STRATEGIC IP MANAGEMENT IN THE BIOPHARMACEUTICAL INDUSTRY:

A study on the accessibility and affordability of Biopharmaceuticals in India.

ABSTRACT:

Biopharmaceuticals are the nebulous revolution in the medical Biotech industry to diagnose and treat rare diseases. Given their complexity in research and development, Patents in the Biopharma landscape have been considered an indispensable incentive to foster innovation and the development of new prescription drugs. The Biopharma Industry entertains Strategic Patenting to gain a competitive advantage and protection against the risk associated with low investment levels and market failure. Intellectual property legislation and the regulatory regime determine the product's price, development, and innovative culture. High prices for these medicines make them inaccessible and unaffordable for the patients. Strategic patenting adopted by pharmaceutical companies is one of the primary reasons for the drugs to be highly priced and its demand. To circumvent the challenge these complex biotech inventions bring to the Intellectual property landscape, revised guidelines in 2016 in addition to the Patent Act and rules, TRIPS mandate, and Drug regulatory guidelines are established by the Government of India. The ambiguity and uncertainty in the Intellectual property regime in a Nation are detrimental to the patentability and protection of the Biopharma product and process. This paper is an attempt to study the strategic Intellectual property management in the Biopharma industry and its impact on the accessibility and affordability of these drugs in India.

Keywords: ***Biopharmaceuticals, Intellectual property, IP Management, Strategic Patenting.***

I. INTRODUCTION:

Biopharmaceuticals estimated to be half of the drugs in the market in the 21st century have brought a promising solution for the treatment of diseases.[1] The complexity and challenge of producing small-molecule drugs have paved the way for the development of these Biologics.[2] On the other hand, the challenges these drugs bring to the regulatory regime are inevitable.[3]

[1] Gene Walsh, Biopharmaceutical Benchmarks—2003, 21 Nature Biotechnology 865 (2003).
[2] Wong G. Biotech scientists bank on big pharma's biologics push. Nat. Biotechnol. 27, 293–295 (2009).
[3] Nicholas Jones* and Alexander Bruce Dean, 'Current patenting trends for biologics versus small molecules', Future Science Ltd Pharmaceutical Patent Analyst Volume 1, Issue 3, July 2012, Pages 225-227 https://doi.org/10.4155/ppa.12.34; Also 9 https://www.chemistryworld.com/molecule-to-market/how-biologics-have-changed-the-rules-forpharma/3010301.article

Pharma companies engage in protecting their product and processes (in the context of Biologics also the *product-process* claim) through strategic Intellectual property management. Though there is a cumulation of protection available for these drugs, Patent plays a predominant role in granting monopoly rights to market these drugs. Strategic IP management is proportionate to an incentive for the lengthy timeline in the development of the product and the high development costs. Strategic IP management heeds due diligence from the potential competitors in the market. The literature argues the intervention of Competition law in the case of strategic patenting that results in harmful market practices leading to the high prices of these drugs.[4] High prices of these drugs resulting from strategic patenting impede the accessibility and affordability of these drugs to the public. This study is an attempt to unveil the strategic IP management of Biopharma companies and the process ahead in the production and marketing of these drugs. In that pursuit, the patent regulatory regime is analyzed on these biopharmaceuticals.

Literature Reviewed:

This paper reviews literature on managerial and business strategies that pharma companies follow leading to the inaccessibility of those medicines. A recent study conducted on strategic IP management and their competitive advantage provides the various strategic IP attributes leading to monopoly in the market.[5] and A study in the Indonesian Economy identified that Government regulation and policy has a significant inhibition in the Innovative culture of the Country.[6] IP is now used as a tool for generating revenue and as a market barrier for competitors to rely on data of the Innovator product including the Data Exclusivity regime.[7] Studies also show that the number of IPR in a pharma company is a direct proportionate to the successful

[4] Olga Gurgula, Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene? IIC 51, 1062–1085 (2020). https://doi.org/10.1007/s40319-020-00985-0

[5] Singh H, Samalia H V, Murthy Y V R, Strategic Management of Intellectual Property Rights for Sustainable Competitive Advantage: A Study of Indian Chemical Industry, Journal of Intellectual Property Rights (JIPR), Vol. 29 No. 3 (2024), DOI: https://doi.org/10.56042/jipr.v29i3.727

[6] Purbasari R, Wijaya C & Rhayu N, Entrepreneurial ecosystem and regional competitive advantage: A case study on the creative economy of Indonesia, Advances in Social Sciences Research journal, 6(6) (2019) 92, doi: 10.14738/assrj.66.6652.

[7] Sukkivan O, Value driven intellectual capital: How to convert untangible corporate assets into market value, John Wiley & Sons, New York, 2000

competition of the product in the market.[8] Studies delve into the relationship between IPR and access to medicine[9]. These studies and the

1.4 Research Questions:

1. *What is the role of IP in the research and development of drugs in India?*
2. *What are the business strategies on IP adopted by the biopharma industry to develop and market biopharma? And how managing IP in the Pharma business would boost innovation and deployment of drugs?*
3. *Is there a need for Policy intervention on Intellectual property in the Pharma Business to achieve the goal of innovation and development of drugs?*

1.5 Methodology Adopted:

Combined Indian sales data of these Biopharmaceuticals with Biopharma patents issued by the IPO were collected and analysed. Patent search related to biopharmaceuticals was carried out using Patestate Platform, IPO, CSIR India Patent Database, PATENTSCOPE, WIPO patent database, EPO's PATSTAT, and Clarivate's Cortellis database to compare and contrast the Patenting regime for Biopharma across the Globe. For the strategic IP Management Information and literature were collected and analysed.[10]

1.1.BioPharma Industry in India

Biopharmaceuticals are genetically engineered drugs made out of biological materials and natural substances.[11] Initially termed as orphan drugs, biologics with investment and development, are marketed prevalently in India and other countries.[12] A study reported by the Association of Biotechnology Led Enterprises (ABLE) in India estimated that the biologics market to grow at a compound annual growth rate (CAGR) of 22% to reach USD 12bn by 2025. In India, there are about 2700 + Biotech startups and they continue to grow this year.

[8] Granstrand. O, Strategic Management of Intellectual Property, *Chalmers University of Technology, Sweden, 2000, 2.*

[9] Motari M, Nikiema JB, Kasilo OMJ, Kniazkov S, Loua A, Sougou A, Tumusiime P. The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement. BMC Public Health. 2021 Mar 11;21(1):490. doi: 10.1186/s12889-021-10374-y. PMID: 33706726; PMCID: PMC7951129.

[10] Singh H, Samalia H V, Murthy Y V R, Strategic Management of Intellectual Property Rights for Sustainable Competitive Advantage: A Study of Indian Chemical Industry, Journal of Intellectual Property Rights (JIPR), Vol. 29 No. 3 (2024), DOI: https://doi.org/10.56042/jipr.v29i3.727

[11] Kesik-Brodacka, Malgorzata. "Progress in biopharmaceutical development." Biotechnology and applied biochemistry 65.3 (2018): 306-322.

[12] Jack Ellis, 'Supporting innovation in next-generation medicines', WIPO Magazine, June 2017 https://www.wipo.int/wipo_magazine/en/2017/03/article_0007.html accessed on 10-01-2024

India, being a global generic drug manufacturer has also heeded the development of biosimilars.[13] India's first biosimilar, a vaccine for hepatitis B, was marketed and approved in 2000.[14] With the continued growth in the legislative framework and regulation, the biosimilar market has continued to grow. According to the Associated Chambers of Commerce of India's 2017 Report,[15] biosimilars amount to $2.2 billion of the $32 billion Indian pharmaceutical market – and are expected to achieve a growth rate of approximately 30% compound annual growth.

With Glenmark launching its anti-diabetic biosimilar this year,[16] there is a gradual growth of this Biopharma in Indian sector. 'Herceptin', a biosimilar for human epidermal growth factor 2 and in cases of positive metastatic breast and gastric cancer is agreed to be manufactured by Emcure in the brand name 'Biceltis' with Swiss-based Roche. Mylan and Biocon has joined to manufacture Trastuzumab, a biosimilar to reduce febrile neutropenia during chemotherapy, and is known to be the first biosimilar produced by an Indian company to be approved in the United States.

1.2 **Access and affordability of medicines**

With advanced judicial ruling and Patent regime in India, these Biopharmaceuticals are entering into the ambit of patent protection to enjoy the monopoly rights and reap the value from these drugs. Protection of an invention depends predominantly on the strategies that innovator companies entertain, the competitive markets, and the dynamic Intellectual property legal regime. The patent regime in India is governed by Indian Patent Act, 1970 and the Patent Rules 2003. Moreover, the regulation of these inventions are governed through various laws such as the Drugs and Cosmetics Act (1940; and Rules 1945); the New Drugs and Clinical Trial Rules (2019); the Guidelines on Similar Biologics; Regulatory Requirements for Marketing Authorisation in India (2016);[17] the Rules for Manufacture, Use, Import, Export and

[13] Panda S, Singh PK, Mishra S, Mitra S, Pattnaik P, Adhikary SD, Mohapatra RK. Indian Biosimilars and Vaccines at Crossroads-Replicating the Success of Pharmagenerics. Vaccines (Basel). 2023 Jan 2;11(1):110. doi: 10.3390/vaccines11010110. PMID: 36679955; PMCID: PMC9865573.
[14] Honavar SG. From Biologics to Biosimilars and Biobetters - Democratization of High-end Therapeutics. Indian J Ophthalmol. 2021 Feb;69(2):207-208. doi: 10.4103/ijo.IJO_150_21. PMID: 33463558; PMCID: PMC7933873.
[15] Allie Nawrat, 'Expanding from generics to biosimilars in India', FEATURE MAGAZINE, Sept 2018 accessbile at https://www.pharmaceutical-technology.com/features/expanding-generics-biosimilars-in-india/?cf-view
[16]https://timesofindia.indiatimes.com/business/india-business/glenmark-pharma-launches-antidiabetic-injectable/articleshow/106524154.cms
[17] In concurrence with the World Health Organization. Guidelines on evaluation of similar biotherapeutic products (SBPs). [homepage on the Internet]. [cited 2019 Oct 14]. Available from: https://www.who.int/biologicals/areas/biological_therapeutics/BIOTHERAPEUTICS_FOR_WEB_22APRIL2010.pdf

Storage of Hazardous Microorganisms and Genetically Engineered Organisms or Cells (1989); the Environment (Protection) Act (1986); the Regulations and Guidelines on Biosafety of Recombinant DNA Research and Biocontainment (2017); the Guidelines for Generating Pre-clinical and Clinical Data for rDNA Vaccines, Diagnostics and other Biologicals (1999); the CDSCO Guidance for the Industry (2008);

The Government of India released the revised Guidelines on Similar Biologics by DBT & CDSCO in August 2016 to provide a simplified efficient regulatory pathway for manufacturing processes ensuring safety and efficacy with quality as per cGMP standards.[18] The regulatory guideline has been acclaimed to ensure access to world-class biosimilars to the public. It is the psychology of patent protection that medicines developed from public funding must benefit the public as a whole rather than the pharma companies owning their profit.[19] For instance, Remdesivir, a drug developed for the Ebola virus by Gilead Pharma has a patent up to 2038.[20]

Biopharma companies on the verge of managing their IP, are involved in strategic patenting of these drugs to gain Competitive Advantage.[21] Strategic patenting stifles the dynamic competition in the market affecting originators and the generic companies. Involving in anti-competitive behavior such as 'reverse payment agreements'[22], and cartel agreements to delay the entry of the generics.[23] R and D investment is growing, yet the innovations are decreasing. [24] There is a trend that Pharma companies are more focused on incremental inventions than on breakthrough innovations or new drugs.[25]

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[18] GUIDELINES ON SIMILAR BIOLOGICS: Regulatory Requirements for Marketing Authorization in India, 2016, available at https://dbtindia.gov.in/sites/default/files/uploadfiles/Guidelines_on_Similar_Biologics,2016.pdf

[19] Bair, Stephanie Plamondon. "The Psychology of Patent Protection." *Conn. L. Rev.* 48 (2015): 297.

[20] Mohajel, N., Arashkia, A. Ebola as a case study for the patent landscape of medical countermeasures for emerging infectious diseases. *Nat Biotechnol* **39**, 799–807 (2021). https://doi.org/10.1038/s41587-021-00970-z

[21] Lahiry, Sutopa, and K. Rangarajan. "Patent Landscape for Indian Biopharmaceutical Sector: A Strategic Insight." *Flexible Strategies in VUCA Markets* (2018): 31-47. Also Feldman, Robin, W. Price, and I. I. Nicholson. "Patent Trolling: Why Bio & Pharmaceuticals Are at Risk." *Stan. Tech. L. Rev.* 17 (2013): 773.

[22] *Reverse payment settlement agreements are a type of litigation settlement that requires the patent holder to pay the alleged infringer, often in exchange for the alleged infringer agreeing not to enter the market until a specified date.* Ref Shah, S., Silva, M. & Malloy, M. Are reverse payments and pay-for-delay settlements business as usual or an anticompetitive practice?. Nat Biotechnol 34, 716–719 (2016). https://doi.org/10.1038/nbt.3627

[23] William W. Fisher III and Felix Oberholzer-Gee, 'Strategic Management of Intellectual Property: An Integrated Approach', California Management Review, Vol. 55, No. 4 (Summer 2013), pp. 157-183 URL: http://www.jstor.org/stable/10.1525/cmr.2013.55.4.157

[24] Pammolli F, Magazzini L, Riccaboni M (2011) The productivity crisis in pharmaceutical R&D. Nat Rev Drug Discov 10(6):428

[25] IMAK (2018) Overpatented, overpriced: how excessive pharmaceutical patenting is extending monopolies and driving up drug prices. http://www.i-mak.org/wp-content/uploads/2018/08/IMAK-Overpatented-Overpriced-Report.pdf. Accessed 08 Jan 2024

This indeed leads to issues relating to the production and availability of these drugs to the countries in need, the willingness of healthcare systems to pay for the product being developed, and potential generic competitors to give accessibility of these drugs to the public. A strict Patent regulatory framework would consequently lead to the country selection differences between different patent filing programs for different types of healthcare products.

II. ROLE OF IP IN THE RESEARCH AND DEVELOPMENT OF BIOPHARMACEUTICAL DRUGS

Biopharmaceuticals are patent-eligible subject matters.[26] A patent is an IP right granted by the Government for a new invention that satisfies the standards of Patent by the Indian Patent Act of 1970. The test is that the invention has to pass through the exclusivity principles set out in Section 3 of the Patents Act.[27] In particular, for biologics patents Subclauses (b)-(e), (h)-(j), and (p) are of significance. A biologic that has a 'Human intervention' in its development is patent eligible; however, if comprising a living organism occurring in nature falls under Section 3(c), which precludes patentability of the mere discovery of a scientific principle or formulation of an abstract theory (or discovery of any living thing or non-living substances occurring in nature). In addition, Section 3(d) prohibits patent protection to: the mere discovery of a new form of a known substance if it does not result in the enhancement of the known efficacy of that substance; or the mere discovery of any new property or use for a known substance. This in turn persuades for a strict patentability standard for Biopharmaceuticals.

While in principle, by the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), patents are available for any invention in any fields of technology, the issue of the patentability of biological materials, isolated or derived from naturally occurring living organisms. US Supreme Court decisions in, for example, eBay v. MercExchange (2006), Mayo v. Prometheus (2012), and Association for Molecular Pathology v. Myriad (2014) endeavored to develop judicial rulings in protecting Biotech inventions in the medical field.

2.1 Biologics Patenting:

[26] Grabowski, Henry G., Joseph A. DiMasi, and Genia Long. "The roles of patents and research and development incentives in biopharmaceutical innovation." *Health Affairs* 34.2 (2015): 302-310.
[27] Indian Patent Act, 1970 provides the definition of invention under section 2 (j) as amended by Act 38 of 2002

There is an indispensable need for the pharma companies firstly to obtain a priority date in the IP office from that of the other pharmaceutical companies. However, the patent rules also specify that the specification of the innovation must accommodate enough description about the innovation which in terms of pharma companies include the clinical trial date of the same. Thirdly, the claim to the innovation could include ample protection to the process and the product. The said claim description is possible only with the process of the innovation reaching its mature stage.

In the Patent system and practice, a process is generally termed a "method,"[28] which involves a series of steps that are manipulated and involve human ingenuity.[29] Regulatory data protection says Dr. Lybecker enhances and encourages innovation thus leading to cost savings and a better healthcare system.[30] *"Patent protection and data exclusivity are complementary forms of IP protection that both serve to incentivize the tremendous investments required for the development of biologic medicines,"* she says. In pursuance of the same, some sectors require special attention while granting patent protection to these Biopharmaceuticals. They are as follows:

2.2 Public health

It is the objective of the Government to imbibe into a regulatory regime that should include the access and affordability of drugs. The limited duration of the Patent aims to render the same to limit the monopoly to a certain duration to create an environment for the manufacturers to reap the value from these drugs. In the interest of the Public, biosimilar drugs are manufactured which provides access to these drugs at an affordable price thus enabling the public interest while balancing the private interest.

2.3 Research and Development- Innovative Biologics

This process involves the optimal utilization of the funding and support for the research and development of the drugs thus leaving ahead for innovations to foster in the field. In India, BIRAC (e.g., the Biotechnology Ignition Grant) and MEiTY, having a quantum of about Rs 5-

[28] Vita-Mix Corp. v. Basic Holding, Inc., 581 F.3d 1317, 1323 (Fed. Cir. 2009) (the preamble of a method claim is utilized to know the method of invention)
[29] John Gladstone Mills et al., Patent Law Basics § 6:1 (2010).
[30] Dr. Kristina Lybecker, an associate professor at Colorado College specializing in pharmaceutical IP rights.

50 lakhs over 6-18 months fund the research and drug discovery.[31] The same is found to be insufficient as it amounts to only 0.7% compared to 2.8% in developed countries.[32]

2.4 Transfer of technology

Licensing policy which includes the transfer of the technology by international trade regime. Commercialization of the product in the country granting protection. These guidelines are set out by WHO to enhance the accessibility of these drugs to the public.[33]

2.5 Competition and Potential Competitors

There is a steady trend in India to focus on smaller companies developing drugs.[34] In fact, the country being one of the leading generic manufacturers is now focusing on its indigenous biopharmaceuticals, follow-on biologics, bio-betters, and bio-equivalent. This leads to a competitive advantage for the biosimilar manufacturer however potentially risks the original Biologic manufacturer thus leading them to practices such as secondary patenting or evergreening of patents. Regulatory requirements that mandate the pharma companies to disclose data potentially risk leakage and thus a competitive disadvantage.[35] In terms of Biologics, the United States has facilitated a Legislative structure to regulate the Competition and accessibility of drugs through the Biologics Price Competition and Innovation Act (BPCIA).[36] Indian framework still guides these risks through the established guidelines but not in line with the Patent regulation.

III. STRATEGIC IP MANAGEMENT IN THE PHARMA BUSINESS TO BOOST INNOVATION AND DEPLOYMENT OF DRUGS

It is a well-established fact that the value of IP is indispensable for the development of the enterprise. However, companies realize the same only after the product has come for litigation. This piece shows the possible scope of patenting Biopharma in India, the regulatory framework of the same, and the trends in how Indian biopharma companies have heeded to the

[31] https://www.financialexpress.com/healthcare/pharma-healthcare/driving-innovation-and-rd-in-the-indian-pharma-sector/2613326/

[32] Global Investments in R&D, Fact Sheet No. 50 June 2018 UIS/FS/2018/SCI/50 accessible at https://uis.unesco.org/sites/default/files/documents/fs50-global-investments-rd-2018-en.pdf

[33] 'WHO guidelines on technology transfer in 5 pharmaceutical manufacturing', Working document QAS/20.869/Rev2 August 2021 accessible at https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/pharmaceuticals/current-projects

[34] Bigger Isn't Always Better, 418 Nature 353 (2002)

[35] Adda C. Gogoris and Patricia J. Clarke, 'Patent due diligence in biotechnology transactions', 2001 Nature Publishing Group http://biotech.nature.com

[36] Available at https://www.fda.gov/drugs/biosimilars/biological-product-innovation-and-competition

opportunities in patenting Biopharma. Biopharma is a patent-eligible subject matter with the advanced rulings of *Mayo, Myriad Genetics,* and the guidelines in the Indian Patent framework.

Understandably, companies and investors want to know how soon this will affect them and the scale to which it will. For their part, brand name companies can attempt to minimize the impact of price erosion following a patent cliff (i) through innovation and development of newer products still enjoying market exclusivity, (ii) through transactions, strategic partnerships, and other alliances between companies, and (iii) strategic IP life-cycle management to extend protection to the extent possible[37]

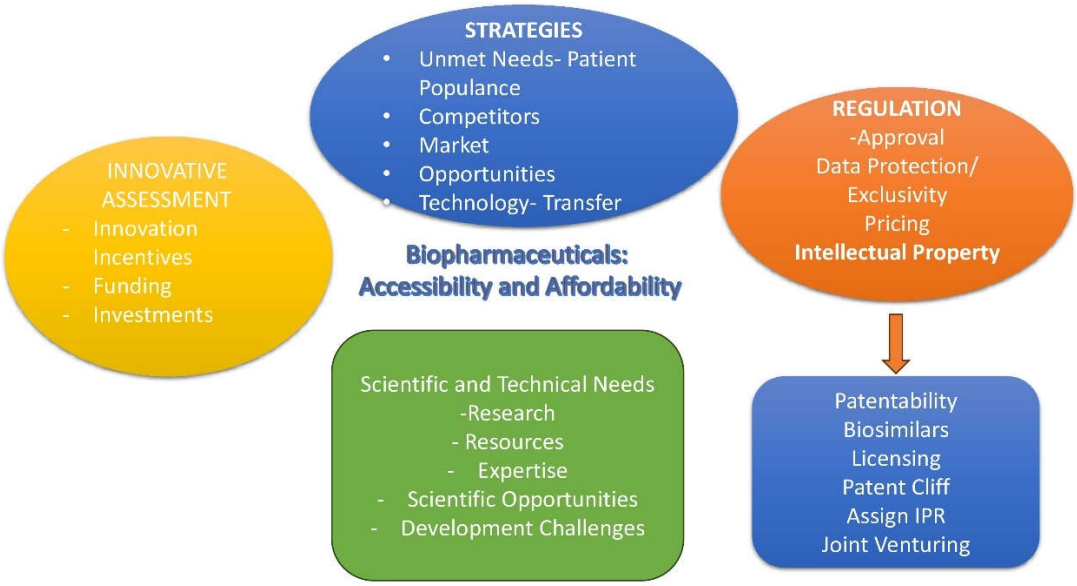

Figure 1: Approaches Involves in Biopharmaceuticals

3.1 A comprehensive Business Plan for a Pharma company involves the following

S. No	Attributes	Roll On	RISKS	Exemptions
1.	RESEARCH AND DEVELOPMENT	Scientific Challenges	Managing Approval/ Use Authorization	• Bolar Exemption • Compulsory Licensing
		Regulatory Challenges	Trade Sanctions/Free-Trade Agreements	
2.	TARGET MARKET	Prevalence of the Disease	Low Marginal Production	

[37] Jason N. Mock, 'The BioPharma Patent Cliff: 2023 and Beyond' 29 March 2023 FOLEY & LARDNER LLP

		The availability of Drugs[38]		• Parallel Importation • Least Developed Country Transition Period.
		Size and Location of the Market		
3.	IPR	Patentability	Competitors such as follow-on Biologics /Biosimilars/ Biobetters/ Bioequivalents	
		Patent Protection		
		Other strategic Ips- Third Party IP and Patent exposure[39]		
		Regulatory Data Protection		
4.	CAPITAL FLOW	Foreign Direct Investment	Patent Cliff	
		Government Funding	FTA's and trade sanctions	
		Research Incentives	Research funding allocation Policy	

However, there are associated risks in strategic patenting by these Pharma Companies such as

- **Reverse Payment Agreements, Anti-Competitive arrangements,** Free Trade Agreements among Nations. There is a grey area in trade agreements between Nations that impede the accessibility and affordability of drugs. Trans-Pacific Partnerships include clauses where the mandatory grant of patents on plants, animals, seed claims the exceptions given

[38] https://www.indegene.com/what-we-think/reports/enhancing-brand-launch-patient-insights-and-real-world-data

[39] Isobel Finnie, "Protecting biotech IP to support deal value", NEWS FEATURE Biopharma Dealmakers 2018 accessible at https://www.nature.com/articles/d43747-020-00505-6 accessed on 16-01-2024

under Art 27.3 of TRIPS as a patentable subject matter (which mandates patents on diagnostic methods too).[40] This provision leads to the wider scope of patent monopoly to natural substances thus impeding the entry of competition. In addition to the same, companies through strategic patenting are involved in the rejection of licence to the Indian entities[41].

- **Evergreening of Patents- Secondary Patents**

This is a practice by pharma industries to bypass the *"Patent cliff"* and the loss of revenue due to the expiration of the patent term.[42] The Patent holder involve in a minor enhancement of the patented invention which does not independently enable it to be patented and acquire patent rights for the same. The same leads to an extension of the monopoly of the product for a longer period that establishes high prices of these products in the market.[43] Many instances in the Indian Patent system showed a discouragement of these strategies including the case of 'GLIVEC' a drug by Novartis was discouraged for "evergreening of patent".[44] Biopharma companies indulge in acquiring secondary patents over their successfully patented products to avoid competition. This strategic management of patent for their products enhances their monopoly in the market and thus lead to the gradual increase in the prices of those drugs.[45] This practice is against the balance that is maintained between Patent Law and competition Law as it hampers the originator's incentives and harms the development of Biosimilars.[46]

- **Broad Patent Claims:**

Biologics in practice are more complex elements for a detailed description of the invention. With the recent controversy in Amgen v. Sanofi[47], the US Supreme Court unleashed

[40] Biotechnology Industry in India, IBEF: India Brand Equity Foundation. 2019. Available from: http://www.ibef.org/industry/biotechnology-india.aspxt.
[41] Swarapn Dey and Vifor International (AG), Case No 05 of 2022)DHC 2022
[42] Granstrand, Ove, 'Evergreening and patent cliff hangers', STOCKHOLM INTELLECTUAL PROPERTY LAW REVIEW VOLUME II ISSUE 1 June 2019
[43] Midha S. Strategies for drug patent Ever-greening in the pharmaceutical industry. Int J Pharm Sci Bus Manage. 2015;3:11–24; Also ref. Racherla, U (2019): "Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Pharmaceutical Industry," Innovation, Economic Development, Inetellectual Property in India and China, ARCIALA Series on Intellectual Assets and Law in Asia, K C Liu and U S Racherla (eds.), Singapore: Springer, pp 327–46.
[44] Prakash A, Sarma P, Kumar S, Medhi B. Intellectual property rights and Indian pharmaceutical industry: Present scenario. Indian J Pharmacol. 2018 Mar-Apr;50(2):57-60. doi: 10.4103/ijp.IJP_320_18. PMID: 30100652; PMCID: PMC6044128.
[45] Kristina M. Lybecker, 'Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measure up. January 2017 FraserInstitute.org
[46] Olga Gurgula, Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene? IIC 51, 1062–1085 (2020). https://doi.org/10.1007/s40319-020-00985-0
[47] Amgen Inc. v. Sanofi (05/18/23) No. 21–757 available at https://www.supremecourt.gov/opinions/22pdf/21-757_k5g1.pdf

on the Patenting practice in Antibodies and the possible infringement landscape in the US.[48] Inventors are in the verge of accomplishing the right equilibrium between the broad protection, enablement requirement, and a lucid description, which is intricate due to the complexity of antibodies and their diverse structural variations.[49]

Illustration can be made through the Patenting Landscape of Monoclonal Antibodies in the US and Indian Patent regime: With the recent development of Biopharmaceutical inventions, there is an increased trend in patenting monoclonal antibodies. For instance, there were 29 applications between 2011 to 2019 either directed to antibody itself, compositions containing one or more antibodies, methods of generating the antibody, therapeutic or diagnostic methods involving the use to the antibody and/or second medical use of the antibody were filed in the Indian Patent Office.[50] There was a surge in the antibody treatments at various stages of clinical trials post-COVID-19 – some were designed solely to deal with the secondary effects of SARS-CoV-2, while others were designed against the virus.

Instance can be seen in Abbvie's Humira which has composition-of-matter patent though expired in 2016 had a Patent thicket for different aspects of the product such as ', *"indication/method of treatment (22), formulation (14), manufacturing (24), "other" (15)) extends protection until 2034"*

Regulatory Data Protection:

The data that provides toxicology and efficacy of these innovative medicines are recognized for their proprietary value and are granted exclusive protection during which the competitors cannot rely on the same for making the generic.[51] The provision sources itself from TRIPS Article 39.3 of 'data protection' and evlolved through Free Trade agreements and Trans-Pacific Partnership agreements. The protection afforded is given by different names in various countries known as "regulatory data protection" (RDP) sometimes addressed as *"Data Exclusivity"*, *"market exclusivity"*, and *"confidential information",* or *'pseudo patent*

[48] Christian Lautenschläger, Antibody Patent Paradox – Impact on Investments in BioPharma?, OPINION, available at https://www.linkedin.com/pulse/antibody-patent-paradox-impact-investments-biopharma-christian/?trackingId=oXu1W4tFRjuEA%2Bgzeh73yA%3D%3D

[49] Mark A. Lemley & Jacob S. Sherkow, The Antibody Patent Paradox, INTELLECTUAL PROPERTY, YALE LAW JOURNAL, Feb 2023 available at https://www.yalelawjournal.org/article/the-antibody-patent-paradox

[50] Ref, Drugs Patent in IP official website of India available at https://www.ipindia.gov.in/writereaddata/Portal/Images/pdf/Drugs_Patent.pdf

[51] Fabian Gaessler, Stefan Wagner, Patents, Data Exclusivity, and the Development of New Drugs, Rationality and Competition, Discussion Paper No. 176 August 5, 2019 accessible at https://rationality-and-competition.de/wp-content/uploads/2021/11/176.pdf

exclusivity' though each slightly varies in their meaning.[52] The protection is given for a certain period of 10 years in some jurisdictions during which the originators are incentivized to recoup the investment and development costs.[53] This is studied to be more sounding as a TRIPS Plus provision grants protection despite the period of Patent protection granted to the product.

IV. POLICY INTERVENTION ON INTELLECTUAL PROPERTY IN THE PHARMA BUSINESS

Above all these developments in the area of Biopharmaceuticals, there is a pressing concern for the Government to roll out the best policy framework model for regulating the Patent, Patent regulation, and strategic IP management trends followed by the Biopharma companies. Department of Biotechnology (DBT), the Biotechnology Industry Research Assistance Council (BIRAC), and the government of India to support the vision of making India a hub for biotechnology-based innovation and research.[54] These efforts focus on policy initiatives and investments, the promotion of industry-institute partnerships, creating entrepreneurship cells to promote biotech start-ups, and skill development.

4.1 Global Patent and Drug Regulation: IP Maximization Strategies:

Countries have adopted IP maximization strategies imposing the least control over the US trade body about Medicine Patents[55]

4.2 Public Health Concerns

A need for the collaboration of the functionaries in the enterprise would best result in the utilization of the IP value of the product.[56] The collaboration shall be linked to allow the *'accessibility and affordability'* of these drugs to the public. It is a matter of concern that Pharma Companies should involve in CSR activity to create an environment for the accessibility and affordability of medicines. However, policy concerns perhaps should focus on legislative framework to enhance competition in the market to allow the transfer of

[52] Yaniv Heled, 'Regulatory Competitive Shelters' (2015) 70 Ohio State L.J. 299, 300.
[53] Hoen, E.'. (2022). Protection of Clinical Test Data and Public Health: A Proposal to End the Stronghold of Data Exclusivity. In: Correa, C.M., Hilty, R.M. (eds) Access to Medicines and Vaccines. Springer, Cham. https://doi.org/10.1007/978-3-030-83114-1_7
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[56] Fabrizio Cesaroni and Andrea Piccaluga, "Operational Challenges and ST's Proposed Solutions to Improve Collaboration between IP and R&D in Innovation Processes," California Management Review, 55/4 (Summer 2013);

technology and production of these drugs. **An** undervalued strategy that companies employ is to suppress competition in the market i.e. to enjoy a monopoly in the relevant market.[57] This trend should be minimalized through a legislative framework.

Indian Pharma industry is aimed to function with an inherent balance between the generic manufacturers, the patent holder, and the public interest.[58] Compulsory licensing is rarely ever used in India, there is a changing trend in how the 'utilization of these provisions' heed to the accessibility and affordability of drugs against anti-competitive activities. For instance, in the US, the Orphan Drug Act (ODA) was in the USA in 1983. Bayh Dole Act 1980 and the *'March-in rights'* which act as a compulsory licensing mechanism for pharmaceutical drugs were enacted for the purpose. In addition to the same, other countries have already adopted this kind of legislation such as Japan in 1993, Australia in 1997, and the European Union (EU) in 1999.

Table 1: Represents a schematic representation of Biopharma Regulation in India

Strategic IP attributes	**Biopharma**	**Price Regulation-NPPA**	**Authorities**	**Policy**
Intellectual Property-Patent	The Drug Regulation Act Guidelines, 2012 and revised guidelines 2016	The Patents Act, 1970	The Indian Patent Office/ Controller of Patents	TRIPS- Standards of Patentability
Data Protection / Exclusivity/ Market Exclusivity	Undisclosed Test Data/Confidentiality	Not Applicable	Drug Controller-CDSCO	Article 39.3 of TRIPS/FTA regulations
Non-Innovator Biologics[59]	Non-similar to Innovative Reference Biologics	NPPA	Non-regulated	

[57] I.M. Cockburn and M.J. MacGarvie, "Entry and Patenting in the Software Industry," Management Science, 57/5 (May 2011): 915-933; Also, Companies make profit by fixing the prices in the market. H. Ernst, "Patent Applications and Subsequent Changes of Performance: Evidence from Time-Series Cross-Section Analyses on the Firm Level," Research Policy, 30/1 (January 2001): 143-157

[58] Chaudhry R. Compulsory licensing of patents in India. Pharm Pat Anal. 2016;5:401–6.

[59] https://gabi-journal.net/overview-of-non-innovator-biological-products-in-india.html

Product Life Cycle Management[60] **1. Development (early)** **2. Commercialization (middle)** **3. Generic competition (late)**	12.9 to 14.6 years	NPPA as per Drugs Price Control Order (DPCO), 1995/2013	DCGI- The Drug Controller General of India	Exclusion from conducting clinical trials; Pre-clinical testing and authorizing import/export for R & D. Bioequivalence test to that of Ref. Biologics which has been granted marketing authorization in India 1. Submission of Clinical Trial Application for Evaluating Safety and Efficacy 2. Requirements for permission of New Drugs 3. Post-approval changes in biological products Preparation of the Quality Information for Drug Submission for New Drug/ Biotech/Biological processes

The National Policy for Rare Disease in India 2021. National Policy on Research and Development and Innovation in Pharma-MedTech Sector in India. - does not give any insight into the intellectual property. It is high time that the Indian policy framework should focus on Biopharmaceuticals on the (1) duration and scope of regulatory data protection, and (2) the lack of an orphan drugs regime (to be involved in R & D for novel drugs).

Quality Non-Innovator Biologics are being developed as a result of poor regulation. It is retrieved that the Country has approved 83 rDNA-derived non-innovator biological products (NIBPs) which exhibit uncertain safety and efficacy when compared to the reference biological and are non-recommended for use. (CDSCO, 2019)[61]

4.3 R and D financing for the development of drugs

Academic institutions are the ones that acquire a majority of patents.[62] In fact, the problem lies in the case that there is a minimal intervention for the clinical translation of these

[60] https://within3.com/blog/life-cycle-management-pharma
[61] Central Drugs Standard Control Organization [homepage on the Internet]. [cited 2019 Oct 14]. Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDQ2Mg==
[62] Ruchi Sharma, Akriti Jain, 'Research and patenting in Indian universities and technical institutes: An exploratory study', World Patent Information, Volume 38, 2014, Pages 62-66, ISSN 0172-2190, https://doi.org/10.1016/j.wpi.2014.04.002.

inventions and a dearth in funding for these projects[63] The Department of Biotechnology (DBT) in collaboration with World Bank, initiated an industry-academia collaborative mission *'National Bio-Pharma Mission'* with a corpus of USD 250 Mn which is implemented by BIRAC. The mission aims to accelerate the R and D for biopharma. For specific focus on the preclinical development of many biotherapeutics such as Insulin Glargine (Vitane Pharmaceuticals), Herceptin (Serum Institute of India), and Plasma fractionation (BIBCOL). This mission also supported the development of a few vaccines such as, the Universal Flu vaccine (MynVax), Pneutgar-15 (Tergene), TV003/TV005 (Indian Immunologicals), DSV4 and DSV4+2E VLP (Sun Pharma). It is also claimed to supports skills development by providing necessary mentoring and training in domains of technology transfer, IP filing, Management of intellectual property, business plan development, etc. However the R and D spending on these sectors should improve compared to the developed Nations.

V. CONCLUSION

Strategic Intellectual property management in a biopharma company involves a well-established functionary to cull out the value and worth of the product using IP protection. In the process of employing the strategic development, the companies not only produce drugs but also paves a way for innovation in the field of the advance medicine and biotechnology. The Intellectual property protection to these drugs is backed by the sanction that the property rights are granted in exchange of 'transfer of technology' for the greater public good. Infact, the foundation of funding for these technologies are built on the fact that 'anything built using common resource must be given back to the common'. In this notion, greater public interest has to be enhanced which in terms of Biopharma requires access and affordability of drugs.

Strategic IP management thus shall involve in also guaranteeing the society of the access and affordability by employing the plus provisions of the Patent Law. The same includes, licensing policy, price regulation, utilising the patent box regime, entertaining the research and development. In the wake of government's initiative, policy shall include a stronger and lucid patent regulatory regime, price regulation, funding for research and development of biopharmaceuticals.

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