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## Roles of Patents in Pharmaceutical Industry in Comparison with the Information and Communication Technology (ICT) Industry and why are Pharma Giants unwilling to Join Patent Pledges and Patent pools to Fight COVID-19

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### ABSTRACT

*The Patent regime confers on the creator the exclusivity to protect, preserve and safeguard technologies, innovations or inventions in accordance to the every industry patent standards. The role of patenting becomes more crucial when patenting system of technology and invention vary in different ways in different industries, thereby requiring the patent regime to outlay and strategies to the needs of the industries.*

*This paper aims to showcase the role of a healthy patent protection regime in two industries. A patent regime in Pharmaceutical Industry aims at the commercial viability, profiteering and advancement in remote areas and also tackle the issue with ever-greening. Whereas, in the Information and Communication Technology technologies have become fragmented proprietary knowledge over the years of development causing difficulty in the commercialization and licensing of the technology and highlighted the issues of Patent Thicket and issuance of FRAND license in the industry.*

*Further the paper aims to evaluate the challenges, complications and reluctance by the Pharmaceutical giants like Pfizer, J&J, etc. to create a UN backed medical patent pledge and patent pool to come together unanimously to develop a vaccine and tackle head-on the Covid-19 pandemic.*

**Keywords:** Patent, Regime, Pharmaceutical, Industry, Patent pool

## I. INTRODUCTION

In the legal domain, the patent refers to the granting of a monopoly right to the creator, improvement of an existing article and useful invention in lieu of disclosing the invention. A patent is a form of industrial property wherein exclusive right to own, use or sell, and stimulate methods or products and new inventions, is granted to the inventor/manufacturer, new invented article or manufacturer of the article for a limited time period.<sup>3</sup>

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<sup>3</sup> Bruce Lehman, The Pharmaceutical Industry and the Patent System, International Intellectual Property Institute

This modern era focuses on science and research and technology. The objective behind the grant of patent monopoly is to encourage scientific research, new technology and industrial progress. This in turn, stimulates in the field of R&D, which directly transforms the industrial enterprises by the ways of economic prosperity, an increase of national wealth, enhance public health and nutrition, dissemination of technology, transfer of technology, vibrant patent regime, discoveries and inventions

## **II. ROLE OF PATENTS IN DIFFERENT SECTORS**

From the onset, a perplexing issue arises as to the significance of patenting under different industries in comparison to others. All inventions of technologies are priority patented before being accessible to the market. The patenting system of technology and invention vary in different ways in different industries. The effectiveness of patents is linked to the specific characteristics of the technology and of the R&D process as well as on the nature of the market and on the patterns of competition. In particular, one of the simplest but perhaps more important results produced by the economics of innovation is that there is no such thing as “technology”, but many different technologies with different properties.<sup>4</sup> The increased rate of patenting is due to the imitation being easier, that is, when relevant knowledge is easily codifiable and substitute of the technology is readily available. Therefore, it is easy to invent around as seen in the industry of consumer electronics, the technology which is patented is shared with competitors by way of licensing whereas in the chemical industry exclusivity of the patent for self-use is epitomized.

Every industry adopts a patent strategy where they primarily focus on maximizing profits by developing and commercializing the technology. A relevant market for the technology or invention is embodied in the patent as in turn it will balance the cost of development, competition and return on investment. Therefore, it does not come as a surprise that different industries apply different values to the role of the patent in the innovation process.

### **Roles of patents in the Pharmaceutical industries**

In the innovative driven pharmaceutical industry prevailing, new and improved drugs are being marketed due to rapidly changing technology. The growth has been sustainable in the pharmaceutical industry for the past decades due to the innovations and inventions being protected by IPR, that is, Patent rights. The commercial viability has led to the creation of a

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[https://users.wfu.edu/mcfallta/DIR0/pharma\\_patents.pdf](https://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf) (last visited on March 18, 2021)

<sup>4</sup> Luigi Orsenigo and Valerio Sterzi, n. 33/2010, Comparative Study of the Use of Patents in Different Industries; <https://pdfs.semanticscholar.org/7eda/e866a3d4f4f5a23f4efb83bbfe732d9a93f6.pdf> (last visited on March 18, 2021).

large reservoir of wealth which has in turn been invested back in R&D and innovation to compete and gain marketshare.

The reliance on the patent regime adopted by the pioneers of this sector is to seek patent protection. The rationale behind this is as a new medicine or a drug involves an investment of large capital and time and the success rate is also unpredictable depending on clinical testing. The only thread by which these pharma companies are willing to invest in the development of novel drugs and medicines is because they have a sincere belief that the innovations will be safeguarded from exploitation and imitation by the competitors for a considerable time. Patent protection allows these companies to market exclusivity and regulatory exclusivity in comparison to other generic pharma companies or direct competitors.

The patent protection regime throughout the world, adopted by the TRIPS has been salutary in the pharma industry helping to adopt changes and investment in R&D. It also opened the doors for contract-based research with MNC's and acquisitions, the most notable one being the acquisition of India's largest pharmaceutical company, Ranbaxy by the Japanese MNC, Daiichi Sankyo back in June 2008 and its re-acquisition by Sun Pharma in 2014.<sup>5</sup> Thus, patent protection plays a vital role in the growth of pharma companies including but not limited to:

a) The patent enables the holder of certain drugs and medicines rights over active ingredients jointly or separately with formulation, salts, pro-drugs etc. It encourages innovation, conveys scientific prestige to researchers, competitive advantage, manufacturing and quality control from other distributors.

b) Manufacturers are able to set prices for the drug in the market, thereby creating a high return on investment on the innovative product/drug. Remarkable drugs are able to create a niche for themselves in the market-leading to commercialization and high-profit margins.

c) The patentee has a monopoly and exclusive privileges in regard to the commercially viable patented product, thereby increasing their market share and position, establishing them as a major stakeholder in the market.

d) The pharma companies are able to, in unison or in consonance, to sell or license the patented drug and create a source of income.

e) In backward and poor countries where the cost of medicine and development of new drugs are either unavailable or unaffordable, patent protection enables to contribute to the

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<sup>5</sup> Amit Aggarwal; ET HealthWorld; Importance of establishing a patent regime in pharmaceutical industry; <https://health.economictimes.indiatimes.com/news/pharma/importance-of-establishing-a-patent-regime-in-pharmaceutical-industry/73084962> (last visited on March 18, 2021).

advancement in such regions and helps in improving the quality in such countries. The non-patent pharmaceutical industries in countries like Thailand and India have attempted to capture the market for antiretroviral drugs for the treatment of AIDS purchased under grants from the Global Fund for AIDS, Tuberculosis and Malaria, by requesting the Fund's Board of Directors to establish a preference for the use of drugs supplied by such companies and to guarantee a profit to such companies as a part of the preference.<sup>6</sup>

A strong patent protection law and judicial discourse prevent potential infringements by the competitor. This has become a standard outlay for pharma innovations. Litigation cost can be cut across by firmly establishing market exclusivity and clearing all the legal intricacies and nuances. Further, patent wars between pharma giants can be judiciously transformed by adopting patent strategies. Companies can obtain patents for methods of manufacture and active ingredients.<sup>7</sup>

However, there are many roadblocks and challenges faced by pharma companies. The pharma companies adopt an 'ever-greening' strategy to extend the time duration of patent allotment. By 'every-greening', companies make minor changes in the existing products that may be in the method, process, structure, formula or product to re-secure the patent rights of the product claiming to be novel. These shrewd strategies bar other competitors to enter with the product, creating a monopoly, leading to frivolous patent suits. The patent regime out-rightly denies claim of novelty to tablets, ointments, solutions, etc, on the basis of formulation or composition where an active ingredient is admixed with acceptable carriers or excipients, such as fillers, binders, disintegrates and lubricants.<sup>8</sup>

The generic pharma companies who invest frugally in innovations have been taking advantage of the lacunas in the patent regime and have, with slightest of modification and changes in structure, by tweaking them to get patents for themselves, caused alarm to revenue of the big pharma companies. The companies, as a result, have been shrinking their patent-portfolio leading to erosion of market capture and commercial viability of the company, commercial drugs and research and development of new drugs.

These patent protections have upset the incentive issues also as certain companies license the drug and exploit it by hiking up the price without investing in R&D of new drugs. Essentially,

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<sup>6</sup> See Supra note 1.

<sup>7</sup> Manoj Poonia and Surbhi Bhardwaj; Importance of patents in pharmaceutical industry; <http://www.pharmabiz.com/ArticleDetails.aspx?aid=92383&sid=21> (last visited on March , 2021).

<sup>8</sup> Ester Martinez, Silvana Alvarez; CIFRA: Challenging the ICT Patent Framework for Responsible Innovation (PDF); D4.2 Projection to other sectors beyond ICT Revision 23.03.2018; Grant Agreement No.731940; [https://www.inno.tu-berlin.de/fileadmin/a38335100/PDF\\_Dateien/Publikationen/cifra/d2\\_1\\_literature\\_review\\_final.pdf](https://www.inno.tu-berlin.de/fileadmin/a38335100/PDF_Dateien/Publikationen/cifra/d2_1_literature_review_final.pdf) (last visited on March 18, 2021).

these patent laws have created a middleman between the inventors and the patients—a market for buying and selling patents, which are unregulated.<sup>9</sup>

Another challenge which is hitting hard is the pre-grant opposition from third parties which disturb and impeach upon the validity of the invention. Therefore, the high cost of research and development and lack of a stronger product patent regime can stifle the growth of the pharmaceutical industry.<sup>10</sup>

A healthy patent regime is of paramount consideration in the pharma industry. But, there still exists controversies in patenting protection which affects economic growth. Therefore, it is critically decisive for an effective patent strategy to realize patent potential.

### **Role of patents in the ICT industry**

The ICT industry is an IPR intensive industry, creating a surge in the economy. ICTs- intended as the set of technologies aimed at processing, storing and transmitting information (including telecommunication equipment, consumer electronics, computers and software products)- are among the most dynamic and innovative segments of modern economies.<sup>11</sup>

Due to the ICT industry being heterogeneous, all the technologies or innovations are fragmented, which means that the inventions/improvements of technologies are of complex nature and characteristics. Therefore, there has been a continuous and steady increase in the patent application. WIPO estimated that the number of patent applications filed worldwide in the year 2018, amounted to around 3.3 million, which represents a 5.2% increase on the previous year.<sup>12</sup> The reason for the surge is that firms have redefined their patent system and applied their efforts in the R&D investment, exploiting cross-license and attracting capital funding. Further, manufacturers aim at expanding their portfolio by investing in the R&D strategies and another Reason for the surge is due to the boutique firms who invest aggressively in patents with the aim of attracting capital and securing patents rights in niche markets.

As technologies become more independent, more fragmented proprietary knowledge is causing difficulty in the commercialization of the technology through patent law. The granting

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<sup>9</sup> Elle Mahdavi; California Review management; Patents and the Pharmaceutical Industry; <https://cmr.berkeley.edu/2017/05/patents-and-pharmaceuticals/> (last visited on March 18, 2021).

<sup>10</sup> See Supra Note 5.

<sup>11</sup> The Role of Patents in Information and Communication Technologies (ICTs). A survey of The Role of Patents in Information and Communication Technologies (ICTs). A survey of the Literature. [https://www.researchgate.net/publication/318040107\\_The\\_Role\\_of\\_Patents\\_in\\_Information\\_and\\_Communication\\_Technologies\\_ICTs\\_A\\_survey\\_of\\_the\\_Literature](https://www.researchgate.net/publication/318040107_The_Role_of_Patents_in_Information_and_Communication_Technologies_ICTs_A_survey_of_the_Literature) (last visited on July 27, 2020)

<sup>12</sup> World Intellectual Property Indicators 2019; [https://www.wipo.int/edocs/pubdocs/en/wipo\\_pub\\_941\\_2019.pdf](https://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2019.pdf) (last visited on March 19, 2021).

of patents give the innovators and inventors substantial protection by way of patent screening, wherein patent officers adjudge patents on the ground of novelty, non-obviousness and industrial applicability. The role of patent law is to strive towards:

- a) Incentives, that is, to create a monopoly of the invention, therein, patentee becomes an exclusive right holder of privilege such as using sale commercialization, importing patented products and processes, for a limited time.
- b) Licensing and cross-licensing, wherein, patents are utilized and commercialized in technology, thereby, causing diffusion of knowledge, encouraging the technology market. For example, by providing information about the value of technologies, they reduce the search costs for partners and informational asymmetries.<sup>13</sup>
- c) Diffusion of non-protected asset knowledge such as technical know-how and assistance, which are crucial for innovation. The knowledge transfer of technology is lower when codified as compared to the transfer of technological know-how through a contract which is high and inefficient.
- d) Disclosure of the contents of a patent helps demarcate the market for the technology, which in turn, helps to regulate the pricing of technology. Economic value is gained through such facilitated transactions in technology which is innovated either by small or large firms.
- e) Developing a new product or technology due to the fragmented and many individuals, intellectual property owners causing commercialization of downstream technologies. Patents help to reduce the gap between science and industrial innovation by ensuring finance in the later stages of development, exploitation by best-positioned firms through licensing, and hence economic returns for research.<sup>14</sup>
- f) Protection of computer-implemented inventions that is software patentability. The software and applications programming algorithms are making in-roads in the ICT industry as it can be combined and recombined in different order and manner to develop a new product and service.

Few of the key concerns with the patent protection in the ICT industry which are:

- a) Issues pertaining to 'Patent Thickets'- In the ICT industrial sectors the combination

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<sup>13</sup> Dominique Guellec and Maria Pluvia Zuniga; The Role of Patents in Technology Markets : Issues pertaining to data collection and Analysis; <https://firstmonday.org/ojs/index.php/fm/article/view/1903/1785> (last visited on March 19, 2021).

<sup>14</sup> See Supra note 11.

of complex technologies and high patenting volumes favors the emergence of the patent thickets, defined as a “dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology”.<sup>15</sup> The reason for the steady increase of the patent thickets is an increase in the ambit of patentable subjects, lack of resources and distorted incentives growing of high tech products. This has led to restricted innovation, ostensible expensive R&D.

b) *Standard Setting Organizations and FRAND licensing*- The ramification of the patent thicket is severe on standardized products as they have to adhere to common technology. These Standards become highly important in high tech products, where many components are assimilated together to form an end product, thereby justifying consumer benefit. Accordingly, the SSO endorses by way of licensing the SEPs on certain terms and conditions which are represented by FRAND

It provides for patent licensing terms, wherein, it provides a reward to holders for the investments and innovations made. It is also used to determine reasonable royalty rates, prevent hold-ups. It also tackles transparent transaction costs. Further lack of a standard procedure to determine FRAND leads to disputes in cases of SEP licensing which in turn hampers the widespread use of the key standardized technologies and development of a true innovation economy.<sup>16</sup>

Another issue plaguing this industry is the litigation in terms of licensing terms and validity of patents. The surge has overburdened the patent officers leading to increased workload resulting in a low-quality patent application, approval or disapproval.

Software patenting has led to a series of legal controversies, such as the competitors' claim against the developers on the basis that such software developed is of inferior quality and there are concerns of possible overlapping patent-protected software and open-source software.

In order to alleviate such entrenching issues in the ICT industry, patenting rules need to be harmonized in order to bring forth the true potential of patent proliferation through cumulative and innovative processes and high-tech complexities.

Industrial heterogeneity and the way in which patents are used by those industries has led to a looming question of whether patent law should recognize different standards for different

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<sup>15</sup> Stephano Comino and Fabio Maria Manenti; JRC Science and Policy Report; Intellectual Property and Innovation in Information and Communication Technology (ICT); <https://publications.jrc.ec.europa.eu/repository/bitstream/JRC97541/jrc97541.pdf> (last visited on March, 19 2021).

<sup>16</sup> Patents based on Information and Communication Technology – ICT Patents; <https://patentbusinesslawyer.com/patents-based-on-information-and-communication-and-technology/> (last visited on January, 19 2021).

industries. The product life-cycle in the pharma industry may be for decades, as compared to the electronic devices as the consumer can discard his old electronic goods for new and improved devices, the ICT industry is desirous of short application pendency procedure. The protection assorted to trade secrets by the industries provides a glaring gap in the patent law as electrical and mechanical products can be reversed engineered, affording no IPR to the competitor on use but in the pharma industry, public disclosure or divulging of trade secrets of inventions are stringently protected through patent laws.

Another point of distinction is the detectability of the patents. In the pharma industry, patents are identifiable to the product as there is standardization in the composition of particular products. Whereas, the ICT industry is yet to outlay a standardized term for identifying programs, procedures, algorithms etc.

Another characteristic difference is the viability of the technology and its cumulateness. In the pharma industry, the cumulateness is weak as the patented product has a limited outreach and cannot be used to form another innovation. However, in the ICT industry, knowledge accumulated of a particular product helps develop an ingenious product from it and also removes the hold-up problems in the industry. Unlike the ICT industry, the pharma industry is heavily regulated by government agencies to assure the safety and efficacy of products which will be sold to consumers.<sup>17</sup> It is so because there is disproportionate capital investment in the clinical phase which requires major safety by the regulators, especially in the patent law.

In recent years the appearance and growth of new technologies and industries interacting with important changes in patent laws have deeply transformed the landscape of patent uses.<sup>18</sup> The Accessibility to patent information accelerates invention, innovation or re-engineering of products in the pharma as well as the ICT industry. The quality of innovation can be manifold increased the quality of patent registration by the fast patent application process and increased maintenance of patent fees.

### **III. PHARMA INDUSTRY- PATENT PLEDGE AND PATENT POOL IN TIMES OF COVID-19.**

The COVID-19 pandemic has shifted the onus on the pharmaceutical industry especially upon the Pharma giants like Pfizer, Johnson & Johnson, Bharat Biotech, etc; and respective national government pharma organizations to innovate a life- saving drug. The health crisis has

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<sup>17</sup> See Supra note 2

<sup>18</sup> See Supra note 3

reinvigorated the role of pharmaceutical and life science to develop drugs and treatment for COVID-19, which will enable the health of the consumers and the government alike.

This pandemic has given the opportunity for collaborative research towards understanding the virus genome structure which had been limited for private eyes only. The scientist, researcher's companies and big pharma have in an unprecedented move given open access to their patents with the aim of a collaborative approach in an open forum via patent pooling and pledging for development of the drug/medicine. This move has been backed by the WHO, European Union and developed nations with the unified objective of creating an UN-backed medicine patent pool which aims at providing global.

The pooling of patents is an agreement between companies, sharing complex and intricate technology, method or process, based on a payment of fees or in proportion to their contribution to the pool etc, without infringing or violating the patent law.<sup>19</sup> In these pandemic times, through pooling, there is a high chance of speedier development to treat COVID-19.

Another way to develop technology to tackle this pandemic is by way of Patent pledge. Therefore, a WHO backed initiative, an 'Open COVID pledge', to tackle COVID-19 has been launched, where companies, universities and others would provide free licenses to their patent, copyrights and few other property rights, to anyone for developing technologies related to diagnosis, prevention or treatment to COVID-19.<sup>20</sup>

The coming together and collaborating of the pharma companies on research will help find a clinical solution to the current pandemic, but companies will face certain unwilling circumstances entailing unsolicited claims and objects and certain legal risks arising out of the development of new drugs and sharing of an informant under the patent law.

In order to find treatment for COVID-19, it has resulted in by passing the formal procedures of mutual exchange of information and has created legal complexities such as, who brings the information, how much is to be shared, who will own the new invention. The reason for reluctance of pharma companies engaged in information sharing is that the more the transfer of technology the more the issues are bound to creep in.

A steep challenge faced by the strategic partnership is the absence of the ownership clause in play between the collaborating parties. The legal ramifications are far-reaching as one party without the consent and licensing, can patent the technology i.e. the novel vaccine. Also, non-

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<sup>19</sup> Namratha Murugesan; Are Patent Pools an Effective Solution to COVID-19's IP Barriers?; <https://spicyip.com/2020/05/are-patent-pools-an-effective-solution-to-covid-19s-ip-barriers.html> (last visited on March, 19 2020).

<sup>20</sup> Krishna Ravi Srinivas; Intellectual Property Rights and Innovation in the Times of Corona Epidemic;

signing of non-disclosure information agreements may lead to the trade secret of the patented invention publicly disclosed, preventing the patenting of the COVID-19 treatment. Absence of such clauses is the only testament to the inevitable legal disputes.

The reluctance of the drug developers to indulge in patent pooling and pledging is due to the complication as to which company will be doing the patent filing. As the patent is bound by the territorial jurisdiction and patent application process needs to be applied in a foreign jurisdiction to obtain a foreign filing license to prevent potential outside disclosure. In the U.S., under 35

U.S.C. § 185, failure to obtain a foreign filing license may result in a patent being invalid unless the failure to procure such license was in error and the patent does not implicate national security.<sup>21</sup>

The strategic collaboration between has to be watchful of the looming anti-competitive conduct as they get work done through partnership. The pricing point has to be affirmative with the view that the benefits of the novel treatment devised for COVID-19 are available to the public. If this is not the case and disruption arises in communication chain in regard to competitive sensitive topic i.e. pricing, business plans, sales information, etc.; then the collaboration can be facing a hardcore violation of the anti-trust laws, causing unwillingness in the partnership.

The legal nuances above help only illustrate the unpreparedness of the IP regime and it becoming a major constraint for affordable access to information leading to the development of treatment for COVID-19. The ongoing pandemic layout is an opportunity to revisit and rethink the role of IP and its use as an incentive, also, give new models and approaches a chance. In these critical times, it is necessary to encourage strategic collaboration between pharma companies and free flow of patent information by patent pooling and pledging as IP and Innovation, might make a huge difference. The question is how much the governments, UN agencies and other stakeholders are prepared for adapting to these changes.<sup>22</sup>

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<sup>21</sup> The Potential Patent Risks Associated with COVID-19 Collaborations; <https://www.lexology.com/library/detail.aspx?g=e52d8ff7-5491-4858-bb3f-eac168d4de6e> (last visited on January, 30 2021).

<sup>22</sup> See Supra note 18.