TRANSPARENCY V. SECRECY: A COMPARATIVE STUDY OF PATENT AND TRADE SECRET IN THE PHARMACEUTICAL INDUSTRY

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ABTRACT

The pharmaceutical industry stands at a key position in terms of protecting the health of the population, and at the same time, this industry is based on the need to use the protection of intellectual property to promote innovation and recover research and development costs. Patent and trade secrets are the two of the most important mechanisms that can be applied in the context of the pharmaceutical industry and replace other types of intellectual property. The given paper will make a comparative study of patents and trade secrets in the pharmaceutical industry that will focus on how these concepts relate to the consumer protection rights. The research paper examines the difference between the two regimes in terms of disclosure requirements, period, exclusivity, and regulation and determines the impact made by the difference on access to medicines, affordability, transparency, and consumer well-being.

Pharmaceutical patents have a comparatively short period in exchange to public disclosure, which fosters openness, permits regulatory control, permits entry of generic drugs post-patent, and provides protection measures as compulsory licensing, and Public interest exceptions to ensure consumer access to medicines. By contrast, trade secrets provide possibly endless protection without disclosure and are being exploited to provide protection to manufacturing process, clinical trial information, and pricing strategies with grave concerns to consumer protection because of the lack of disclosure, delay to generic competition as well as the absence of protection of the interests of the people. Regarding the issue of consumer protection, this comparison confirms a more balanced and responsible system offered by patents compared with trade secrets with regard to the necessity of legal changes and harmonized regulation that would preserve incentives to attract pharmaceutical innovation, transparency, affordability, and equitable access to pharmaceuticals.

Keywords: Pharmaceuticals, trade secret, Patents, consumer protection

INTRODUCTION

Innovations in the pharmaceutical industry are protected by patent or by trade secrets. Patents provide a temporary monopoly with the advantage of public disclosure, trade secrets safeguard undisclosed secret information for a long term, if secrecy is preserved. This organisational distinction has far-reaching impacts on the process of medicine discovery, production, prices, and accessibility to the masses. Consumer rights are explicitly involved in the conflict between these two mechanisms of protection in the industry, such as pharmaceuticals, where lives are at stake due to access to affordable and effective drugs. The legal system in India is an intentional attempt to strike a balance between the incentives to innovate and the needs of the populace to have health services. The Patents Act, 1970, particularly the famous Section 3(d), limits the process of evergreening by not allowing patents on slight advances without proven therapeutic advantages. The trade secret safeguarding of tacit manufacturing knowledge, process information, and quality-assurance guidelines is becoming a new bottleneck in the access field, unlike the expired patents. This became clear in the context of the COVID-19 pandemic, when the discussion of patent waivers in the framework of the TRIPS Agreement has shown that successful vaccine production also relied on non-publicised know-how that pharmaceutical companies tightly locked in. Programs like the mRNA technology transfer hub by the WHO were explicitly created to fill this knowledge gap by attempting to disseminate knowledge that no patent could reveal. However, since the trade secret remains heavily dependent, regulators, civil society, and consumers are often left without access to safety data or the ability to reproduce the production, which creates barriers that can be difficult to overcome ultimately. The main issue, thus, is whether the status quo of the balance between trade secrets and patents is sufficient to safeguard the rights of consumers to be affordable, safe, and transparent. With India still aiming to become the pharmacy of the Global South, there is a two-fold challenge of attracting pharmaceutical innovation and, at the same time, providing equitable access. This paper critically reviews the comparative effects of trade secret law and patent law in the pharmaceutical industry in the context of the entire international arena. It claims that trade secret protections are a serious threat to consumer welfare, even more serious than the protections of patents, without reforms, including conditional disclosure obligations in the case of public health emergencies, more effective technology-transfer mechanisms, and clearer statutory carve-outs.

1.1 PATENT

Patent protection is a right granted by the government to the inventor who made innovation. In pharmaceutical, innovation includes a new drug molecule, a method formulation, or a new method of using an existing drug. This patent right gives the inventor an exclusive right to use, sell or distribute for a limited period, according to the Indian Patent act, 1970 the period of 20 years from the date of filing application of patent[1]. In return of this exclusive right, the patentee should disclose the details of the inventions mentioned in the patent specification. This disclosure allows public to get knowledge of the innovation. The disclosure allows the public also to gain information and restrains from monopolising an innovation[2].

The Benefits of Patent Protection of Pharmaceuticals.

1. **Promotes Innovation:**

Developing a new drug requires enormous financial expenditure for the experimentation of the research. The implementation of patents offers the companies 20 years to refund such investments and invest in future innovations. Market Exclusive and Revenue: Exclusive rights enable businesses to charge and regulate output that guarantees revenue streams that can cover the risks associated with conducting research and development. To use the example of Pfizer spending 125 million and 10 years to develop Feldene, without patents, the company was imitated even before its official launch in Argentina.

2. **Public Disclosure and Knowledge Sharing:**

Patents are supposed to disclose the invention, which ultimately gets into the public domain. This enhances the development of science in that researchers and competitors can develop based on any existing innovation. Encourages Foreign Investment and Technology Transfer: Strong patent systems are more likely to attract multinational companies to invest in local markets, forge partnerships and introduce new technologies. This assists the developing countries in developing their healthcare infrastructure[3].

[1] Section 53 of the Patent act defines Term of patent
[2] Vaibhav Sinha & Prerna Gulati, *Patents in the Pharmaceutical Industry: Role and Strategies*, 11 Int'l J. for Res. in Soc. Sci. & Humanities 1 (2025), https://doi.org/10.53555/ssh.v11i1.2471
[3] Lakshmi Tulasi D.Y. et al., *A Review on Evolution and Challenges of Pharmaceutical Patent Protection in India*, J. Pharma Insights & Res., https://jopir.in/index.php/journals/article/view/273

3. **Consumer Safety:**

Patents may lead to high costs of drugs, but they also guarantee their quality and safety. Fraudulent or counterfeit drugs, which are prevalent in nations that have poor patent systems, result in risks of wrong dosages, substitutes, or ineffective treatment and subsequent health emergencies in populations.

4. **International Recognition and Global Trade**:

Patent protection on agreements such as TRIPS guarantees that the rights of pharmaceutical companies will be acknowledged worldwide. The result of this harmonisation is decreased piracy and enhanced international enforcement[4].

1.2 TRADE SECRET

Trade secret is another form of Intellectual property to any innovations. They are confidential, commercially valuable business information that can be formulas, designs, or any procedure of manufacturing. One of the essentials features is that the information should be valuable and kept as secret and only a limited number of persons should have the knowledge. A trade secret is a valuable business if the information remains a secret. International law through the TRIPS recognises the protection of undisclosed information, but the challenge faced is the enforcement.

DISTINCTION BETWEEN PATENT AND TRADE SECRET

The key distinction of the two is the disclosure and the time. Patents must be publicly disclosed inventions and have a definite term of existence at the same time trade secrets need not be disclosed and can be maintained indefinitely if their secrecy is maintained. Regarding enforcement, patents are supported by law and government, while trade secrets are more dependent on individual protection, such as contracts and are more challenging to enforce. Patents operate, in a simplistic manner, based on the principles of sharing your knowledge and getting protection over a period. Meanwhile, trade secrets work on the principle of keeping

[4] Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 29 Nw. J. Int'l L. & Bus. 1 (2008), https://scholarlycommons.law.northwestern.edu/njilb/vol29/iss1/14

their knowledge secret if it is possible, which protects it. Both systems promote innovation, however, in a highly dissimilar way and with diverse impacts on the community[5].

2. WHY PHARMACEUTICAL FIRMS CHOOSE TRADE SECRET OVER PATENT

2.1 Bypassing Disclosure, Maintaining Tacit Know-How, and Protecting the Know-How in Long-Term.

Pharmaceuticals tend to shun patents in cases where they have the fear that the information would be known and the competitors would then be able to develop around their invention or even develop generics upon expiry of the patent. Patents require the complete disclosure of the invention and at the end of the 20 years period, the information is released into the public domain. In comparison, trade secrets do not require any disclosure and may have endless duration in case of preserving their confidentiality[6]. This especially benefits complex biologics, vaccines and biosimilars where the secret sauce is not just the molecule but tacit knowledge - cell-line selection, purification steps and quality-control processes, which cannot be easily patented. As an illustration, the COVID-19 mRNA vaccinations showed that the patent was not the only bottleneck of global manufacturing, but also process know-how that companies maintained as a secret. So, companies use trade secrecy as a mechanism of enabling them to have sustainable competitive advantages much after the patent protection has expired[7].

2.2 Data Protection and Strategic Control of Supply Chains by regulation.

The other important motive why firms engage in secrecy is to safeguard regulatory information - results of clinical trials and safety reports to agencies to allow the firm to be licensed and market the products. Article 39.3 of TRIPS commits itself to the protection of the undisclosed test or other data effectively protecting such data as a trade secret. This does not give generic or biosimilar companies the chance to use the data of the originator to easily pass through the approval process to postpone competition. Moreover, firms tactfully deny the licensee or contractors access to certain manufacturing phases of the product life cycle, thus, dominating international chain of supply. As an example, a multinational can outsource formulation but

[5] Elizabeth A. Rowe, *Trade Secrets, Patents, and the Pharmaceutical Industry*, 8 Marq. Intell. Prop. L. Rev. 1 (2004), https://heinonline.org/HOL/Page?collection=journals&handle=hein.journals/marqip8&id=7

[6] Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?, 51 Int'l Rev. of Intell. Prop. & Competition L. (IIC) 1062 (2020)

[7] W. Nicholson Price II & Arti K. Rai, *Are Trade Secrets Delaying Biosimilars?* 348 Science 188 (2015), https://doi.org/10.1126/science.aab1684.

keep its synthesis process as a trade secret so that the licensees in the developing countries cannot turn into fully autonomous producers. These are practices that increase corporate leverage and postpone affordable access to medicines by the consumer[8].

2.3 Response to Weak Standards of Patentability and Legal Risks

Section 3(d) of the Patents Act in India prohibits claims on incremental innovations unless such innovations are proven to have an improved therapeutic effect. This is a high threshold substantiated in *Novartis AG v. Union of India (2013)*[9], complicating the ability of the multinational firms to obtain secondary patents on changes. As a result, firms tend to use trade secrets to oversee incremental innovations in processes, manufacturing, or delivery systems that are unlikely to be patented. Equally, trade secrecy offers a backup in jurisdictions where patent protection is not guaranteed, or the lawsuit is associated with a high risk. Such strategic confidentiality, therefore, secures further market power even in cases where the patent law provides minimal possibilities of exclusivity[10].

2.4 Protecting Products and Processes against Public Armor.

Trade secrecy also allows firms to escape scrutiny from regulators, independent scientists, and civil society. Trade secrets are never distributed, unlike patents, which are publicly known. This confidentiality is at times capable of protecting unsafe or ineffective products. The Theranos scandal is a significant case outside the mainstream pharma: the company used trade secrets to deny the disclosure of its blood-testing technology, which would later become known as fraudulent. In the pharmaceutical sector, such secrecy may slow down independent confirmation of safety and efficacy, compromising consumers' rights. For instance, the manufacturing specifications of such drugs as Humira (adalimumab) are not publicised, which postpones the introduction of biosimilars and makes the treatment expensive. This demonstrates that secrecy, although legal, can harm consumer welfare by hindering transparency and encouraging monopolistic pricing[11].

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[8] Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer*, 16 J. Intell. Prop. L. & Prac. 1182 (2021), https://doi.org/10.1093/jiplp/jpab144

[9] AIR 2013 SUPREME COURT 1311

[10] Shamnad Basheer & T. Prashant Reddy, The "Efficacy" of Indian Patent Law: Ironing Out the Creases in Section 3(d), 5 Scripted 232 (2008), https://doi.org/10.2966/scrip.050208.232

[11] Emily Hanson, *The Economic Burdens of Life: Trade Secrecy and the Insulin Pricing Crisis in the United States*, 27 J. Intell. Prop. L. 99 (2020), https://digitalcommons.law.uga.edu/jipl/vol27/iss2/4

3. CONSUMER RIGHTS AND TRADE SECRETS.

The trade secrets are on the rise amongst the pharmaceutical industry. Trade secrets, unlike patents, require the specification of information in exchange of temporary monopoly; a trade secret allows companies to maintain the secrets of how they make a drug, clinical trial, or quality-control procedure secret forever[12]. This secrecy may protect investment of a company, but this would normally be detrimental to the consumer who needs to be offered cheap and safe medicines. The major problem is that the entry of generic competition is prohibited by trade secrets. Upon expiry of a patent, the generic manufacturers are likely to produce generic drugs which are less expensive. With a secret production process, generics can easily copy the process. This is especially in the case of biologic drugs that have very complex production. This means that the consumers will pay extra in the long run as there is no competition even after the patents have been expired.

Trade secrets also lose their transparency. Patents are published documents which are available to regulators, doctors and patients. There are trade secrets that are not revealed; no one can find easily whether a drug is safe or effective. The Theranos case, where the company alleged trade secrets to hide a blood-testing technology proves the necessity of secrecy to cover-up problems and put consumers in danger. Such confidentiality could withhold an objective scientific evaluation at the cost of the patients in the health care. The other issues occur in emergencies of public health. Patents are not the only barrier to the production of vaccines during the COVID-19 pandemic[13]. It was the information about real technical knowledge- cell-line development and storage requirements which were trade secrets of companies that acted as the actual bottleneck. With the absence of such information being exchanged, many developing countries would not produce vaccines domestically as patent waivers were sought at the World Trade Organisation. Low- and middle-income nations were slower in terms of access to vaccines and escalated health outcomes[14].

Unfair price can also be perpetuated by trade secrets. The companies will have dominance on the supply chain by keeping the processes a secret whereby they will not need to contend with

[12] Srividhya Ragavan, *The Utility of Utility: Selective Enforcement of Patent Rights in the Pharmaceutical Industry*, 61 Am. U. L. Rev. 739 (2012), https://heinonline.org/HOL/P?h=hein.journals/aulr61&i=751
[13] S. Kapczynski, *The COVID Vaccine Patent Waiver Debate Reveals the Limits of Patent Law for Technology Transfer*, 102 Am. J. Pub. Health 1636 (2022), https://doi.org/10.2105/AJPH.2022.306977
[14] J. Watal, *Implementing the TRIPS Agreement: Options for Developing Countries*, 32 J. World Trade 77 (1998), https://www.jstor.org/stable/10.2307/25762126

other companies. This has been the case in the insulin market whereby the prices are still high despite the expiration of patents[15]. Consumers are daily faced with limited access and financial stress; in some cases, they must be capable of rationing or doctor-recommended life-saving medicine. Simply put, the trade secrets are protecting the company secrets at the cost of consumers. They delay generic cheaply made products, decrease transparency, impede community health response and sustain the premium cost of medicine.

EXAMPLES

1. INSULIN PRICING CRISIS

In 1921, Insulin was found, and the patent was sold for one dollar to ensure the drug remained affordable everywhere. However, as time passed, the pharmaceutical industry moved on to use trade secrets instead of patents to ensure that insulin manufacturing was safe. Because Insulin is a biologic, its manufacture incorporates complex processes like recombinant DNA technologies, cell-line development, and purification procedures. These cannot be patented easily and are more easily safeguarded as a confidential know-how under the United States law, namely, the Defend Trade Secrets Act of 2016, which permits this information to be permanently kept secret, if it is not disclosed. Consequently, these competitors are blocked by firms such as Eli Lilly, Novo Nordisk, and Sanofi, which control the market and do not allow their rivals to find out the know-how to create a biosimilar.

The significant problems that this secrecy causes to the consumer are the high prices of drugs, the non-existence of competition, and the lack of transparency. Although the original patents for Insulin expired years ago, insider knowledge has ensured that generic producers can hardly create generic versions at lower prices. There are regulatory mechanisms of biosimilars incapable of breaking information barriers formed through trade secrets. It has contributed to the skyrocketing cost of Insulin, with the patients being compelled to ration their drugs, sometimes leading to their death. The article notes that although trade secrets are beneficial in serving corporate interests, they contradict intellectual property interests in the pharmaceutical industry, which encourages innovation and the provision of life-saving drugs to the

[15] Ryan Knox, *Insulin Insulated: Barriers to Competition and Affordability in the United States Insulin Market*, 7 J. L. & Biosci. 1 (2020), https://doi.org/10.1093/jlb/lsaa029

population[16].

2. COVID-19 Vaccinations and Trade secrets.

The largest impediment to world vaccine access in the case of the COVID-19 pandemic was patents, trade secrets, and unpublished know-how. Like Pfizer-BioNTech and Moderna products, mRNA vaccines necessitated very specialised procedures, such as the use of lipid nanoparticles, cell-line creation processes, purification approaches and preservation experiments. This information was not revealed in patents, and it would remain a trade secret on a lifetime basis. Consequently, developing countries could have failed to copy the production of vaccines in the absence of such a vital manufacturing expertise despite possible patent waiver under TRIPS.

Absence of exchange of trade secrets slowed down local production in most of the regions and increased the global inequities. Rich countries got most of the vaccines, and less industrialized and developing countries got shortages and delays. Compulsory licensing that is used traditionally to deal with patents cannot be used with trade secrets, as there is no disclosure requirement. It proposes the need to investigate mandatory licensing of trade secrets, controlled technology transfer, and collaboration between the government and the private sectors to be able to offer equal access in the event of future health emergencies[17].

3. Theranos scandal

Theranos was a health technology startup company based in the Silicon Valley, California that was established in 2003 by Elizabeth Holmes. The company alleged that it had developed a ground breaking technology of blood-testing that could enable hundreds of tests to be conducted with just a few drops of blood in a prick of the finger, as opposed to the normal large vials that are usually drawn out of the veins. This promise was met with gigantic attention and billions of investments. Theranos at its highest point was worth about nine billion dollars and Holmes was dubbed the female Steve Jobs.

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[16] Emily Hanson, *The Economic Burdens of Life: Trade Secrecy and the Insulin Pricing Crisis in the United States*, 27 J. Intell. Prop. L. 251 (2020), https://heinonline.org/HOL/Page?handle=hein.journals/intpl27&collection=journals&id=261

[17] Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines via Involuntary Technology Transfer*, 16 J. Intell. Prop. L. & Prac. 1182 (2021), https://doi.org/10.1093/jiplp/jpab144

The issue was that the technology never worked. Back the scenes Theranos had been using the traditional machines to conduct most of the tests but sold its Edison machine as revolutionary. The company used the protection of trade secrets to avoid investigation and deny the independent scientists, regulators, or even business partners to analyze its practices. This secrecy had deterred the detection of the fraud over the years. However, after a certain time, research conducted by The Wall Street Journal in 2015 revealed the reality, which was followed by regulatory measures, lawsuits, and the fall of the company in 2018.

The problem was in the fact that Theranos did not want to be transparent as is the case with medical technologies using the veil of trade secrets. Patients were given unreliable test results and, in some cases, false positive results or missed diagnoses which were hazardous to the health of patients. Holmes and its ex-COO, Sunny Balwani, were indicted on charges of fraud; in 2022, Holmes pleaded guilty and was sentenced to a jail term[18].

4. RECOMMENDATIONS

4.1 Bring on board Transparency Protection in Life Saving Drugs.

Among the recommendations, it is important to reduce indefinite secrecy of trade secrets on vital medicines. Although firms must be free to safeguard valid know-how, regulators may demand some knowledge in important safety or production to be disclosed in situations where there is threat to the life of the population. It would eliminate scandals such as Theranos, where hidden mistakes of defective technology were covered with silence, and provide regulators, scientists, and consumers with more control.

4.2 Compulsory licensing of trade secrets in the event of a health emergency.

Compulsory licensing is already available with patents but not with trade secrets. In crises such as COVID-19, where time-sensitive access to manufacturing know-how is critical, governments ought to think of legal outlines of compulsory licensing of trade secrets. This would be an escort technology transfer with reasonable payment to the company so that in the middle of lives being lost knowledge is not held indefinitely.

[18] John Carreyrou, *Hot Startup Theranos Has Struggled With Its Blood-Test Technology*, Wall St. J. (Oct. 16, 2015), https://www.wsj.com/articles/theranos-has-struggled-with-blood-tests-1444881901.

4.3 Enhance International Technology Transfer.

The COVID-19 crisis demonstrated that IP waivers cannot be effective. Plans such as the WHO mRNA vaccine hub in South Africa need to be increased with strong commitments by companies and governments to share the patents and tacit knowledge. Obligations to transfer technology in case of emergency in the case of multilateral treaties would allow the equitable access to medicines globally[19].

4.4 Enhance Competition Law against Abuse based on Secrecy.

Competition authorities must be also given authority to protect market dominance in unjust manner; when businesses seek to control market with the help of trade secrets, i.e. bar entry of biosimilars or use pay-off agreements. Stricter antitrust control would make sure that the trade secrets are not transformed into an anti-competitive tool to maintain consumer price artificially high.

4.5 Design International Ethical Standards on Essential Medicine.

Lastly, in addition to legal measures, ethical principles should also be developed at the WHO and WIPO levels, to regulate the application of trade secrets in pharmaceuticals. Such guidelines may emphasize the fact that trade secret is necessary to innovate, but in case of life saving medicines another consideration must be put in place where human health and consumer rights take pre-eminence over the unlimited corporate secrecy[20].

CONCLUSION

Trade secrecy and the patent law are complementary mechanisms of promoting pharmaceutical innovation - but they are sharply differentiated in their effects on the population. Patents are sold temporary privilege over disclosure, whereas trade secrets can maintain an edge of the firm permanently and prevent the leaks of crucial manufacturing information. The COVID-19 pandemic demonstrated that patents are not enough to overcome any barrier to the scale of production; tacit know-how and trade secrets exist as real barriers to the production of complex

[19] Tanya Aplin & Johnathon Liddicoat, *The Interplay Between Patents and Trade Secrets in Medical Technologies*, WIPO Discussion Paper (2023), https://www.wipo.int/edocs/pubdocs/en/wipo-pub-1075.pdf
[20] J. Watal, *Implementing the TRIPS Agreement: Options for Developing Countries*, 32 J. World Trade 77 (1998), https://www.jstor.org/stable/10.2307/25762126

biologics and vaccines.

In the case of India and other nations that need to balance innovation with the policy response to the public health, it should be a multipronged approach: the introduction of more transparent trade-secrets regulations with an exception to promote the interests of the population, the use of more pragmatic, practical instruments concerning the compulsory license and conditional government funding, regulatory transparency and consumer protection, and investment of domestic production and technology transfer centers. Legal transparency coupled with the leverage of the public procurement and capacity building would help safeguard consumer rights (access, affordability, safety) without removing incentives at R&D.