ADLIYA: Jurnal Hukum dan Kemanusiaan –ISSN: 1978-8312 (p), 2657-2125 (e)
Vol. 18, no. 1 (March 2024), pp. 67-92, doi: 10.15575/adliya.v18i1.27010

PATENTABILITY OF PATENT EVERGREENING IN THE PHARMACEUTICAL SECTOR: NOVARTIS AG VERSUS THE UNION OF INDIA

Angga Wijaya Holman Fasa[1], Tommy Hendrix[2]*

[1] *Directorate of Strategic Studies, Ministry of Tourism and Creative Economy/Tourism and Creative Economy Agency, Indonesia*
[2] *Regional Research and Innovation Division, Regional Planning Research and Development Agency - Bogor Regency Indonesia*
**Correspondence: tommy.hendrix@bogorkab.go.id*

Received: 22 June 2023; Accepted: 28 March 2024; Published: 30 March 2024

Abstract
This paper discusses the inventions in the pharmaceutical sector containing the nature of 'evergreening' based on the Supreme Court of India's ruling in Novartis's versus the Union of India. Patent 'evergreening refers to the business practice of patent applications for inventions in the pharmaceuticals or medicines sector that are insignificant novel compared to previous similar inventions to extend the patent protection period that implies the increasing selling price of drugs on the market. These differences resulted in India's having to anticipate the legal issues and exclude patents for inventions containing 'evergreening' properties by applying high patentability requirements. Patent' evergreening' has implications for blocking the purpose of patent existence as a tool of dissemination of science because this practice extends the period of temporary monopoly rights ownership of patents and hinders public access to medicines at affordable prices. This research uses comparative legal methods to determine the characteristics of the patentability requirement between the Indian Patent Law, TRIPs, and the Indonesian Patent Law. This research finds that Indian patent law can prevent the practice of patent evergreening and thus prevent price increases of drugs due to minor modifications without significant efficacy effects. Furthermore, the decision has implications for Indonesia as a consideration, especially for the Government of Indonesia in drafting the new law that anticipates the practice of patent 'evergreening' in Indonesia.

Keywords: patent evergreening; patentability; pharmaceutical sector.

Abstrak
Makalah ini membahas penemuan di sektor farmasi yang mengandung sifat 'evergreening' berdasarkan putusan Mahkamah Agung India dalam Novartis's versus Union of India. Paten 'evergreening mengacu pada praktik bisnis aplikasi paten untuk penemuan di sektor farmasi atau obat-obatan yang tidak signifikan dibandingkan dengan penemuan serupa sebelumnya untuk memperpanjang periode perlindungan paten yang menyiratkan meningkatnya harga jual obat di pasar. Perbedaan-perbedaan ini mengakibatkan India harus mengantisipasi masalah hukum dan mengecualikan paten untuk penemuan yang mengandung sifat 'evergreening' dengan menerapkan persyaratan paten yang tinggi. Patent' evergreening' berimplikasi pada pemblokiran tujuan keberadaan paten sebagai alat diseminasi ilmu pengetahuan karena praktik ini memperpanjang jangka waktu kepemilikan hak monopoli sementara atas paten dan menghambat akses masyarakat terhadap obat-obatan dengan harga terjangkau. Penelitian ini menggunakan metode hukum komparatif untuk mengetahui karakteristik persyaratan paten antara UU Paten India, TRIPs, dan UU Paten Indonesia. Keputusan tersebut berimplikasi pada Indonesia sebagai pertimbangan, khususnya bagi Pemerintah

Indonesia dalam menyusun undang-undang baru yang mengantisipasi praktik 'evergreening' paten di Indonesia.

Kata Kunci: evergreening paten; paten; sektor farmasi.

Introduction

The Protection of Intellectual Property Rights (IPR) is an important issue in the current global context. [1] The existence of patents as a form of legal protection intellectual property rights (IPRs) has two sides that accommodate interests, both for the community and inventors. For the public, patents ensure individuals can effectively access new technologies resulting from patented inventions. For inventors, patents as a form of incentive for innovation for problem-solving in technology resulting from high costly research and development processes.

Nevertheless, the existence of patent protection cannot be separated from criticism, especially against patents in the pharmaceutical sector. Granting patents in the pharmaceutical sector results in drug prices being high above the price of generic drugs, where the average is increasing above 10 to 45 times.[2] Even studies conclude that patents significantly impact the average price of drugs produced by European Union pharmaceutical companies marketed in Indonesia. That is because patents open opportunities for pharmaceutical companies to monopolize the application of prices, and the price of such drugs will remain high as long as they have not received competition from other similar drug products.[3] Further implications, patents result in significant health loss from consumers, and vice versa, patent owners benefit from such protections.[4] Nowadays governments, drug companies and advocacy groups continue to engage in a decade-long battle over the type of patent rights that will be available to industry, particularly in poor countries. [5]

During the problem of the existence of patents considered to increase the price of drugs, there are business practices in the pharmaceutical sector or drugs that abuse the existence of legal patent protection. This abuse is in the form of a patent application for an invention that is no longer new but the result of a slight

1 Ria W Putri et al., "Protecting Indonesia's Communal Intellectual Property Rights: A TWAIL Perspective," *Uti Possidetis: Journal of International Law* 5, no. 1 (2024): 69–105, http://www.ijodls.in/uploads/3/6/0/3/3603729/vol-5_issue-2.117-123.pdf.

2 Hira Jhamtani, "Understanding The Trade-Related Intelectual Property Rights Regime (TRIPS)" (Jakarta), accessed October 28, 2021, https://komunitaskreatifbali.files.wordpress.com/2008/09/memahami-rejim-hak-kekayaan-intelektual-terkait-perdagangan.pdf.

3 Yurina N. Tumang, "Impact of Patents on Average Drug Price Level," *Jurnal Kajian Wilayah Eropa* II, no. 1 (2006): 57–71.

4 Tomi Suryo Utomo, "The Pharmaceutical Patent Protection Impact on Indonesia Drugs Price," *Jurnal Mimbar Hukum* 21, no. 3 (October 3, 2009): 409–628, http://www.undp.or.id/pubs/ihdr2004_.

5 Jean O Lanjouw, "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry" (Cambridge, May 2005), http://www.nber.org/papers/w11321.

modification of a previous invention. It is intended that the price of the drug will remain high due to more extended patent protection. This practice is known as 'evergreening.'

Concerning the issue of patent applications for 'evergreening' inventions, on April 1, 2013, the Supreme Court of India in Novartis AG's versus Union of India handed down a ruling rejecting a cassation application for the rejection of a patent application filed by Novartis, a Swiss pharmaceutical company for the invention entitled 'Crystal Modification of a N-Phenyl-2-Pyrimidineamine derivatives. Processes for its manufacture and its use', for medicinal products for the treatment of leukemia disease produced under the trademark 'Glivec,' which has obtained a patent in the United States with patent number US 6,894,051 B1. This rejection is based on the argument that this new version's invention is slightly different from the previous version.[6]

In the Indian patent system, a patent application, especially a patent in the pharmaceutical sector, the applicant is not only required to show that the chemical composition inside has a different form of chemical composition in the previous invention. However, it must also show that the new invention's modifications produce a significantly new healing effect (medical treatment) for the patient (enhanced efficacy). It is based on the provisions of Section 3(d) of the Patents (Amendment) Act of 2005 (Indian Patent Law).[7] With aims to prevent the granting patents for applications that in its invention with claims contain 'evergreening' properties.[8]

Based on the decision of the Supreme Court of India, it is obtained knowledge that an invention can be granted a patent if it meets the requirements of patentability. The Indian patent system's patentability requirements prevent the granting of patents containing 'evergreening' properties. However, the standard of patentability concerning efforts to prevent patents against inventions containing the nature of 'evergreening' inventions in the pharmaceutical sector meets patentability requirements under the provisions of the legislation in India. Moreover, whether the differences with the concepts of patentability requirements, in general, have not found a clear and comprehensive answer and require further study to gain a clear and comprehensive description of the issue of patentability requirements.

Although the lawsuit between Novartis AG and India's union did not occur in Indonesia, it remains relevant to review the implications. The implication is with

---

6 Frederick M Abbott, "Inside Views The Judgment In Novartis v. India: What The Supreme Court of India Said Intellectual Property Watch," April 4, 2013, http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-co...

7 Ministry of Law and Justice India, "The Patents (Amendment) Act, An Act Futher to Amend the Patents Act, 1970 Vol. 1972" (New Delhi, April 5, 2005), http://www.wipo.int/edocs/lexdocs/laws/en/in/in018en.pdf.

8 Chatterje Patralekha, "Novartis Loses Patent Bid: Lessons From India's 3(d) Experience," Intellectual Property Watch, January 4, 2013, https://www.ip-watch.org/2013/04/01/novartis-loses-patent-bid-lessons-from-indias-3d-experience/.

the Supreme Court of India's decision, which rejected Novartis AG's cassation application. The Indian pharmaceutical industry that produces generic drugs, including Glivec-like drug products, can avoid patent infringement and does not require a license to affect these generic drugs' rising price. [9] The existence of generic drugs originating from India circulating in Indonesia with low prices helps leukemia patients in Indonesia, especially those from the poor people, to look for alternative drugs other than Glivec circulating in Indonesia with a price per grain reaching Rp. 220,000.00 for every 100 mg. Whereas the dose of a leukemia patient every day must consume a minimum of 400 mg to reach 600 or 800 mg for certain patents' cases.[10] If generic drugs are not available or the price goes up, it may deter patients from accessing the drug.

Furthermore, as a country that provides patent protection, Indonesia is duly ready for patent protection issues. Concepts on invention patentability avoid granting patents to patent applications whose invention claims contain properties. Moreover, it does not turn a blind eye to the fact that patent applications contain 'evergreening' in other countries and do not close the possibility of similar applications occurring in Indonesia. It requires an in-depth and comprehensive understanding of the Indian Patent Law, the ruling in Novartis AG's case against the Union of India. This in-depth and comprehensive understanding is essential because the substance in Law No. 13 of 2016 concerning Patents (abbreviated as Law 13/2016) does not anticipate the regulation of patentability requirements that aim to prevent 'evergreening' practice. Therefore, this study becomes relevant and can contribute to the development and protection of patents in Indonesia.

Based on searches, there are several previous research regarding and elaborated patent evergreening, and in relation to the case Novartis v. Union of India. Patent evergreening is seen as a practice by pharmaceutical companies to seek profits without regard to the poor's access to affordable medicines.[1112] In addition, there are also findings that conclude that the practice of patent evergreening is contrary to several strands of legal theory that justify patent protection as a form of incentive aimed at advancing technological development. [13] The decision of Novartis v. Union of India seen as breakthrough because the ruling

---

9 VOA, "Keputusan MA India Soal Paten Bisa Dorong Obat Murah," Mahkamah Agung India, April 2, 2013, https://www.voaindonesia.com/a/keputusan-ma-india-bisa-dorong-obat-murah/1632920.html.

10 Oce Kojiro, "GLIVEC vs HYDREA," https://ocekojiro.wordpress.com/glivec-gleevec-vs-hydrea/, 2010, https://ocekojiro.wordpress.com/glivec-gleevec-vs-hydrea/.

11 Michelle Chen, "Patents Against People: How Drug Companies Price Patients out of Survival," *Dissent* 60, no. 4 (September 2013): 71–77, https://doi.org/10.1353/dss.2013.0074.

12 Say-yed Hesameddin Tafreshi, "Anti Pharmaceutical Patent Ever-Greening Law: Global Need in Support of Public Health," *Journal of Intellectual Property Rights* 24 (August 2019): 103–12, https://www.researchgate.net/publication/339998402.

13 Muhammad Z Abbas, "Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System," *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector* 15, no. 2 (June 16, 2019): 53–60, https://doi.org/10.1177/1741134319848797.

inhibits the efforts of pharmaceutical firms looking to extend their patent protections in India by applying for patents on various characteristics of the same drug, which allows them to maintain monopolies and postpone the release of affordable generic alternatives.[14][15] And the effects will resonate not only within India but also in other nations reliant on Indian generic drugs.[16][17][18] However, there has been no research that specifically elaborates the comparison of patent protection regulations in Indonesia and India based on a case decision and looks at its implications.

In the facts above, two questions arise from the problems. The first-term patentability does not contain and obtain a patent reviewed from the Supreme Court of India No. 2706-2716 of 2013 in the Novartis AG Case versus the Union of India and the invention concepts. The second is Novartis AG's implications versus the Union of India case to patent legal protection provision in Indonesia.

Methods

To elaborate data, examine, and answer the problems above, comparative legal methods were employed. [19] The comparison emphasizes the legal materials such as the Indian Patent Law, the Indonesian Patent Law, and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). The provisions are compared between these three legal materials, especially regarding the terms of invention patentability. TRIPs are used to analyze the requirements for invention patentability, which are generally ratified by Indonesia and India, which must be adhered to in India and Indonesia. In this case, the Indian Patent Law, specifically the provision on the terms of invention, explains the fundamental differences between the provisions outlined in the Indian Patent Law that preventing the practice of 'evergreening' patents.

---

14 Jae Sundaram, "India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?," *Information & Communications Technology Law* 23, no. 1 (January 2, 2014): 1–30, https://doi.org/10.1080/13600834.2014.891310.

15 Surbhi Shriti, Akansha Jain, and Sampa Das, "Evergreening: An Equivocal Affair in Pharmaceutical Industries," in *Intellectual Property Issues in Microbiology* (Singapore: Springer Singapore, 2019), 323–35, https://doi.org/10.1007/978-981-13-7466-1_17.

16 Arun Kumar and Arun Nanda, "Ever-Greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries," *Pharmaceutical Regulatory Affairs: Open Access* 06, no. 01 (2017), https://doi.org/10.4172/2167-7689.1000185.

17 Uday S. Racherla, "Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry," 2019, 271–98, https://doi.org/10.1007/978-981-13-8102-7_12.

18 Sundaram, "India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?"

19 Bernard Arief Sidharta, *Rekleksi Tentang Struktur Ilmu Hukum*, Cetakan Ketiga (Bandung: CV. Mandar Maju, 2009).

This legal comparison focuses on differences in legal basis that have implications for how a legal rule can prevent the practice of patent evergreening as a trade tactic to increase drug prices. The use of legal material in the form of a Union of India case decision is an example of how the legal rules in India are applied. Furthermore, it is also explained the terms of invention patentability according to Law 13/2016. From this explanation, it can be known that there are differences in the characteristics of patentability requirements to inventions between the Indian Patent Law and the Indonesian Patent Law. This characteristic difference resulted in India anticipating the regulation of invention requirements that exclude patents for inventions by applying high patentability requirements compared to the Indonesian Patent Law.

This comparison is helpful in order to analyze Novartis's invention claims that were rejected patentability based on the ruling of the Supreme Court of India. From this explanation, it can be known clearly and comprehensively whether Novartis invention claims have qualified patentability or not.

Results and Discussion

Comparison of Invention Patentability between Indian Patent Law with TRIPs Provisions and Indonesian Patent Law

After the ratification and enactment of TRIPs provisions in India, the Indian patent system was transformed. Post TRIPs, India imposed patents on pharmaceutical products after 34 years. The countries excluded them from patentable subjects, which has made India the world's leading high-quality generic medicines industry. [20]

Nevertheless, the transformation in India's patent system still makes India anticipate patent protection in the pharmaceutical sector, especially related to the terms of invention patentability in the framework of granting patents. It aims to maintain a balance between encouraging innovation and public access to affordable medicines.[10] The implication is that there are differences in the determination of standard requirements for invention patentability in India with TRIPs in general and especially the Indonesian Patent Law, as will be discussed further in this section.

The TRIPs provision does not govern the definition of 'invention' due to the lack of consensus among TRIPs member states. However, the lack of explanation of this 'invention' does not necessarily give TRIPs member states uncertainty in defining 'invention.' Because Article 27 TRIPs, especially in the phrase "any fields of technology," explains that inventions that can then be patented are the results of intellectual works that have a 'technical character' in

[20] Janice M Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation," *University of Pittsburgh Law Review* 68 (2007): 491–641.

the field of technology. Intellectual works in technology, but do not have 'technical character' cannot be classified as 'inventions'. [21]

With the definition of 'invention', the Indian Patent Law defines 'invention', as follows:

> *"a new product or process involving an inventive step and capable of industrial application."* [22]

Meanwhile, Indonesia's patent law defines 'invention' as follows:

> *"inventor ideas that are poured into a specific problem-solving activity in the field of technology can be in the form of products or processes or refinement and development of products or processes".* [23]

Based on the two different provisions above, it can be explained that both the Indian Patent Law and the Indonesian Patent Law define inventions that can be granted patents for products and processes. However, the fundamental difference is in the formulation of the rules. In particular, the phrase "a new product or process" known to the Government of India only regulates 'inventions' to the extent that it has, and does not include the improvement or development of an invention in the form of a product or process as it is regulated in the Indonesian patent law. Therefore, it can be concluded that the Government of India only gives patents to inventions in the form of products or processes that have. On the contrary, the Government of Indonesia provides patents results refinement or development of products or processes.

In the definitive formulation of 'invention', the Indian patent law also regulates patentability invention, namely novelty, inventive steps, and industrial applied. Meanwhile, the Indonesian Patent Law regulates the terms of invention patentability in the formulation of other articles. [24]

Provision of Article 27 paragraph (1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) also regulates the criteria regarding the requirements for patentability of inventions that patents can be granted, which reads as follows:

> *"Patents shall be available for all inventions, whether products or process in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application…Patents shall be available and patent rights enjoyable without*

---

21 Shamnad Basheer, "Limiting The Patentability of Pharmaceutical Inventions and Micro-Organisms: A TRIPS Compatibility Review," November 2005, http://ssrn.com/abstract=1391562.

22 Patent Office of India, "Patent Office of India," Pub. L. No. Vol. 1, 1 (1970), https://www.wipo.int/export/sites/www/scp/en/exceptions/replies/india_2.pdf.

23 President of Republic of Indonesia, "Law of The Republic of Indonesia Number 14 Year 2001 Regarding Patents," Pub. L. No. 14, 1 (2001).

24 Indonesian Law Office, "Indonesia Patent Law as Amended by Law No. 14" (2001).

> *discrimination as to the place of invention, the field of technology and whether products are imported or locally produced (bold by the author as emphasis)".*

Based on the above provisions, it is known that patents can be granted if they fulfill the invention patentability requirements, namely having novelty, inventive steps, and industrial applied. Such provisions are not explained by 'novelty', 'inventive steps', and 'industrial application'.

Furthermore, the provisions of Article 27 TRIPs allow member states to define patentability criteria following their national interests, especially in terms of realizing socio-economic conditions to the welfare of their people. [25] Therefore, it can be concluded that each member state of TRIPs has different standards of patentability criteria from each other.

The differences can be seen from the comparison between patentability criteria regulated in the Indian Patent Law and the Indonesian Patent Law, as follows:

Novelty

The Indian Patent Law defines 'novelty' as follows:

> *"any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application with complete specification, i.e., the subject matter has not fallen in the public domain or that it does not form apart of state of the art".* [26]

The purpose of the above definition is to remove barriers to geographical restrictions related to the origin of the prior art. In other words, India has adopted a patent system that defines 'novelty' as new compared to previous inventions and publications in India and against previous inventions and publications in other countries or around the world. India has expanded the standard of anticipation of the invention to be limited to its regional sphere only. Therefore, the nature of 'novelty' in India includes "absolute novelty". [27]

Meanwhile, in the Indonesian Patent Law, the criteria for 'novelty is that an 'invention' is considered new if, at the date of receipt, the invention is not the same as the technology previously disclosed. The understanding of technology not previously disclosed has been announced in Indonesia or outside Indonesia in a writing, oral description, or through a demonstration, or in any other way

---

[25] Rajnish Kumar Rai and Rajnish Kumar, "Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations under the TRIPs Agreement and Options for India," *Kent J. Intell. Prop* 8, no. 1 (2008): 41–84, http://scholarship.kentlaw.iit.edu/ckjiphttp://scholarship.kentlaw.iit.edu/ckjip/vol8/iss1/2.

[26] Sundaram, "India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?"

[27] Carlos M. Correa, "Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective" (New York, June 2016), https://doi.org/DOI:10.13140/RG.2.1.1659.3526.

that allows an expert to carry out the invention before the date of receipt; or priority date. [28]

Besides, what is meant by 'technology that has been disclosed before' is both patent literature and non-patent literature. Moreover, the notion of 'not the same with the technology that has been previously expressed is not only different but must be seen in the inequality of the function of technical characteristics (features) of the invention with the technical characteristics of previous inventions. While the provisions on 'oral description' or through demonstrations or other means are made in Indonesia and on such matters conducted abroad provided that written evidence must still be submitted. [29]

The definition of 'novelty' provided by the Indonesian Patent Law is equivalent to that given by the Indian Patent Law. The anticipation of novelty is not limited to inventions or publications that have previously existed at the national or regional level and cover the whole world. Therefore, both the Indian Patent Law and the Indonesian Patent Law have absolute novelty properties.

Inventive Steps

India Patent Law defines 'inventive steps' as follows:

> *"a feature of an invention that involves technical advance compared to the existing knowledge or having economic significance or both, and that makes the invention not obvious to a person skilled in the art."* [30]

The existence of the phrase "economic significance" mandates that only inventions that have a signification for the national economy only qualify for 'inventive measures'. The purpose of this phrase's existence is to limit the granting of patents to foreign pharmaceutical companies that do not play many roles for India's national economy and provide opportunities or incentives for local inventors to continue to innovate.[10]

Furthermore, in the Indonesian Patent Law, it is determined that an invention contains an 'inventive step' if the invention is for someone who has specific skills in engineering is unexpected. The assessment of an Invention is done by considering the expertise that existed when the application was submitted or that existed at the time of the first application if the application was submitted with priority rights.[14] The definition of the 'inventive step' requirement in the Indonesian Patent Law is different from that stipulated in the Indian Patent Law.

Therefore, it can be concluded that there is a significant difference between the understanding of 'inventive measures' in the Indian Patent Law and the

---

[28] Kumar and Nanda, "Ever-Greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries."

[29] Kumar and Nanda.

[30] Sundaram, "India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?"

Indonesian Patent Law. That is because the 'inventive step' provisions of the Indian Patent Law include economic aspects as assessments. Therefore, India's standard of 'inventive step' requirements is higher than the Indonesian Patent Law standard.

Industrial Application

Concerning the terms of 'industrial application', the Indian Patent Law regulates that the criteria are as follows:

> *"the invention is capable of being made or used in an industry."*

Meanwhile, the Indonesian Patent Law regulates the criteria referred to as 'industrial application,' if the invention can be implemented in the industry as described in the application. If the invention is intended as a product, the product must be made repeatedly of the same quality. In contrast, if the invention is a process, the process must be executed or used in practice. [31]

Therefore, referring to the comparison of the two rules of law above, it can be concluded that the criteria for 'industrial application' stipulated in the Indian Patent Law are widespread without further explaining the specific criteria in question that can be applied in the industry. Meanwhile, the Indonesian Patent Law has clarified the industry's criteria or 'industrial application.'

India has special arrangements regarding patents for inventions in the pharmaceutical sector. The arrangement is contained in Section 2 (1) (ta) of the Indian Patent Law, which reads as follows:

> *"Pharmaceutical substance means any new entity involving one or more inventive steps".*

Terminology "pharmaceutical substance" refers to every invention in the pharmaceutical sector, whether in products or processes. This arrangement is closely related to the Indian Government's concern in the field of public health. So that health problems have a connection with patent problems, especially in the pharmaceutical sector. [32]

This provision is not stipulated in the Indonesian Patent Law. The regulation of inventions in the pharmaceutical sector can be seen as a characteristic of the Indian Patent Law, which pays more attention to patent protection in the pharmaceutical sector concerning public health issues.

Previously, it has been described the terms of granting patents that are selfed from 3 (three) conditions, namely novelty, inventive steps, and can be applied in industry or industrial application. However, there are also restrictions on granting patents or exemptions to inventions as additional patentability conditions.

---

[31] Kumar and Nanda, "Ever-Greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries."

[32] Abbas, "Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System."

Some inventions cannot be legally granted patents because they are excluded from patents. In Indonesia, there is a rule that patents are not granted to the following inventions: (a) Processes or products whose announcement and use or implementation are contrary to applicable laws and regulations, religious morality, public order, or decency; (b) Established methods of examination, treatment, treatment, and/or surgery on humans and/or animals; (c) Theory and method in the field of science and mathematics; (d) All living things, except microorganisms; Biological processes are essential for producing plants or animals, except non-biological processes or microbiological processes.

Meanwhile, in line with the provisions in the Indonesian Patent Law, in TRIPs, there is also an invention exemption provision that cannot be granted a patent that reads:

> *"Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law".*

In TRIPs, it is also determined that member states mayor have the right to exclude some types of inventions that cannot be granted patents, of which the type or scope is also regulated in the provisions of the Patent Law in Indonesia, as follows: [33] (a) Diagnostic, therapeutic, and surgical methods for the treatment of human or animals; (b) Plants and animals other than microorganisms and essentially biological processes for plants and animals' production other than non-biological and microbiological processes.

Exclusion arrangement aims to strike a balance between the interests of the industry on the one hand and the social or societal interests on the other, by the purpose of the patent system's existence, which is not merely a tool that accommodates the industry to develop its technology. [34]

Therefore, referring to the above two legal provisions, it can be concluded that there are exceptions to particular inventions even though the invention has fulfilled 3 (three) terms of granting patents as described above. The Indian Patent Law has previously described that India specifically regulates the provisions on patents on inventions in the pharmaceutical field. The existence of this regulation then also gives rise to the regulation of the granting of patents for inventions in the pharmaceutical sector that do not meet the requirements of patentability as stipulated in the provisions of Section 3 (d) of the Indian Patent Law.
The provisions read as follows:

---

[33] Kumar and Nanda, "Ever-Greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries."

[34] M Bruce Harper, "TRIPS Article27.2: An Argument for Caution," *William & Mary Environmental Law and Policy Review* 21, no. 2 (April 1997).

> *"The following are not inventions within the meaning of this Act, ... the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant".*

Then in the explanation, there is an explanation as follows:

> *"For the purposes of this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".*

The above provisions, especially the phrase "new use for a known", affirm to exclude new uses of inventions in the form of products or processes. That has existed before, except if their existence gives rise to new properties or improves the enhanced efficacy to patients. It is then explained that the existence of chemical substances that existed before in the invention is equivalent to similar inventions unless it gives rise to new properties or improves the quality of medical effects of post-consumed drugs.[35]

This arrangement then became a condition of 'novelty' and an additional 'inventive step,' which led to India's patent law having high standards of 'novelty' and 'inventive measures'.15 The existence of exceptions for inventions in the pharmaceutical sector then caused criticism because the provisions in the TRIPs do not regulate the exclusion of inventions in the pharmaceutical sector.[36]

However, in the WTO Dispute Resolution Board's ruling in the case of "Canada-Patent Protection of Pharmaceutical Products", referred to the nature of 'discrimination' referred to article 27 TRIPs, from the existence of a legal provision if the provision of such law gives rise to "unjustified imposition" and different adverse treatment. In this case, the exclusion provision in Section 3 (d) aims to ward off patent applications whose inventions are legally 'evergreening' because they do not fulfill the requirements of invention patentability and lead to unhealthy business competition practices well as impede access to drugs. The provisions of Article 27 TRIPs allow member states to define patentability criteria under their national interests, especially in realizing socio-economic conditions conducive to their people's welfare.[37] Therefore, the provision of such exemptions cannot be said to violate the provisions of TRIPs.

---

35 Ryan Abbott, "Of Evergreening and Efficacy: The Glivec Patent Case," http://www.equilibri.net/nuovo, April 2013, http://ssrn.com/abstract=2258904.

36 Rajarshi Sen and Adarsh Ramanujan, "Pruning the Evergreen Tree or Tripping Up over TRIPs? - Section 3(d) of the Indian Patents Act, 1970," *IIC - International Review of Intellectual Property and Competition Law* 41, no. 2 (January 2010): 170–86.

37 Racherla, "Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry."

Therefore, based on the previous description, it can be concluded that the Indian Patent Law has its characteristics compared to the provisions in the TRIPs and the Indonesian Patent Law, in setting the standard of invention patentability, especially in the pharmaceutical sector, has not been anticipated in the provisions of TRIPs and The Indonesian Patent Law.

As previously described, there is a regulation of special invention patentability requirements in the pharmaceutical sector where its existence provokes criticism. The existence of strict patentability requirements or criteria, including the exclusion of inventions in the pharmaceutical sector, manifests the application of flexibility of TRIPs in Articles 7 and 8 and Paragraph 4 of the Doha Declaration with realizing the welfare and public health.[38]
Provision of Article 7 TRIPs states:

> *"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".*

Meanwhile, the provision of Article 8 TRIPs states: (1) In formulating or amending their laws and regulations, members may adopt measures necessary to protect public health and nutrition and promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. (2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.
Paragraph 4 of the Doha Declaration states:

> *"We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."*

The phrases boldly printed above indicate that TRIPs have provisions aimed at advancing economic well-being and public health. So that a national rule of law in member states trips that aims to realize economic welfare and public health and does not conflict with the provisions of TRIPs, although the standard of such rules is higher than that regulated by TRIPs, which indeed only set minimum requirements.[39]

[38] Racherla.
[39] Racherla.

In the Indian context, the application of flexibility concerning the establishment of patentability standards aims to strengthen the patent protection system to inhibit or reduce the practice of patent applications. That benefit 'evergreening' resulted in an increased length of patent protection for inventions that are technologically superior to anticipate. This practice inhibits the transfer of technology and, more importantly, inhibits people's access to affordable medicines that can reduce the welfare of people in the health sector.[40]

Legal Analysis of Novartis AG versus the Union of India Case

Case Brief

Novartis AG filed a patent application on July 17, 1998, for an invention titled "Crystal Modification of a N-Phenyl-2-Pyrimidineamine derivatives, processes for its manufacture and use', to the Chennai Patent Office, India, under the application number No. 1602/MAS/1998.

On January 25, 2006, based on the provisions of Section 2(i) (j) jo. Section 3 (d) of the Indian Patent Law, the Patent Office then issued a ruling to reject the application because it did not meet the requirements of invention patentability, accompanied by three arguments, as follows: (1) The presence of chemical compounds in the invention, although there is an increase in bioavailability levels by 30% compared to the previous invention, shows no significant difference with previous inventions in terms of efficacy; (2) A previous scientific publication has anticipated the proposed invention. The existence publication means the invention has been in the public domain to abort the novelty of the invention; (3) Chemical compounds in the invention have been manifestly contained in chemical compounds that have existed before so that the invention does not meet the requirements of inventive steps.

Then, in 2007 Novartis AG appealed the patent office's ruling to the Madras High Court with the material of the application regarding the material test/constitutionality of section 3 (d) of the Indian Patent Law against the Indian Constitution the TRIPs Provisions ratified by India. On August 6, 2007, the Madras High Court rejected the application because the provision of Section 3 (d) did not violate the provisions of the Indian Constitution. Furthermore, the existence of such provisions aimed at preventing the emergence of adverse 'evergreening' practices, and related to TRIPs, the court held that it did not have the competence to test the Indian Patent Law's constitutionality against TRIPs.

On this High Court ruling, Novartis AG then appealed the award of the rejection of the patent application issued by the Patent Office to the Intellectual Property Appellate Board (IPAB) of India. On June 26, 2009, IPAB rejected the

[40] Xuan Li, "The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement – A Comparative Study of China and India," *The World Economy* 31, no. 10 (October 29, 2008): 1367–82, https://doi.org/10.1111/j.1467-9701.2008.01133.x.

appeal and corroborated the Patent Office's ruling, which stated that the invention did not meet the requirements of the invention patentability.

On the IPAB ruling, Novartis AG then applied for cassation to the Supreme Court of India. The Supreme Court of India also rejected the application because Novartis AG's invention submitted a patent application did not meet the requirements of invention patentability.

Therefore, based on the chronology description of the above case, it is known that the inventions submitted by Novartis AG have been proven to be ineligible for the invention patentability indicated by each of the above awards. The inability of such inventions to qualify for invention patentability resulted in the invention being unable to be granted in India.

Invention Patentability Analysis

As previously stated, the legal issues that color the Novartis AG case relate to inventive patentability. The issue is then discussed as follows:

Novelty issues

Regarding novelty, both patents owned by Novartis and Chiba are inventions in the same field, are related, and are derivatives of the same drug formula invention, namely N-Phenyl-2-pyrimidine-amine derivatives. However, there are differences between the two in terms of the claims filed limitations.

In figure 1. an invention of Chiba, the claims filed in the patent documents are chemical compounds (compound), as follows:

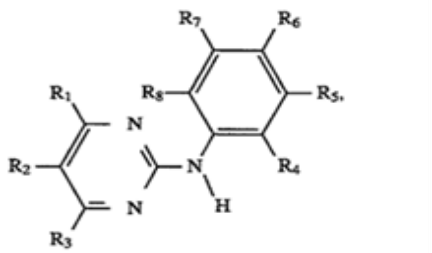

Figure 1. An N-Phenyl-2-Pyrimidine-Amine Compound of Formula I
Source: U.S. Patent Document No. US 5,521,184, May 28, 1996

Meanwhile, in Novartis invention, the claim submitted is the form of a crystal (Beta crystalline form) of the compound above and its preparation process, as follows:

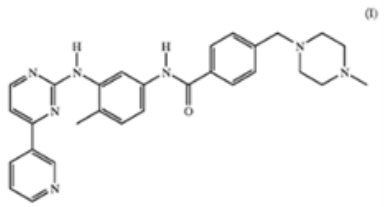

Figure 2. A Crystalline Form of the Monomethanesulfonic Acid Addition Salt of a Compound of Formula I
Source: U.S. Patent Document No. US 6,894,051 B1, May 17, 2005

Furthermore, differences are also seen in claims regarding method claims. In the invention of Chiba, it is stated as follows:

> *"A method of treating warm-blooded animals including humans, which comprises administering to such a warm-blooded animal suffering from a tumoral disease a dose, effective against tumours, of a compound of formula I according to claim 1 or of a pharmaceutically acceptable salt of such a compound having at least one salt-forming group".*

It explained that this claim from Chiba is a treatment method for patients with tumor disease by determining the effective dosage of related chemical compounds.

Meanwhile, in Novartis invention, there are claims as follows:

> *"A method for treating a tumor disease in a patient comprises administering an adequate amount of the methanesulfonic acid addition salt of a compound of the formula in its β-crystal modification".*

From these claims, it can be explained that this method is the treatment of patients with tumor disease that aims to determine the exact amount of chemical composition of the results of modifications to the form of crystals related to chemical compounds that are, in fact, a form of development of Chiba inventions.

Conceptually, an invention considers new if the invention application is not the same as the technology previously stated. While what is meant by not the same is not just different but must be seen as the same or not the same function of technical characteristics (features) of the invention with the technical characteristics of the previous invention.[41] The technical feature between the two inventions lies in modifying the shape of crystals in the invention of existing compounds. The modification implies that Novartis inventions do not effectively determine the number of chemicals associated with chemical compounds in the same formula.

Furthermore, judging the doctrine equivalents, the similarity of inventions does not look at the overall similarity between an invention allegedly violated with the prior art but looks at the substantial similarities in the function of the two inventions in the claim[42] The similarities assessed are in terms of the two inventions' function, rather than the title invention or the form invention. In the claims made in Novartis's invention, the difference is due to a new form of crystal, which then there is a new method that is effective in determining the

---

41 Kumar and Nanda, "Ever-Greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries."

42 Sue Ann Mota, "The Doctrine of Equivalents and Prosecution History Estoppel: The Supreme Court Supports Flexibility Over Certainty in Patent Cases in Festo v. SMC," *Richmond Journal of Law and Technology* 9 (2002): 9, http://scholarship.richmond.edu/jolt/vol9/iss1/4http://jolt.richmond.edu/v9i2/article2.html.

additional amount of chemicals. However, the method claimed to be different from the previous method has the same technical function as Chiba's patent, so that the Novartis invention does not fulfill the novelty requirements.

Inventive Step Issues

In terms of 'novelty,' if there is a slight difference in an invention with the prior art, an invention can be new (a slight difference is sufficient). However, the 'inventive step' requirement adds that an invention is new if it has a significant difference (significantly different) from the prior art. The 'inventive step' requirement is 'enhanced novelty,' which causes it to have a very close attachment to the condition of 'novelty.'[43] Therefore, an invention that has been qualified for 'novelty' may not meet the 'inventive step' requirement if it does not show an advantage (development) over the prior art.[44]

From the doctrine, an invention has an inventive step if the previous invention has not anticipated the claim's technology. This rationale has had a function to determine whether the prior art has anticipated a claim. If experts must not anticipate: (i) an invention in the technology field (claimed invention); and (ii) such invention cannot be anticipated in advance by the prior art. To determine a claim can be anticipated (anticipate) or not with the prior art must be disclosed clearly and firmly each of the limitations of the claim contained in such invention. There must be a clear description of the claim contained in the prior art reference.

From the doctrine, an invention has an inventive step if the previous invention has not anticipated the claim's technology. If experts must not anticipate: (i) an invention in the technology field (claimed invention); and (ii) such invention cannot be anticipated in advance by the prior art. To determine a claim can be anticipated (anticipate) or not with the prior art must be disclosed clearly and firmly each of the limitations of the claim contained in such invention. [45] This rationale has had a function to determine whether the prior art has anticipated a claim. There must be a clear description of the claim contained in the prior art reference.

Referring to the explanation, the existence of the claim submitted by Novartis as described above, when compared with the claim submitted by Chiba, it appears that Chiba's claim is a chemical compound. In contrast, the claim on Novartis invention in the form of a crystal (Beta crystalline form) of the compound on Chiba invention and its preparation process. Therefore, this crystal form (Beta crystalline form) results from the compound's modifications, which

---

43 Mario Franzosi, "Article: Novelty And Non-Obviousness-The Relevant Prior Art," n.d.

44 UNCTAD-ICTSD, "Patents: Subject Matter and Patentability Requirements," in *Resource Book on TRIPS and Development* (Cambridge University Press, 2005), 351–67, https://doi.org/10.1017/CBO9780511511363.019.

45 Robert P Merges, Peter Seth Menell, and Mark A Lemley, *Intellectual Property in the New Technological Age*, Sixth edition. (Austin : Wolters Kluwer Law & Business, 2012).

causes it to become a separate entity that could not anticipate in the previous invention. Also, this difference causes differences in claims of patient care methods, as mentioned above.

Judging from the best-mode doctrine, which generally conveys that the inventor must disclose that the invention produced is better or has advantages compared to the previous invention (prior art). The disclosure of advantages can be quite possible to be known and assessed by someone who expert in the field of technology where the invention is covered, in the background of invention in the patent document stated that:

> *"It has now been surprisingly found that a crystal form may under certain conditions be found in the methanesulfonate salt of this compound, which is described hereinafter as Beta crystalline form, and which has very advantageous properties".*

The presence of chemicals in the form of methanesulfonate salt in the compounds that make up the crystal form is expressed as the thing that distinguishes this invention from the previous invention, so it said that its existence has very advantageous properties compared to previous inventions.

From the double patenting doctrine, there is patent invalidity if there is a similarity between the newer invention (junior patent) and the existing invention (senior patent), which proves the similarity in the claims of each invention submitted by the patent application. Later known that the invention that was previously filed or has existed has similar claims with junior patents or modifications or variations on the same type of invention, then the patent application for the invention becomes invalid or cannot be granted patent protection. [46]

Novartis's proposed inventions, both seen in the Beta claims of crystalline forms and treatment methods of tumor disease patients, result from modifications and variations from previous inventions. Referring to the double patenting doctrine as stated above, Novartis inventions can be said to be ineligible for inventive measures. In other words, Novartis inventions do not qualify for invention patentability.

The point of view from doctrine is to affirm then the opinion of the Panel of Judges in the case stating that;

> *"Imatinib Mesylate is a known substance from the the Zimmermann patent itself. Not only is Imatinib Mesylate known as a substance in the Zimmermann patent, but its pharmacological properties are also known in the Zimmermann patent".*

However, at this point, there is a problem for Indonesia that does not have the standard of granting similar patents because the Indonesian patent system regulates the refinement and development of products or processes as an invention (patentable subject matter).[47]

---

[46] Alan L Durham, *Patent Law Essentials : A Concise Guide*, 5th ed. (Bloomsbury Publishing, 2018).

[47] Kumar and Nanda, "Ever-Greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries."

Industrial Applicability Issues

In Novartis's case, the discussion on the patentability of the invention does not include industrial or utility availability as one of the problems in examining the case. India's Supreme Court ruling falls on an opinion that focuses on novelty, inventive measures, and drug efficacy. That is interesting to study because the terms of this utility are a condition that must meet in granting patents. Conceptually, the existence of utility requirements is caused by the following conditions:

> *"..that a more compelling consideration in the determination of whether a patent should be granted is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form there is insufficient justification for permitting an applicant to engross what "...* [48]

The existence of the phrase "a patent should granted the benefit derived by the public", hinting that the existence of patents should have benefits to society. Then gave rise to beneficial or moral utility criteria. An invention meets the requirements of patentability if it has benefits for the community (social benefit). The minimum limit of the sense of 'benefit' here is that the invention does not threaten the community. [49]

As previously described, the problem raised in this Novartis case is the causality relationship between patent granting Novartis, which allegedly contains 'evergreening' properties. If the application is granted, the thing that happens is an increase in the drug price. This issue is closely related to beneficial or moral utility criteria. However, this ass missed in the discussion on this matter.

Drugs Efficacy Issues

Patentability requirements that are characteristic of the Indian Patent Law to distinguish it from the regulations in trips and the Indonesian Patent Law are the regulation in Section 3 (d), which reads:

> *"The following are not inventions within the meaning of this Act, ... the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant".*

And then in its elucidation, there were descriptions as follows:

> *"For the purposes of this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".*

---

48 Abe Fortas, "Brenner v. Manson, 383 U.S. 519 (1966)," March 21, 1966.

49 Correa, "Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective."

This arrangement excludes granting patents for inventions in the pharmaceutical field that do not have a better therapeutic effect or efficacy than previous inventions as a form of rule to prevent the practice of patent evergreening. [50]

As previously described, Novartis invention results from modification and variation of Chiba invention as prior art. In Novartis patent documents, there are no claims regarding the drug's efficacy for the existence of its inventions. Therefore, it can be concluded that Novartis invention does not qualify for the patent grant, and the decision of the Panel of Judges, in this case, is appropriate because Novartis invention is the result of modification and variation of Chiba invention as prior art.

Patent Testing of Pharmaceutical Products

According to ICSTD Guidelines, WHO, and UNCTAD on Patent Testing in the Pharmaceutical Field, there are exceptions to inventions in the pharmaceutical field that do not meet all three invention patentability requirements. The existence of claims on the invention of Novartis AG is mainly on the addition of chemical compounds in the form of salt. So that they cannot be patented if only in the form of addition of chemical compounds, such as salt, esters, ether, or polymorphs, including the process of bonding ions and molecules of dissolved substances by water molecules (hydrates) and complex particles in the solution as a result of the process of solvation (solvates), i.e., complex particles between dissolved substances and solvents in a solution, from a previously existing chemical entity. [51] Therefore, the invention submitted by Novartis AG is not eligible for invention patentability when laminating or substantive testing of patents in the pharmaceutical sector.

The Implications of Decision to Patent Protection in Indonesia

The Indian Supreme Court's ruling in Novartis AG's versus the Union of India case provoked a mixed reaction internationally. Pros and cons are inevitable. For pro groups, the existence of this ruling makes it a 'landmark decision' for the link between patents and the problem of access to medicines that imply the welfare of the public in the field of health, which is duly imitated by developed or western countries that are major pharmaceutical manufacturers in the world. [52] Even this verdict referred to as the 'Wise Decision'. [53]

---

50 Abbas, "Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System."

51 Sundaram, "India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?"

52 SA Aiyar, "West Should Learn from India's High Patent Standards," Swaminomics, April 7, 2013.

53 Joseph E Stiglitz and Jayadev. Arjun, "India's Patently Wise Decision," The Indian Supreme Court's, April 8, 2013.

On the other hand, the counter-parties stated that Section 3(d) rules, which were later strengthened by the Indian Supreme Court ruling, could create uncertainty that global innovators must face in applying research and development results and innovation in India. Instead of being an incentive for innovation development, the application of patent requirements in India is precisely an obstacle for innovators to develop their innovations.[54] It believes in inhibiting the growth rate of the pharmaceutical industry.

Regardless of the pros and cons, one thing is sure, as previously outlined, that compared to the Indian Patent Law, the Indonesian Patent Law does not anticipate the regulation of invention requirements that can prevent the practice of 'evergreening' patents in Indonesia. Besides, Indonesia has not provided its arrangements for patents in the pharmaceutical sector as in India.

The Indian Supreme Court's ruling could serve as an example of how a government protects its citizens' interests in the health sector through patent protection arrangements. The establishment of high standards requirements aims to strike a balance between strategies to advance innovation so that emerging innovations are not just the result of insignificant technological modifications in the field of health. On the other hand, advanced patient access to affordable medicines becomes generic after the patent protection period runs out. [5556]

In the Indonesian context, there are empirical facts that patents have an enormous impact on the average price of drugs produced by E.U. pharmaceutical companies marketed in Indonesia in 1997-2003. [57] This problem will be closely related to the practice of patent 'evergreening' if, in the future, a form of a similar patent application appears aimed at increasing the selling price of medicinal products in the Indonesian market.

With this fact, the Government of Indonesia should consider these issues to patent protection in the pharmaceutical sector to prevent paten t 'evergreening.' The fundamental step of such attention is to set a higher standard of requirements in granting patents, especially patents in the pharmaceutical sector in Indonesia. Revision of Patent Law becomes the path that the Government of Indonesia must take.

Based on those analyses, the author recommends taking concrete steps to revise the Indonesian Patent Law. The proposed revision of the Indonesian Patent Law to prevent the practice of patent 'evergreening' is aimed at the provisions of the

---

54 Amitendu Palit, "Drug Patents in India: Turf Battles" (Singapore, April 8, 2013), www.isas.nus.edu.sg.

55 Thomas Pogge, "The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices," in *Incentives for Global Public Health: Patent Law and Access to Essential Medicines*, ed. Thomas Pogge, Matt Rimmer, and Kim Rubenstein (Cambridge: Cambridge University Press, 2010), 135–54, https://doi.org/10.1017/CBO9780511750786.008.

56

57

definition of 'invention' by redefining and adding the type of invention that exclude from patent protection. Therefore, the author proposes as follows:
Redefinition of 'Invention'.

The definition in Article 1 paragraph (2) of the Indonesian Patent Law, namely:

> *"inventor ideas that are poured into a specific problem solving activity in the field of technology, can be in the form of products or processes, or refinement and development of products or processes".*

While the proposed definition changes are as follows:

> *"inventor ideas are poured into a problem solving activity that is specific in the field of technology, can be in the form of products or processes, or refinement and development of products or processes that have significant differences and levels of technological excellence with a specific problem solving activity in the field of technology that has existed before, which is beneficial to the community".*

Addition of Excluded Invention Type

In Article 7 of the Indonesian Patent Law, there is a rule that patents are not granted to inventions as follows: (a) Processes or products whose announcements and uses or implementation are contrary to applicable laws and regulations, religious morality, public order, or decency; (b) Established methods of examination, treatment, treatment, and/or surgery on humans and/or animals; (c) Theory and method in the field of science and mathematics; (d) All living things, except the bodies of the microorganisms; (e) Biological processes are essential for producing plants or animals, except for non-biological processes or microbiological processes. (f) The proposed addition of excluded types of inventions is as follows: (1) Processes or products whose announcement and use or implementation hinder the community's welfare in the field of health; (2) Development or modification of processes or products in the pharmaceutical sector has not increased efficacy or caused a new therapeutic effect.

Conclusion

Based on the legal analysis submitted, authors can conclude that patent protection is granted if an invention submitted by the application meets the requirements of patentability consisting of novelty, inventive steps, and industrial availability. In Novartis AG's versus the Union of India case, it is clear that the invention entitled 'Crystal Modification of A N-Phenyl-2-Pyrimidineamine derivatives, processes for its manufacture. Moreover, its use' submitted by Novartis AG does not meet patent invention requirements, both reviewed from the Indian Patent Law and the concept of patentability in general. So the filing of the patent application made by Novartis AG is nothing more than an attempt to extend the period of patent protection, also known as an 'evergreening' patent. Determining an invention does not contain the nature of 'evergreening' if the

invention meets the patent invention requirements in general. In the case of India, it must also meet specific criteria for invention in the pharmaceutical sector. Therefore, it is appropriate and appropriate for the Indian Court of Justice to reject the appeal of Novartis AG's patent application for the invention. Based on the verdict in this case, it can be seen that patent law in India can significantly prevent the practice of patent evergreening which in turn prevents the practice of increasing drug prices, and allows people to access affordable drugs.

Compared to the Indian Patent Law, the Indonesian Patent Law does not anticipate regulating the terms of invention patentability that can prevent the practice of 'evergreening' patents in Indonesia. Indonesia has not provided its arrangements for patents in the pharmaceutical sector as in India. So, the Supreme Court's implication of India's decision for Indonesia is that the ruling can use as a real example of how a government protects the interests of its citizens in the health sector through patent protection arrangements. The establishment of high standards of patentability requirements aims to strike a balance between strategies to advance innovation so that emerging innovations are not just the result of insignificant technological modifications in the field of health. On the other hand, advanced patient access to affordable medicines becomes generic after the patent protection period runs out. Therefore, it is appropriate for Indonesia to pay special attention to patent protection in the pharmaceutical sector in order to prevent the practice of 'evergreening' patents. As a recommendation, it is vital to the Government of Indonesia to consider revising patent law provisions, especially about invention definition and type of patent excluded clause.

References

Abbas, Muhammad Z. "Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System." *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector* 15, no. 2 (June 16, 2019): 53–60. https://doi.org/10.1177/1741134319848797.

Abbott, Frederick M. "Inside Views The Judgment In Novartis v. India: What The Supreme Court of India Said Intellectual Property Watch," April 4, 2013. http://www.ip-watch.org/2013/04/04/the-judgment-in-novartis-v-india-what-the-supreme-co...

Abbott, Ryan. "Of Evergreening and Efficacy: The Glivec Patent Case." http://www.equilibri.net/nuovo, April 2013. http://ssrn.com/abstract=2258904.

Aiyar, SA. "West Should Learn from India's High Patent Standards." Swaminomics, April 7, 2013.

Basheer, Shamnad. "Limiting The Patentability of Pharmaceutical Inventions and Micro-Organisms: A TRIPS Compatibility Review," November 2005. http://ssrn.com/abstract=1391562.

Chen, Michelle. "Patents Against People: How Drug Companies Price Patients out of Survival." *Dissent* 60, no. 4 (September 2013): 71–77. https://doi.org/10.1353/dss.2013.0074.

Correa, Carlos M. "Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective." New York, June 2016. https://doi.org/10.13140/RG.2.1.1659.3526.

Durham, Alan L. *Patent Law Essentials : A Concise Guide*. 5th ed. Bloomsbury Publishing, 2018.

Fortas, Abe. "Brenner v. Manson, 383 U.S. 519 (1966)," March 21, 1966.

Franzosi, Mario. "Article: Novelty And Non-Obviousness-The Relevant Prior Art," n.d.

Harper, M Bruce. "TRIPS Article27.2: An Argument for Caution." *William & Mary Environmental Law and Policy Review* 21, no. 2 (April 1997).

Hesameddin Tafreshi, Say-yed. "Anti Pharmaceutical Patent Ever-Greening Law: Global Need in Support of Public Health." *Journal of Intellectual Property Rights* 24 (August 2019): 103–12. https://www.researchgate.net/publication/339998402.

Indonesian Law Office. Indonesia patent law as Amended by Law No. 14 (2001).

Jhamtani, Hira. "Understanding The Trade-Related Intelectual Property Rights Regime (TRIPS)." Jakarta. Accessed October 28, 2021. https://komunitaskreatifbali.files.wordpress.com/2008/09/memahami-rejim-hak-kekayaan-intelektual-terkait-perdagangan.pdf.

Kojiro, Oce. "GLIVEC vs HYDREA." https://ocekojiro.wordpress.com/glivec-gleevec-vs-hydrea/, 2010. https://ocekojiro.wordpress.com/glivec-gleevec-vs-hydrea/.

Kumar, Arun, and Arun Nanda. "Ever-Greening in Pharmaceuticals: Strategies, Consequences and Provisions for Prevention in USA, EU, India and Other Countries." *Pharmaceutical Regulatory Affairs: Open Access* 06, no. 01 (2017). https://doi.org/10.4172/2167-7689.1000185.

Lanjouw, Jean O. "Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry." Cambridge, May 2005. http://www.nber.org/papers/w11321.

Li, Xuan. "The Impact of Higher Standards in Patent Protection for Pharmaceutical Industries under the TRIPS Agreement – A Comparative Study of China and India." *The World Economy* 31, no. 10 (October 29, 2008): 1367–82. https://doi.org/10.1111/j.1467-9701.2008.01133.x.

Merges, Robert P, Peter Seth Menell, and Mark A Lemley. *Intellectual Property in the New Technological Age*. Sixth edition. Austin : Wolters Kluwer Law & Business, 2012.

Ministry of Law and Justice India. "The Patents (Amendment) Act, An Act Futher to Amend the Patents Act, 1970 Vol. 1972." New Delhi, April 5, 2005. http://www.wipo.int/edocs/lexdocs/laws/en/in/in018en.pdf.

Mota, Sue Ann. "The Doctrine of Equivalents and Prosecution History Estoppel: The Supreme Court Supports Flexibility Over Certainty in Patent Cases in Festo v. SMC." *Richmond Journal of Law and Technology* 9 (2002): 9. http://scholarship.richmond.edu/jolt/vol9/iss1/4http://jolt.richmond.edu/v9i2/article2.html.

Mueller, Janice M. "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation." *University of Pittsburgh Law Review* 68 (2007): 491–641.

Palit, Amitendu. "Drug Patents in India: Turf Battles." Singapore, April 8, 2013. www.isas.nus.edu.sg.

Patent Office of India. Patent Office of India, Pub. L. No. Vol. 1, 1 (1970). https://www.wipo.int/export/sites/www/scp/en/exceptions/replies/india_2.pdf.

Patralekha, Chatterje. "Novartis Loses Patent Bid: Lessons From India's 3(d) Experience." Intellectual Property Watch , January 4, 2013. https://www.ip-watch.org/2013/04/01/novartis-loses-patent-bid-lessons-from-indias-3d-experience/.

President of Republic of Indonesia. Law of The Republic of Indonesia Number 14 Year 2001 Regarding Patents, Pub. L. No. 14, 1 (2001).

Putri, Ria W, ; Febryani, ; Kasmawati, ; Shafa, and R A Hanumsari. "Protecting Indonesia's Communal Intellectual Property Rights: A TWAIL Perspective." *Uti Possidetis: Journal of International Law* 5, no. 1 (2024): 69–105. http://www.ijodls.in/uploads/3/6/0/3/3603729/vol-5_issue-2.117-123.pdf.

Racherla, Uday S. "Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry," 271–98, 2019. https://doi.org/10.1007/978-981-13-8102-7_12.

Rai, Rajnish Kumar, and Rajnish Kumar. "Patentable Subject Matter Requirements: An Evaluation of Proposed Exclusions to India's Patent Law in Light of India's Obligations under the TRIPs Agreement and Options for India." *Kent J. Intell. Prop* 8, no. 1 (2008): 41–84. http://scholarship.kentlaw.iit.edu/ckjiphttp://scholarship.kentlaw.iit.edu/ckjip/vol8/iss1/2.

Sen, Rajarshi, and Adarsh Ramanujan. "Pruning the Evergreen Tree or Tripping Up over TRIPs? - Section 3(d) of the Indian Patents Act, 1970." *IIC - International Review of Intellectual Property and Competition Law* 41, no. 2 (January 2010): 170–86.

Shriti, Surbhi, Akansha Jain, and Sampa Das. "Evergreening: An Equivocal Affair in Pharmaceutical Industries." In *Intellectual Property Issues in Microbiology*, 323–35. Singapore: Springer Singapore, 2019. https://doi.org/10.1007/978-981-13-7466-1_17.

Sidharta, Bernard Arief. *Rekleksi Tentang Struktur Ilmu Hukum*. Cetakan Ketiga. Bandung: CV. Mandar Maju, 2009.

Stiglitz, Joseph E, and Jayadev. Arjun. "India's Patently Wise Decision." The Indian Supreme Court's, April 8, 2013.

Sundaram, Jae. "India's Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?" *Information & Communications Technology Law* 23, no. 1 (January 2, 2014): 1–30. https://doi.org/10.1080/13600834.2014.891310.

Tumang, Yurina N. "Impact of Patents on Average Drug Price Level." *Jurnal Kajian Wilayah Eropa* II, no. 1 (2006): 57–71.

UNCTAD-ICTSD. "Patents: Subject Matter and Patentability Requirements." In *Resource Book on TRIPS and Development*, 351–67. Cambridge University Press, 2005. https://doi.org/10.1017/CBO9780511511363.019.

Utomo, Tomi Suryo. "The Pharmaceutical Patent Protection Impact on Indonesia Drugs Price." *Jurnal Mimbar Hukum* 21, no. 3 (October 3, 2009): 409–628. http://www.undp.or.id/pubs/ihdr2004_.

VOA. "Keputusan MA India Soal Paten Bisa Dorong Obat Murah." Mahkamah Agung India, April 2, 2013. https://www.voaindonesia.com/a/keputusan-ma-india-bisa-dorong-obat-murah/1632920.html.