PRODUCT AND PROCESS PATENT DICHOTOMY IN INDIAN PATENT LAW: A CRITICAL DOCTRINAL AND POLICY ANALYSIS

Kratika Verma, LLM IPL Scholar, Christ University, Bangalore[1]

ABSTRACT

The difference between product and process patent has been a revolution in the development of Indian patent jurisprudence. Historically India had adopted process-patent regime under the Patents Act, 1970 in order to ensure access to affordable medicines and promotion of domestic industrial growth. This framework allowed for protection only of the method of manufacture of a product, especially pharmaceuticals and chemicals, but no protection of the product itself. However, India's accession to World Trade Organization and related compliance to TRIPS Agreement gave a fundamental turnaround to this approach. The 2005 amendment to the Patents Act provided protection of product patents in all fields of technology, including pharmaceuticals and agrochemicals.

This research paper explores critically the doctrinal underpinnings, legislative development, judicial construction as well as economic implications associated with the product-process patent dichotomy in India. It considers key judicial statements like Novartis AG v. Union of India and v. Bayer Corporation Union of India to examine the balance adopted by Indian courts between the incentives of innovation and public interest and access to medicines. The study has a doctrinal and comparative approach, analysing what has headed on in the United States and the European Union.

The paper argues that while product patents complemented India's global compliance and innovation ecosystem, they started intensifying concerns relating to monopolistic pricing, evergreening and public health. It ends with a proposal for a calibrated harmonised model, which maintains the compliance with TRIPS while ensuring the constitutional values of social justice and access to healthcare.

Keywords: Product patent Process patent TRIPS Pharmaceutical patents Evergreening Access to medicines Compulsory licensing

[1] By Kratika Verma, LLM IPL Scholar, Christ University, Bangalore

INTRODUCTION

Patent law deals with the clash of two competing interests, encouraging innovation and making others acknowledge technological advancements[2]. The conceptual difference between product and process patents has in the past influenced the way this balance is maintained[3]. A product patent gives an exclusive right to the end product itself, regardless of the end product's method of manufacture[4]. A process patent, on the other hand, only protects the method that is used to create a product so that competitors may be able to create the same product using different processes[5].

India's patent history is as a consciousness development strategy. The colonial regime of patents under the Indian Patents and Designs Act, 1911 mostly benefited foreign corporations[6]. After independence, the recommendations of the Ayyangar Committee resulted in enactment of Patents Act, 1970, which always abolished the product patents in food, chemicals and pharmaceuticals[7]. This reform allowed the development of India's generic pharmaceutical industry and made India the "pharmacy of the developing world"[8].

However, India's integration in the global trading system in the form of WTO and TRIPS made the product patent registration necessary in 2005[9]. This shift constituted a paradigmatic transformation in the policy of India in respect to patents. The product-process dichotomy is thus not simply a technical categorisation, but a reflection of competing ideologies of democracy of developmental nationalism versus globalised intellectual property harmonisation[10].

This paper examines whether or not the current framework has achieved a sustainable balance between innovation and public welfare, and especially in the pharmaceutical sector[11].

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[2] William M. Landes & Richard A. Posner, *The Economic Structure of Intellectual Property Law* 294 (2003).
[3] Robert P. Merges & John F. Duffy, *Patent Law and Policy: Cases and Materials* 89 (7th ed. 2017).
[4] World Intellectual Property Organization, *Understanding Patents* (2016).
[5] Janice M. Mueller, *Patent Law* 62 (5th ed. 2016).
[6] Indian Patents and Designs Act, 1911.
[7] Patents Act, 1970; N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (1959).
[8] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries* 45 (2000).
[9] World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, 1869 U.N.T.S. 299.
[10] Ruth L. Okediji, *Global Intellectual Property and Development* (2015).
[11] Daniel J. Gervais, *The TRIPS Agreement: Drafting History and Analysis* (4th ed. 2012).

BACKGROUND

A. Historical Context: From the Colonial Regime to Developmental Model

The scope and development of the patent system in India has to be viewed in the context of its received colonial legal heritage and developmental aspirations during its post independence period[12]. The Indian Patents and Designs Act, 1911 enacted in the British rule regime was mostly based on the British patent system and ensured excellent product patent protection in technological fields including pharmaceuticals[13]. However, this regime was held to be highly criticised after independence for providing for the dominance of the foreign corporate sector in Indian markets[14]. Multinational pharmaceutical corporations controlled a large portion of patents, which most frequently meant high priced imported medicines and low levels of technological capacity in the country[15]. The patent system was seen not as a tool of national development but as a legal framework for strengthened economic dependency[16].

In response to these concerns, the Government of India set up the Ayyangar Committee, whose report (1959), altered the philosophical outlook of the country towards IP entirely[17]. The Committee held that strong product patent protection, especially in the pharmaceutical and chemical industries, had helped to push up the price of drugs and had prevented industrial development at the domestic level[18]. In this report it suggested the need for a reorientation of patent policy to development goals, and argued that the patent system should be for the benefit of national economic and social priorities, rather than simply being for protecting private monopoly interests[19].

These recommendations culminated in the passage of the Patents Act, 1970 which brought in a radical shift in structure[20]. The Act intentionally excluded product patents in the domain of pharmaceuticals and agrochemicals with only process patents recognised in these sectors[21]. This legislative design was guided by two, inter related, objectives. First of all it was intended

[12] Shamnad Basheer, India's Tryst with TRIPS: The Patents (Amendment) Act 2005, 1 Indian J.L. & Tech. 15 (2005).
[13] Indian Patents and Designs Act, 1911.
[14] Ayyangar Committee Report, supra note 6.
[15] Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry* 30 (2005).
[16] Id.
[17] Ayyangar Committee Report, supra note 6.
[18] Id.
[19] Id.
[20] Patents Act, 1970.
[21] Id. § 5 (prior to 2005 amendment).

to promote indigenous manufacturing capacity by enabling domestic companies to reverse engineer patented drugs and develop alternative manufacturing processes[22]. Second, it was to make sure that necessary medicines were available at an affordable price by avoiding the monopoly of pharmaceutical products over extended periods[23].

The process only regime proved to be a transformational one. Indian pharmaceutical companies took advantage of the legal loopholes to develop manufacturing skills, improve the reverse engineering skills, and compete both domestically and internationally[24]. Over the years, India became a world leader in the domain of generic medicines and managed to provide cheap drugs to many developing countries[25]. A framework of the 1970 it functioned not just like mass legislation for intellectual property but like a strategic tool of industrial and public health policy[26].

TRIPS and the Global Harmonisation

The human international property world changed dramatically with the founding of the World Trade Organization in 1995 and the adoption of the TRIPs Agreement[27]. India became a founding member of WTO and thus acquired binding obligations under TRIPS[28]. Article 27 of the TRIPS Agreement states that patents should be accessible to inventions in all fields of technology without discrimination which in essence means that member states must offer patent protection for products in the field of pharmaceuticals and agrochemicals[29].

Realising the enormity of this transition, India chose the phased compliance approach. The amendment in 1999 gave birth to the "mailbox" mechanism, whereby pharmaceutical product patent applications will be filed up and kept pending full compliance[30]. The amendment of 2002 extended the term of patents to twenty years as per the global standards[31]. Finally 2005 amendment completed the process regarding protection of product patents for pharmaceuticals

[22] Chaudhuri, supra note 14.
[23] Id.
[24] Id.
[25] Correa, supra note 7.
[26] Basheer, supra note 11.
[27] TRIPS Agreement, supra note 8.
[28] Id.
[29] Id. art. 27.
[30] Patents (Amendment) Act, 1999.
[31] Patents (Amendment) Act, 2002.

and agrochemicals, by adding it as an amendment to the Patents Act, 1970[32].

The 2005 amendment was the actual ending of the process only regime in India and it saw a right shift from the pure developmental patent model to the TRIPS compliant product patent model[33]. However, there was careful calibration of the transition. India at the same time, included safeguards such as section 3(d) and bolstered mandatory licensing provisions in order to retain public interest considerations in the new regime[34].

Thus, India's evolution of patenting exemplifies the evolution of a programme of imitation from colonies, experimentation from developing countries and calibrated harmonisation with the international system all part of a continuing negotiation between international imperatives and socio-economic imperatives of the developing economies[35].

STATEMENT OF PROBLEM

The shift from a process patent regime to a product patent regime in the light of the Patents Act, 1970 has raised much legal and economic concern and such concerns need to be systematically examined. The reversal of the moratorium on the patents of pharmaceutical products after the compliance with the TRIPS Agreement raises important questions over the balance between innovation incentive and public welfare. Whether this change has had a disproportionate effect in strengthening the multinational pharmaceutical corporations at the expense of domestic generic manufacturers remains to be seen and has altered the competitive scenario in India. Further, the extension of the protection of product patents opens up the possibility of scrutiny as to whether the strong exclusivity may conflict with the constitutional commitment of India towards public health, particularly as it relates to access to affordable medicines under article 21.

Although, safeguards such as Section 3(d) were introduced in order to prevent evergreening and excessive monopolisation, the effectiveness of these in practice continues to be debated. Additionally, it is necessary to determine whether the product process dichotomy continues to have doctrinal and practical significance in current patent jurisprudence, or has been greatly watered down by the 2005 amendments. The very apparent fragmentation between innovation

[32] Patents (Amendment) Act, 2005.
[33] Basheer, supra note 11.
[34] Patents Act, 1970, § 3(d) (India); §§ 84–92 (Compulsory Licensing).
[35] Gervais, supra note 10.

policy objectives and access to medicines concerns predict the need for holistic doctrinal reassessment of the patent framework in India.

OBJECTIVES OF THE STUDY

The present study aims at undertaking a structured and integrated study of the product-process patent dichotomy within the ambit of the Patents Act, 1970 in the light of India's obligations under the TRIPS Agreement. The following are the objectives:

1. To trace and to critically examine the historical development of product and process patent protection in India, in particular, the change in patent law from the process only regime to the post 2005 product patent.

2. To analyse the difference in doctrines between patent protection for products and processes under Indian law along with their scope of rights, means of enforcement and policy implication.

3. To assess the judicial interpretation of patentability criteria, and in particular after the 2005 changes, paying particular attention to Section 3(d) and anti evergreening doctrine.

4. To determine the economic implications of the transition to product patent protection in terms of innovation incentives, competition in the market and access to medicines.

5. To propose changes in policies so that it harmonises the interest of public with the compliance of TRIPS and thus the balance between innovation and social justice.

RESEARCH QUESTIONS

In accordance with the above objectives, the following corresponding questions are the focus of the research:

1. How did the historical development of the Indian patent regime contribute to the transformation from a process based regime to a product patent regime and what were the developmental considerations involved in this change?

2. What are the doctrinal differences between product and process patents in India and

what is the effect of the same on extent of exclusivity and enforcement?

3. How have Indian courts interpreted the provisions of Section 3(d) and so on in such suits which deals with the allegations of evergreening post the amendments in 2005?

4. To what extent has the introduction of product patents under TRIPS affected the balance between the incentives for innovation and access to medicines in India?

   Does the product process dichotomy still have theoretical and practical relevance in modern patent jurisprudence and what reforms are needed to bring it in line with constitutional and public interest goals?

Each research question is directly related to a stated objective, in order to establish coherence between the analytical objectives of the study and the doctrinal and policy issues being researched.

HYPOTHESIS

This study is based on the assumption that the transformation of the patent regime into the product based patenting regime within the framework of the TRIPS Agreement obligation has significantly increased the degree and strength of the patent exclusivity, particularly in the pharmaceutical industry. The introduction of the product patents in the amended Patents Act, 1970 has conferred to the proprietary right of patentees by giving them full control of the manufacture, sale, importation and distribution of patented products irrespective of the process involved. On the one hand, this period of exclusivity which is supposed to stimulate innovation and investment also on the other hand has raised concerns of monopolistic pricing and stifled generic competition and patenting strategies (so called evergreening) to secure patents. Strong product monopolies in industries such as pharmaceuticals where patented products should directly reflect population health and access to vital medicaments place structural limitation of affordability which heightens the conflict between intellectual property protection and constitutional duties of social welfare.

The hypothesis continues to indicate that judicial intervention has played a moderating role of critical importance in re calibration of this balance. Specifically, the tendency of the Supreme Court to an interpretative approach that was followed in Novartis AG v. Union of India particularly in relation to Section 3(d) of the Patents Act shows that there is an actual effort to

forestall the abuse of product patent protection by minor or incremental changes which show no demonstrable therapeutic effect. The judiciary has tried to increase the patentability bar to pharmaceuticals inventions so that only genuine innovations are patented, which will curtail the evergreening phenomenon and leave space to generic competition.

To this effect, this study further supports the hypothesis that, although the TRIPS compliant product patent regime has indeed led to the heightening of the exclusivity of the patent rights, it does not act in isolation. By the provisions of doctrinal protection like that of Section 3(d), the compulsory licensing, and purposive judicial interpretation, the Indian patent law has developed in house corrective mechanisms that are meant to reconcile the innovation incentives with wider constitutional principles of social justice, public health and equitable access to resources. The paper finally postulates that a properly tuned reform agenda (i.e. one that maintains international compliance and yet reinforces public interest protections) is capable of supporting this fine line between the promotion of economic growth and upholding constitutional morality.

RESEARCH METHODOLOGY

Doctrinal Method

The doctrinal method (also called black-letter law approach) is applied in the sense of a systematic and analytical study of the rules of law, statutes, judicial precedent, and authoritative texts by the aim of finding out where the law stands at the given issue. It is largely interested in interpreting legislative provisions, judicial reasoning and determination of principles underlying the legal structure. The doctrinal approach is applied in current studies to examine the statute developments and judicial interpretation in relation to the product process patent dichotomy in India critically. The research performs a detailed examination of the Patents Act, 1970, particularly modified in 2005, to be aware of the introduction of product patent protection in Indian legal system. It proceeds to discuss the provisions of the TRIPs Agreement that are relevant in order to discuss the scope of the international commitments of India, and the latitude that it has in the global intellectual property regime.

Besides the statutory analysis, the study draws on parliamentary debates and legislative history to find out the policy causes of the change of process only regime to a product patent regime. This doctrinal enquiry includes judicial interpretation. Cases against Novartis AG. The case of

Union of India and Bayer Corporation. The union of India are examined in further details in order to comprehend how the Indian courts have construed the criteria of patentability, the clauses of compulsory licensing and safeguarding against evergreening. This doctrinal analysis helps the research to determine the principles of law which are active in the current patent regime and measure the extent to which they are effective in striking the right balance between innovation and the interests of the populace.

Comparative Method

The comparative approach to legal research involves study and analysis of legal systems in different jurisdictions, with the aim of discovering commonalities and differences between the two and deriving possible lessons about them, as regards to reform. It assists in building a broader understanding of the variety of reaction of various legal systems to the same problem and provides the information about other possible paradigms of regulation. The comparative approach has been used in this work to put the Indian patent law in the global perspective of intellectual property.

The study contrasts the Indian regime with the regime that was used under the Patent Act in the United States that provides good protection of product patents and highly depends on market based exclusiveness incentives. It also bears in mind the standard set up provided under the European Patent Convention that harmonises the standard of patents in the various European jurisdictions and adopts a systematic approach to the inventive step and patentability.

The study explores the question using this comparative analysis whether the safeguards secured by India like Section 3(d) and compulsory licensing provisions are a special hybrid model to strike a balance between compliance of TRIPS and development goals. The approach that will be applied in the entire study will be qualitative and analytical grounded on the interpretative rationale and critical interpretation of legal texts rather than empirical or statistical interpretation.

SCOPE AND LIMITATIONS

The research study scope is what establishes the limits within which the investigation is being undertaken, and it defines the definite dimensions of the topic under investigation. The scope of the present study is deliberately narrowed down to the discussion of the product-process

patent dichotomy as it applies to pharmaceutical and chemical patents. These industries are chosen since they have historically been the most disputed region of contention between the process based and product based protection in India particularly under the Patents Act, 1970. The pharmaceutical industry is especially a good place where tension between the incentives to innovate and the health requirements of the population can be understood because it is in the industry that the transition between the regime of process and a regime of compliant with TRIPS on product patent has taken place. This examination can dive deeper into the doctrinal consequences of patent exclusivity, compulsory licensing, evergreening and affordability, without pitting the analysis spread thinly over irrelevant domains of technologies.

Doctrinal, judicial and policy considerations of patent law are also involved in the research. In a doctrinal aspect, it looks into provisions of laws especially when it comes to criteria of patentability, extent of rights and protection of public interest. It is judicially tested by looking at the way in which courts have interpreted and applied these provisions on landmark cases and it constitutes the working practice of the patent regime. In policy terms, the study looks at the broader economic and developmental purposes which the patent regime of India is built upon, such as its adherence to the TRIPS Agreement and to the purported avowed aims of the policies of its Constitution in terms of the well-being of the people. A comparative approach is also considered in the research through the analysis of the approach followed in the United States and in Europe under the framework of the Patent Act and European Patent Convention respectively. Such a comparative analysis allows identifying structural dissimilarities and potential lessons to be learned to initiate reform to put Indian patent law in a broader global perspective.

LIMITATION OF THE STUDY

Although the aim of this paper is to provide a comprehensive doctrinal and comparative study, of course, there are some limitations which limit the scope of the study. To begin with, the study is not based on any empirical economic modelling and quantitative research of data on the precise effect of protection of products patents on drug prices, investment in research, and competition on the market. In spite of the fact that the economic implications are addressed in the abstract and indirect way, due to the absence of primary empirical research, it is hard to infer statistically measurable market consequences. The research remains largely normative and legal in nature as opposed to econometric.

Secondly, the judicial review is restricted to the published judgments of Supreme Court and High Courts and the available judgments of the tribunals, where necessary. Judgments that are not reported, confidential settlements and litigation are not verified due to the constraints of accessibility and reliability. As a result, there is a possibility that the study is failing to capture emerging trends which are still emerging in the judicial system.

Lastly, the study acknowledges that the accuracy and transformation of the patent law is emerging as one of the significant contributors to the increasing technological advancement, particularly in technologies like biologics and biosimilars, and artificial intelligent inventions. Although these developments are addressed as far as they can illuminate the ongoing relevance of the product-process differentiation, they are introduced contextually. An in depth technical or sector specific examination of biotechnology patents or artificial intelligence inspired innovation lies outside the immediate area of research. These are, however, not detrimental to the primary objective of this study, the critical analysis of the doctrinal and policy promotion of the product-process patent dichotomy in the Indian legal system.

The intellectual examination of the history of the Indian patent law evidences the depth and complexity of the interaction between the global intellectual property harmonisation and the national developmental concerns. A visible literature has been examining how India has changed its regime of process based regime under patents act,1970 to a TRIP compliant regime of product patent under its obligations to the TRIPS agreement. In this literature, the effort has been made in defining the Indian approach as not passive compliance but as strategic adaptation in the context of international law.

One such conceptualisation is the one that Shamnad Basheer develops of the evolution of the patent in India as the exercise of calibrated compliance, i.e., that India formally aligned the domestic law with the demands of TRIPS, but in the process introduced protective features that ensured the policy autonomy. It is argued under this perception that the conditions such as Section 3(d), compulsory licensing and high standards of inventive step is an endeavor to strike a balance between the international undertakings and the constitutional and developmental requirements. The point that is brought out by Basheer in his scholarship is that the post 2005 patent regime in India is not a mere shift towards more rights to monopoly but rather a negotiated compromise between the necessity of innovation and the necessity of the common good.

Correa, on the same note, highlights the intrinsic elasticity that is held in the TRIPS framework. Correa insists that TRIPS offer minimum protection criteria and leave much room to the member states to determine the standard of patentability and the terms of obligatory licensing and the protection of the common good. In this regard, the incorporation of such provisions as Section 3(d) by India is a lawful act of sovereign regulatory space rather than a deviation of international norms. The policy of patents in India, as discussed by Correa, is viewed within a broader discussion in the world on how the developing countries can take advantage of the flexibilities of the TRIPS so that they can protect the health of the populace without violating the international trade agreements.

Scholarship in the area by Frederick Abbott elicits even greater contribution to the role of compulsory licensing as a structural counter to the exclusivity conferred on product patents. Abbott asserts that compulsory licensing mechanisms are not extraordinary and punitive steps but they are a component of the patent system to prevent misuse of monopoly power. The Indian context has greatly perceived compulsory licensing as one of the major protection against excessive charging and non-use of patents and thus, it enhances the public interest aspect of patent law. Jurisprudence v. Novartis AG. Union of India has had a fair share of scholarly commentaries and is widely regarded as a milestone in the anti-evergreening discussion in the global context. According to scholars, the interpretation of the Supreme Court of Section 3(d) is a special and new application of TRIPS flexibilities. The Court, by making it a pre-requisite to demonstrate measurable enhancement of therapeutic activity in order to be patentable, in effect increased the bar to pharmaceutical patents, in a manner such that minor or cosmetic modifications made to extend the range of monopoly protection are not patentable.

Scholarly coverage of the Novartis ruling tends to portray it as a legal victory of India in demonstrating its commitment to strike a balance between innovation and access to drugs. This is a relatively large amount of scholarship, but nonetheless, a gap in the research lies. A large part of the literature that exists looks at TRIPS compliance or compulsory licensing or the anti-evergreening doctrine in isolation.

There are comparatively less studies that critically examine the current doctrinal and economic significance of the product-process patent dichotomy after the transition of 2005. The previous process only regime is commonly seen as a historical stage and not a conceptual model that has a legacy that still influences the patent interpretation and policy decisions. Little is done to

analyse in a unified manner the doctrinal interpretation, the comparative international perspective and economic implications or within the same analytic perspective.

The proposed research will address this gap by conducting a general analysis of the product process dichotomy in the modern Indian patent law. The study will aim to contribute to the existing academic discussion and develop a more comprehensive picture of the sustained significance of this conceptual difference by matching the two types of analysis, comparative assessment with other jurisdictions and critical assessment of the economic and policy implications.

REVIEW OF LITERATURE

The academic and scholarly discourse about the formation of the patent law in India is indicative of a rich and nuanced engagement with the tension between intellectual property's harmonisation in the global context and the developmental priority of the Indian state. A sizeable body of literature has taken into consideration India's shift from a process-based regime under the Patents Act, 1970 to a TRIPS compliant product patent regime on it entering its obligations under the TRIPS Agreement. In this literature, observers have also tried to describe the Indian approach not as a form of passive compliance, but as adaptation under the parameters of international law.

Shamnad Basheer, for instance, conceptualises India's evolution of its patent law, in terms of "calibrated compliance," in the sense that while India formally adjusted its domestic law to be in line with TRIPs requirements and at the same time embedded safeguards within the law to preserve policy autonomy. According to this view, provisions such as Section 3(d), compulsory licensing and strict standards of inventive step represent a deliberate attempt to juggle between international commitments on the one hand and constitutional and developmental imperatives on the other hand. According to the scholarship of Basheer, the current post 2005 patent regime in India is not the issue of a shift towards more protection of monopoly but a negotiated compromise between the interests of encouraging innovation and the well being of the populace.

Similarly, Carlos Correa emphasises on the inherent flexibility embedded with the TRIPS framework. Correa posits that TRIPS sets minimum levels of protection but leaves much room to individual member states to determine the criteria of patentability, compulsory licensing

conditions and public interest safeguards. From this perspective, the fact that India had included certain provisions such as section 3(d), is a legitimate exercise of sovereign regulatory space and is not a deviation from the international norms. Correa's analysis situates the patent policy of India in much broader global context on how developing countries can use the flexibilities provided under TRIPS to protect public health without violating the multilateral trade obligations.

Frederick Abbott's scholarship goes further, however, to bring out the role of compulsory licensing as a structural counterweight against product patent monopoly. Abbott argues that compulsory licensing mechanisms are not unusual and punitive measures but part and parcel of the patent system to prevent the abuse of monopoly power. In the Indian context, compulsory licensing has been viewed as an essential tool against excessive pricing and non-working of patents and therefore enhances the public interest side of patent law.

The jurisprudence that has resulted from Novartis AG v. Union of India has been the subject of a huge amount of academic commentary and it is considered in wide quarters to be a landmark in the global anti evergreening discourse. Scholars believe that the Supreme Court's interpretation of Section 3(d) is a unique and innovative way of using flexibilities of the TRIPS. By insisting that the new forms of known substances have to exhibit demonstrable improvement in therapeutic efficacy for patentability, the Court effectively raised the standard for patentability for pharmaceuticals, which limited incremental or cosmetic changes intended to extend the period of monopoly. Such an analysis of the Novartis decision commonly offers the decision as a judicial confirmation of Indian dedication to innovation-medicine balance. Despite this pretty large amount of scholarship, there is one significant gap of research. Much of the literature out there focuses on TRIPS compliance or compulsory licensing or the anti evergreening doctrine in isolation. Relatively fewer studies make an in depth examination of the continued doctrinal and economic significance of the product-process patent dichotomy following the 2005 transition.

The previous process only regime is frequently taken as having been a historical period, as opposed to a conceptual regime the legacy of which continues to be experienced in patent interpretation and policy decisions. In this regard, there is a lack of integrated analysis to link in one analytical context, doctrinal interpretation, comparative international analysis and economic implications. This research is an attempt to fill this gap by giving a holistic analysis

of the dichotomy of product versus process in Indian patent law in the modern era. The study aims to contribute to a current scholarly discussion by integrating the analysis of the doctrine, the comparison with other jurisdictions, and the evaluation of the economic and policy implications to provide a more detailed view of the long-term importance of this underlying distinction.

DOCTRINAL PRODUCT AND PROCESS PATENT DELINEATION

Conceptual Foundations

Dichotomy product-process is based on the classical patent theory and represents two different modes of protection of technical innovation[36]. At its conceptual heart, patent law is to provide an incentive to the inventive activity of its bearers with time bound exclusivity in exchange for public disclosure[37]. However, this exclusivity is granted to a varying extent depending on the nature of the patent being granted whether for a product or a process[38].

A product patent gives exclusive rights to the actual or identifiable end product itself regardless of the manner in which it was made. The right of the patentee is to prevent any one from unauthorisedly making, using, selling, offering for sale or importing such a product[39]. Infringement is therefore constituted if the protected product is in the market without authorization however the means of its production[40]. This monopoly is over the substance or composition as such[41]. This type of protection is especially important in the pharmaceutical business where the molecule or active ingredient is the commercial valuable asset[42].

In contrast, a process patent only has a specific method/technique of making a product. The exclusive right is not extended to the product itself, rather it is restricted to the prohibition of use of the patented process by others[43]. Competitors are able to legally do the same end product as long as they come up with a non-infringing alternative process[44]. Thus, the monopoly also becomes more narrow and technical[45]. Enforcement is also more complex because in order to

[36] Robert P. Merges & John F. Duffy, *Patent Law and Policy* 37 (7th ed. 2017).
[37] William M. Landes & Richard A. Posner, *The Economic Structure of Intellectual Property Law* 294 (2003).
[38] Janice M. Mueller, *Patent Law* 56 (5th ed. 2016).
[39] Id
[40] Id
[41] Id
[42] Merges & Duffy, supra note 1.
[43] Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry* 45 (2005).
[44] Mueller, supra note 3.
[45] Id.

prove infringement it is often necessary to prove the alleged infringing was using the method that has been patented and this can involve evidentiary challenges relating to industrial secrecy[46].

The statutory expression of this difference is contained at Section 48 of the Patents Act, 1970[47]. The provision differentiate between rights conferred by product patents and the rights conferred by the process patents. In case of product patents the patentee has the exclusive right to restrain the third parties to make, use, offer for sale, sell or import the patented product in India. In the case of process patent, the patentee can prevent the third party use of the process patented as well as the sale and importation of products obtained directly from such process[48]. The language of the section 48 itself shows that the legislature knew that there was a qualitative difference in the extent of monopoly granted under each of the categories[49].

This doctrinal distinction has tremendous effect upon the scope of exclusivity, the complexity of enforcement and market competition[50]. A product patent creates a complete barrier on a market around the protected substance and a process patent leaves space for technological competition by means of alternative manufacturing routes[51]. Consequently, the choice between these two models have huge implications with regard to industrial policy, access to medicines and innovation incentives[52].

RATIONE BEHIND PROCESS PATENT Regime of India (1970 - 2005)

When Patents Act, 1970 was passed, Parliament had purposely left out the product patents in the field of food, chemicals and pharmaceuticals[53]. This legislative choice was neither accidental nor technical but it was very much a consequence of the post colonial philosophy of development in India[54]. Policymakers were influenced by fears of foreigners purchasing out foreign corporate dominance and strangling domestic industrial growth in the form of potent product monopolies (especially in pharma)[55].

[46] Id.
[47] Merges & Duffy, supra note 1.
[48] Id.
[49] Patents Act, 1970, § 48.
[50] Id.
[51] Id.
[52] Landes & Posner, supra note 2.
[53] Id.
[54] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries* (2000).
[55] Patents Act, 1970, § 5 (prior to amendment).

The general thinking was that product patents in the essential sectors would result in high drug prices, limited access to life saving drugs and continued reliance on multinational corporations[56]. The experience of the past under the patent regime of the colonial era gave rise to this apprehension where the foreign handled a significant percentage of the pharmaceutical market and imported the finished products at high prices[57]. The changeover to a process only regime was therefore intended as a structural reform in the interest of self reliance and technological ability[58].

Under this model Indian manufactures were legally entitled to reverse engineer patented drugs and develop alternative manufacturing processes[59]. As long as the process was unique and did not violate the rights of others, production and sale of same pharmaceutical product was legal[60]. This type of regulatory design fostered scientific experimentation and incremental innovation of the manufacturing techniques[61]. It also played important role for reducing the barriers of entry to domestic firms[62].

The consequences were earth shaking. Indian pharmaceutical companies like Cipla, Ranbaxy and Dr Reddy's Laboratories became big player in the global generics market[63]. The import dependence of the industry was enforced in the 1960s, and by 1990s the industry was in a position of competitive strength[64]. Domestic competition was stiffened and so did the prices of the drugs which are said to have fallen considerably in comparison with international standards[65].

Thus, the process-only regime became not only the regime of intellectual property, but an instrument of industrial policy[66]. It helped in technology learning, domestic capacity building and better access to medicines[67]. This time's product process dichotomy would be very important to the Indian patent identity and development strategy[68].

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[56] N. Rajagopala Ayyangar, *Report on the Revision of the Patents Law* (1959).
[57] Id.
[58] Chaudhuri, supra note 8.
[59] Id
[60] Ayyangar Report, supra note 21.
[61] Chaudhuri, supra note 8.
[62] Id.
[63] Id.
[64] Id.
[65] Id.
[66] Id.
[67] Correa, supra note 19.
[68] Id.

TRIPS Compliance & Return of Product Patent

The world intellectual property system was changed fundamentally with the creation of the World Trade Organization in 1995 and the adoption of the TRIPs Agreement[69]. Article 27 of TRIPS provides that Patents shall be available for inventions in all fields of technology on a non discriminatory basis whether the products are imported or locally made[70]. This provision was in effect requiring member states to offer product patent protection in the area of pharmaceutical and agro-chemicals[71].

India being an original member of WTO took a phased approach of complying with the same by ending in the amendment of Patents Act, 1970 in year 2005[72]. With this amendment, pharmaceutical and agrochemical products were developed as patentable subject matter[73]. The transition was the formal end of the process only regime, and brought product patents back to sectors which had previously been excluded for developmental reasons[74].

The change was radical when it came to the competitive landscape. Innovator pharmaceutical companies had better and more complete exclusivity over patented molecule[75]. Generic manufacturers would no longer be able to sell identical products throughout the duration of the term of the patent except through having obtained a licence, or successfully attacked the validity of the patent[76]. As a result, generic entry was slowed down in some cases and patent litigation exploded as firms had validity, infringement and public interest safeguards challenged[77].

Although, product patents were revived, at the same time India retained such protection mechanisms as stringent patentability criteria and compulsory licensing provisions[78]. Nevertheless the centrality of product-process dichotomy as a defining feature of Indian patent policy was considerably narrowed down[79]. The emphasis was more upon the calibrated

[69] Id.
[70] Chaudhuri, supra note 8.
[71] World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994.
[72] Id. art. 27.
[73] Id.
[74] Patents (Amendment) Act, 2005.
[75] Id.
[76] Basheer, India's Tryst with TRIPS, supra note 11.
[77] Correa, supra note 19.
[78] Id.
[79] Id.

regulation of the scope and enforcement of product patents, than structural exclusion of product patents[80].

To sum up, it was due to the re introduction of product patents under the ambit of TRIPS compliance there was a change in the doctrinal architecture of Indian patent law[81]. While the formal dichotomy between product and process patents is still in place under Section 48, the policy significance of the dichotomy has changed[82]. The debate is now not so much, should there be product patents at all, but how should their scope be interpreted and limited so as to ensure that the incentives for innovation are reconciled with public health and developmental goals[83].

SECTION 3(d) AND EEVERGREENING THE DOCTRINE

Legislative Intent

Section 3(d) of the Patents Act, 1970 is one of the most peculiar features of post 2005 regime of patents in India[84]. The exclusion in this provision is "the mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy of that substance" is not patentable[85]. By adding this exclusion to the statutory definition of subject matter that cannot be patented, Parliament was consciously adding a doctrinal shield against the practice, usually called "evergreening[86]."

Evergreening is a term used for strategies that are utilized by pharmaceutical patentees to delay the expiration date of a monopoly by obtaining secondary patents for minor changes in the drug product (e.g. new crystalline forms, salts, polymorphs, dosage forms, or methods of delivery) without appreciable therapeutic improvement[87]. While such modifications may be technically ingenious, critics complain that they often are intended to delay generic competition, rather than add any meaningful clinical benefits[88].

[80] Patents Act, 1970, §§ 3(d), 84–92.
[81] Basheer, supra note 11.
[82] Id.
[83] Gervais, *The TRIPS Agreement*, supra note 10.
[84] Patents Act, 1970, § 3(d) (India).
[85] Id.
[86] Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 Indian J.L. & Tech. 15 (2005).
[87] Carlos M. Correa, *Guidelines for the Examination of Pharmaceutical Patents* (WHO 2007).
[88] Id.

The legislative history of Section 3(d) demonstrates that it was introduced in order to avoid exactly this phenomenon in the context of India's transition to a product patent regime under the TRIPS Agreement[89]. Parliament wanted to ensure that the reintroduction of patents on pharmaceutical products would not prejudice access to medicines by permitting the successive layers of monopoly protection to be extended for trivial improvements[90]. In doctrinal terms Section 3(d) acts as an additional filter of patentability, which is in addition to the traditional requirements of novelty, inventive step and industrial applicability[91].

Thus, Section 3(d) is a check against the strong product patent rights[92]. It is a legislative choice and one that is well calibrated: product patents are allowed in pharmaceuticals, but are tempered down in the form of a higher bar for incremental innovations[93]. The provision is the result of an attempt of India to balance between complying with the TRIPS agreement and the compulsory constitutional provisions in regard to public health and social welfare[94].

Judicial Interpretation: Novartis AG Vs the Union of India

The most authoritative judicial interpretation of Section 3(d) had been in Novartis AG v. Union of India was a landmark decision that has influenced the worldwide debates on pharmaceutical patent standards[95]. In this case, Novartis was attempting to seek patent protection over the beta-crystalline form of the drug Imatinib Mesylate known as Glivec as it pertained to the treatment of chronic myeloid leukemia[96]. The patent application was challenged on the ground that the claimed invention is just a new form of a known substance without greater efficacy as is required under Section 3(d)[97].

The Supreme Court made a point by point analysis of the text of the statute and the legislative intent[98]. It held, first, that greater bioavailability is not necessarily greater "therapeutic efficacy.[99]" The Court construed "efficacy" as referring to pharmaceuticals to mean therapeutic efficacy that is, a demonstrable improvement in clinical performance. Mere physico-chemical

[89] Basheer, supra note 3.
[90] Id.
[91] Patents Act, 1970, §§ 2(1)(j), 2(1)(ja).
[92] Basheer, supra note 3.
[93] Correa, supra note 4.
[94] Id.
[95] Novartis AG v. Union of India.
[96] Id.
[97] Id.
[98] Id.
[99] Id. ¶ 180.

property improvements, for example, improved stability or flow properties, would not be sufficient but for improved therapeutic outcome[100].

Second, the Court made it clear that Section 3(d) provides a higher threshold for pharmaceutical inventions involving new forms of known substances[101]. The provision was not seen as an arbitrary hurdle but the outcome of a deliberate policy measure for the avoidance of evergreening[102].

Third, and significantly, the Court affirmed that it does not mean that compliance with TRIPS would prevent India from setting more stringent standards for patentability on the condition that minimum obligations are complied with[103]. The judgment emphasised that TRIPs sets the floor requirements, it is left to the members to have discretion in setting the substantive requirements for patentability[104].

Novartis decision generally regarded as a restatement of India philosophy of developmental patent in the ambit of global law of trade[105]. It reaffirmed the need for striking the right balance between the need for patent protection and public health concerns and that incremental changes in pharmaceuticals cannot automatically entitle extended monopoly rights[106].

Compulsory Licensing: People's Interest Preserved

Apart from Section 3(d), the other important check in the Indian patent system is the compulsory licensing. Section 84 of the Patents Act, 1970 allow grant of CL after three years from date of grant of patent on following grounds: where the reasonable requirements of the public are not met, where the patented invention is not made available at reasonable price or where the invention is not worked in the territory of India[107].

The first and most notable application of this kind of provision was in the case of Bayer Corporation vs. Union of India was in respect of a cancer drug, Nexavar (sorafenib tosylate).

[100] Id.
[101] Id.
[102] Id.
[103] Id.
[104] Id.
[105] World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights art. 1.1 (1994).
[106] Basheer, supra note 3.
[107] Novartis AG, supra note 12.

The Controller of Patents had granted a compulsory licence to an Indian manufacturer on a ground that the drug was priced out of the reach of the vast majority of the patients and that Bayer had failed to meet the reasonable requirements of the public[108]. The decision was then confirmed at appeal[109].

Following the granting of the licence, the price of the drug reportedly dropped dramatically, enabling much more patients access to it[110]. The case exemplified compulsory licensing is not a theoretical mechanism to moderate the rigidity of product patent monopoly but a practical regulation tool[111]. It reaffirmed the principle patent right was conditional and the public interest considerations was at the centre of the enforcement of patent rights[112].

Together with Section 3(d), compulsory licensing comprises a twin system of doctrinal and remedial limitations to the extent of the patent in the case of pharmaceutical products[113].

ECONOMIC IMPLICATIONS OF THE PRODUCT PROCESS SHIFT

Impact on Price of Pharmaceuticals

The introduction of product patents once again in 2005 changed the scenario of competition in the market for pharmaceuticals[114]. Empirical and policy analyses suggest that increased exclusivity can increase the entry barriers for generic manufacturers particularly in the context of patent term[115]. In some cases strategic forms of patent filing have been noted such as layered claims and secondary filings. Litigation between innovator and generic firms also has been increased which has led to delays in market entry[116].

However, India is still reliant on parallel regulating methods to try and address the affordability issue. The control of the prices of essential medicines is done by National Pharmaceutical Pricing Authority (NPPA) under the Drugs (Prices Control) framework[117]. This regulatory overlay is the result of the never ending battle between patent monopoly and the constitutional

[108] Patents Act, 1970, § 84.
[109] Bayer Corporation v. Natco Pharma Ltd..
[110] Id.
[111] Id.
[112] Correa, supra note 4.
[113] Id.
[114] Id.
[115] Basheer, supra note 3.
[116] Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry* (2005).
[117] Id.

mandate of access to medical healthcare[118]. The policy debate is still on going: while patents are an attempt to reward innovation, in a developing country context their economic consequences are subject to debate[119].

Innovation Incentives

Proponents of product patent protection believe that enhanced intellectual property rights encourage foreign direct investment, domestic research and development and integration of the national industry into international networks of innovation[120]. The argument is based on a premise of predictable and enforceable exclusivity, which will motivate long-term investment on high-risk research within the pharmaceutical field[121].

However, the critics argue that the structural orientation of the pharmaceutical industry in India is still oriented towards generics and biosimilars and not original drug discovery[122]. Although some firms have put more money into the R&D spending, the shift to an innovation ecosystem which is research intensive has been slow and uneven[123]. The fact that product patents are there has not automatically resulted in India emerging as a world leader in this field of novel drugs development[124].

Accordingly, while product patents may create conditions favorable to innovation, its actual development impact requires complementary factors such as public research funding, regulatory efficiency and technology transfer policies[125].

Strategic Use of Patent Drafting Process Claims

Even in a process patents regime product patents have not been eliminated in being relevant. Contemporary patent drafting commonly involves the use of layering claim structures which use both product claims and process claims in order to create multiple layers of protection[126].

Such drafting strategies add to the enforceability as well as the scope of defense perimeter

[118] Id.
[119] Id.
[120] National Pharmaceutical Pricing Authority, Government of India.
[121] Drugs (Prices Control) Order.
[122] Chaudhuri, supra note 33.
[123] World Intellectual Property Organization, *World Intellectual Property Report* (2017).
[124] Id.
[125] Chaudhuri, supra note 33.
[126] Id.

around valuable pharmaceutical inventions[127].

For sectors such as biologics and complex formulations the centrality of process innovation is still there. The manufacturing process itself may determine characteristics of the product; efficacy or stability[128]. As a result process patents still have a commercial significance even if there are product patents[129].

Nevertheless, process patent enforcement is subject to serious evidentiary problems. Proving that an alleged infringer used the process covered by the patent may require access to confidential manufacturing information that may be difficult to obtain[130]. Although there are statutory presumptions and rules of evidence which can be relied upon by patentees in certain cases, practical enforcement of these will be more complicated than in the case of product patents[131].

Thus, the product-process dichotomy still retains its operational importance. While the focus of the policy has been shifted towards regulating product patents, process patents have strategic and doctrinal importance in the present Indian patent regime[132]**.**

COMPARATIVE ANALYSIS

United States

In the United States product and process patents are recognised on an equal basis under Patent Act[133]. The American patent system is not doctrinally skewed in one category over the other, but rather exploiting a powerful model of exclusivity whereby patent rights are widely applicable in technology fields that include pharmaceuticals. A product patent provides for wide market exclusivity and process patents for process methods provide for equal patenting legitimacy to process methods.

The United States reinforces patent monopoly even more with regulations, most notably,

[127] Id.
[128] Organisation for Economic Co-operation and Development, *Pharmaceutical Innovation Report* (2018).
[129] Mueller, *Patent Law*, supra note 1.
[130] Id.
[131] Correa, supra note 4.
[132] Id.
[133] 35 U.S.C. §§ 101–103 (2018).

Hatch-Waxman system (Drug Price Competition and Patent Term Restoration Act, 1984)[134]. This regime provides a regulatory data exclusivity, patent term extensions and a structured process of litigation between innovator and generic manufacturers. While this system is said to be a balancing point between innovation and generic competition, it increases the commercial value of pharmaceutical product patents immensely.

Concerns regarding evergreening also exists in the US system. Pharmaceutical patentees often set secondary patents for formulations, methods of use or delivery mechanism[135]. However, unlike India, the United States lacks an exclusionary provision in its statute that is equivalent to section 3(d). Instead, the evergreening is tackled by applying the careful application of non obviousness standards and doctrines such as anticipation and obviousness-type double patenting[136]. Courts consider whether the invention that is being claimed would have been obvious to someone skilled in the area at the time that the filing occurred. Thus, US approach has more general patentability dependent on the general criteria than that of the sector-specific statutory filters.

Overall, the American model is that of a pro innovation, pro exclusivity orientation in which competition is introduced, not so much by restrictive provisions concerning patentability, but by post-grant challenges and generic litigation mechanism.

European Union

Within Europe patent protection is harmonised by the European Patent Convention which is administered by the European Patent Office (EPO)[137]. These patents of product and process have been recognised without any formal distinction regarding eligibility. The EPO follows a structured inventive step analysis on the basis of "problem-solution approach" which often results in a stern scrutiny of pharmaceutical inventions[138].

However, the European framework does not have a statutory provision which is equivalent to Section 3(d) of the Patents Act, 1970. Incremental pharmaceutical innovations are assessed

[134] Drug Price Competition and Patent Term Restoration Act (Hatch–Waxman Act), Pub. L. No. 98-417, 98 Stat. 1585 (1984).
[135] Rebecca S. Eisenberg, The Role of the FDA in Innovation Policy, 13 Mich. Telecomm. & Tech. L. Rev. 345 (2007).
[136] 35 U.S.C. § 103 (2018).
[137] Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973.
[138] European Patent Office, *Guidelines for Examination in the European Patent Office* (2023).

under general novelty and inventive step criteria as compared to under a specialised anti evergreening clause[139]. As a result, patenting of secondary patents may be given where there are the inventive step requirements.

Moreover, the European system strengthens the patent protection of pharmaceutical products by the use of Supplementary Protection Certificates (SPCs) which may extend the period of effective exclusivity beyond the normal twenty year term of a patent intended to compensate for delays in regulatory approval[140]. SPCs play a major role, leading to an increase in the patent dominance of the products in the pharmaceutical industry and sometimes favoring the monopolies for several more years.

Thus, although Europe has very strict examination standards, the overall regulatory architecture has a regulatory bias towards prolonged exclusivity of innovative pharmaceutical products, suggesting a policy focus on incentivising high cost research and development.

Comparative Insight

A comparative analysis shows that the model in India is in a unique middle ground. India is following its commitment taken as per the TRIPs agreement and recognising product patents in all field of technology[141]. At the same time, it has anti evergreening protections under section 3(d), and it has compulsory licensing as an active affordability mechanism.

Unlike the United States, India has a statutory barrier which is precisely geared towards pharmaceutical incremental innovation. Unlike the European Union it does not provide additional protection certificates that extend the term of the monopoly over the normal term of the patent. Simultaneously, India does not go back to the process only regime and product patents are fully recognised and enforceable.

So, the product-process dichotomy in India is an example of hybrid innovation model. It does not take unqualified pro monopoly position, but at the same time, does not fall back to the regime of purely developmental process of the pre 2005 period. Instead, it is a system which is

[139] Id.
[140] Regulation (EC) No. 469/2009 of the European Parliament and of the Council concerning the Supplementary Protection Certificate for Medicinal Products.
[141] TRIPS Agreement, supra note 5, art. 27.

set to balance between exclusivity and social welfare.

CONTEMPORAIRY APPLICABILITY OF THE DICHOTOMY

Although product patents now predominate in the field of pharmaceutical protection, the distinction between the product and process is of contemporary importance, especially in new areas of technology. In areas such as biologics, nanotechnology, gene therapies and artificial intelligence based drug design, process innovation is often the difference between being commercially viable, or being a failure[142].

Complex biologics, for example, are very sensitive to manufacturing conditions. The process of production may have an impact on molecular structure, stability and performance as a therapy. As a result, manufacturing know-how often comes to equal in value to the product itself. In many cases, protection is not only provided for through patents, but trade secrets and confidential technical expertise[143].

Similarly, in the case of nanotechnology and gene therapies, certain specialised methods of manufacture may be the key inventive contribution. Even where there are product claims there are process claims and this gives an additional level of protection in strategy terms. Thus, it has not been that the dichotomy has disappeared, it has just changed in its practical application. In the modern world of patents we observe process innovation as the essence of competitive advantage, especially in technologically complex industries.

CONSTITUTIONAL PERSPECTIV E & THE PRODUCT- PROCESS DEBATE

Patent law and the Indian Constitution

Although patent rights are statutory in origin, the interpretation of such rights in India is in the wider constitutional context. The Supreme Court has repeatedly ruled that intellectual property rights are not absolute natural rights, but are privileges that are granted under statute and as such, can be subject to reasonable limitations[144].

Article 21 of Constitution provides for the right to life which judicial interpretation has

[142] WIPO, *World Intellectual Property Report: Breakthrough Innovation and Economic Growth* (2015).
[143] Id.
[144] Entertainment Network (India) Ltd. v. Super Cassette Indus. Ltd., (2008) 13 S.C.C. 30 (India).

extended to mean the right to health and access to medical treatment[145]. Patent enforcement resulting in denial of life saving medicines may therefore raise the issue of constitutional implications. While patents provide incentive to innovation, exercise of patents must be consistent with principles of public interest and social justice which are rooted in the constitutional order.

In Novartis AG v. Union of India it was implicitly recognised by the supreme court that this was the constitutional background[146]. The Court explained that despite respecting India's international commitments under the framework of the World Trade Organization, India has the sovereign right to decide on the standard of patentability which is consistent with India's national public health priorities.

Accordingly, the product process dichotomy extends beyond being a technical statutory dichotomy and is part of a larger constitutional balancing act. The interpretation of provisions in patents needs to find the right balance between the incentives for innovation and the underlying fundamental values of human dignity, equity and social welfare.

POLICY REFORM PROPOSALS

The change to a product patent regime in the context of TRIPS is irreversible. However, there is scope and need for doctrinal cleansing and policy calibration. A harmonised reform model can help harness innovation incentives and not break the developmental commitments of India[147].

1. Strengthening Section 3(d) by Increased Clarity in Guidelines

Although Section 3(d) has gone to work trying to limit evergreening there remains ambiguity on exactly what "enhanced efficacy" means[148]. To eliminate some of the uncertainty and litigation, the Patent Office should offer detailed and periodically updated guidelines for examination. Therapeutic efficacy could be defined in certain clinical terms that could be measured and supported by empirical evidence. At the same time, the incremental innovations with a real public health benefits (e.g. improved safety profile, improved compliance for

[145] Consumer Educ. & Research Ctr. v. Union of India, (1995) 3 S.C.C. 42 (India).
[146] Novartis AG v. Union of India, (2013) 6 S.C.C. 1 (India).
[147] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27, Apr. 15, 1994, 1869 U.N.T.S. 299.
[148] The Patents Act, 1970, § 3(d) (India).

patients) should not be unduly discouraged. Increased clarity, without protection from anti evergreening.

2. Improving the Transparency of CL

Section 84 of the Patents Act, 1970 is therefore a powerful, but underutilised mechanism[149]. Reforms could include time bound adjudication of compulsory licence applications, transparency around benchmarks for deciding the question of affordability and clarity around the "working" requirement in India. The precedent in case of Bayer Corporation v. Union of India proved that compulsory licensing was a practical guarantee of public interest[150]. An improved and better structured transparency would be a service to increase regulatory credibility and investor certainty.

3. Increasing Process Innovation through Incentives

Even given the patent world for products, process innovation is of strategic and economic significance[151]. India could have certain tax benefits for process based R&D, public-private partnership in advanced manufacturing and better protection of trade secrets to attract proprietary know-how. Such measures would help rekindle the spirit of the previous process-oriented model, without going against the TRIPS obligations[152]. The goal should be to create technological sophistication (in manufacturing), as well as product discovery.

4. Strengthening Patent Examination Capacity

The quality of patents has a direct impact on the innovation vs competition balance. Weak or improperly examined patent of products can lead to unjustified monopoly[153]. Reforms should therefore include, among others, an increase in the number of technically trained examiners in the Patent Office, and the use of tools for artificial intelligence assisted prior art search, and regular specialised training in pharmaceutical chemistry and biotechnology. High quality examination minimises litigation, and increases certainty and ensures that exclusivity is given

[149] The Patents Act, 1970, § 84 (India).
[150] Bayer Corp. v. Union of India, (2014) 6 S.C.C. 626 (India).
[151] World Intellectual Property Organization (WIPO), *World Intellectual Property Report: Breakthrough Innovation and Economic Growth* (2015).
[152] TRIPS Agreement, supra note 1.
[153] Mark A. Lemley & Carl Shapiro, Probabilistic Patents, 19 J. Econ. Persp. 75 (2005).

to truly meritorious inventions.

5. Fostering Licensing Voluntarily and Patent Pools

Voluntary licensing arrangements are one way to provide a mechanism for negotiating a tradeoff between the goals of innovation and access[154]. Particularly in the case of essential medicines and for global health emergencies, structured voluntary licensing agreements, can be a way of providing an expanded availability, whilst still providing royalty based compensation to innovators. India may encourage participation in global pooling of patents and collaborative licensing platforms with the perspective of keeping in mind the domestic flexibility. Such cooperative approaches reduce the adversarial litigation and promote the efficient technology diffusion.

In sum, therefore, it would be a mistake to say that the future of the product-process dichotomy in India is in the death knell of product patents, but rather the perfection of the regulatory ecosystem around the same. A calibrated reform strategy can bring coherence and balance to international commitments, constitutional values and economic development goals in a coherent and harmonious patent framework.

CRITICAL EVALUATION: IS THE DICOTOMY NOW IRRELEVANT?

The process only regime in the pharmaceuticals and agrochemicals sectors was formally abolished by amendments to the Patents Act, 1970 in 2005 and thus brought India into line with its commitments under the TRIPS Agreement[155]. At first blush, such structural transformation could be seen to mean that the product-process dichotomy has lost its normative and practical value. However, on closer examination of its doctrinal and economic perspectives the distinction plays a role even in the development of patent strategy, patent enforcement dynamics and innovation paths. Rather than being an issue gone away, the dichotomy has been evolving in the context of a product patent regime.

First, enforcement burden of process patent ensures that they retain their peculiar legal nature. Unlike product patents where infringement can be demonstrated by showing that the patented product is in the market, process patents require that the alleged infringer must have used the

[154] World Health Organization, *Public Health, Innovation and Intellectual Property Rights* (2006).
[155] The Patents (Amendment) Act, 2005, No. 15 of 2005 (India).

specific patented method by showing[156]. This evidentiary problem has an ongoing doctrinal significance. Although the effect of statutory presumptions may be to the advantage of patentees in some instances relating to identical products, the practical enforcement of the two categories is materially different. The distinction still has an impact on litigation strategy and judicial analysis, therefore.

Second, strategic patent writing in the pharmaceutical sector can often be a combination of product and process protection in a layered claim. Innovator companies regularly write patent specifications including the active pharmaceutical ingredient, formulations of that ingredient, methods of manufacture and sometimes methods of use[157]. This layered architecture is in recognition of the fact that process claims, despite a product dominant environment, do have commercial value. The co-existence of these categories of claim demonstrates that the dichotomy still remains as a structural characteristic of patent design.

Third, the development of biologics and complex therapeutic products has revived the importance of process innovation. Manufacturing biologics requires complex methods of cell culture, purification and quality control which have a direct impact on therapeutic performance[158]. In such cases, proprietary processes may be the component of competitive advantage. Even where there is product patent, enforcement and exclusivity in the market could depend to a large extent on some confidential know how of manufacturing. As a result, the distinction between products and processes is still of economic importance at technologically advanced industries.

Fourth, global trade strategy provides for the continued validity of the dichotomy. Pharmaceutical production and export occurs in a multijurisdictional system in which patent times, regulatory approval and exclusivity times differ from country to country[159]. Reverse engineering and alternative process development, however, may be possible in jurisdictions where patents on the product have expired or where patents were not granted for the product. So the conceptual difference between product and process protection still has a role to play in cross-border manufacturing and supply strategies.

[156] The Patents Act, 1970, § 104A (India).
[157] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries* (2000).
[158] WIPO, supra note 5.
[159] Frederick M. Abbott, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 Am. J. Int'l L. 317 (2005).

Accordingly, as the process only regime has passed away so the product-process dichotomy has not fallen into oblivion. It has evolved from a fundamental difference of policy to an operational and strategic difference in the execution of patents in modern times.

STRIKING A BALANCE BETWEEN INNOVATION AND ACCESS: A HARMONISED MODEL.

There are several normative and economic goals that have to be balanced by a sustainable Indian patent system. It needs to meet international obligations under the TRIPS regime, protect against monopolistic waste, constitutional commitments in health of the population, and domestic innovation[160]. This balance cannot be achieved through the utilization of a single doctrinal instrument and will only be attainable through a multi-layered regulatory architecture.

The initial level of such a model is the high standards of patentability. The Patents Act, 1970 section (d) 3(d) is to be maintained as a protection against evergreening[161]. The strict enforcement of the requirements of inventive steps and novelty makes sure that exclusivity is granted to the actual technological progress. Novartis AG v. Judicial interpretation. Union of India proves that scrupulousness may go hand in hand with the compliance with TRIPS[162]. Strong examination standards will ensure the stability of the patent system, as well as avoid frivolous monopolies. The second level entails the public interest protections.

Compulsory licensing on the premises under Section 84 should still be effectively utilised in case of failure to satisfy reasonable needs of the people or because of the prohibitive prices[163]. The case law that was set in the case of Bayer Corporation v. The feasibility of this mechanism is depicted in Union of India. The social cost of exclusivity is further alleviated with complementary price regulation of essential medicines which is carried out by corresponding regulatory bodies. A combination of these tools will make patent rights work within acceptable limits in the society.

The third level focuses on the promotion of innovation. Protection of product patents will not create a research-based ecosystem in itself. To encourage indigenous innovation, more

[160] TRIPS Agreement, supra note 1.
[161] The Patents Act, 1970, § 3(d) (India).
[162] Novartis AG v. Union of India, (2013) 6 S.C.C. 1 (India).
[163] The Patents Act, 1970, § 84 (India).

funding on research and development of pharmaceuticals by the general population, tax incentives on research and development, and coordinated partnership between universities and the industry is needed[164]. Policy provision should also be given to process innovation especially in the advanced manufacturing and biotechnology fields. India can ensure its technological progress becomes balanced by enhancing its domestic research capacity so that it is no longer a generics based paradigm.

This harmonised framework enables the objectives of product patents protection and the welfare of the population to co exist in a unified regulatory framework. It recognizes that exclusivity and access are not exclusive to each other but have to be institutionally balanced.

CONCLUSION

Growing up in the context of the product-process dichotomy patenting is seen to have had significant impact within the Indian intellectual property law. In the process only regime under the Patents Act, 1970, was a calculated tool of development policy aiming at promoting the growth of domestic pharmaceutical industries and increasing access to cheap medicines. The incorporation of India into the global trade under World Trade Organization and the TRIPS Agreement created the necessity of transitioning to the protection of products patents in 2005, which radically transformed the environment in the legal sphere[165].

The change reinforced the exclusivity of patents but raised issues with regard to monopolistic prices, evergreening and slow entry of generics. Innovation by the courts, best embodied in the case of Novartis AG. Union of India this is indicative of an attempt by India to reconcile international compliance and national developmental as well as constitutional priorities[166]. The courts have confirmed that the patent law should be exercised under a wider framework of public health and that the compliance protective of TRIPS does not lead to the abolition of the sovereignty of determination of the standards of patentability.

Although the process-only regime has been eliminated, the product and process dichotomy in patent regulations is still a doctrine of economic relevance. The protection of pharmaceuticals has shifted to product patents but process innovation remains to impact enforcement,

[164] Bayer Corp. v. Union of India, (2014) 6 S.C.C. 626 (India).
[165] Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry* (2005).
[166] Novartis AG v. Union of India, (2013) 6 S.C.C. 1 (India).

competition and development in technology[167]. The difference has transformed into a structural exclusion to a subtle operational instrument of a hybrid patent system.

The issue that India is facing is not that it should revert to a pre-TRIPS model but perfect its calibrated strategy. Strict patent standards, strong enforcement of policy to safeguard the interests of the larger public and active promotion of innovation can enable India to maintain its constitutional obligation of ensuring social justice and at the same time to maintain economic growth and remain competitive in the world market.

Finally, the product process argument exposes a more important fact concerning the patent law within a developing democracy: this is not just a technical system of protecting inventions, rather, a normative framework, which attempts to negotiate the ethical and economic limits of monopoly in the attempt to attain a just development.

[167] Carlos M. Correa, *Intellectual Property Rights, the WTO and Developing Countries* (2000).