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PHARMACEUTICAL PATENT STANDARDS AND REGULATORY APPROACHES: A COMPARATIVE ANALYSIS OF INDIA, THE UNITED STATES, AND THE EURO

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ABSTRACT

At the intersection of intellectual property rights that seek to incentivise innovative activity (notably through patent law), the imperatives of public health that call for affordable access to essential medicines, and the requirements of international trade law that binds states to minimum standards of patent law protection. The ways, standards and tests of various jurisdictions with respect to the patentability of pharmaceuticals can have a serious impact not just on the commercial interests of pharmaceutical firms and generics but on the health and life of millions of human beings who rely on affordable medicines for treatment of life-threatening diseases. This article carries out a detailed comparative legal study of pharmaceutical patent standards and regulatory regimes of India, the US and the EU, which all stand at different poles in the international pharmaceutical patent debate. The purpose of the analysis is to examine how each jurisdiction interprets, and applies core patentability requirements to pharmaceutical inventions, how each jurisdiction addresses challenges that pharmaceutical patents pose including, evergreening, the patent-regulatory interface and so on, and how each jurisdiction uses compulsory licensing, opposition mechanisms and other features to manage the tension between the private rights of pharmaceutical patent holders and public health obligations of states. According to the article, the three jurisdictions have developed fundamentally different approaches reflecting their particular economic circumstances, public health priorities and positions in the global pharmaceutical value chain. Furthermore, the article makes evidence-based reform recommendations aimed at improving the alignment between pharmaceutical patent standards and global public health objectives.

Keywords: Pharmaceutical Patents; TRIPS Agreement; Section 3(d); Evergreening; Compulsory Licensing; Hatch-Waxman Act; Supplementary Protection Certificates; Data Exclusivity; Access to Medicines; Global Health Equity; Novartis AG v. Union of India.

I. INTRODUCTION

The area of overlap between pharmaceutical patents and public health is one of the most important and contested areas of contemporary international intellectual property law. Patents on the pharmaceutical products and processes provide the legal means by which pharmaceutical companies recover the massive investment necessary for research and development of their drugs. Patents provide exclusive rights that allow the patent holder to set prices much higher than the marginal cost of production for a set period.

The argument asserts that the absence of such exclusivity would critically undermine the motivation to invest in the costly and uncertain

process of creating new medicines. The consequence likely would be reduced innovation in pharmaceuticals and worse health outcomes for populations worldwide. The premise which underlies the international pharmaceutical patent system of providing an innovation incentive for pharmaceutical patent protection is one that has been accepted by varying degrees of critical scrutiny by the governments and international organisations and legal systems that have built and sustained that system.

A patent's exclusion creates incentive for innovators but also hinders access for patients. Patent holders can use their exclusive rights to charge supracompetitive prices for essential medicines. And this can make life-saving medicines unavailable to patients who cannot afford these prices. This is a serious issue in low and middle-income countries (LMICs) where the majority of the world's population lives. Moreover, the healthcare budgets in LMICs are a small fraction of those in developed countries. The conflict between the rights that pharmaceutical patents give to the private and the obligations states owe the public to protect public health is thus a structural element of the present international intellectual property system not a contingent failure that will correct itself with better enforcement or minor regulatory amendments, but a fundamental choice embedded in the design of a system that simultaneously provides two incompatible social goods, pharmaceutical innovation and pharmaceutical access.

The TRIPS agreement, adopted with the establishment of the World Trade Organization in 1995, set the international standard for pharmaceutical patents. . The adoption of this resolution was not without controversy. Under the TRIPS Agreement, all WTO member states must comply with minimum standards requiring that patent protection for pharmaceutical products and processes shall be made available. Furthermore, there is an elimination of the option used by many developing countries to exclude pharmaceutical products from patent protection. In this way, the T.R.I.P.S. Agreement enhances the effectiveness of patent protection on a world-wide scale. The Patents Act 1970 of India excluded pharmaceutical products from being patented. It helped in the establishment of a strong domestic generic pharmaceutical industry that supplies affordable medicines to the world. Thus, this change is absolutely fundamental and fiercely contested.

The WTO Ministerial Conference's adoption of the Doha Declaration on the TRIPS Agreement and Public Health in November 2001 gave important normative affirmation that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. WTO members may grant compulsory licences; have the freedom to determine the grounds for such licences; and have the right to use the full flexibilities available to them under these provisions in the pursuit of public health. The Declaration's political importance – the clearest international statement that drug patent rights should be subordinated to public health when required – is not matched by any equivalent practical impact. Indeed, TRIPS-plus bilateral trade agreements are progressively eroding the policy space that the Declaration affirmed.

This article analyzes the patent standards and regulatory strategies regarding pharmaceuticals in India, the United States and the European Union three jurisdictions that form three most significant poles in the global pharmaceutical patent system. The vast majority of global pharmaceutical R&D investment, pharmaceutical patent grants and generics production is concentrated in the two regions. Thus, a comparison of their approaches offers insights into the menu of policy options that are available to states within TRIPS, as well as the reforms that are necessary in the field of patenting pharmaceutical to better align standards with global public health.

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II. THE TRIPS FRAMEWORK AND ITS PUBLIC HEALTH FLEXIBILITIES

A. Minimum Standards and Policy Space

The TRIPS Agreement establishes certain bottom of the barrel standards for offering patent protection to pharmaceuticals but does not prescribe what the content of those patentability requirements is through which those standards are implemented. Article 27(1) creates an obligation on member states to make patents available for any inventions whether products or processes, in all fields of technology that are new, involve an inventive step, and are capable of industrial application. According to Footnote 5, inventive step and industrial applicability may be treated as the same as non-obviousness and utility, respectively. Apart from this minimal sketch, the Agreement says nothing more about the content of those requirements, which gives WTO members considerable interpretative leeway in defining them in accordance with their own domestic patent law tradition and public policy goals.

The comparative evaluation of pharmaceutical patent standards is based on this interpretive flexibility. As stated by Correa's authoritative commentary, members of the WTO are not obliged to apply any particular standard of inventive step or novelty; they are only obliged to make patents available for inventions meeting those requirements however they choose to define them within the terms of the Agreement. A member that applies a high inventive step standard requiring significant and demonstrable advancement over the prior art like India's Section 3(d) for pharmaceutical inventions is not violating the TRIPS Agreement as long as it applies this high standard consistently and does not discriminate against foreign patent applicants in violation of the non-discrimination provisions of the TRIPS Agreement.

B. The Doha Declaration and Compulsory Licensing

The Doha Declaration, paragraph 4, says that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Further, the Agreement must be interpreted and implemented in a manner supportive of WTO members' right to protect public health and promote access to medicines for all. Paragraph 5 acknowledges that each member has the authority to give compulsory licences and the discretion to choose the justification on which such licences are granted, a crucial acknowledgment that is directly relevant for compulsory licensing in India.

Under Article 31 of the TRIPS Agreement, World Trade Organization (WTO) members are allowed to authorize the use of patent subject matter without the authorization of the right holder. This authorization will not be granted in all circumstances and authorization will only be granted in case there is compulsory licensing. Moreover, there will be requirements which are as follows: efforts to obtain voluntary authorization on reasonable commercial terms were made prior to the license (there are exceptions for emergencies also), the scope and duration of the license is limited to the purpose, adequate remuneration is paid to the right holder, the authorization is subject to judicial review. Due to the procedural complexity of these conditions and the extra complexity of the Paragraph 6 mechanism for export compulsory licences to countries with insufficient manufacturing capacity, compulsory licensing as an access to medicines tool has been of limited practical use in most developing countries outside India.

C. TRIPS-Plus Obligations and the Erosion of Policy Space

The TRIPS-plus provisions found in bilateral and regional free trade agreements extend the pharmaceutical patent obligations beyond the minimum standards set out in the TRIPS Agreement. This is the major threat to

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developing countries' ability to implement public health-oriented patents. International trade agreements negotiated by the US and EU with developing country partners have included obligations going well beyond minimum TRIPS obligations to include patent term extensions for regulatory delay; prohibition of parallel importation; patent linkage; enhanced data exclusivity periods; and limitation on grounds for compulsory licensing of patents.

The combined impact of these provisions results in a two-level international pharmaceutical patent system, where developed nations maintain the power to tailor their drug patenting systems to meet their national goals while developing nations are prevented from exercising similar public health flexibility. There is a basic contradiction between the Doha Declaration, which affirms developing countries' right to use TRIPS flexibilities for public health, and the bilateral trade practices of the countries that endorsed it.

III. INDIA: THE MOST DELIBERATE USE OF TRIPS POLICY FLEXIBILITY

A. Historical Context and the Pre-TRIPS Regime

The post-independence development strategy of India is reflected in pharmaceutical patent history. The Patents and Designs Act, enacted in 1911 during the colonial period, provided full product patent protection for pharmaceutical compounds. This concentrated market power in foreign multinationals and ensured medicine prices beyond the reach of most Indians. The 1959 Justice Ayyangar Committee Report noted that medicine prices were primarily high due to the pharmaceutical patent system and recommended its reorganization. As a result of the Patents Act 1970, product patents of pharmaceutical compounds were abolished in India. Only process patents were permitted with a curtailed term of seven years allowing Indian manufacturers to produce generic versions of patented drugs elsewhere through alternative processes of manufacture.

This intentional choice brought about change. Before the TRIPS Agreement, India's pharmaceutical industry acquired the capacity for the production of low-cost generic versions of patented medicines and emerged as one of the largest generic pharmaceutical industries worldwide. India provided about 20% of the world's generic medicine by volume and 60% of the world's vaccine supply in 2005. Additionally, it was the main supplier of affordable antiretroviral medicines for the treatment of HIV/AIDS that were offered to governments across sub-Saharan Africa. As a result, the risks associated with the implementation of TRIPS were especially high, not only for India's domestic industry but for the global access to medicines agenda.

India demonstrated its response to the TRIPS obligations through the passing of the Patents (Amendment) Act 2005. It is evident that this Act implemented the minimum obligations imposed by the Agreement but did use every flexibility possible to limit the scope of the pharmaceutical patent. Of all the such limitations, probably the most important one is Section 3(d). This is the most unique and arguably internationally significant aspect of Indian pharmaceutical patent law..

B. Section 3(d) and the Enhanced Efficacy Requirement

According to Section 3(d) of the Patents Act 1970 (as inserted by the Patents (Amendment) Act 2005), 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 will not be treated as an invention. As per the Explanation, any salt, ester, ether, polymorph, metabolite, pure form, particle size, isomer, mixture of isomers, complex, combination and other derivatives of a known substance would be treated as that substance unless they differ in properties with regard to efficacy significantly.

The provision in Section 3(d) of the Indian Patents Act 1970 was incorporated specifically to curb the practice of patenting a new form of

a known pharmaceutical substance so as to extend the monopoly on it. The evergreening modifications that companies usually use like polymorphs, salts, esters, and new formulations are exactly the same as those mentioned in the Explanation needing proven efficacy enhancement for patent protection. The specificity of this measure suggests an advanced appreciation of patenting strategies within the pharmaceutical sector, coupled with a deliberate attempt to prevent the abuse of evergreening.

The term "efficacy" is the most litigated term under Section 3(d). The pharmaceutical industry has been arguing for a broad interpretation. This is the meaning which includes improved pharmaceutical properties. This includes improved solubility, stability or bioavailability. It must include any improvement in those properties which takes effect. The Indian Patent Office has been advocating for a narrow interpretation. The new interpretation requires the demonstration of improved efficacy. The efficacy should be an improvement in the treatment of a disease. Issue and judgment of the Supreme Court of this contest in Novartis AG v. Union of India is the most important judicial decision in the history of Indian pharmaceutical patent law.

C. Novartis AG v. Union of India: The Landmark Judgment

The Supreme Court's 2013 decision in the matter of Novartis AG v. Union of India (2013) 6 SCC 1 took place when Novartis applied for a patent regarding the beta-crystalline form of imatinib mesylate, i.e., the active ingredient of the cancer medicine Glivec. This patent application was rejected by the Indian Patent Office on the grounds that it failed to meet the enhanced efficacy requirement of Section 3(d). Novartis argued and demonstrated that beta-crystalline polymorph had about 30% higher bioavailability than the amorphous form of imatinib mesylate, an improvement in the physico-chemical properties, which constituted enhanced efficacy.

Supreme Court made it clear that 'efficacy' in the pharma context means therapeutic efficacy ability to produce a therapeutic effect in the treatment of a disease in humans and not the physico-chemical properties like solubility and bioavailability. The Court reasoned that the effect should not be interpreted in terms of physico-chemical properties, as it would destroy the very object of Section 3(d) if companies are permitted to patent a new form on the basis of property improvement without any outcomes.

The failed clinical evidence for better therapeutic effect for cancer patients despite improved bioavailability alone was insufficient to prove enhanced therapeutic efficacy under Section 3(d).

The Court rejected the constitutional challenge under Article 14 filed by Novartis as well as the TRIPS-compatibility argument by concluding that Section 3(d) is a legitimate exercise of India's TRIPS policy space. The TRIPS Agreement's silence on the content of the inventive step requirement gave India the right to define it in a manner consistent with public health, provided that the standard was applied consistently and without discrimination. This conclusion, directly supported by Correa's authoritative TRIPS commentary and Kapczynski's landmark analysis of TRIPS implementation in India, indicates that demanding pharmaceutical-specific patentability standards comply with TRIPS minimum obligations.

The judgment had significant practical implications. The generic makers of imatinib were not challenged legally, despite the fact that their prices were significantly below that of branded Glivec of Novartis. To be more specific, the ruling set a global precedent affirming that high demands for pharmaceutical patent standards would withstand constitutional and TRIPS-compatibility challenges. Moreover, it could provide a model for other developing countries looking to do the same. The empirical study of Sampat and Shadlen demonstrates the

effectiveness of Section 3(d). India experiences much lower rates of secondary pharmaceutical patenting from Brazil, which adopted a more lenient TRIPS implementation.

D. Compulsory Licensing: The Natco-Bayer Decision

There is a provision in India's patent law for compulsory licensing. Three years after a patent is granted, the Patents Act 1970 enables application for compulsory licences on various grounds. These include that the reasonable requirements of the public are not satisfied, that the patented invention is not available at a reasonably affordable price, or that the invention is not worked in India. The compulsory licence granted by the Controller of Patents in March, 2012 to Natco Pharma for sorafenib, the cancer medicine branded Nexavar by Bayer, is India's most significant pharmaceutical compulsory licensing decision.

In the Controller's view, Bayer was supplying only a tiny fraction of India's requirement for sorafenib, branded Nexavar was ₹ 280,000 a month which was beyond the reach of the overwhelming majority of patients and Bayer was not making it in India and as such all the 3 grounds of Section 84 were satisfied. Natco was ordered to pay a royalty at 6% of its net sales, which was consistent with the adequate remuneration required by TRIPS Article 31(h). Natco's generic sorafenib, the price was reduced by more than 96% at ₹8,880 per month. The Intellectual Property Appellate Board and subsequently the Bombay High Court upheld the ruling confirming the legal validity and working of compulsory licensing regime in the country.

The Natco-Bayer ruling showed that pharmaceutical compulsory licensing can be operationally effective producing extraordinary access benefits in a reasonable time-frame when legal standards are clear, institutional capacity is adequate and there is political will.

IV. THE UNITED STATES: THE PERMISSIVE INNOVATION-ORIENTED MODEL

A. Patentability Standards and the Non-Obviousness Requirement

The US patent system, which gives protection to a patent, is the patent Act 1952(35 U.S.C.), that specifies patent protection over any new and useful process, machine manufacture, or composition of matter. In pharmaceutical patent disputes, the claim of non-obviousness a Section 103 requirement of the US (as opposed to the inventive step requirement of the TRIPS) is the most significant and contested patentability standard. The 2007 Supreme Court case KSR International Co. v. Teleflex Inc. (2007) 550 US 398 rejected the Federal Circuit's teaching-suggestion-motivation test. While the Court maintained that patent obviousness must nonetheless be examined, it suggested that patentability to combine known ideas must not be overly demanding. In the case of predictable arts like pharmaceutical chemistry, however, the bar should be set higher.

The application of KSR in reviewing pharmaceutical patents has not produced as broad an impact as its words might suggest. Given that the decision was intended to tighten the non-obviousness standard in theory, one would expect fewer secondary pharmaceutical patents to be granted. Yet, as Feldman's well-known study shows, roughly 78% of drugs associated with new patents during the period studied happen to be old drugs rather than new ones. More importantly, the USPTO continues to grant a high proportion of secondary pharmaceutical patents on polymorphs, salts, new dosage forms, and combination products that are arguably an obvious modification of a known compound.

The institutional limitations of patent examination and the resources that pharmaceutical companies are willing to dedicate to building prosecution records to support patentability arguments have led to this implementation gap.

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B. The Hatch-Waxman Act and Evergreening

The Hatch-Waxman Act, enacted in 1984, which is also referred to as the Drug Price Competition and Patent Term Restoration Act, established a specialized system for the interplay between pharmaceutical patents and FDA regulatory approval. This has had a major impact on the US pharmaceutical market.

The Act allowed an abbreviated new drug application process for generic entry allowing for generic approval based on demonstrated bioequivalence and patent term restoration compensating patent holders for the regulatory approval period. The framework for evergreening using patent listings resulted from the Orange Book listing system and the patent linkage mechanism. Generic ANDA applicants must certify their position on listed patents when they file. Furthermore, Orange Book provisions create automatic 30-month stays of generic approval in case brand manufacturers file suits for infringement.

Hemphill and Sampat show that brand pharmaceutical firms exploit the listing and linkage mechanisms of the Orange Book to effectively extend market exclusivity through secondary patents through the use of formulation patents, metabolite patents, and method-of-use patents. Brand-name drug manufacturers often enter into pay-for-delay settlements with first-filer generic companies, where they pay the latter to delay market entry. These settlements effectively extend exclusivity for the brand-name manufacturer, and while the legality of these settlements has been addressed by the Supreme Court in FTC v. Actavis (2013) 570 US 136, the Court did not find them to be illegal. In his empirical scholarship, Kesselheim continuously finds that drug prices fall substantially, often by 80 percent or more, when generic competition enters the market. As such, evergreening patents that cause delays to generic entry impose substantial costs on American patients and payers. The total welfare cost of pharmaceutical evergreening in the US is estimated to be in the billions of dollars each year. In other words, this represents a huge transfer from patients and payers to pharmaceutical patent holders without offsetting benefits in new medicines that are really innovative.

C. Biologics and Regulatory Exclusivity

The BPCIA (Biologics Price Competition and Innovation Act 2010) established a similar structure for biological medicines with even stronger market protection provisions. Reference biologics should also enjoy 12 years of regulatory data exclusivity. In addition, there is a complicated multi-round "patent dance" procedure which governs biosimilar patent disputes. The experiences where multiple approved biosimilars adalimumab (Humira) were delayed from entering the US market for years through an extensive secondary patent portfolio and complex licensing arrangements by AbbVie highlights how the biologics patent system enables evergreening activities, at least as extensive as in the small-molecule context.

The United States does not have a general pharmaceutical compulsory licensing provision. The primary way in which the government uses patented technology is under 28 U.S.C. § 1498, which limits the patent holder's remedy to reasonable compensation when the U.S. government or a contractor uses the patented invention without authorization. During the anthrax episode of 2001, this mechanism was endangered but never formally used. The Inflation Reduction Act 2022, which empowers Medicare to negotiate drug prices for a set of selected drugs, is the most significant recent policy change. This provides a market-oriented mechanism for price reduction that serves as a partial substitute for the compulsory licensing mechanism which is not available in the US context.

V. THE EUROPEAN UNION: THE INTERMEDIATE MODERATELY DEMANDING APPROACH

A. The EPO's Problem-Solution Approach

The European Union's pharmaceutical patent system operates through the European Patent

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Office established under the European Patent Convention 1973, which grants patents across EPC member states through centralised examination applying harmonised patentability standards. The EPO has a unique input into the evaluation of usefulness of a pharmaceutical patent called the problem-solution approach to inventive step. The problem-solution approach is a structured method requiring identification of the closest prior art, determination of the objective technical problem solved by the claimed invention, and evaluation as to whether the proposed solution would have been obvious to a person skilled in the art.

The EPO's application of the problem-solution approach to pharmaceutical inventions generates a somewhat more demanding inventive step standard than the USPTO's non-obviousness test particularly for selection inventions, where the EPO requires that selected sub-groups of pharmaceutical compounds exhibit a surprising technical effect not predictable from the prior art. The standards provided by this standard afford a somewhat better protection against the more obvious secondary pharmaceutical patents than the US approach, although the EPO's practical application of the surprising effect requirement has been criticized for being insufficiently demanding, with modest evidence of unexpected properties sometimes accepted as sufficient.

The EPC Article 54(5)'s provision for second medical use patents permits patents on second medical uses of known compounds where the use is novel and inventive. This offers scope for the continuing accumulation of use patents on existing pharmaceutical compounds with indication-specific patent protection extending effective exclusivity. The CJEU's assessment in the case of Warner-Lambert Company LLC v. Generics (UK) Ltd (C-423/17) [2018] concerns the extent to which generic carve-out labelling avoids infringement of a second medical use patent without unduly hindering competition on unpatented indications.

B. Supplementary Protection Certificates

The Supplementary Protection Certificate system of the European Union, developed by Regulation (EC) No 469/2009, provides effective patent protection for an additional five years for approved pharmaceutical products in order to compensate for the regulatory approval period during which the patent holder is not able to commercially exploit the invention. The SPC system is based on a sound rationale of restoring patent term lost to regulatory delay, similar to the US patent term extension mechanism under Hatch-Waxman, but has been implemented in ways that often extend effective exclusivity beyond what any plausible estimate of regulatory delay would justify.

The CJEU has developed an extensive but sometimes inconsistent SPC jurisprudence in its preliminary reference rulings. The judgments in Actavis Group PTC EHF v. Sanofi (C-443/12) [2013] and Teva UK Ltd v. Gilead Sciences Inc. (C-121/17) [2018] tackled the basic question of which products may be protected by an SPC based on a particular basic patent. They adopted and partially qualified the "core inventive advance" test, creating a lot of legal uncertainty for both the originator and the generic producers attempting to plan market entry. The basic patent protection, SPC extension, and EU regulatory data exclusivity combined can give rise to effective market exclusivity periods of twenty years or more from marketing authorisation often well beyond the twenty-year basic patent term of the TRIPS Agreement in practical effect.

C. Data Exclusivity and Regulatory Exclusivity

As per Directive 2001/83/EC, Europe has a regime that provides 8+2+1 regulatory exclusivity. In other words, after marketing approval, generics get eight years of data exclusivity during which they cannot rely on the reference medicine's clinical data. Subsequently, there are two years of market exclusivity during which approved generics cannot be placed on the market. Moreover, it allows for a possible additional one-year

extension of exclusivity for new therapeutic indications. This framework creates barriers to generic entry that are entirely independent of patent protection. These barriers are not capable of being challenged through patent opposition, invalidity proceedings or compulsory licensing. There is therefore a significant gap in the access to medicines toolkit available to EU member states.

VI. COMPARATIVE ANALYSIS: DIVERGENCE, CONVERGENCE, AND LESSONS

A. Patentability Standards: A Spectrum of Stringency

The comparative analysis showcases an increasing level of rigidity with regard to pharmaceutical patentability.

The strictest bar is Section 3(d) of the Indian Patents Act requiring demonstration of enhancement of efficacy for the new form of known substance and which is specifically aimed at the most common forms of pharmaceutical evergreening. The EPO's moderately demanding intermediate position requires evidence of surprising technical effect as a problem-solution approach. The USPTO's non-obviousness standard despite KSR's theoretical tightening is the most liberal in practice, allowing for routine grant of secondary pharmaceutical patents on modifications which India and occasionally the EPO would reject.

A likeness of the two is educational. A pharmaceutical polymorph application claiming enhanced bioavailability in the absence of clinical proof of superior therapeutic benefit would fall foul in India (under the Novartis interpretation of Section 3(d)); might be turned down, and if not granted must contain a finding of prior art establishing that the outcome was a predictable expectation of screening for polymorphs, by the EPO; and be granted (frequently) by the USPTO, since improved bioavailability, it would seem, is a sufficient demonstration of a non-obvious step.

These different results have repercussions for generic market entry timing and drug pricing in each jurisdiction.

B. The Evergreening Problem: A Comparative Assessment

The United States has the most extensive and most structurally-embedded pharmaceutical evergreening. According to Feldman, roughly 78% of drugs linked to new patents were actually not new drugs, but rather existing ones. This statistic communicates the magnitude of the problem and highlights the systematic patenting of existing drugs through the exploitation of patenability standards. India has the best measures to evergreening prevention. Section 3(d)'s therapeutic efficacy requirement specifically targets the most common forms of evergreening patent modification. Robust pre-grant and post-grant opposition mechanisms provide easy tools for contesting undeserving applications. The European Union presents an intermediate picture. EPO standards provide some protection against obvious secondary patents but the SPC and regulatory exclusivity framework provide alternative channels for extending effective exclusivity that cannot be challenged through patent-specific mechanisms.

C. Compulsory Licensing: Political Will as the Critical Variable

The comparative study of compulsory licensing shows that the crucial variable in determining whether compulsory licensing works as an effective access mechanism is political will, and not legal standards or institutional capacity. India's Natco-Bayer decision illustrated how operationally effective compulsory licensing that produces 96% price reductions is feasible within the parameters of the TRIPS Agreement when appropriate legal standards are established, institutional capacity is sufficient, and there is political will. The United States refuses to invoke § 1498 in practice owing to the political influence of the pharmaceutical industry over US policy. The EU's system poses political challenges that are reflected in the

member state level quasi-competitiveness. The COVID-19 pandemic revealed the insufficiency of existing ways to deal with global health emergencies, which has led to proposals for reform in all three jurisdictions and the most significant recent initiative is the European Commission's proposed EU Compulsory Licensing Regulation.

D. Global Health Equity: The Most Important Evaluative Criterion

An evaluation criterion applied to assess each jurisdiction which pharmaceutical patents contribute to equitable global distribution of pharmaceutical innovation and access results in a noteworthy differential. India makes the most positive contribution as the principal Provider of generic medicines which are affordable for the markets of developing countries. Also, it shows through Section 3(d) that demanding pharmaceutical patent standards are achievable within the TRIPS framework. The United States arguably stands out as the most negative contributor to global systems affecting patents and public health through both permissive domestic evergreening facilitation and systematic use of bilateral trade leverage to impose TRIPS-plus pharmaceutical obligations on its developing country partners that constrain the ability of these partners to adopt Section 3(d)-equivalent standards. The European Union is concerned about access to medicines in its development policy rhetoric. But its trade negotiating positions on patenting pharmaceutical intellectual property are captured by the pharmaceutical industry most of the time.

VII. POLICY RECOMMENDATIONS

A. For Developing Countries: Adopt Section 3(d)-Equivalent Provisions

WTO members from developing countries should incorporate provisions into their legislation equivalent to India's Section 3(d), which imposes the requirement of therapeutic efficacy for patents on new forms of known substances in pharmaceuticals. The Novartis ruling establishes that such clauses are in line with TRIPS and the Constitution. Empirical evidence demonstrates that they effectively reduce secondary pharmaceutical patenting. The Doha Declaration affirms the right of WTO members to use TRIPS flexibilities to protect public health. Section 3(d)-equivalent provisions represent the most operationally tested exercise of this right. WHO and WIPO technical assistance should support developing countries wishing to implement equivalent provisions.

B. For the United States: Reform the Hatch-Waxman Framework

To prevent evergreening by the pharmaceutical companies, the US Congress and the FDA must modify the Orange Book listing system. Only patents directing claiming the approved active ingredient should be eligible and not secondary patents on formulations, metabolites and method of use. The automatic 30-month stay of generic approval must be restricted to patents that directly claim the active ingredient. A shorter period, not exceeding 30 days, must replace the automatic stay of an appeal. These reforms would address the most severe structural vulnerability of Hatch-Waxman to abuse, but they would not undermine the framework's positive facilitation with respect to genuine patent expiry.

C. For the European Union: Reform the SPC System

The SPC system should be revised by the EU so that certificates compensate only for regulatory setbacks caused by the approval process and that the SPC does not provide effective exclusivity periods beyond what is justifiable for innovation policies. The eligibility criterion of SP is confined to the active ingredient which is claimed as a core inventive advance of the parent patent. The maximum SPC term should be reset according to the real average delay in regulation. The ongoing review conducted by the Commission of EU pharmaceutical legislation is a suitable moment for this reform.

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D. For the International Community: Strengthen Compulsory Licensing Mechanisms

The WTO should comprehensively reform the Article 31bis mechanism implementing Paragraph 6 of the Doha Declaration to eliminate the procedural complexity that has rendered export compulsory licensing practically unusable. The WTO notification by an importing country of intention to import under a compulsory licence, followed by issuing of the licence by the exporting country without any individual approval by the WTO, should replace the current multistage approval process.

E. For All Jurisdictions: Exclude TRIPS-Plus Provisions from Trade Agreements with Developing Countries

The US and EU should adopt formal negotiating mandates excluding TRIPS-plus pharmaceutical patent provisions from free trade agreements with developing country partners. These provisions limit the policy space available to WTO members for public health purposes that the Doha Declaration affirmed. These provisions creation of data exclusivity, patent term extensions, patent linkage requirement and limits on compulsory licensing ground. Agreements that include such provisions should be reviewed and amended so that they do not contain obligations on developing countries beyond the minimum standards of TRIPS.

VIII. CONCLUSION

The comparative examination by the Organization for Economic Co-operation and Development (OECD) of the pharmaceutical patent standards and regulatory approaches in three major jurisdictions, India the United States and the European Union, confirms that these three jurisdictions have developed fundamentally different approaches reflecting different political choices about whose interests the pharmaceutical patent system is designed to serve.

These choices have large and direct implications for the health and lives of millions of people who depend on affordable medicines.

The Indian government has consciously used the TRIPS policy flexibility under Section 3(d), which shows that the public health flexibilities contained in the TRIPS Agreement are real and meaningful. Further, it shows that a developing country government with the necessary political will and institutional capacity can ensure that the pharmaceutical patent standards they adopt accord with public health imperatives, without violating international legal obligations.

The confirming of the TRIPS-compatibility and constitutional validity is the most significant legal barrier in other developing countries' adoption of the Novartis judgment's section 3(d).

The United States and European Union, by contrast, have systematically given priority to the commercial interests of the pharmaceutical industry over patient access through permissive patentability standards, complex regulatory exclusivity mechanisms, and the gradual use of their bilateral trade leverage to export such standards to developing countries. The COVID-19 pandemic has demonstrated that the current international pharmaceutical patent system is not fit for purpose for responding to global health emergencies. For the first time in over 30 years, there is arguably important momentum to make the necessary legislative, regulatory, and trade negotiating reforms to create a system of pharmaceutical patent standards which is aligned with global public health objectives. This article identifies the key reforms which must be pursued to sustain this momentum.

The most enduring lesson of the comparative study is at once the simplest and most important: the standards of pharmaceutical patents are not technical legal rules that exist in a political vacuum. Rather, they are consequential political choices essentially determining who has access to medicines and who has not. Choice of India to place human

lives above pharmaceutical industry profits within its international legal obligations is a model that other jurisdictions, and the international community, have both the legal capacity and the moral obligation to follow. According to the report, the experts advised low-cost generic drugs for COVID-19 and also supported licensing to India.

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