because of the accuracy of the information provided. The information is ranked and it is on the sole discretion of the Company that which search result appears first which afterwards. Most of the times the top most answers to the query are from the Google subsidiaries. Therefore, it puts Google in a position of dominance and therefore the abuse has taken place due to discrimination to third party content providers.

Patent Rights and Competition Law: Conflicts and need for Harmonization

Saksham Malik*

Abstract

Patent rights and Competition law have developed as disciplines distinct from each other, with their unique set of objectives and modes of achieving them. However, the two disciplines also interact extensively, especially in the current scenario where innovation is a major catalyst for the growth of corporations as well as the economy. The paper will discuss this relationship between the two disciplines, focusing on complicated and fact-specific issues such as tying agreements, Standard Essential Patents, patent pooling, and others. It will analyse jurisprudence from three of the most mature jurisdictions in this respect, the United States of America, the European Union and India. The extent to which patent rights can exist in harmony with competition concerns by preventing infringement and thus encouraging fair market behaviour will be examined. We will also analyse instances wherein patent rights can be exploited to engage in anti-competitive behaviour. The paper will suggest ways in which the interaction between patent rights and competition law can be regulated to aid the development of the competitors, consumers, and various other stakeholders.

Keywords

patents, refusal-to-deal, interface, competition law, intellectual property rights, IPR, standard essential patents

*Year V, B.A. LL.B. (Hons.), Rajiv Gandhi National University of Law (RGNUL), Punjab.
INTRODUCTION

Knowledge and technology have proved to be important catalysts for economic growth in recent times. The patent system promotes the same, allowing an inventor to essentially cover his investments and even profit off his invention. The nature of such protection has undergone changes over the years. The first patent in India was famously granted to George Alfred De Penning from Calcutta for a Punkah Pulling Machine in 1856. Back then, the nature of patent rights was limited to providing exclusive privileges that incentivize the inventions of new manufacturers.\(^{130}\) In the past 150 years, the nature of patent rights has undergone significant changes. While novelty, utility and inventiveness still make up the very essence of a patent; concepts such as Standard Essential Patents (“SEP”), i.e. patents covering portions of a technical standard that is essential to ensure device interconnectivity and interoperability\(^{131}\) have developed in response to the rapidly changing economic scenario. Patents are now valued as key assets by multi-national corporations, proving essential to bringing in profits and enhancing productivity.\(^ {132}\) In a knowledge-based economy, patents can be responsible for the growth and in some cases, exploitation. Essentially, patents create the right to keep others from making, using, importing, selling, offering for sale, the invention, and essentially creating a monopoly right.\(^ {133}\) The misuse or abuse of these rights, if it amounts to anti-competitive behavior, is part of what Competition Law seeks to prevent and punish.

The conversation on the interface of patent and competition law rights is especially relevant in the current scenario in various industries such as pharmaceuticals and telecom devices technology. Reports from the United States suggest that between 2012 and 2017, prices of 12 best-selling drugs increased by 68%, with the price of Lyrica (a drug used for treating neuropathic pain) increasing by 163%. Pharmaceutical companies seek to eliminate competition by generic players in the market by seeking protection for close to 38 years. This is done by filing multiple patent applications for the same drug, in an attempt to extend the validity of the patent. Herceptin (cancer drug), for example, has numerous patent applications pending which would effectively extend its patent life till 2033.\(^ {134}\) The situation in India is bleak too. In January 2019, a high-level Indian government panel made recommendations to lower the prices of patented medicines. Intended to bring down the prices of drugs for cancer and rare

diseases, it suggested issuing compulsory licenses, notwithstanding the consent of the patent holder.\textsuperscript{135} The trend thus suggests that if the abuse of monopoly is left unchecked, it can prove harmful to the concerns of competitors and consumers alike.

The European Union, the United States and India have significant literature in the form of case laws, guidelines and legislations on the interface of intellectual property rights (“\textit{IPR}”) and competition law. Courts in these jurisdictions have long attempted to delineate the purview of patent rights. For example, the first half of the 20\textsuperscript{th} century often saw the American courts consider rights inherent in the patent grant essential to determine whether there was a possible competition concern. The courts observed that antitrust law has a role to play only when the rights inherent in a patent are breached or exploited.\textsuperscript{136} However, in the course of time, disputes of various kinds have arisen before the courts, from considering restrictive licensing agreements to the treatment of SEPs. This paper will discuss the relationship of patent law and competition law in the context of the United States, the European Union and India, three of the most experienced jurisdictions in this regard. The author will discuss issues revolving around refusal to deal and tying arrangements as they have come up in the United States of America and refusal to license cases in the European Union. In the Indian context, the discussion will revolve around licensing of IPR. Questions relating to SEPs, being a crucial aspect of the interface between competition law and patent rights, will be discussed in relation to each of the above-mentioned jurisdictions.

\textbf{CO-EXISTENCE OF PATENT RIGHTS WITH ANTI-TRUST CONCERNS IN THE UNITED STATES – FTC, DOJ AND EVERYTHING IN BETWEEN}

The Sherman Act, 1890, the Clayton Antitrust Act, 1914 and the FTC Act, 1914 are the primary statutes concerned with competition law disputes in the United States. In addition, the Federal Trade Commission (“\textit{FTC}”) and Department of Justice (“\textit{DOJ}”) occasionally notify guidelines on the antitrust policy of the country with regard to IPR.\textsuperscript{137} This part will initially look at the interface from specific kinds of anti-competitive activities, i.e. refusal-to-deal and tying agreements. In the latter part, the author will discuss competition law issues that have arisen with respect to SEPs.

\textbf{Relationship of patent rights with Refusal to deal and Tying Agreements}

Issues pertaining to the interface of competition law and IPR have often arisen in refusal-to-deal cases and are therefore relevant for our discussion. The law relating to refusal to deal has been provided in the Sherman Act. The manner in which the law on refusal to deal is to be interpreted was discussed in


the cases of United States v. Colgate & Co. and in Russell Stover Candies, Inc. v. Federal Trade Commission. The Sherman Act prohibits and punishes combinations and agreements that restrain trade. One of the first interpretations of the legislation in this regard was laid down in the case of United States v. Colgate & Co. The case related to Colgate’s refusal to deal with agents selling below the retail price suggested by the Company. The United States Supreme Court ruled that a manufacturer is not prevented from announcing the prices at which his goods may be resold and refusing to deal with wholesalers and retailers who do not conform to such price. The rule was replaced in Russell Stover Candies, Inc. v. Federal Trade Commission which established the ‘rule of reason’. The test takes into consideration the relevant market and the power of the defendant’s position in the market. The claim is then decided on the basis of whether the act imposes an unreasonable restraint on competition. Other considerations including the purpose of the alleged act and the intent behind it can also influence the decision of the court.

The case of Eastman Kodak Co. v. Image Technical Services Inc. is relevant for the discussion on refusal to deal. In the instant case, Kodak was following a policy of selling repair parts – patented and unpatented, only to direct purchasers. Dozens of Independent Service Organizations (“ISO”) were not given the necessary repair parts. Kodak had also signed agreements with Original Equipment Manufacturers (“OEM”), preventing them from supplying the parts to ISOs. The decision of the 9th Circuit Court was reaffirmed by the Supreme Court stating that even though Kodak lacked sufficient power in the market for its primary product i.e. imaging equipment, it did have significant market power in the repair parts market. The defendant could thus be held liable for an antitrust violation for its refusal to deal with the ISOs. The court also highlighted the fact that the customers were “locked-in” once they agreed to buy Kodak equipment since they could no longer move to another company for repair parts. Once a customer is locked-in, it cannot switch to another seller without incurring substantial costs. The conduct of Kodak in the instant case amounted to a tying agreement, which exists when the seller places conditions on the sale of a product which entails the purchase of secondary product along with the primary product. Tying agreements are per se illegal under Section 3 of the Clayton Act. The court further stated that in order to prove a tying agreement, it has to be established that: first, the sale of the primary item was conditioned on the sale of the secondary item and second, that both the goods are separate and not constitute a single product. In addition, it is to be established that the tying agreement has impacted commerce sufficiently and detrimentally. The case presents an appropriate

144 Eastman Kodak Case, supra note 12.
instance of how a seller can refuse to sell its patented products, which may not even be the primary product, and thereby engage in anti-competitive behavior.

**Anti-competitive activities through licensing of Standard Essential Patents**

SEP are patents that are essential for the implementation of an industry standard. Standards, in this context, are those specifications that aim at providing a common design for a product. These standards have been adopted by Standard Setting Organizations or SSOs like International Electrotechnical Commission, International Organization for Standardization and World Standards Cooperation. In this context, the role of FRAND terms, also called fair, reasonable, and non-discriminatory terms are relevant. In order to utilize a technical standard, a license must be issued by the patent holder, which, it may refuse. The FRAND terms thus regulate the terms of such license agreements in order to ensure fair treatment of both parties. One of the first instances in the United States of violation of SEP terms was in 1992. Dell Corporation had been a part of VESA or the Video Electronics Standards Association which necessitated its members to disclose their IP rights to each other. Dell, in 1991, revealed that it had obtained a patent which it sought to enforce through licensing. The Company was held liable for unfair competition under Section 5 of the FTC Act since it did not reveal its patents to VESA. Dell entered into a consent agreement with the FTC, wherein Dell was prohibited from enforcing the patent against any company for such company’s use of VESA’s relevant standards.

One of the most important decisions in the IPR-Antitrust debate in recent times was given by Judge Koh in *FTC v. Qualcomm Inc.* Conduct of Qualcomm in licensing patents has been investigated in various countries in Asia, Europe and in the United States. In 2015, the Company paid $975 million for its anti-competitive practices in China. The South Korean Antitrust agency also imposed a fine of

---


$853 Million for Qualcomm’s ‘monopolistic’ practices,\textsuperscript{153} as did the European Commission to a tune of €997 million.\textsuperscript{154}

In the USA, the Company was sued by the FTC for violating Section 5 of the FTC Act, which enlists unfair methods of competition and unfair/deceptive acts affecting commerce as being unlawful.\textsuperscript{155} It was alleged that Qualcomm enjoys a dominant position in the supply of modem chips and has the ownership of various patents essential for CDMA and LTE. The company allegedly refused to license these SEPs while maintaining an exclusive dealing arrangement with a downstream handset company.\textsuperscript{156} The Court ruled that Qualcomm had to issue licenses for its SEPs to its competitors on FRAND terms.\textsuperscript{157} The instance is significant as it shows that anti-competitive behavior in relation to SEPs can have an impact across jurisdictions and can attract enormous penalties.

The approach of the FTC and DoJ has been focused on checking whether there has been a breach of FRAND terms by SEP owners. However, recently, public statements by the two agencies suggest that a new approach, called the Madison approach, might gain more prevalence. According to the Madison approach, the patent owners should “have adequate incentives to innovate and create exciting new technologies, and that licensees have appropriate incentives to implement those technologies.”\textsuperscript{158} The approach suggests that competition law should not be utilized as an instrument to regulate FRAND agreements that are made unilaterally to SSOs by patent holders. In addition, rules that rigorously limit the right of patent holders to exclude should be adopted only with a high burden. And lastly, the approach also provides that refusal of license unilaterally by the patent holder, even if it is unconditional, should not be considered \textit{per se} illegal by antitrust law.\textsuperscript{159}

The interaction of antitrust and patents has given rise to numerous issues, some of which were discussed in the above section. However, other serious concerns have also arisen and are worthy of discussion. The next section on EU law will deliberate upon a few of these concerns.

\textbf{THE INTERFACE OF PATENTS AND COMPETITION LAW IN THE EUROPEAN UNION}


The European Union ("EU") policy treats the economic consequences of IPR realistically — it does not make the assumption that exercise of IP rights, including patent rights leads to infringement of competition laws on its own. Instead, it seeks to empirically establish the issue on a case to case basis. The European Courts, while discussing cases, also give due regard to the impact of IP rights on innovation in the field and whether it leads to consumer welfare. Article 101 and 102 of the Treaty on the Functioning of the European Union are the primary provisions dealing with competition concerns in the region. The chapter will analyze landmark cases on refusal to deal and tying arrangements before moving on to the discussion on SEPs.

Refusal to License and Tying Agreements in context of the Microsoft Case

One of the landmark cases with regards to enforcement of IPR rights in the competition background in the EU is Microsoft v. Commission,160 which will be discussed at length. The company allegedly withheld information that was essential to interoperate its operating system, which was the dominant OS. The complaint was filed by Sun Microsystems, and the CCI found Microsoft to be indulging in anti-competitive practices through abuse of its dominant position in the market. The CCI stated that the refusal to supply the complainant with the information but providing Sun’s competitors with it amounts to a breach of Article 82. The Company was directed to disclose the required information within 4 months.161 In addition, the issue of tying agreements also arose in the case. Microsoft was allegedly tying its product, the Windows Media Player with the operating system. The Company was given 90 days’ time to provide a version of the Operating System which did not include the player. In addition, a penalty of 497.2 million Euros was imposed on the company.162

The decision was of great significance to potential licensees and other companies engaging in similar conduct, involving a huge penalty to deter companies from engaging in similar practices. An additional 899-million-euro fine was imposed in 2008 for the company’s failure to comply with the 2004 decision. This was the largest fine imposed in 50 years preceding the judgment till 2009 when Intel was fined 1.06 billion Euros for breach of competition laws.163 In order to discourage other companies from anti-competitive behaviour, penalties of high magnitude are necessary.

While considering the case of Oscar Bronner GmbH and Co. KG v. MediaprintZeitungs, an indispensability test was developed by the European Court of Justice. Certain conditions to determine whether the refusal to deal is an abuse of dominant position were given: whether the refusal eliminates all competition in the relevant market, whether there is an actual or potential substitute available and

---

160 Microsoft Corp. v Commission of the European Communities, T-201/04 (2007) [hereinafter ‘Microsoft Case’].
161 Id.
162 Microsoft Case, supra note 31.
whether the refusal can be justified by the company objectively. Most importantly, the competitor needs to prove that it is not economically feasible to develop alternatives to the product or service.\textsuperscript{164} While it may appear that the European system is inclined towards holding that owning important IP rights is prone to abuse, it is not necessarily true. Even in the Bronner case, the ECJ applied the strict test mentioned above and consequently did not hold the company liable. In CICRA v. \textit{Renault}\textsuperscript{165} and \textit{Volvo} v. \textit{Veng},\textsuperscript{166} the CCI reiterated its position, observing that merely refusing a grant of a patent or imposing royalty cannot be considered to be anti-competitive. Only when the conduct is abusive or arbitrary, can the company be held liable.

\section*{Standard Essential Patents (SEPs)}

EU competition law acknowledges that dealing with patents by dominant firms must include a return adequately reflecting the inventive function of patents.\textsuperscript{167} When the conduct of firms moves drastically away from the reward and innovation aspect and towards reaping anti-competitive advantages, the European courts intervene. One of the primary reasons for the same is that patent holders might use their dominant bargaining position in the market to demand unnecessarily high royalties once the patents are locked into a standard. This conduct is also known as patent “hold-up.”

There have been numerous cases decided by the CCI keeping in mind FRAND term violations. In 2012, concerns around companies seeking unnecessary injunctions came to the fore. In 2014, EC held even though Apple had already agreed to enter into licensing deals with Motorola, the latter company still obtained and enforced injunction orders in a German court. Motorola also required Apple to renounce the right to challenge the validity of its SEPs. The conduct, the Commission observed, was an abuse of dominant position under Article 102 of the TFEU.\textsuperscript{168}

One of the most noteworthy judgments with regards to SEPs is \textit{Unwired Planet} v. \textit{Huawei}. The complainant, an American patent assertion entity, brought the case against Huawei, Google, and Samsung for patent infringement. Some of the patents were acquired from Ericsson and were important for 2G, 3G, and 4G technologies. During the course of the proceedings, Huawei was left as the only defendant as Google and Samsung reached settlements with the Complainant. The court ruled that there is a single FRAND royalty rate that applies to numerous SEPs and circumstances. In order to bring a claim for competition or breach of contract, it is necessary that the offer of the SEP holder is substantially more than the FRAND rate. In addition, Justice Colin Birss also observed that licenses

\begin{thebibliography}{99}
\bibitem{164} Oscar Bronner GmbH and Co KG v. Mediaprint Zeitungs, Case C-7/97 (1998).
\bibitem{166} \textit{Volvo} v. \textit{Veng}, C-238/87 (1988).
\bibitem{167} \textsc{Steve D. Anderman}, \textsc{The Interface Between Intellectual Property Rights And Competition Policy} (Cambridge University Press, 2009).
\end{thebibliography}
under FRAND terms should not be restrained to a single jurisdiction since the licenses are meant for companies across the world. Lastly, the “non-discrimination (ND) prong of the FRAND commitment does not imply a hard-edged test in which a licensee may challenge the FRAND license that it has been granted on the basis that another similarly situated licensee has been granted a lower rate, so long as the difference does not distort competition between the two licensees.”\(^{169}\) The EC has also been strict as far as imposing penalties for breaching FRAND terms is concerned. Qualcomm was fined close to 997 million Euros in relation to its licensing program. The Company was found guilty of asserting its market dominance for over five years by pushing out competitors in the LTE baseband chipsets market. It even paid billions of dollars to Apple to ensure the latter exclusively uses its chipsets in all its devices. As a result, competitors were denied legitimate business opportunities and consumers were denied access to innovation.\(^{170}\)

In the process of holding the Company guilty, the CCI kept in mind the impact on consumers and competitors, the extent of payments made to Apple and evidence that these payments minimized Apple’s incentives to look to rival products for chipsets. The CCI also kept in mind that Apple being a highly influential player in the market can persuade, intentionally or intentionally, choices of other companies. In addition, the CCI also held that the conditions created by Qualcomm created any benefits to stakeholders, including consumers. There was no evidence of any efficiencies arising out of the conduct of Qualcomm.

In an era when innovation is deemed synonymous to growth, the EU law has attempted to keep a balance in protecting inventiveness and market fairness. While certain conduct may be considered legitimate under intellectual property laws, it may not be lawful under competition laws. European Courts have handled such concerns proactively, taking stern action when necessary, for instance, in the case of Qualcomm. At the same time, it will be unfair to assume that every instance of possible breach of competition laws invites strict action, without regard to the nature of the intellectual property. Safeguards are provided within the European law to ensure that the courts get involved only when necessary. For instance, it is widely recognized that monopoly in a market achieved by research and development and the investment that goes in it is legitimate. If and when the conduct of a party moves toward exploitation of monopoly, do the courts interfere. The next part of the paper will discuss the interface of competition law and patent rights in a jurisdiction with relatively less competition law literature, i.e. India. The paper will look at how competition authorities have responded to challenges posed by the interaction of the two disciplines within the last couple of years.


BALANCING OF PATENTS RIGHTS AND COMPETITION LAW IN INDIA

A combined study of IPR and Competition law suggests that while their goals are different, the concern for public good and welfare still lies at the heart of the two disciplines. Intellectual property laws seek to do that through differentiation, i.e. incentivizing newer inventions and products, which results from the product’s unique process, design, and inventiveness. Moreover, IP laws provide for compulsory licensing provisions for instances where the patent owner is unable to meet the requirements of the public. On the other hand, competition law ensures the public good by promoting efficiency in the market. This efficiency is encouraged through fair trade principles and keeping the dominant players in check.

The laws in the United States and EU have attempted to achieve the goal of balancing patent rights and competition law through guidelines, regulations and sound judicial pronouncements. While the Indian IP and Competition regime have matured slowly and more recently than the other two jurisdictions, there is significant literature available in the country. The Competition Commission of India (‘CCI’) and the High Courts have delivered sound judgments that have been discussed further on issues in the IPR-Competition sphere, keeping in mind concerns of differentiation, dynamic efficiency and most importantly, public good. At the same time, it is necessary to keep in mind that India’s economy is at a stage where innovation is being increasingly operationalized. For instance, the number of patents granted by the Controller was 6,022 in 2015, 8,248 in 2016 and 12,387 in 2017, an increase of almost 50 percent in 2017.\(^{171}\) The total number of applications filed in 2017 was 46,582, meaning close to 27% of patents filed was granted by the Patent Office.\(^{172}\) The figures are indicative of the government’s focus on innovation-driven growth as part of the policy in recent years.

In addition to questions relating to SEPs, the chapter will also look at jurisdictional issues as well as a landmark decision on licensing of patent rights.

ROLE OF CCI VIS-À-VIS THE CONTROLLER OF PATENTS

The CCI does have the jurisdiction to rule on IP matters when a competition concern is involved.\(^ {173}\) However, its role, keeping in mind the authority of the Controller of Patents, is necessary to be discussed, especially in the context of compulsory licensing. The Controller while granting a license under Section 84 of the Patents Act can look into “reasonable requirement of the public, availability of

---


\(^{172}\) Id.

invention at an affordable price and its working in India.”\textsuperscript{174} The provision, therefore, allows the Controller to take decisions as far as licensing activities are concerned.

However, the effect of the patent holder’s conduct on competition in the market is the exclusive purview of CCI.\textsuperscript{175} While the nature of proceedings under Section 84 of the Patents Act is narrow and in personam, the proceedings in front of the Commission are much broader and in rem. This is further evidenced by the fact that while an application for a compulsory license can only be filed by a “person interested”,\textsuperscript{176} proceedings can also be initiated under the Competition Act by any person or even the CCI itself.

In addition, Section 62 of the Competition Act further clarifies its position with respect to laws that are not in conflict with it. The section states that “provisions of this Act shall be in addition to, and not in derogation of, the provisions of any other law for the time being in force.”\textsuperscript{177} This necessarily means that if in case Section 84 of the Patents Act and Section 3 and 4 of the Competition Act do overlap, remedies under both the – the Competition Act and the Patents Act – shall be available to the aggrieved party. On the other hand, Section 60 states that “the provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force.”\textsuperscript{178}

The obvious inference of the section is that if an interpretation of the compulsory licensing provision in the Patent Act is contrary to the Competition Act, the latter shall have an overriding effect. The Competition Act thus foresees and provides for the interaction between the CCI and other authorities.

**Monsanto Case and its impact on various stakeholders**

The conflict between IPR and Competition is often thought to be a purely mercantile issue, with minimum impact on the lowest rung of the economic ladder, i.e. small traders, farmers, etc. However, the issue can have far-reaching consequences for stakeholders other than the patent-holding entity and its competitors in the market. An ideal example of this is the *Monsanto* saga, which unfolded in 2015 and is likely to take a few more years to conclude. The case of the Department of Agriculture, Cooperation & Farmers Welfare v. M/s Mahyco Monsanto Biotech (India) Limited\textsuperscript{179} came before the CCI in relation to Monsanto’s BT Cotton Technology. It was alleged that the Respondent, i.e. Monsanto, imposed restrictive conditions on certain licensing agreements with seed manufacturers. The seeds were genetically engineered, possessing traits making them insect resistant. The covenants,

\textsuperscript{175} The Competition Act, 2002, No. 12, Acts of Parliament, 2003 (India) at. §18 [hereinafter ‘The Act’].
\textsuperscript{176} Patents Act, supra note 45, at §84.
\textsuperscript{177} The Act, supra note 46, at §62.
\textsuperscript{178} The Act, supra note 46, at §60.
\textsuperscript{179} Department of Agriculture, Cooperation & Farmers Welfare v M/s Mahyco Monsanto Biotech (India) Limited, (2015) Case No. 02/2015 [hereinafter ‘Monsanto Case’].
among other things, contained conditions requiring the manufacturers to intimate Monsanto if the formerly developed cotton seeds based on a trait of Monsanto’s competitors. Failing to do this, the clause said, would result in immediate termination of the agreement. Termination would invariably lead to the cessation of selling seeds and destroying seeds already in possession. In addition, it was alleged that the Opposite Party (“OP”) was charging an excessive trait value\textsuperscript{180} which was determined without any rationale.\textsuperscript{181}

The CCI took the view that the OP holds a dominant position in the relevant upstream market for ‘provision for BT cotton technology in India’. It also held that the termination conditions imposed by the OP in its license agreements were “\textit{stringent and unfair, particularly in the light of the ongoing litigations and legislation passed by the Central and State Governments from time to time}”.\textsuperscript{182} The CCI observed that the conduct leads to denial of market access and a constraint on the manufacturers to develop alternate BT cotton technologies. Further, it also stated that the trait value was not based on sound economic principles. Its determination on the basis of maximum retail price (“\textit{MRP}”) ignored factors such as genetic composition and climatic conditions leading to an unfair trait value.

The Commission held the conduct of OP violated Section 4 of the Act, stating that OP seems to be using its monopoly in the upstream market to safeguard its presence in the downstream market with the help of group entities. The agreements entered into by Monsanto were deemed to be violating Section 3(4)(b) and 3(4)(d) of the Competition Act. The protection accorded by Section 3(5) for IPR was also not accorded to the OP, considering the clauses in the agreement were ‘excessively harsh’.\textsuperscript{183} Holding that there is a \textit{prima facie} case, a DG report was thereby ordered by the Commission.

The author believes that the CCI order suffers from a certain naivety, failing to take into account some relevant factors. With regards to Monsanto’s dominance in the market, there is no denying that it holds a significant dominance in the market since Monsanto’s BT Cotton technology is used in more than 99\% of the area under BT Cotton cultivation in India\textsuperscript{184}. However, the CCI should have also considered whether the downstream player or the seed manufacturer has alternatives to the technology and whether it can survive without it. The Commission should have considered the fact that farmers can use pesticides to fight the Boll Worm, instead of using the OP’s technology. This was exactly what farmers did before 2001. Moreover, the patent for only a single genes sequence was granted to Monsanto, leaving scope for competitors to innovate and create novel hybrids of Genetically Modified seeds. Thus,

\textsuperscript{180} ‘Trait value’ is the estimated value for the trait of insect resistance conferred by the gene. The value, OP claimed, is calculated on the basis of MRP of each packed, before each crop season.
\textsuperscript{181} Monsanto Case, supra note 50.
\textsuperscript{182} Monsanto Case, supra note 50.
\textsuperscript{183} Monsanto Case, supra note 50.
\textsuperscript{184} Monsanto Case, supra note 50.
holding that competitors were entirely denied access to the market should have been done only after considering the substitutability of the product.

Section 3(5) of the Act provides that the provision on anti-competitive agreements shall not restrict the right of any person to restrain any infringement of his IPR. He may impose reasonable conditions necessary for the same. The CCI held the agreements by the OP violated Section 3(5) without providing a satisfactory rationale for the same. The CCI’s explanation was limited to words like ‘stringent, excessively harsh, and unfair’ perhaps an indication of the country’s underdeveloped competition jurisprudence. In fact, it is the understanding of the researcher that clauses inserted in the agreements are standard in the context of Technology Transfer Agreements, something that the CCI failed to consider. The CCI ought to have also elaborated further on the laws and litigations in the light of which the agreement was deemed particularly unfair and stringent.

The CCI further ordered a probe into the role of Monsanto’s top executives under Section 48 of the Competition Act, which allows the CCI to proceed and punish a person responsible to the company for the conduct of the business of the company at the time of such a breach.185 The order was allowed by Delhi High Court in 2018186 and then by the Hon’ble Supreme Court in February 2019.187 The Supreme Court, therefore, clarified that executives of the Company can be probed before the company is found guilty of competition norms.

Monsanto had earlier filed a suit against Nuziveedu Seeds for utilizing its patenting technologies even after the license agreement between the two terminated in 2015. The Delhi High Court had ruled that “plant varieties and seeds cannot be patented under Indian law by companies such as Monsanto and that royalties on GM technology would be decided by a specialized agency of the agriculture ministry.”188 However, in February 2019, the Hon’ble Supreme Court restored the Company’s claim on the patent, till a Single Judge of the Delhi High Court decided the issue. The Apex Court setting aside the earlier Division Bench order of the High Court, directed Monsanto to resume honouring its sublicense agreements with regards to the patented technology.189

185 The Act, supra note 46, at §48.
The author believes that the *Monsanto* tale is not merely a story of patent holders and manufacturers, but of farmer suicides and the alienation of the lowest strata of society from economic development. Various reports and publications have attributed the increasing number of farmer suicides in the country to the monopolization of the cotton seed sector. Fears of crop failure, elimination of effective alternatives, dominance through patent control and increase in production costs are some of the factors that have aggravated the farmer suicide epidemic in India.\textsuperscript{190} Even the Acharya Committee report held the BT cotton cultivation to be a major reason for farmer suicides.\textsuperscript{191} Reports also reveal that in Vidharbha and Andhra Pradesh, 90\% of farmer suicides involved those who had planted BT cotton.\textsuperscript{192}

The Monsanto dispute is thus a perfect yet unfortunate example of the inextricable relationship of competition and intellectual property concerns with the well-being of the masses. It effectively sums up that monopoly power granted by IPR can bring prosperity if used sincerely, but can be contrary to the objectives of the laws if abused.

With regard to SEPs, Indian courts including the CCI are constantly using FRAND terms to determine their validity. The courts are looking to develop a comprehensive approach to deal with cases of SEP-related issues, while still giving room to fact-based determination. The digital revolution in the country needs to be kept in mind in order to understand the significance of SEPs, with new technologies being constantly developed and becoming the subject of standard SEPs. The number of smartphone users in the country was a whopping 404.1 million in 2017 and is anticipated to reach 829 million by 2022, reports have suggested.\textsuperscript{193} Simultaneously, there is quick growth in the number of internet users as well. The number of internet users is expected to reach 627 million in 2019.\textsuperscript{194} The figures reveal the extent of penetration of technology in the country, which translates into increased relevance of standardization and licensing.

**STANDARD ESSENTIAL PATENTS AND THEIR TREATMENT UNDER COMPETITION LAW IN INDIA**

India, at present, has various Standard Setting Organizations or SSOs including the Telecom Standards Development Society of India (TSDSI) and Bureau of Indian Standards (BIS). These SSOs involves

\textsuperscript{194}India’s Internet users to reach 627 million by this year, Business Today (Mar. 6, 2019), available at https://www.businesstoday.in/current/economy-politics/india-internet-users-to-reach-627-million-this-year-report/story/325084.html.
the participation of numerous stakeholders to develop standardization, keeping in mind the unique needs of the country. These organizations also focus on safeguarding IPR, including rights involved in SEPs.

One of the most important disputes to have taken unfolded in the context of SEPs and Competition Law is the one between **Micromax** and **Ericsson**. Micromax filed a case against the Swedish company with the CCI alleging abuse of dominant power. It is necessary to discuss how the issue was dealt in front of the CCI and its relevance to the SEP – Competition law debate in the context of FRAND.

Micromax alleged that Ericsson was asking for royalty rates that were ‘*unfair, discriminatory and exorbitant for patents regarding GSM technology*’. CCI observed the following in the case that the royalty rates were not in consonance with FRAND terms and were discriminatory, with no justifiable connection with the patented product. Further, the fact that Ericsson did not share commercial terms of other similar licenses with Micromax further strengthens the claim of the informant. The CCI further held that it can proceed with the case, even if the suit is pending before the Delhi High Court. With regards to Patent hold-up, the Commission noted that hold up can subvert the competitive process of choosing technologies and undermine the integrity of standard-setting activities.

The CCI order was challenged through a writ in front of the Delhi High Court, stating that the remedy given in the Patent Act for compulsory licensing has an overriding effect on the role of CCI. The Delhi High Court concluded that the remedies provided by both Acts were different and CCI does have jurisdiction to entertain the case. The issue was finally resolved in March 2018 through a settlement between the two companies. A global license agreement was reached wherein “Micromax agreed to pay royalties to Ericsson for every 2G and 3G set sold worldwide.” The two companies also agreed to withdraw all pending cases, including the suit in Delhi High Court and the complaint in front of CCI.

The author believes that the CCI and the Delhi High Court by holding Ericsson guilty of taking advantage of pricing practices ignored the fact the right to charge a price is implicitly included in rights granted by Section 48 of the Patents Act. Monetizing the patent through licenses is an essential right of the patentee, even if the provision does not explicitly mention it. The necessary consequence of the court’s observation is that the patent holder is not allowed to set a high price for his/her invention even

---

196 Id.
197 Micromax Case, supra note 66.
198 Telefonaktiebolaget Lm Ericsson (Publ) v. Competition Commission of India And Another, (2014) W.P. (C) 464/2014 (India).
if the same is not barred by market forces. The patentee may thus refuse to license his patent, leading to an unfortunate situation where consumers do not benefit from the invention at all. The courts need to ensure that the right of patent holders to effectively exploit their invention is protected while protecting the rights of competitors. However, the court’s decisions, in general, have been in line with FRAND licensing principles including “using the net sales price of the downstream product as the royalty base and relying on comparable licenses to derive a FRAND royalty rest on sound economic reasoning.”

The courts are still in the nascent stage of interpreting FRAND license terms. Sufficient time and disputes are required before the principles can be seamlessly applied to the Indian patent regime.

CONCLUSION

Keeping in consideration the current era of large-scale innovation and development, the Indian judicial system is expected to receive increasingly complex cases with regards to SEPs. The courts and the CCI will have to ensure that while adjudicating these issues, they do not act as price regulators, and stick to the determination of fairness of prices. The CCI, in particular, needs to make references to patent authorities when encountered with a question it is not competent to determine. Civil courts, CCI and patent authorities need to work in conjunction to ensure jurisdictional issues do not come in the way of effective resolution of cases in the sphere of patent and competition law.

The conflicts and challenges that arise out of technological advancements in the world of IPR will need to be dealt with by countries across the world. SEP related conflicts have largely been dealt with efficiently by authorities in various jurisdictions over the course of years. With the growth of blockchain technologies, artificial intelligence and advanced research in biotechnology and nanotechnology, it is likely that increasingly complicated IPR issues will come up. However, issues relating to competition law concerns and how they are dealt with remains unclear at this stage. Research in legal implications of these technologies should be initiated to prepare for upcoming challenges.

Through the course of this paper, an attempt has been made to establish that there are more stakeholders involved in the discussion than may be depicted. Through the judgment in *Monsanto* and others, we observed that it is not just rich competitors or consumers that are affected by anti-competitive practices. Even small businesses, new start-ups and farmers are important stakeholders in the whole scenario. This further view widens the scope of the whole discussion since it impacts not only the economic growth of the country but the share of ‘the little guy’ in dividends of development.

---


202 *Monsanto* Case, *supra* note 50.
Legislators and courts need to keep in consideration the above factors, and also explicitly recognize that the fundamental aim of both patent rights and competition law is the same, i.e. consumer welfare. A wider objective of the two fields is to protect the interest of the masses through economic development. Theoretical inculcation of this idea in laws and decisions along with practical steps towards its enforcement will go a long way in balancing patent rights and competition law.

***
Thanking Note

We thank the authors for their invaluable contributions to the journal and hope to receive your submissions for the upcoming editions in the same or better spirit. We also thank our readers and the members of our Editorial and Advisory Board for investing time in the Journal. We hope to make quality contributions to the existing literature on Intellectual Property law, Competition law and Information Laws.

Ashna Chhabra
Editor-in-Chief

Thank you for reading JICIL. Your feedback is valuable to us.

Please send in your feedback and/or requests for subscription to us on sameer@agradoot.in. We would be happy to connect with you and work with you on improving the quality of our publications.