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# Editorial Note

# Traversing patent law's 'evergreening' maze vis-à-vis Pharma Industry

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## I. What is so 'Evergreen'?

The term 'patent evergreening' refers to the practice of securing a patent for a slightly updated version of an existing invention.[1] Evergreening aids patent holders in prolonging patents that are about to lapse by allowing them to apply for a new patent that protects either an essential manufacturing step, a corresponding business activity, or an insignificant molecular modification of a previous discovery.[2] Since many patented pharmaceuticals now have generic substitutes, evergreening of pharmaceutical patents has become increasingly common. Without patent protection, generic pharmaceuticals can be manufactured and sold to the

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1 Andrew W Hitchings, 'Making Medicines Evergreen' [2012] 345 British Medical Journal 7886.

2 Erika Lietzan, 'The "Evergreening" Metaphor in Intellectual Property Scholarship' [2019] 53 Akron Law Review 805.

public at large. It is possible that the generic drug's formulation is still patented, but the active component may not have an active patent protection.[3]

The patent system is meant to incentivise both dynamic rivalry and the promotion of innovations by offering inventors legal means to establish a temporarily exclusive position in the market, which is adequate to reclaim their investment.[4] When the time frame for enjoying such exclusive monopoly can be strategically bypassed by its users, this type of structure might backfire and encourage people to engage in abusive behavior.[5] This is also why companies have clear motivations to engage in evergreening and prolong their exclusive dominance in the market.[6]

The repercussions of such a situation especially exacerbated in the context of the pharmaceutical industry as every prolonging of the patent period is proportional to the increase in time period where the health benefits of the drug are denied availability to the common masses. This was also recently observed by US Federal Judge Richard Posner after rejecting the high-profile litigation between Apple and Motorola, that most businesses may move ahead fine without patent protection but not the pharmaceuticals industry.[7] In addition to public healthcare concerns, he cited reasons such as the prohibitive price of growth and development of drugs and the relatively brief 20-year period to recuperate expenses as concerns stemming exclusively due to the pharmaceutical industry.[8] This Paper proceeds with the underlying premise of how evergreening of patents drastically impacts the access to healthcare and the suggestions proposed have been recommended taking into account public healthcare.

Evergreening can be achieved through the use of entry barriers of various types, the delay of entries, the development of own competitive advantages, etc. A patent thicket can protect patent owners' rights.[9] Under this method, by preventing rivals from designing around a patent, dense networks of related patents preserve patent holders' investments. This method is known to often unfairly limit competition.[10]

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3 ibid.

4 ibid.

5 Siddalingaiah S, Fugh-Berman A, 'Evergreened Drugs or Evergreened Profits?' [2022] 6 Journal of Evaluation in Clinical Practise 28.

6 Javier Esparza, 'Indian Patent Law: Working Within the Trips Agreement Flexibilities to Provide Pharmaceutical Patent Protection While Protecting Public Health' [2014] 24 Journal of Transnational Law 26.

7 Richard A Posner, 'Why there are Too Many Patents in America' (*The Atlantic*, 12 July 2012) <https://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/> accessed 20 October 2023.

8 Scott Parker & Kevin Mooney, 'Is 'Evergreening' A Cause for Concern? A Legal Perspective' [2007] 7 Journal of Commercial Biotechnology 17.

9 Michael R Herman, 'The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation' [2011] 8 Columbia Law Review 111.

10 ibid.

Marketing tactics are frequently used in the pharmaceutical sector to extend the term of a patent. Drug companies patent capsule variations of formerly patented drugs and use costly marketing campaigns to discourage the use of the old one, which is clinically identical to the new one.[11] These follow-up patents may be issued practically continually throughout the business growth process, and they typically involve only minor technological advancements. For instance, Japanese businesses usually leave a patent trail of both products and procedures as they progress along the learning curve and begin to implement continuous improvement processes.[12]

## II. Implications of evergreening

Granting any patent protection is encountered with balancing the rights of the patent holders against others. Protecting patents in the case of the pharmaceutical industry can quickly become controversial if it is interpreted as restricting patients' ability to gain access to low-priced drugs or if it is thought to hamper innovation.[13] Some of the many impacts of evergreening have been discussed below.

### A. Hindering Innovation

Although there is scant evidence to support the claim that patents increase the rate at which innovation occurs, there is evidence to suggest that evergreening can seriously hamper innovation and restrict competition.[14] One of the biggest sources of income for patent holders is the money they make from commercialising their inventions. Companies that manufacture pharmaceuticals and hold patents on their active ingredients can charge exorbitant prices for their products, keeping them out of reach for the general people. With no competition and complete market control, monopolistic firms can charge whatever they choose for their product.[15] The only way to avoid this is for the patent to expire so that the drug can enter the public domain. The economic worth will drop as material enters the public domain and may be accessed by anybody. Therefore, these items become more affordable and accessible to individuals.[16] To get around this, the original patent holder will typically apply for a new patent on a slightly

[11] Gregory H Jones, Michael A Carrier, Richard T Silver & Hagop Kantarjian, 'Strategies that Delay or Prevent the Timely Availability of Affordable Generic Drugs in the United States' (*Pub Med*, 17 March 2016) <https://pubmed.ncbi.nlm.nih.gov/26817958/> accessed 20 October 2023.

[12] Parker and Mooney (n 8).

[13] Ralf Boscheck, 'Intellectual Property Rights and the Evergreening of Pharmaceuticals' [2015] 4 Intereconomics 50.

[14] Debarchan De & Kevin Samuel, 'Evergreening of Patents: A Barrier to New Inventions' [2020] 22 Supremo Amicus 252.

[15] 'Patent Database Exposes Pharma's Pricey "Evergreen" Strategy', UC Law (24 September 2020) <https://uclawsf.edu/2020/09/24/patent-drug-database/> accessed 22 October 2023.

[16] Uri Y Hacohen, 'Evergreening at Risk' [2020] 33 Harvard Journal of Law & Technology 479.

modified version of the patented product.[17] This keeps other innovators from building upon the existing creations thereby, hindering innovation. The economic effects of extending the patent's validity for another twenty-year period by making small adjustments to the initial patented product that keep out competitors are described further below.

## B. Economic Implications

In the words of Adam Smith, healthcare is a commodity that is indispensably necessary for the sustenance of life.[18] Increasing healthcare costs and the need to guarantee reasonable access to medicine in both emergent and developed economies are fueling calls to rein in the so-called evergreening methods employed by drug manufacturers worldwide.[19] However, such practices are an inevitable consequence of a framework that adapts to market forces and looks to be adequately governed by defined patentability guidelines.[20]

National governments are often justified in paying, supplying, and regulating healthcare due to concerns about access and externalities. Furthermore, receiving quality medical attention is becoming recognised as a basic human right. However, markets are not given sufficient regulatory guidance to fulfill this potential. Disputes between advocates of market-based and non-market-based forms of coordination have resulted in more public or corporate grandstanding and less efficient administration in no other field.

Drug prices rise with patent extension strategies that offer patients no real benefits. Modifying the formulation or dosage by a small amount might not improve patient outcomes.[21] When compared to generic alternatives that would save money without compromising quality of care, many fixed-dose combinations are prohibitively expensive without providing cost-justified gains in clinical outcomes.[22] To give an example of the same, one can consider the case of Humira, which is manufactured by AbbVie and enjoys an especially robust patent protection. The medicine has over 100 patents, according to a recent complaint filed

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17 Allie Erwat, 'From Evergreening to Thicketing: Exploring the Manipulation of Pharma Patents' (11 November 2019) <https://www.pharmaceutical-technology.com/features/pharma-patents-manpulation/> accessed 24 October 2023.

18 ibid.

19 Marta Radelli, 'Patent Evergreening: Technological Advancement and Abusive Commercial Practices - Availability of Essential Medicine in the Case of Access to Insulin' [2021] 20 QMLJ 66.

20 ibid.

21 Inderjit Singh Bansal, 'Evergreening - A Controversial Issue in Pharmaceutical Milieu' [2009] 2 Journal of Intellectual Property Rights 14.

22 Rebecca Robbins, 'How a Drug Company Made $114 Billion by Gaming the U.S. Patent System' (*NY Times*, 28 January 2023) available at <https://www.nytimes.com/2023/01/28/business/humira-abbvie-monopoly.html> accessed 14 October 2023.

by the business.[23] Sales, which were approved in 2002, are expected to reach $21 billion by 2021, according to company executives.[24] Last year, it brought in $16 billion in sales, making it the most profitable medicine in the world.[25]

## III. Indian Patent Law Landscape

### A. The Patents Act, 1970

When the Indian Patents Act, 1970 (hereinafter 'Patent Act') was enacted, it expressly forbade the patenting of pharmaceutical products, with the exception of pharmaceutical compound-making processes. The Patent Act was an attempt to boost India's sluggish economy by encouraging indigenous medication manufacturing, Indian enterprises could produce, distribute, and use medicines developed elsewhere at low cost since they lacked access to patent protection.[26] As multi-national corporations were unable to get patents in India, the generic medication sector flourished during the next three decades to such an extent that India's generic pharmaceutical business and exports have helped earn the country the moniker 'pharmacy of the world'.[27] In 1995, however, India attempted to become one of the World Trade Organization's ('WTO') founding members, which changed the course of events.[28] Despite India's initial opposition to TRIPS and its insistence that patent protection should be scaled to a country's level of economic development, India ultimately signed the treaty fearing constraints on its exports.[29]

### B. TRIPS Guidelines

Although the lack of strict patent protection in the pre- Trade Related Aspects of Intellectual Property Rights, 1995 ('TRIPS Agreement') regime was preferable because medicines were easily accessible and readily available, the advent of the TRIPS Agreement and subsequent events have been working to disadvantage the poor.[30]

Patent eligibility, patent criteria, and patent length are addressed in TRIPS Agreement. As for patentable innovations, they are required to be unique,

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[23] Manasi Vaidya, 'Abbvie's Successful Hard-Ball with Humira Legal Strategy Unlikely to Spawn Similar Efforts; Potential Appeals Outcome Unclear' (*Pharmaceutical Technology*, 19 February 2021) <https://www.pharmaceutical-technology.com/comment/abbvies-successful-hard-ball-with-humira/> accessed 14 October 2023.

[24] ibid.

[25] Cynthia Koons, 'This Shield of Patents Protects the World's Best-Selling Drug' (*Bloomberg*, 7 September 2017) <https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug> accessed 12 October 2023.

[26] Emmanuel Kolawole Oke, Exploring the Flexibilities in TRIPS: Lessons from India's Pharmaceutical Patent Law' [2015] 41 Commonwealth Law Bulletin 82.

[27] ibid.

[28] ibid.

[29] Bansal (n 21).

[30] Oke (n 26).

non-obvious, and beneficial, but no precise definition of 'invention' has been provided.[31] Countries like India were obligated by the TRIPS Agreement to offer patent safeguards for pharmaceutical products because this protection must be accessible to all technologies regardless of the sector.[32] Furthermore, patents must be granted without regard to the origin of the innovation or the country of manufacture.[33] If a country does not follow the rules, the WTO Dispute Settlement Body can force them to, which could lead to trade sanctions. While the TRIPS Agreement did its best to standardise worldwide patent law, it did not prevent individual countries from setting their own patentability rules so long as they did not conflict with the agreement. It is pertinent to emphasise on this flexibility provided by the TRIPS Agreement to its member states, including India. It mandates the need to analyse the changes and additions incorporated by India, and how they impact the evergreening process.

It is observed that India made the most of this lull in the action by filing a 'mailbox' application in 1995 which was not processed until 2005.[34] Section 3(d), which was added to India's new TRIPS-compliant patent legislation as part of its final 2005 changes, was intended to cut down the number of secondary patents that can be issued ('Section 3(d)').[35] This section and its effectiveness has been discussed at length in the upcoming sections of the paper.

## C. The 2005 Amendment

In an effort to obey the WTO and utilise the flexibility granted under the TRIPS Agreement, India passed the Patents (Amendment) Act of 2005 ('Amendment'). Among other things, the Amendment allowed for the patenting of pharmaceuticals, which was expressly disallowed until then. Clause (d) of Section 3 explains that mere discovery without any enhancement of prior patent or formation of a new product or even a reactant would not constitute an invention under the Act. The text of Section 3(d) can be found below:

> *"The following are not inventions within the meaning of this Act, —*
>
> *the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or 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*

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31 Trade Related Aspects of Intellectual Property Rights, 1995, Art. 27.

32 ibid

33 Andrew Q Leba, 'Lowering the "Efficacy" Threshold for Section 3(d) of the Indian Patents (Amendment) Act 2005: A Case for a Broader Scope' [2014] 28 Emory International Law Review 649; Carlos M. Correa, 'Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options' [2000] 26(1) Sage Journals 36.

34 Jodie Liu, 'Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(*d*) of the Indian Patents Act' [2015] 56 Harv. Int'l L.J. 207.

35 ibid.

*known process results in a new product or employs at least one new reactant."*[36]

## D. Testing the effectiveness of Section 3(d)

Section 3(d) has been challenged by the pharmaceutical sector on the grounds that it violates the TRIPS Agreement.[37] The Madras High Court, in *Novartis AG v. Union of India* (*hereinafter* 'Novartis'), when Novartis asserted that Section 3(d) violated the TRIPS Agreement, ruled that it did not have the authority to assess whether or not Indian law conformed with the treaty.[38] The Court was of the opinion that the WTO would have to rule on any questions of compliance with the TRIPS Agreement. Despite the United States' concerns with the Section 3(d) criterion of establishing greater efficacy, no action has been filed with the WTO as of yet.[39]

Even though the court has dismissed the claim challenging Section 3(d) on grounds of jurisdiction, we can proceed with the hypothesis if the claim had been admitted. Any claim contesting Section 3(d)'s conformity with the TRIPS Agreement will probably focus on: *first*, whether the exclusion of items as given under Section 3(d) also falls outside the ambit of patentable products as given under the TRIPS agreement. According to Article 27 of the TRIPS Agreement, patents must be issued for innovations that are both innovative and non-obvious, as well as those that have practical uses in industry.[40] However, it falls short of providing a clearer definition of patentability and hence, so long as it does no t favor one type of technology over another, India can set its own patentability requirements if it so chooses.[41] On these grounds, India's take of excluding a "new form of a known substance" which does not enhance the efficacy of the existing substance is justified. *Second,* a claim can be raised that efficacy as a criterion unfairly targets the pharmaceutical patents. But it is needless to say, the WTO is unlikely to be persuaded by the claim that Section 3(d) prejudices pharmaceutical patents just because it requires a higher criterion of patentability. Therefore, the likelihood of any potential claim before the WTO on these grounds is likely to fail as long as the Indian laws do not discriminate against the pharmaceutical sector or unfairly target a specific field.

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[36] The Indian Patents Act, 1970, s 3(*d*).

[37] K D Raju, 'Interpretation of Section 3(d) in the Indian Patents Act 2005: A Case Study of Novartis' [2008] 1 Indian J Intell Prop L 1.

[38] Dorothy Du, 'Novartis Ag *v* Union of India: "Evergreening," Trips, and "Enhanced Efficacy" Under Section 3(d)' [2014] 21 J Intell Prop L 223.

[39] Zoee Lynn Turrill, 'Finding the Patent Balance: The Novatis Glivec Case and the Trips Compliance of India's Section 3(D) Efficacy Standard' [2012-2013] 44 Geo J Int'l L 1555.

[40] Roger Collier, 'Drug Patents: The Evergreening Problem' [2013] 9 CMAJ 185.

[41] Avisha Barange & Alisha Thomas, 'Right to Intellectual Property in Novartis: Interpretation of Section 3(d) in the Indian Patents Act 2005' [2021] 4 Int'l JL Mgmt & Human 3332.

## E. Is the 'efficacy' in Section 3(d) effective?

Although there is some disagreement on the enhanced efficacy criteria, there is consensus that Section 3(d) makes it more difficult to secure pharmaceutical patents.[42] The first problem is that the term 'efficacy' is not well defined. Additionally, it is not specified what sort of evidence will be needed to prove efficacy in order to meet the requirements of Section 3(d). The enhanced efficacy requirement is not addressed in either the Indian Patent Rules or the Indian Manual of Patent Office Practice and Procedure, so it is uncertain to inventors and practitioners how much research and development is required to obtain a patent in India.[43]

When compared to other nations' patent laws, Section 3(d) stands out for a few reasons. *First,* it requires 'enhancement of efficacy' of the prior patent to get a patent on a new formulation or alteration of the underlying pharmaceutical component. *Second*, patents for pharmaceutical products are the only ones covered by Section 3(d), while patents for other technologies are not. *Third*, as interpreted by the Madras High Court in the Novartis case, the term 'efficacy' in Section 3(d) is restricted to 'therapeutic efficacy'.[44] The petitioner, Novartis, took issue with this restricted interpretation, arguing that it is not backed by the wording of the legislation and discourages pharmaceutical research. To delve further into application and interpretation of Section 3(d), it is pertinent to Indian jurisprudence on this matter.

## F. The Novartis Saga

Through an application challenging the rejection of its patent application, Novartis AG challenged the validity of Section 3(d).[45] Additionally, Novartis AG sued several Indian pharmaceutical businesses for patent infringement to defend its monopoly on Glivec, which is anti-cancer drug.[46] Imatinib, the main active ingredient, was patented in 1993, and its beta salt crystal form did not benefit patients. Section 3(d) addressed if the Patent Specification showed that beta crystals were more therapeutic than the recognised chemical.[47] The Supreme Court reasoned that the 2005 Amendment's goals of easing access to life-saving pharmaceuticals and satisfying the country's constitutional duty to provide appropriate health care had been considered.[48] If Novartis won, many of India's poor would

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42 Raju (n 37).

43 ibid.

44 *Novartis AG v Union of India* (2013) 6 SCC 1 : (2013) 13 SCR 148.

45 *Novartis AG v Union of India* 2007 SCC OnLine Mad 658 : (2007) 4 Mad LJ 1153.

46 Graham Dutfield, 'Who Invented Glivec? Does it Matter Anyway?' [2013] 32 Economic and Political Weekly 48.

47 Anand Grover, 'Analysing the Supreme Court Judgment' [2013] 32 Economic and Political Weekly 48.

48 Archit Dhir, 'Novartis: A Critique' [2010] 3 GNLU L. Rev. 131.

have gone without medication. The verdict has raised global concerns, yet it will protect public health by prohibiting patents from harming it.

Novartis AG filed another infringement complaint against Meher Pharma and others in the Bombay High Court to stop the sale, promotion, and export of their anti-cancer medicine containing the 'B-crystalline form of imatinib Mesyiate salt'.[49] The Bombay High Court dismissed the injunction because Novartis could assess the financial loss from the alleged breach. Glivec is a life-saving treatment that is widely sought and demanded, yet the plaintiffs do not make it in India. Instead, they import the same. Thus, any manufacturing or shipping difficulties and costs suffered by the plaintiffs could cause a medicine shortage in India, which would devastate people.[50]

The Supreme Court of India ruled on Novartis' Glivec patent application after two months of debate.[51] The Court ruled against Novartis because the medicine failed the legislation's criteria of 'inventive step'.[52] The patent application was filed because the chemical improved pharmaceutical bioavailability and absorption within the human body.[53] The impact of the decision can be summed up as thus: Nine years ago, Glivec cost US$ 2600 globally,[54] while generics cost US$ 200 in India,[55] a 300 percent difference. The Supreme Court's ruling unflinchingly established that existing pharmaceuticals cannot be rebranded as unique entities by making slight changes to their appearance or content to obtain new patents.[56]

## IV. Brazil and its dual approval structure: learnings for India

India and Brazil, as member states of the WTO and signatories to the TRIPS Agreement, received the same set of flexibilities to incorporate changes into their domestic patent laws provided they were in line with the principles of the TRIPS Agreement. While a major step towards preventing evergreening or issuing of secondary patents by India was the incorporation of Section 3(d) in the Patents Act, Brazil undertook a different path altogether. It is noted here that an analysis of the Brazilian system is taken as it reflects shared ideas with the Indian

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[49] *Novartis AG v Mehar Pharma* 2004 SCC OnLine Bom 1063 : (2005) 3 Bom CR 191, Ajay Shukla, 'The Novartis Case: India's Gateway to Affordable Drugs' [2020] 3 Int'l J L Mgmt & Human 2248.

[50] Priyanka Mangaraj, 'Patent in Respect of Medicine & Drug with Special Reference to the Case of Novartis' [2019] 2 Int'l JL Mgmt & Human 1.

[51] ibid.

[52] *Novartis AG v Union of India* (2013) 6 SCC 1 : (2013) 13 SCR 148.

[53] Cynthia M Ho, 'Unveiling Competing Patent Perspectives' [2009] 46 Hous L Rev 1047.

[54] ibid.

[55] Roberto Romandini, 'Flexibilities under Trips: An Analysis of the Proposal for Reforming Brazillian Patent Law' [2016] 15 J Marshall Rev Intell Prop L 21.

[56] Sara Beth Myers, 'A Healthy Solution for Patients and Patents: How India's Legal Victory against a Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights' [2008] 10 Vand J Ent & Tech L 763.

system. For instance, both these countries strongly opposed granting extensive IP protection during the Uruguay Round of negotiations at the TRIPS Agreement.[57] Moreover, both Brazil and India recognise the importance of public healthcare and how granting secondary patents could hamper easy access to the same. In pursuance of the same, Brazil came up with the 'Dual Approval' system of granting patents.

The 1997 Brazilian patent law was revised in 2001 to require the prior authorization of the National Agency for Sanitary Vigilance ('ANVISA') for pharmaceutical products and method patents.[58] This means that any pharmaceutical patent application must be approved by the Brazilian patent office ('INPI'), and the Ministry of Health's monitoring department, ANVISA.[59] If INPI decides that the patent should not be issued, the procedure ends there since the Prior Consent mechanism mandates that the patent should be refused. Nonetheless, if INPI determines that the patent should be granted, ANVISA is notified, and the application is forwarded to them.[60] Upon receiving an application and technical report from INPI, ANVISA reviews both, and frequently requests more information from INPI and the applicants.[61] With ANVISA's go-ahead, INPI can grant the patent. Even though ANVISA does not have the jurisdiction to turn down patent applications, INPI will only issue patents if the same has been approved by ANVISA.[62] According to Shadlen, it is important to note that ANVISA has stricter assessment procedures compared to INPI, which are aimed squarely against secondary patents.[63] Furthermore, Brazil has a sequential examination process, with assessments hardly ever progressing to the second stage of the sequence. Unreviewed applications are a hallmark of the Brazilian patent law regime. In the event of a molecular failure in human trials, applicants hardly ever try applying for patent, but rather move on to the next technology. To that effect, very few applications are assessed by ANVISA because they are either denied by INPI or withdrawn prior to investigation.[64]

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[57] Omar Ramon Serrano Oswald and Mira Burri, 'India, Brazil, and Public Health: Rule-Making Through South–South Diffusion in the Intellectual Property Rights Regime?' [2021] 15 Regulation & Governance 616.

[58] Edson Beas Rodrigues Jr & Bryan Murphy, 'Brazil's Prior Consent Law: A Dialogue Between Brazil and the United States Over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines' [2006] 16 Alb L J Sci & Tech 423.

[59] Jae Sundaram, 'Brazil's Implementation of TRIPS Flexibilities: Ambitious Missions, Early Implementation, and the Plans for Reform' [2014] 23 Info & Comm Tech L 81.

[60] ibid.

[61] Romandini (n 55).

[62] Rana Gosain, 'Recent Reform on Brazilian Pharmaceutical Patents Showing Results' (*FICPI*, 11 April 2022) <https://ficpi.org/blog/recent-reform-brazilian-pharmaceutical-patents-showing-results#:~:text=Recent%20reform%20on%20Brazilian%20pharmaceutical%20patents%20showing%20results,-Posted%20by%20Rana&text=In%202021%2C%20the%20Brazilian%20legislature,in%20examining%20Brazilian%20patent%20applications.> accessed 10 October 2023.

[63] Ken Shadlen, 'The Political Contradictions of Incremental Innovation in Late Development: Lessons from Pharmaceutical Patent Examination in Brazil' [2011] 2 Politics & Society 39.

[64] Bhaven N Sampat & Ken Shalden, 'TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India' [2015] 50(2) Studies in Comparative International Development

Therefore, it is observed that the combination of the Prior Consent mechanism, sequential examination process, and the stringent assessment procedures envisaged by ANVISA has resulted in the low issuing of secondary patents by Brazil. In fact, the grant rate is the lowest in Brazil.[65] Aside from these technicalities, there is more evidence which suggests that Brazil is more efficient in restricting secondary patents than India.[66] This raises the question as to how two countries who were given the same set of flexibilities and stood for the same agendas have a stark difference in terms of the grant rate of patents.

It is argued that a 'Dual Approval' model like that of Brazil can be replicated in India. A Prior Consent mechanism can be established in India where any pharmaceutical patent would be subjected to a two-tier approval system: *first*, the patent office, namely the Indian Patent Office; and *second*, a regulatory body expertizing in public healthcare such as the Central Drugs Standard Control Organization ('CDSCO'). The rest of the technicalities would be the same as the Brazilian Model. Further, the role played by the CDSCO can be strengthened in the approval process by empowering it to assess the 'efficacy' of the patent applications in light of Section 3(d). As a body specialising in the health-sector it would be more equipped to deal with the uncertainties surrounding the real ambit of the term 'efficacy' and whether a product is actually classified as a new development. This would clear the issue of ambiguity and vagueness associated with the test of efficacy as raised earlier. Further, combining this with the sequential examination process that lays down stringent criteria would filter out unwarranted patents which would otherwise be granted protection. Adopting such a mechanism would reflect the common spirit shared by both countries of ensuring healthcare and preventing evergreening of patents. It would also aid India reduce its patent grant rate.

## V. Conclusion

The practice of evergreening patents, particularly in the pharmaceutical industry, poses significant challenges to innovation, competition, and public health. India and Brazil, as signatories to the TRIPS Agreement, have implemented different strategies to address this issue. While India introduced Section 3(d) in its Patents Act to scrutinise secondary patents, Brazil adopted a dual approval system involving both the patent office and a regulatory body. Brazil's approach, characterized by a sequential examination process and stringent assessment procedures by ANVISA, has led to a lower grant rate for secondary patents compared to India.

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[65] Huynh-Ba & Beumer Sassi, 'Anvisa: An Introduction to a New Regulatory Agency with Many Challenges' [2018] 4 AAPS Open 9.

[66] ibid.

Moving forward and drawing lessons from Brazil, this Paper recommends that India can consider enhancing its patent approval process by empowering regulatory bodies like the CDSCO to evaluate patents for efficacy and public health impact. Implementing a dual approval mechanism similar to Brazil's could help India mitigate the challenges associated with evergreening and strike a balance between promoting innovation and ensuring access to affordable healthcare. By adopting such measures, India can align with its commitment to public health and contribute to the global efforts to address the complexities of patent evergreening.