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FLEXIBILITIES UNDER TRIPS: AN ANALYSIS OF THE PROPOSAL FOR REFORMING BRAZILIAN PATENT LAW

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ABSTRACT

This article analyses the proposal for reforming the Brazilian patent system pending before the Brazilian Parliament as Bill No. 5402/13. The proposed legislation addresses such issues as the assumed insufficiency of the inventive step requirement in preventing unjustified “monopolies,” the proliferation of so-called secondary patents, and the extension of market exclusivity positions through strategic filings, which are being debated also in Europe and the U.S. The proposed legislation offers an example for possible actions in these critical areas of the patent system. In doing so, it puts forward options that depart from consolidated Western normative patterns. In analyzing the reform attempt, this article pursues two purposes. First, starting from the provisions of the Bill, it explores the flexibilities that WTO members enjoy under the TRIPS Agreement in designing rules and procedures in their patent acts. Second, it examines whether the changes proposed by Bill No. 5402/13 are consistent with its proclaimed goals, such as the aim to reserve patent protection only to “genuine innovations,” to hamper so-called “evergreening” practices by pharmaceutical applicants, and to foster incremental innovations by domestic actors. Specific attention is given in this regard to the proposals to introduce: (i) as separate criteria for patentability a “significant technical advance” in all technological fields and an “enhanced efficacy” in the chemical sector; (ii) a general prohibition of use patents; and (iii) a pre-grant and post-grant opposition system.

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ROBERTO ROMANDINI*

I. INTRODUCTION

In 2013, the Center for Strategic Studies and Debates of the Brazilian Parliament published a report (“Report”) on the national patent system.¹ One of the primary outcomes of the Report was a proposal to reform some features of the Brazilian Industrial Property Act² (Law No. 9279/96), which relates to patents and utility models.³ A bill to that effect is pending in the Brazilian Chamber under the number H.R. 5402/2013 (Bill No. 5402/13).⁴

The purpose of this paper is to assess whether or not the provisions of Bill No. 5402/13 comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS Agreement”).⁵ While this article does not intend to question the policy at the basis of attempts at reform, it will address the consistency between avowed purposes and the selected means in the framework of the TRIPS provisions.⁶

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¹ Ctr. for Strategic Stud. & Debates, *Brazil’s Patent Reform—Innovation Towards Competitiveness*, Estudos Estrategicos 1 (Braz. 2013).

² Ley No. 9279, de 14 de Maio de 1996, DIÁRIO OFICIAL DA UNIÃO [D.O.U.] de 15.5.1996, Seção 1, p. 8353 [hereinafter Law No. 9279/96]. The quotes from the provision of the Law No. 9279/96 contained in this article are taken from the translation available on the WIPO website, at www.wipo.org.

³ Ctr. for Strategic Stud. & Debates, *supra* note 1.

⁴ See H.R. 5402 (Braz. 2013) [hereinafter Bill No. 5402/13]. The quotes of the articles of the Bill No. 5402/13 contained in this article are taken from the English translation of the Bill in Annex 4 of the Report, see Ctr. for Strategic Stud. & Debates, *supra* note 1, at 112.

⁵ 1869 UNTS 299; 33 ILM 1197 (1994) [hereinafter TRIPS Agreement]. The TRIPS Agreement was adopted in Marrakesh (Morocco) on April 15 1995, and is included as Annex 1C in the Marrakesh Agreement Establishing the World Trade Organization. The Treaty came into force on January 1, 2015, but provides for a period of transition for developing Members which expired on January 1 and one for less developed WTO Members which expired on January 1, 2006, which is extendable upon request. In the specific field of patents, the TRIPS Agreement further provides developing countries the option to delay the application of provisions on product patents of Section 5 of Part II for an additional period of five years. On the implications of the TRIPS Agreement for the specific field of patents, see Joseph Straus, *Implications of the Trips Agreement in the Field of Patent Law*, FROM GATT TO TRIPS—THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 160, 178 *et seq.* (ICC Studies Vol. 18, Friedrich-Karl Beier & Gerhard Schrickler eds., 1996).

⁶ On the flexibilities provided by the TRIPS Agreement as the substantive provisions on patents, see Max Planck Inst. for Innovation & Competition, *Declaration on Patent Protection—Regulatory Sovereignty under TRIPS*, 45 INT’L REV. INTELL. PROP. & COMPETITION L. 679 (2014) (with commentary by Matthias Lamping).

There are several reasons why the proposal for reform deserves such an analysis.

First, the Bill addresses issues such as the assumed insufficiency of the inventive step as a “qualitative” requirement in preventing unjustified monopolies, the proliferation of so-called secondary patents, and “evergreening” practices, all of which are reason for concern in both Europe and the U.S.⁷ The proposed legislation offers an example for possible actions in these critical areas of the patent system. In doing so it puts forward options that depart from consolidated Western normative patterns. A clarification concerning TRIPS compliance of the measures proposed, as well as their practical implications, should prove insightful. If the outcome of the TRIPS analysis is positive for the reform, this would broaden the set of known legislative tools at the disposal of WTO members for pursuing their own innovation policy. If not, the study could at least show the way for possible adjustments to reduce the prospect of a WTO violation complaint. This seems valuable in a context where several countries are considering reforming their national patent laws⁸ or fusing them into a transnational patent system.⁹

Second, Brazil is a significant jurisdiction in the field of intellectual property. On the one hand, it has a long tradition of providing legal protection for technical innovations. As a founding member of the Paris Union for the Protection of Industrial Property, the South American republic adopted its first patent legislation as early as 1804, long before the majority of Western countries.¹⁰ Additionally, Brazil became a Contracting State of the Patent Cooperation Treaty (PCT) in 1978, and a Member of the World Trade Organization (WTO) in 1994.¹¹ By implementing the TRIPS Agreement, the Brazilian legislature adopted provisions that likely went beyond the WTO obligations. Even though, within the WTO system, Brazil has been critical towards the Western patent system, this stance has never translated into legislative measures. With a few exceptions, domestic law has followed the European model since 1996.

On the other hand, Brazil is an emerging economic power. As the seventh largest economy in the world¹² with robust industry, though stronger in sectors where patents do not traditionally play a substantial role, it represents a significant

⁷ See the literature review by Ove Granstrand & Frank Tietze, *IP strategies and policies for and against evergreening*, CIM Working Paper 2014:4, 8 et seq.

⁸ For a similar initiative on possible reform of the domestic patent law in South Africa, see Caroline B. Ncube, *The Draft National Intellectual Property Policy Proposals for Improving South Africa's Patent Registration System: A Review*, J. INTELL. PROP. L. & PRAC. 9 (10): 822 et seq. (2014).

⁹ For initiatives aimed at building a regional patent system in the ASEAN Member States, see Elizabeth Siew-Kuan Ng, *ASEAN IP Harmonization: Striking the Delicate Balance*, 25 Pace Int'l L. Rev. 129 et seq. (2013).

¹⁰ See Denis Borges Barbosa, *Patents and the Emerging Markets of Latin America—Brazil*, in EMERGING MARKETS AND THE WORLD PATENT ORDER, 135, 135 (Frederick M. Abbott et al. ed., 2013).

¹¹ On the history of Brazilian Patent System see VIVIANE YUMY MITSUUCHI KUNISAWA, *THE TRIPS AGREEMENT IMPLEMENTATION IN BRAZIL—PATENTS IN THE PHARMACEUTICAL AREA*, 23 et seq. 87 et seq. (2015).

¹² See IMF, *World Economic Outlook Database* (April 2015) available at <http://www.imf.org/external/pubs/ft/weo/2015/01/index.htm>.

market for pharmaceutical sales and manufacturing.¹³ As a result, the country is one of the main destinations for international applicants.¹⁴

In light of all these factors, a change in the patent policy of the country may have an impact at the international level. The reform could encourage imitation, challenge competitors, and affect the content of bilateral as well as regional Free Trade Agreements. Thus, it is likely to attract more than just academic attention.¹⁵

II. OUTLINE OF THE REFORM

The rules contained in Bill No. 5402/13 are not uniform, but do share a common aim: to make use of alleged TRIPS flexibilities to adapt the current patent regime to the specific needs of the Brazilian economy.¹⁶ The assumption of the reform is that Brazilian law, which in several aspects goes beyond what is required under TRIPS, has, thus far, benefited foreign applicants more than domestic players.¹⁷

The changes envisaged relate to both substantive and procedural aspects. As far as the former are concerned, Bill No. 5402/13 intends to: (1) increase the standard of inventive step required for granting a valid patent; (2) introduce a rule corresponding to Section 3(d) of the Indian Patent Act of 1970;¹⁸ (3) limit the maximum patent term to 20 years;¹⁹ and (4) provide a procedure to declare lawful public, non-commercial use of patented inventions.

With regard to procedural aspects, the aim of the proposal is to: (1) create a pre-grant opposition procedure; and (2) strengthen the role of Brazil's Health Agency, the Agência Nacional de Vigilância Sanitária ("ANVISA"), in granting proceedings concerning pharmaceutical inventions.²⁰

¹³ See EMIS, *Pharmaceutical Sector Brazil*, 2 et seq. (December 2014), www.securities.com/emis/sites/default/files/EMIS%20Insight%20%20Brazil%20Pharmaceutical%20Sector%20Report.pdf. In 2013, the Brazilian pharmaceutical market was already the sixth largest in the world in terms of revenue (\$27.3 bn). See VISIONGAIN Ltd, *Brazilian Pharmaceutical Market Outlook 2015-2025*, 2015, <https://www.visiongain.com/Report/1400/Brazilian-Pharmaceutical-Market-Outlook-2015-2025>.

¹⁴ The Instituto Nacional da Propriedade Industrial (INPI) is among the top 10 patent offices worldwide by number of patent applications filed. Filings by non-residents in Brazil in 2013 amounted to 84.6 % of all applications filed. See WIPO, *World Intellectual Property Indicators*, 2015, at 37.

¹⁵ The U.S. Biotechnology Industry Organization already requested in 2014 that Brazil be placed on the Priority Watch List. The organization's report expressly mentions Bill No. 5402/13 as a source of concern, since it "represents many of the policy asks of the generic industry and anti-IP NGO community." Biotech. Indus. Org., *Special 301 Submission*, 21 (2014), <https://www.bio.org/sites/default/files/2014%20BIO%20Submission.pdf>.

¹⁶ See Ctr. for Strategic Stud. & Debates, *supra* note 1, at 13 et seq. (arguing that "Brazil should use its inherent creative ability to adapt and tropicalize its patent system to promote public policies for innovation in the country").

¹⁷ See *id.*, at 41 et seq.

¹⁸ Under the Indian Patent Act of 1970, the following are not considered to be inventions: (1) "any property or new use of a known substance, or the mere use of a known process, unless such known process results in a new product"; and (2) "new forms of known substances that do not result in an improvement in the known efficacy of the substance." See Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India).

¹⁹ See Bill No. 5402/13, at Article 2.

²⁰ See *id.*

Finally, one additional amendment is intended to clarify the nature and limits of the protection of undisclosed data in Brazil.²¹ This protection is to be conferred only on the basis of the general rules on unfair competition. Since this article focuses on the patent provisions, this aspect of the reform will not be addressed further.²²

III. SUBSTANTIVE PROVISIONS

A. Inventive Step and Technical Advance

1. Legal aspects

According to Article 13 of Law No. 9279/96, “an invention is endowed with inventive step provided that, to a technician versed in the subject, it is not derived in an evident or obvious way from the state of the art.”²³ The provision is in line with European standards²⁴ as well as the rules of the Patent Cooperation Treaty (“PCT”).²⁵

Bill No. 5402/13 aims to amend this article. Pursuant to the proposed new wording of Article 13 of Law No. 9279/96, an invention involves an inventive step only when, for a person skilled in the art, “it does not derive in an obvious or evident manner from the prior art, and provided it represents a significant technical advance compared with the prior art.” This wording would make the inventive step dependent upon two cumulative sub-requirements: (1) non-obviousness, as already provided for under the present law; and (2) technical advance, which has to be significant to make the invention eligible for protection.²⁶

²¹ *See id.*

²² On the issue of the TRIPS-compliance of a regime of protection based on unfair competition rules for undisclosed data, *see* Max Planck Inst. for Innovation & Competition, *supra* note 6, at 690; Christopher Wadlow, *Regulatory data protection under TRIPs Article 39(3) and Article 10bis of the Paris Convention: Is there a doctor in the house?*, IPQ, 355 et seq. (2009).

²³ For a thorough analysis of this requirement in Brazilian patent law with ample references to European doctrine and case law, *see* DENIS BORGES BARBOSA, *TRATADO DA PROPRIEDADE INTELECTUAL—TOMO 2*, 1255 et seq. (2010).

²⁴ *See* Eur. Pat. Convention, *Convention on the Grant of European Patents*, Article 56 (Oct. 5, 1973, as revised Nov. 29, 2000), <http://www.epo.org/law-practice/legal-texts/html/epc/2013/e/ma1.html> [hereinafter EPC]; Council of Europe, *Convention for the Protection of Individuals With Regard to Automatic Processing of Personal Data*, Article 6 (Strasbourg, Jan 28 1981), <http://conventions.coe.int/treaty/en/Treaties/Html/108.htm> [hereinafter Strasbourg Convention].

²⁵ *See* EPC, *supra* note 24, Article 56; WIPO, *Regulations Under the Patent Cooperation Treaty*, Rule 33 (July 1, 2014), <http://www.wipo.int/pct/en/texts/rules/rtoc1.htm> [hereinafter Regulations PCT].

²⁶ Technical advance as a sub-requirement for protection is also provided under Indian law. According to Sec. 2 1 (ja) of the Indian Patent Act “inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.” Nevertheless, there are two differences to Article 3 Bill 5402/2013. First, under Indian law technical advance does need to be significant to make the invention eligible for protection. Second, technical

The first commentaries on the rules hold that this amendment is TRIPS-compliant.²⁷ According to this view, the Member States have leeway to determine their own standards of patentability. Therefore they may provide the technical advance as a prerequisite for the validity of a patent and a utility model without violating international law. However, with respect to patents,²⁸ the amendment could turn out to be more problematic than expected under the perspective of the TRIPS Agreement. Whether or not this is the case will depend on how the concept of “significant technical advance” is understood. At least two interpretations are possible and have, in fact, been adopted by those jurisdictions which provided in the past,²⁹ or still provide nowadays,³⁰ for an advance in the art as a requirement for patentability.

If a technical advance is always considered present when a new solution to achieve a result is disclosed, regardless of whether or not it works better than previous means—as has been the German³¹ and Swiss³² practice in the last century

advance is provided as alternative and not cumulative to the requirement for economic significance. Therefore, a solution that does not imply a significant technical progress could still be eligible for protection under Indian patent law. See on the Indian practice Feroz Ali Khader & Srividhya Ragavan, *Proof of Progress: the Role of the Inventive Step/Non-Obviousness Standard in the Indian Patent Office*, PATENT LAW IN GLOBAL PERSPECTIVE (Ruth L. Okediji & Margo A. Bagley eds., 2014), 572, 583 *et seq.*

²⁷ See Open Letter from Global Academics in Support of Proposal to Amend Brazil’s Patent Law to Take Advantage of TRIPS-compliant Flexibilities, (July 10, 2013) *available at* <http://infojustice.org/wp-content/uploads/2013/10/Expert-Letter-with-Signatures-10072013.pdf>; *see also* Brief Technical Review of Brazil’s Proposed Patent Law Reforms, *available at* <http://infojustice.org/wp-content/uploads/2013/10/Brief-Technical-Review-of-Brazilian-Legislation.pdf>.

²⁸ Utility models are not envisaged and not prohibited by the TRIPS Agreement. The Member States are free to provide them and define their requirements for protection. See Henning Grosse Ruse-Khan, *The International Legal Framework for the Protection of Utility Models*, Max Planck Inst. for Intell. Prop. & Competition Law Research Paper No. 12-10, at 2 *et seq.* (Oct. 1, 2012), http://www.wipo.int/edocs/mdocs/aspac/en/wipo_ip_kul_12/wipo_ip_kul_12_ref_t2b.pdf.

²⁹ In Switzerland and Germany, existence of a technical advance was required by case law, but not explicitly specified as a prerequisite for patentability by the respective patent acts. For Switzerland, *see* ALOIS TROLLER, IMMATERIALGÜTERRECHT 175 (Helbing & Lichtenhahn eds., 2nd ed. 1959). For Germany, *see* REBEKKA ÜBLER, DIE SCHUTZWÜRDIGKEIT VON ERFINDUNGEN 85 (Mohr Siebeck Tübingen eds., 2014).

³⁰ See Article 22 of the Patent Law of the People’s Republic of China (promulgated by the Standing Comm. Nat’l People’s Cong., Mar. 12, 1984, as amended, effective Oct. 1, 2009). According to the English translation, *available at* <http://www.wipo.int/edocs/lexdocs/laws/en/cn/cn028en.pdf>, “creativity means that, compared with the existing technologies, the invention possesses prominent substantive features and indicates remarkable advancements.” The Guidelines for Patent Examination of the State Intellectual Property Office of the People’s Republic of China, by commenting on Article 22 of the Patent Law, explain: “Inventive step of an inventions means that, as compared with the prior art, the invention has prominent substantive features and represents a notable progress . . . That an invention has prominent substantive features and represents a notable progress mean, that having regard to the prior art, it is non-obvious to a person skilled in the art . . . That an invention represents notable progress means that the invention can produce advantageous technical effect as compared with the prior art . . .” See State Intellectual Property Office of the People’s Republic of China, GUIDELINES FOR PATENT EXAMINATION, 2010, *available at* <http://www.sipo.gov.cn/zlsqzn/sczn2010eng.pdf>, Part IV, Chapter 4, margin numbers 2, 2.1 and 2.3.

³¹ See German Federal Supreme Court, Decision of 24 February 1970, Reasons for the decision no. 3, INT’L REV. INTELL. PROP. & COMPETITION L. 1970, 258 X ZB 3/69—Anthrädipyrazole, according to which technical advance may exist even if the invention “resides in the fact the

and as seems to be the Chinese practice³³ today—there is no room for arguing that this criterion limits the patentability in a way that conflicts with WTO norms. Indeed, the only cases where the criterion would not be met are when the invention is already known or does not solve the problem indicated in the patent application.³⁴ Then, however, either the invention is not new, or the disclosure of the patent (application) is not enabling. In both scenarios, a rejection of the application would be justified on the basis of legal grounds, which TRIPS allows.³⁵

By contrast, if a technical advance is held to exist only when the invention is superior to the prior art³⁶—an interpretation that would be supported by the adjective “significant” adopted by Bill No. 5402/13³⁷—then the provision could be questioned under Article 27 of the TRIPS Agreement for the following reasons.

The Treaty exhaustively regulates the criteria for patentability.³⁸ This follows from the wording of:

- (i) Article 27(1) of TRIPS, according to which “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application;”³⁹

technology is furnished not with a better, but with a further “means” for which a need still exists despite the one or more relevant “means” already known.” *See also* Ortwin Schulze, *Technischer Fortschritt und Erfindungshöhe—Welche Bedeutung hat der durch die Erfindung erzielte technische Fortschritt bei der Prüfung auf Erfindungshöhe?*, *Mitteilungen der deutschen Patentanwälte*, 132, 133 et seq. (1976).

³² *See* Swiss Federal Supreme Court, Decision of 27 January 1912, *Entscheidungen des Schweizerischen Bundesgerichts*, 38 II 286 (Switz.), according to which a mechanical device implies a technical advance if the device works and is industrially applicable, independent of whether the device concerned is better than devices already used or presents disadvantages compared with them; *see also* RICHARD WEIDLICH & EUGEN BLUM, *DAS SCHWEIZERISCHE PATENTRECHT* 87 (Staempli ed., 1934).

³³ According to the Guidelines for Patent Examination of the State Intellectual Property Office of the People’s Republic of China a notable progress may exist not only when “the invention has overcome the defects and deficiencies in the existing technology,” but also when it has provided a new way to solve a specific technical problem. *See* GUIDELINES FOR PATENT EXAMINATION, *supra* note 30, Chapter 4, margin numbers 2-3. *See also* YUANSHI BU, *PATENTRECHT UND TECHNOLOGIETRANSFER IN CHINA* 21 (C.H. Beck ed., 2010); MATTHIAS STEINMANN, *GRUNDZÜGE DES CHINESISCHEN PATENTRECHTS* 121 et seq. (Carl Heymann ed., 1992).

³⁴ With reference to Chinese law, *see also* Yin Xin-Tian, *The Inventive Step Requirement Under Chinese Patent Law*, *INT’L REV. INTELL. PROP. & COMPETITION L.* 151, 156 (1989).

³⁵ TRIPS Agreement, *supra* note 5, Art. 27 & 29.

³⁶ For such understanding of the requirement in the old German literature and case law, *see* A. HAUSDING, *DIE ERFODERNISSE EINER PATENTFÄHIGEN ERFINDUNG*, 15 et seq. (1900); HANNS ULLRICH, *STANDARDS OF PATENTABILITY FOR EUROPEAN INVENTIONS* 13 et seq. (1977).

³⁷ The expression in Portuguese reads as follows: “Um avanço técnico significativo em relação ao estado da técnica.”

³⁸ *See* PETER ROTT, *PATENTRECHT UND SOZIALPOLITIK UNTER DEM TRIPS-ABKOMMEN* 210 et seq. (2002); E. Richard Gold & Alain Gallochat, *The European Biotech Directive: Past as Prologue*, 7 *EUR. L.J.* 331, 359 et seq. (2001); Dorothy Du, *Novartis AG v. Union of India: ‘Evergreening,’ TRIPs, and ‘Enhanced Efficacy’ Under Section 3(d)*, 21 *J. INTELL. PROP. L.* 223, 244 (2014).

³⁹ *See* NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF PATENTS AND TEST DATA* 288 (4th ed. 2014). De Carvalho observes that if Article 27 of the TRIPS Agreement allowed substantive requirements other than novelty, industrial applicability, and inventive step, the Member States would have chosen a different wording (“provided that *at least*, they are new, involve an inventive step, and are capable of industrial application”).

- (ii) Article 70(2) of TRIPS, according to which “the Agreement gives rise to the obligation in respect of any subject matter existing at the date of application of the Agreement for the Member in question, and which is protected in those Member States on said date, or which meets or subsequently comes to meet the criteria for protection” under the terms of the Treaty;
- (iii) Article 70(8) of TRIPS, according to which the Member States must apply to patent applications filed under the mailbox system on the date of application of the Treaty the criteria for patentability “as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member.”

The transitional provisions mentioned above—Articles 70(2) and 70(8) of TRIPS—both seem to exclude the possibility of criteria for protection other than those listed in Article 27(1) of TRIPS applying to subject matter existing before the entry in force of the Agreement or to mailbox applications filed after that date.⁴⁰

The term “patentability” pursuant to Article 70(8)(b) of TRIPS refers to the ontological features required for a subject matter to be eligible for protection.⁴¹ Technical advance as a condition for grant would be one of these features. Indeed, it relates to the invention, and not to the patent application or the inventor. Article 27 of TRIPS does not mention a technical advance as being a prerequisite for protection.⁴² As a result, if this term in the wording of Bill No. 5402/13 is intended to imply something different and more than the disclosure of a novel, inventive, and industrially applicable subject matter, such a rule could be found to be *prima facie* inconsistent with Article 27(1) of TRIPS.

A possible argument against this conclusion is that the inventive step is not defined in the Agreement. For this reason, Member States may allow patenting only when the claimed invention advances the prior art. However, a WTO challenge could bring forward three objections against this interpretation of the treaty.

First, the footnote to Article 27 states that the Member States may deem inventive step to be synonymous with non-obviousness.⁴³ If the national legislature were free to fill the concept of inventive step with any content, this footnote would be superfluous.⁴⁴

Second, Article 31(l)(i) of TRIPS distinguishes between patentable (and thus inventive) dependent inventions that meet the condition for granting a compulsory license because they imply an important technical advance of considerable economic significance, and patentable (and thus also inventive) dependent inventions that do not meet these criteria. The wording of this provision makes it clear that technical advance⁴⁵ and inventive step are not synonymous.⁴⁶ They represent two different concepts in the Agreement.⁴⁷

⁴⁰ See *id* at 288.

⁴¹ See TRIPS Agreement, *supra* note 5, Art. 70(8)(b).

⁴² See *id.* at Art. 27.

⁴³ See *id.*

⁴⁴ See Straus, *supra* note 5, at 196.

⁴⁵ “Avanço técnico” in the Portuguese version of TRIPS; the same expression is used by Bill No. 5402/13.

⁴⁶ See GIUSEPPE SENA, I DIRITTI SULLE INVENZIONI E SUI MODELLI DI UTILITÀ (133) (Giuffrè ed., 2011) with reference to the domestic rules of the Italian Law implementing Articles 27 and 31

Third, the practice of many WTO-Members consistently differentiates between technical advance and non-obviousness. The former is regarded as a secondary indicium for, and not as an intrinsic element of, the inventive step.⁴⁸ This distinction between the two terms is reflected in the PCT Guidelines.⁴⁹ Such practice and understanding are relevant to the construction of Article 27 of TRIPS.⁵⁰

Against this background, one might conclude that Member States are free to clarify the concept of inventive step. However, they are not entitled to subsume under this term—through legal fictions—additional criteria for patentability which are not provided for under Article 27(1) of TRIPS.⁵¹ They may not thus deny protection to an invention which is new, non-obvious, and industrially applicable on the ground that it is not better than the prior art.

While these considerations would be susceptible to being supported from a legal point of view, three counterarguments seem more convincing.

First, the footnote to Article 27(1) TRIPS allows the Member States to consider inventive step synonymous with non-obviousness, but it does not oblige them to do so.⁵² Therefore, no exhaustive definition can be inferred therefrom. Also, even if inventions that are not superior to existing products or processes can be nonobvious, the Member States nevertheless remain free to apply a stricter definition to the concept of inventive step.⁵³ They may hold an advance over the prior art to be a necessary feature of the inventive step required before granting a patent. Article 27(1) seems to allow this. The semantic content of the expression “inventive step” covers the requirement for advance.⁵⁴

TRIPS; *see also* CHRISTIAN VON KRAACK, TRIPS ODER PATENTSCHUTZ WELTWEIT: ZWANGSLIZENZEN, ERSCHÖPFUNG, PARALLELIMPORTE 185 (2006); SONIA ELISABETH KOIKKARA, DER PATENTSCHUTZ UND DAS INSTITUT DER ZWANGSLIZENZ IN DER EUROPÄISCHEN UNION 86 (2010); GESINE BERTHOLD, EVERGREENING VON ARZNEIMITTELPATENTEN 181 (2011).

⁴⁷ It might be argued that if inventive step within the meaning of Article 27 consisted of or incorporated a technical advance, then Article 31(l)(i) would have been given a different wording. For instance, it would have mandated the granting of a compulsory license only when the subsequent invention involved a *significant inventive step* of great economic importance.

⁴⁸ *See* AIPPI, *Summary Report Question Q217—The patentability criteria of inventive step/non-obviousness* (2011), at 7, available at <http://aippi.org/wp-content/uploads/committees/217/SR217English.pdf>.

⁴⁹ *See* MARKUS NOLLF, TRIPS, PCT & GLOBAL PATENT PROCUREMENT 57, note 147 (2001). Nollf refers to the PCT Preliminary Examination Guidelines, IV-1.3. “The PCT does not require explicitly or implicitly that a claimed invention must entail some technical progress. Nevertheless, advantageous effects, if any, with respect to the prior art should be stated in the description, and any such effects are often important in determining ‘inventive step.’” *Id.*

⁵⁰ *See* Vienna Convention on the Law of Treaties, Article 31.2(b) (1969), <https://treaties.un.org/doc/Publication/UNTS/Volume%201155/volume-1155-I-18232-English.pdf>.

⁵¹ *See* NOLLF, *supra* note 49, at 57.

⁵² *See* Janice M. Mueller, J.D., *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicines*, 356 NEW ENG. J. OF MED. 541, 543 (2007).

⁵³ For a similar conclusion, *see also* Max Planck Inst. for Innovation & Competition, *supra* note 6.

⁵⁴ According to the Oxford English Dictionary, the word “step” literally means not only “the act of putting one leg in front the other,” but also “the distance covered by the step” and the “progress by stepping or treading.” As a figurative meaning, the Oxford English Dictionary gives “an action or movement which leads towards a result,” and “a particular move or advance in a course of action.” The semantic range of the word can thus cover the requirement for a step forward in the technical development—i.e., for a technical advance. Of course, this is only one of the possible meanings; also

Second, Article 31(l)(i) of TRIPS defines the conditions for allowing the use of a patented dependent invention without the authorization of the holder of the dominant patent.⁵⁵ Member States violate this rule if a compulsory license is obtainable, although the invention claimed in the second patent does not imply a significant advance over the invention protected by the older right. They do not violate this rule if they define the concept of inventive step in such a way that every invention, if patentable, automatically would satisfy the requirement for a license under Article 31(l)(i).⁵⁶ Furthermore, the requirement under this article incorporates an economic element (“important technical advance of considerable economic significance”) which Article 3 of Bill No. 5402/13 does not provide.⁵⁷

Third, it is true that several Member States distinguish between technical progress and inventive step, and the PCT Guidelines reflect this fact. Still, these guidelines represent neither an agreement on the interpretation of TRIPS nor a “subsequent practice” within the meaning of 31.3(a) and (b) of the Vienna Convention on the Law of Treaties. On the one hand, the PCT does not limit the freedom of the national legislatures to define their own standards of patentability.⁵⁸ On the other hand, some Member States consider technical advance a condition for the grant.⁵⁹ Even if a subsequent practice does not require consistent action from all parties to an

a mere distance from the prior art, a modification of the prior art without improvement or even with a worsening (a step backwards), would be covered by the term “step” as well. Otherwise, if a step forward were the only possible meaning of the term inventive step, then the WTO Members were obliged, and not only allowed, to provide technical progress as a requirement for protection. Indeed the requirements set up in Article 27 of TRIPS are mandatory. On the use of the Oxford English Dictionary in the case law of the WTO Panels see Isabelle Van Damme, *Treaty Interpretation by the WTO Appellate Body*, 21 (3) Eur. J. Int. Law 2010: 605, 620.

⁵⁵ See TRIPS Agreement, *supra* note 5, Art. 31(l)(i).

⁵⁶ It might be argued that the only inference to be drawn from Article 31(l)(i) TRIPS is that the Member States are not obliged to require—in order to grant a valid patent—“an important technical advance of considerable economic significance” in relation to the invention claimed in the first patent. *Id.* Indeed, the wording of the provision presumes the existence of inventions which do not meet this requirement with respect to a specific older invention but which can nevertheless be patented. *See id.*

⁵⁷ The examination under Article 31(l)(i) TRIPS differs from that would be requested under Article 3 of Bill No. 5402/13. In the first case, the “important technical advance” has to be assessed compared with the invention claimed in the older dominant patent. In the case of Article 3 of Bill No. 5402/13, by contrast, the significant technical advance has to be compared with the entire prior art. An examination of whether the invention represents a technical advance with respect to the older invention under Article 31(l)(i) TRIPS may prove problematic. Other than the closest prior art to be selected under the problem/solution approach of the EPO, the dominant patent might, for instance, cover an invention which serves a purpose other than that of the later invention or that is completely neutral for that purpose. Take for instance a procedure for manufacturing a known class of chemical compounds. If the invention consists of using the manufactured substance as a means of fertilization, a comparison between the use of the substance and the process for its manufacture—whether the former represents a technical advance compared with the latter—is difficult. The invention claimed in the dependent patent—that is a new use for the known substance—does not aim to improve the invention claimed in the first patent, i.e., the manufacturing process.

⁵⁸ See also Article 27(5) of the PCT, which states that “[n]othing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each contracting state to prescribe such substantive conditions of patentability as it desires”

⁵⁹ See AIPPI, *supra* note 48, at 7. See also *supra* notes 26 & 30 for the legal situation in China and India.

agreement,⁶⁰ it is at least questionable whether the (current) European or U.S. practice on this matter may be regarded as implicitly acknowledged by the other TRIPS Member States.

If the legacy of the proposed provision were therefore open to opposite conclusions, a slight change in its wording would reduce the room for challenges under Article 27(1) of TRIPS without watering down its practical impact. The proposal could indeed require only a technical advance—and not a significant one—for granting a valid patent. An explanatory note could clarify that such advance does not exist merely because another way to solve a technical problem has been disclosed. In this way, two effects would be achieved.

First, the requirement for a technical advance would perform an eliminatory function that is not fully coextensive with that of a non-obviousness standard, as the latter is practiced in Europe⁶¹ and the U.S.⁶² Patent applications for further ways to solve a known problem, without evidence of an improvement over the prior art, would fail even if the claimed inventions were not obvious under the law in force.

Second, the deletion of the adjective “significant”⁶³ would leave more scope to distinguish patentable inventions which are eligible for a compulsory license under Article 31(l) of TRIPS, from patentable inventions which are not. Since the term “inventive step” pursuant to Article 27 of TRIPS implies, linguistically, a distance from the prior art, and this distance, in turn, may also comprise a technical advance, the chance of a successful attack against the TRIPS compliance of Bill No. 5402/13 would diminish, whilst the possibility of imitation by other legislatures would increase.

Such a change, however, would have a collateral effect on the intended reform. According to the new wording proposed by Bill No. 5402/13 for Article 14 of Law No. 9279/96, a utility model should be patentable “when, for a person skilled in

⁶⁰ See OLIVER DÖRR, VIENNA CONVENTION ON THE LAW OF TREATIES: A COMMENTARY, ARTICLE 31, 521 *et seq.* (Oliver Dörr & Kirsten Schmalenbach eds., 2012).

⁶¹ According to the EPO, “for an inventive step to be present in claims referring to the alternative solution of a known problem, it is not necessary to show substantial or gradual improvement over the prior art.” See T 0620/99, Decision of 8 May 2003, Reasons of Decision no. 30, unpublished; see also T 0588/93, Decision of 30 January 1996, Reasons for the Decision no. 6.1, unpublished, according to which “in accordance with the established case law of the Boards of Appeal, however, when deciding on the question of inventive step in the present case, there is no need to show an improvement of the claimed adsorbent, whether substantial or gradual, over those adsorbents described in the prior art.” See also T 0100/90, Decision of 2 April 1991, Reasons for the Decision no 4.5.1, unpublished; EPO, CASE LAW OF THE BOARDS OF APPEAL OF THE EUROPEAN PATENT OFFICE, 165 (7th ed., 2013). Alternative solutions to a known problem may be patented, if not obvious, even if they do not outperform the relevant prior art. Whether or not such cases occur often is another matter that cannot be investigated here and that would require empirical research in the case law.

⁶² See *Demaco Corp. v. F. Von Langsdorff Licensing Ltd., et al.*, 851 F.2d 1387 (Fed. Cir. 1988) (“The district court held that the Barth stone gave ‘no significant structural advantage . . . over other pavers,’ and that ‘there is no evidence that the Barth paver makes a stronger or more durable pavement.’ The patent statute does not require a patentable invention to be superior to all prior devices.”). See also *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 960 no. 12 (Fed. Cir. 1986) (finding that whether an invention is an “improvement” is not a prerequisite for patentability); DONALD S. CHISUM, CHISUM ON PATENTS, § 5.03 [5] [a], 5-310 *et seq.*; Giles S. Rich, *The Principles of Patentability*, 42 J. PAT. OFF. SOC’Y 75 (1960).

⁶³ “*Significativo*” in Portuguese. See Bill No. 5402/13, Art. 3. The Portuguese version of Article 31(l) TRIPS uses by contrast the adjective “*importante*.”

the art, it does not derive in a common or vulgar fashion from the prior art, and provided it represents a technical advance compared with the prior art.”⁶⁴ Bill No. 5402/13 intends to differentiate, through a graduation of the technical advance required, between inventions eligible only for utility model protection on the one hand, and inventions eligible for both utility model and patent protection on the other. In this way, it would reduce the scope of patentable inventions, which proponents of protectionism will see as a good policy. Patents are requested mostly by foreign companies and utility models by domestic applicants.⁶⁵ If the adjective “significant” were deleted from the proposed Article 13 of Law No. 9279/96, a criterion for delimiting the sphere of inventions that can be protected through both patents and utility models from the sphere of inventions that can be protected only through utility models would therefore vanish.⁶⁶ Still, the distinction between patents and utility models does not require limiting patent protection to “significant technical advance” in the art. Such delimitation can be ensured by giving up a technical advance or even the inventive step as a validity requirement for utility models. In this case, in accordance with the principle that the scope of protection should match the requirement for protection, the scope of protection conferred by the utility model should be reduced accordingly—for instance, by eliminating any protection for equivalents.⁶⁷

At the same time, the legislature should carefully consider the implications of granting an absolute right under the utility model law for creations which are obvious within the meaning of the patent provisions. This level of prudence is due at

⁶⁴ Bill No. 5402/13 (Braz. 2013) (emphasis added).

⁶⁵ See WORLD INTELLECTUAL PROPERTY ORGANIZATION [WIPO], WORLD INTELLECTUAL PROPERTY INDICATORS, p. 36 (2010).

⁶⁶ The difference in the current Brazilian law seem to be both a qualitative and a quantitative one. It is qualitative because it seems that, following the Khölerian conception, the utility model pursuant to Law No. 9279/96, Art. 9 does not protect a technical teaching, but rather only a concrete physical tridimensional form; see Denis Borges Barbosa, *Proteção dos Modelos de Utilidade e do Designs* (2002), available at denisbarbosa.addr.com/modelos.ppt, p. 3 (“A doutrina enfatiza que o modelo de utilidade não protege uma idéia, mas uma forma”). But the difference is also quantitative because the law requires a minor degree of inventive activity. However, the fundamental problem is that once obviousness is adopted as a requirement of protection, it is doubtful whether this element can be graduated. Obviousness is considered a qualitative element, and the invention is either obvious or not. See Paul G. Cole, *Inventive Step: Meaning of the EPO Problem and Solution Approach, and Implications for the United Kingdom: Part 1*, 20 EUR. INTEL. PROP. REV. 214, 215 (1998); FRANZOSI, *La nozione di modello di utilità*, IL DIRITTO INDUSTRIALE, 205 et seq. (1998). For this reason, the German Federal Supreme Court came to the conclusion that, despite a different wording of the applicable law, the inventive step required for utility patents may not be distinguished from the inventive activity requested for patents, and that to allow a protection for inventions obvious under patent law through utility model would likely conflict with constitutional principles that protect the economic freedom of the competitors. See German Federal Supreme Court (Bundesgerichtshof, BGH), 2006 GRUR 842, et al. (June 20, 2006)—*Demonstrationsschrank*. The Austrian and the Italian case law came to similar conclusions as the German Federal Supreme Court. See Rainer Beetz, *Zur Erfindungsqualität im Gebrauchsmusterrecht*, Österreichische Blätter für Gewerblichen Rechtsschutz und Urheberrecht, 148 et seq. (2007); Roberto Romandini, *La distinzione tra brevetti e modelli di utilità: una diversa interpretazione della disciplina positiva*, RIVISTA DI DIRITTO INDUSTRIALE, Vol. 60, Nr. 1, 200 et seq. (2011).

⁶⁷ For such a proposal with respect to German utility model law, see MANFRED BÜHRING ET AL., GEBRAUCHSMUSTERGESETZ 153 (8th ed. 2011).

least when the limitations of competition deriving from a utility model, though shorter in time, are no less intensive in effect than those resulting from a patent.⁶⁸

If the competition policy considerations underlying the reason for having obviousness as a condition for granting a patent are considered cogent, a legislature should refrain from creating, under an alternative regime, equivalent monopoly rights for technical innovations which are obvious within the meaning of the applicable patent law.⁶⁹

2. Practical Aspects

If incorporated into the current law, the requirement for a “significant technical advance” would raise several issues.

Assuming that a significant technical advance requires the invention to be superior to the prior art in at least one respect—otherwise the condition would be superfluous—the other questions relate to:

- (i) the method of examination, whether it is permissible to combine the prior art by assessing the existence of a significant technical advance (as is the case for an inventive step), or whether it should be prohibited (as is the case for novelty);⁷⁰
- (ii) the burden of proof and the evidence requested;
- (iii) whether the indication of advantageous effects and possibly requested experimental evidence can be included for the first time in the Brazilian patent application, even if they were not mentioned in the first foreign filing, without compromising the right of priority;
- (iv) whether such indication of advantageous effects may occur after the filing date and during the grant proceeding before the National Industrial Property Institute or *Instituto Nacional da Propriedade Industrial* (“INPI”), without violating the prohibition of adding new subject matter to the original content of the patent application⁷¹ (if this is not the case, the question becomes whether the applicant may rely on advantages not mentioned in the application as originally filed, but alleged during the

⁶⁸ This seems to be true for the Brazilian legislation. Article 41 of Law No. 9279/96 contains identical wording to Article 69 EPC. See also Article 42(I) of Law No. 9279/96, which implements Article 28(1)(a) of TRIPS, applying to both utility models and patents. See also BARBOSA, *supra* note 23, at 1721.

⁶⁹ For the debate in Germany, see generally RUDOLF KRABER, *Wird der Gebrauchsmusterschutz noch gebraucht? in SCHUTZ VON KREATIVITÄT UND WETTBEWERB—FESTSCHRIFT FÜR ULRICH LOEWENHEIM ZUM 75. GEBURTSTAG 157 et seq.* (R.M. Hilty et al. eds., 2009).

⁷⁰ The Chinese practice seems to examine the technical progress of the invention against each single piece of prior art considered individually, as in the case of novelty, at least as indicated in the report by Xin-Tian. See Yin Xin-Tian, *supra* note 34, at 151, 154 et seq. However, the Guidelines of the Patent Office (SIPO) do not contain in this respect a corresponding instruction for the examiner.

⁷¹ See Law No. 9279/96, Art. 32, according to which, in order to improve the patent application, the applicant “may make changes until the time of the request for examination, provided these are limited to the subject matter initially disclosed in the application.” According to Article 50(III) of the Law No. 9279/96 the patent may be revoked when its “object extends beyond the contents of the application filed originally.” Similar provisions apply in Europe; see Article 123(2) and Article 138(1) lit. (c) EPC respectively.

- patent granting proceeding, although they may not be included in the patent specification); and
- (v) finally, whether, during the granting proceeding, the applicant may submit post-published evidence to support the statement made in the original application according to which the claimed subject matter has specific advantages.

It would be advisable to clarify these aspects in guidelines or secondary legislation rather than leaving them to the case law that will come into play only several years after the reform takes effect.

3. Policy Considerations

The introduction of a technical advance as an additional requirement in the law of obviousness could raise some legitimate doubts in the patent community. Modern patent law has consolidated over the years. The current set of requirements for protections is the result of long-term experimentation. New grant conditions would make the operation of the system more complicated. It would also make it more difficult for the INPI to cooperate with foreign patent offices to tackle the backlog. Such cooperation requires harmonized conditions for granting a patent.

But the approach also has some arguments in its favor. For years, a part of the literature has been voicing criticism against presumed insufficiencies of the inventive step, at least as conceived or practiced in Europe and the U.S. Raising the bar became a political issue.⁷² But how to implement these abstract policy desires in practice was unclear and remains so. The task is fraught with analytical difficulties deriving from the very nature of the requirement concerned. Inventive step as laid down in western legal models is a qualitative concept. It places the examiner and the judge before a strict binary decision: either the invention is obvious (or evident) or it is not.⁷³ *Tertium non datur*.⁷⁴ In European and U.S. case law, the invention is obvious only when, dispersed in different pieces of the prior art, there is a suggestion to combine the single features of the invention.⁷⁵ By this understanding, increasing the level of the requirement is first a logical problem. Doing it without making the whole assessment subjective or even arbitrary is a practical challenge still awaiting a conclusive proposal. Significantly, the attempt to graduate the inventive step in order to distinguish an invention eligible for both patent and utility model protection from an invention eligible (only) for utility protection has failed—at least in continental Europe.⁷⁶

The idea of creating a new sub-requirement could turn out to be an approach also worth consideration for a mature jurisdiction.

⁷² See Klaus Grabinski/Thomas Adam, Vor Präambel, in BENKARD, *Europäisches Patentübereinkommen*, 2. ed 2012, at 50 *et seq.*

⁷³ Cole, *supra* note 66, at 215 *et seq.*

⁷⁴ William R. Cornish, *The Essential Criteria for Patentability of European Inventions: Novelty and Inventive Step*, INT'L REV. INTEL. PROP. & COMPETITION L., 765, 773 (1983); GHIDINI, *PROFILI EVOLUTIVI DEL DIRITTO INDUSTRIALE*, 2 ed., 107 (2008).

⁷⁵ On the could/would approach of the Board of Appeals of the EPO see EPO, *supra* note 61, at 182 *et seq.*

⁷⁶ See discussion *supra* note 66.

In this regard, it may be useful to explore the reasons why in Germany—the main jurisdiction in which a technical advance was requested and examined for grant of a patent—the relevance of this requirement was gradually lost in the 20th century, with the result that the German legislature in 1978 finally abandoned it without significant opposition in the interest of European harmonization. There were three more recurring objections against such a requirement for protection.

The first objection was that a patent office is ill-equipped to assess a technical advance. Examiners do not conduct experiments, and therefore cannot really check whether the invention outperforms the prior art. Furthermore, a solution can become advantageous after the filing date because of changes in relevant factors, such as the cost of commodities and energy or the efficiency of collateral technologies and auxiliary equipment. As a contingent feature of the claimed technology, progress would prove to be an uncertain element to assess and open to arbitrary judgment.⁷⁷

Second, a patent for inventions that advance the prior art can hurt a competitor more than a patent for an invention that is not better than existing technologies.⁷⁸ If an invention that is not better than the prior art is patented, competitors can resort to known substitutes without suffering any loss in competitiveness. The exclusivity right does not really affect them. By contrast, if a solution implying a technical advance is removed from the public domain, despite being obvious, competition is affected. As a consequence, consumers and final users are hurt as well.

Third, the existence of the technical advance could induce the examiner to establish a “reciprocal proportionality” with the inventive step,⁷⁹ jeopardizing the role that the latter performs in the interest of free competition.

However, from a present-day perspective, the perception of these problematic aspects may have changed and these objections may turn out to be less convincing than they were in 1978.

The argument that patent offices are not qualified to examine a technical advance may indeed be valid. However, this has not changed the fact that, in several technical fields, the alleged advantageous effects of the invention are in any case the controlling factors over patentability. This is the case, in the chemical field, when a structural similarity when compared with existing products has been shown by the examiners, and the effects of the compounds are material for patentability—something which is true of the vast majority of patent applications for new chemical substances. Comparative tests are requested, submitted, and examined in the grant procedure⁸⁰ without, apparently, any insurmountable practical shortcomings.⁸¹

The contention that patents for a nonobvious equivalent or inferior additional way of solving a problem are less harmful than patents for an invention that is

⁷⁷ See Richard Wirth, *Schöpfung und Fortschritt als Kriterium der Erfindungshöhe?*, Gewerblicher Rechtsschutz und Urheberrecht [GRUR], 73, 81 *et seq.* (1923); Fritz Walleser, *Das Leistungsprinzip und der technische Fortschritt*, Gewerblicher Rechtsschutz und Urheberrecht [GRUR] 533, 535 *et seq.* (1964). See also the historical analysis of the debate by Übler, *supra* note 29, at 86 with further references; ULLRICH, *supra* note 36, at 15 *et seq.*

⁷⁸ See Walleser, *supra* note 77, at 535.

⁷⁹ See *id.*

⁸⁰ See EPO, *supra* note 61, at 231 *et seq.*

⁸¹ For the U.S. practice, see U.S. PAT. & TRADEMARK OFFICE, U.S. DEPT' OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE Ch. 2100, § 2142 (9th ed. March 2014) [hereinafter MPEP].

obvious, but superior to the prior art, argues against replacing inventive step by technical advance, but not against combining both as conditions for patenting. The risk of the resulting coexistence requiring a reverse proportionality is preventable. For instance, legislative indications or guidelines could clarify that the two requirements are cumulative.

Third, even the opinion that there is no problem with the grant of patents for inventions which do not work better than the prior art may be challenged today. Patenting such inventions can indeed harm competitors if the use of the claimed subject matter then becomes necessary for heterogeneous, non-technical reasons—for instance, to comply with a standard.⁸² Patenting such invention can further affect competitors when the use of the claimed subject matter becomes advantageous after the filing date. This could occur, for example, when a second inventor shows a new use for a patented substance which is by far more useful and relevant than the uses disclosed in the product patent by the first inventor.⁸³ Lastly, patenting of inventions that are not superior to the prior art could deter competition when it is part of a strategy aimed at creating an artificial barrier to market entry.

Nevertheless, while the standardization issue does not seem to be on the agenda of the Brazilian Proposal⁸⁴, and while the question related to new uses of patented subject matter can be properly handled under inventive activity,⁸⁵ the issue of “evergreening” in the chemical field is addressed by another rule of Bill No. 5402/13 that deserves careful attention.

⁸² For some standards-essential patents, empirical research has confirmed a higher forward citation rate, which may imply a technical merit of the protected inventions. However, this does not hold true for a significant number of these patents. Further, these studies found that the participation of the patentee to the standard process was “even a stronger determinant for patent inclusion than the patent’s value.” See Fraunhofer Institute for Communication System, *Study on the Interplay between Standards and Intellectual Property Rights (IPRs)*, Final Report (April 2011), at 22 *et seq.*, available at http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=5414&lang=en&title=Study-on-the-Interplay-between-Standards-and-Intellectual-Property-Rights-%28IPR%29, with further references. For an invention to be included in a standard, it is not required to outperform the alternatives already known at the filing date. The criteria for inclusion are ultimately based upon the ability of the technical teaching to achieve the standardization aims.

⁸³ Cf. Lorenzo, *Advance in the Art: The Essential Criterion of Patentability*, 56 J. PAT. OFF. SOC’Y 195, 202 *et seq.* (1974).

⁸⁴ For the relevance of the issue in the context of the Brazilian legal order, see Denis Borges Barbosa, *Patents, Technical Standards and Frand License Offerings Under Brazilian Law* (March 11, 2015), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2576956 (last visited July 3, 2015).

⁸⁵ A proper balance between the interest of the inventor of new entities and the inventor of subsequent uses could be achieved, for instance, by allowing absolute product claims only when the creation of the compound itself is inventive, or by generally allowing only purpose-bound protection. Both measures are TRIPS-compliant. See Max Planck Inst. for Innovation & Competition, *supra* note 6.

B. Incorporation of Section 3(d) of the Indian Patent Act (IPA) into Brazilian Law

1. Premise

According to Article 3 of Bill No. 5402/13, intended to amend Article 10 of Law No. 9279/96, the following kinds of subject matter are not to be considered inventions:

- i) any new property or new use of a known substance;
- ii) the mere use of a known process, unless this known process results in a new product; and
- iii) new forms of known substances that do not result in an improvement in the known efficacy of the substance.

The wording of the proposed exclusions follow, with slight variations, Section 3(d) of the Indian Patent Act of 2005 (IPA 2005).⁸⁶

The declared purpose of the legislature for the Indian provision is to reduce “evergreening” and foster incremental innovation.⁸⁷ A similar intention seems to underlie Bill No. 5402/13.⁸⁸

The provision refers to items which, in the view of the Bill’s drafters, should not be considered inventions within the meaning of the Law No. 9279/96. The same holds true for Section 3(d) of the IPA. However, the dogmatic unity and consistency of the list is only apparent. Some of the subject matters listed do indeed constitute an invention in the field of technology, pursuant to Article 27 of TRIPS, and not a discovery. Further, the exclusions do not share an identical rationale and uniform content. Both elements matter in a TRIPS compliance analysis.

2. New Properties of a Known Substance

The exclusion of new properties of a known substance from patent protection is straightforward. Patents are granted under Article 27(1) of TRIPS for inventions “in all fields of technology.” A technical invention teaches how to solve a problem and how to use specific means and/or natural forces for this purpose. The disclosure, therefore, that a material or a substance has specific properties does not describe a patentable subject matter, but merely conveys abstract information. This information may indeed be the basis of a technical teaching.⁸⁹ However, the information, as such, is not patentable. The patent claim may therefore refer only to

⁸⁶ See Ctr. for Strategic Stud. & Debates, *supra* note 1, at 112; Patents (Amendment) Act, § 3(d), 2005, No. 15, Acts of Parliament, 2005 (India).

⁸⁷ See Janice M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation*, 68 U. OF PITT. L. REV., 491, 550 *et seq.* (2007).

⁸⁸ See Ctr. for Strategic Stud. & Debates, *supra* note 1, at 112 *et seq.*; Jae Sundaram, *India’s Trade-Related Aspects of Intellectual Property Rights Compliant Pharmaceutical Patent Laws: What Lessons for India and Other Developing Countries?*, 23 INFO. & COMM. TECH. L., 2, 81, 111 *et seq.* (2014).

⁸⁹ The exploitation of the properties of the material concerned in order to achieve a result may consist of an invention eligible for protection under general conditions.

the teaching on how to use said properties and for which purposes, and not to the properties of the material as such. Furthermore, the disclosure of properties of a substance which is already part of the prior art does not make the substance itself new. At least this is not required by the WTO norms.

Article 3 of Bill No. 5402/13, by excluding from patent protection the new properties of a known substance, does not, therefore, point to an exception to patentability. The rule merely specifies negatively the concept of invention, insofar as it does not raise any TRIPS issues. But the Indian legislature, by enacting Section 3(d) of the IPA, probably wished to achieve more than the mere clarification that abstract knowledge *per se* is not eligible for protection or that finding a new property does not render new a known substance. Similarly, the Brazilian Bill likely intends to address situations where the patent application discloses a new technical effect of a known substance with respect to methods of use already described in the prior art. In this case, it might be argued that, even if the activity claimed is the same as in the prior art, the new technical effect could be incorporated into the claim as a functional feature and make the method patentable once again. Such an approach has sometimes been followed by the European Patent Office (“EPO”).⁹⁰ However, it is not required by the WTO provisions. Article 27 of TRIPS does not prohibit considering the new effect inherently anticipated if the same is necessarily produced by the already known use of the substance. The provision does not make any limitation for regulating the content of the prior art and the novelty requirement. Therefore, if the method steps claimed are not different in any element from those already practiced in the prior art, the Member States may deny patent protection without violating any WTO obligation.

If the abovementioned understanding of the exclusion concerned will be accepted, the norm will close the door to any grants concerning use inventions where the physical activity claimed has already been described in the prior art, even if the applicant has discovered a new effect and therefore a new purpose for which such physical activity may be carried on.⁹¹ While such a rule would likely have limited practical impact even in the European legal system, where use claims are admissible, its relevance for current Indian law and the prospective Brazilian Act is unclear. That is because another prong of Section 3(d) of the IPA 2005 and of the corresponding provision in Bill No. 5402/13 deals, in a more radical way, with all use claims.

⁹⁰ The case law on this matter is not consistent. *See* EPO, *supra* note 61, at 141 and 154 *et seq.*

⁹¹ For instance, the prior art shows that a known compound can be used for increasing the growth of plants, and a pending patent application discloses that the same known compound can be used also for preventing fungal infections in plants. In this case, since the way of pursuing the two effects is the same and consists in spraying the plants with the substance, the activity claimed by the patent application is identical to that anticipated by the prior art. The only novel feature is the purpose for which it is performed. Despite that, in Europe, provided that the purpose was not obvious, the use of the substance for preventing fungal infections in plants could be eligible for protection; *see* T 0231/85, Decision of 8 December 1986, OJ EPO 1989, 7—Triazole derivatives/BASF, from which the example is derived.

3. *New Uses of a Known Substance*

The exclusion for new uses of known substances does not clarify the concept of invention and is not based on the requirement for inventive activity. Indeed, the subject matter concerned may be a technical invention according to Article 27 of TRIPS, and is denied patent protection regardless of whether it is novel or inventive. The provisions therefore enshrine an exception to patentability, preempting protection for subject matter which would otherwise represent a patentable invention. However, as far as medical uses of known substances are concerned, the exclusion is allowed under TRIPS. Under Article 27(3)(a) of TRIPS, Member States are free to exclude medical methods from patent protection.⁹² The use of a substance for the treatment of a disease is one of these methods.⁹³

By contrast, insofar as no medical uses are concerned, the provision tests the limits of Article 27 of TRIPS. It excludes from patentability a category of inventions even if they are novel and inventive and no exception under Article 27(2) or (3) of TRIPS applies.

This conclusion is not shared by all authors. According to some scholars, TRIPS would require that a patent be granted only for processes and products.⁹⁴ Methods of use do not fall under any of these categories.⁹⁵ Therefore, they may be excluded from patent protection without violating the Treaty.⁹⁶ This is said to be true even if the claimed use is novel and inventive. I cannot agree with this opinion for three reasons.

First, Article 27 of TRIPS mandates patent protection for any invention in the field of technology, whether product or processes. The wording of the provision assumes that no invention exists which would not fall into either of these two

⁹² See TRIPS Agreement, *supra* note 5, Art. 27(3)(a) (“Members may also exclude from patentability: diagnostic, therapeutic and surgical methods for the treatment of humans and animals.”).

⁹³ See, with reference to European Patent Law, BENGT DOMEIJ, PHARMACEUTICAL PATENTS IN EUROPE 178 (2000).

⁹⁴ See CARLOS MARÍA CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 274 (2006); Linda L. Lee, 23 Berkeley Tech. L.J. 281, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India*, 281, 281, 307 *et seq.* (2008); Edson B. Rodrigues Jr. & Brian Murphy, *Brazil's Prior Consent Law: A Dialogue Between Brazil and the United States Over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines*, 16 ALB. L.J. SCI. & TECH. 423, 430 (2006); see also Commission of the Andean Community, Decision 486, Common Intellectual Property Regime Art. 21 (Sept. 14, 2000).

⁹⁵ See CORREA, *supra* note 94, at 274. This author considered an exclusion of new medical uses of known substances from patent protection to be TRIPS-compliant also on the basis of Article 27(3) of TRIPS, according to which the Member States may exclude the patentability of “therapeutic methods to which second indications claims are essentially equivalent.” *Id.* However, both arguments—that medical uses of known substances are not processes within the meaning of Article 27(1) and that they are medical methods within the meaning of Article 27(3)—are contradictory and may not be pleaded together. Article 27(3) TRIPS refers indeed to methods which are patentable inventions pursuant to Article 27(1) TRIPS.

⁹⁶ See CYNTHIA M. HO, ACCESS TO MEDICINE IN THE GLOBAL ECONOMY: INTERNATIONAL AGREEMENTS ON PATENTS AND RELATED RIGHTS 92 *et seq.* (2011); CORREA, *supra* note 94, at 274; UNCTAD-ICTSD, PROJECT ON INTELLECTUAL PROPERTY RIGHTS AND SUSTAINABLE DEVELOPMENT, 356 *et seq.* (2005).

categories. The mention of product and processes therefore does not limit the scope of the obligation to grant patents for any innovation in the field of technology.

Second, TRIPS uses the word “process” as a genus comprising, as a species, processes for manufacturing a product and methods for performing an activity. This follows from Article 34 of TRIPS, which applies only to a “process for obtaining a product,” and to Article 27(3), which allows methods of treatment to be excluded from patent protection.⁹⁷ The latter optional exception would be of no use if methods were not a (process) invention within the meaning of Article 27(1) of TRIPS.

Third, a claim for “a method for killing insects by administering substance Y” and a claim for the “use of substance Y for killing insects (or as insecticide)”⁹⁸ concerns the same activity. Both claims confer, under Article 28(1)(b) of TRIPS, identical protection.⁹⁹ Therefore, even if it were successfully argued that a use is not a method and that Article 27(1) of TRIPS mandates protection for the latter but not for the former, under no circumstances would a legislature be entitled to prohibit method claims.

Against this background, if the exclusion concerning use claims did not ban method claims also aimed at the same activity, it would be irrelevant; if it included them, it would be at odds with Article 27 of TRIPS, insofar as no medical uses are involved.¹⁰⁰

4. *New Forms of Known Substances*

a. Legal Aspects

The exclusion for “new forms of known substances that do not result in an improvement in the known efficacy of the substance” reproduces the wording of Section 3(d) of the IPA 2005 as well.¹⁰¹ For this provision, Indian law adds an explanatory note according to which, for the purpose of the exclusion “salts, esters, ethers, polymorphs, metabolites, pure form, size of particles, isomers, mixtures of

⁹⁷ See TRIPS Agreement, *supra* note 5, Art. 34; *see id.* Art. 27(3).

⁹⁸ This example is taken from UK Intellectual Property Office, *Examination Guidelines for Patent Applications Relating to Chemical Inventions in the Intellectual Property Office*, p. 16 (Aug 2012) (“It should also be noted that a claim such as ‘the use of substance X as an insecticide’ is regarded as equivalent to a ‘process’ claim of the form ‘a process of killing insects using substance X.’”).

⁹⁹ See G 0005/83, Decision of 5 December 1984, OJ EPO 1984, 64 Reasons for Decision no. 11, — Second medical indication/Eisai (“The European Patent Convention, in general, allows both method claims and use claims but whether any activity is claimed as a method of carrying out the activity (setting out a sequence of steps) or as the use of a thing for a stated purpose (the sequence of steps being implied), is, in the opinion of the Enlarged Board, a matter of preference. For the European Patent Office there is no difference of substance.”).

¹⁰⁰ Additional inquiries under Article 8 of TRIPS are not necessary, since this article does not justify exclusions from patent protection not provided under Article 27(2) and (3) TRIPS; *see* CHARLES LAWSON, JUSTIN MALBON & MARK DAVISON, *THE WTO AGREEMENT ON TRADE: RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY* 236, margin number 8.70, Art. 8 (2014).

¹⁰¹ *See* Patents (Amendment) Act, § 3(d), 2005, No. 15, Acts of Parliament, 2005 (India).

isomers, complexes, combinations and other derivatives of a known substance shall be considered the same substance, unless they significantly differ in terms of properties regarding efficacy.”¹⁰²

This explanatory note raises two issues for the literature. First, it uncritically adopts the wording of Article 10.2(b), Directive 2004/27/EC, a provision that does not deal with patentability, but rather with drug-regulation issues.¹⁰³

Furthermore, its wording is not fully consistent with the rule it intends to explain.¹⁰⁴ For Section (3)(d) of the IPA, a new form is patentable if an improvement on the known efficacy of the substance is shown. For the explanatory note, such a new form is to be regarded as the same substance if it does not differ in properties relating to efficacy. According to Section (3)(d) of the IPA, differences in properties concerning efficacy are not sufficient and not relevant for patentability. For the explanatory note, they seem, by contrast, necessary to consider the substance new. The first provision seems to address which advance over the prior art is required for new forms of known substances to be patentable. The explanatory note seems, by contrast, to address novelty. The apparent discrepancy between the two norms was justified in the Indian literature¹⁰⁵ by the haste with which the law was approved. The Brazilian reform nevertheless intends to incorporate both provisions in domestic law.

From a systematic viewpoint, the Supreme Court of India has understood Section 3(d) of the IPA 2005 as an exception to patentability¹⁰⁶ Indeed, in the view of the Supreme Court, a subject matter—that is an invention and that is novel and inventive within the meaning of Section 2(1)(j) and (ja) IPA—could nevertheless turn to be not patentable because of Section 3(d) IPA. Part of the literature considers Section 3(d) IPA 2005 to be instead a clarification of the inventive step.¹⁰⁷ In the opinion of those authors, the rule wants only to explain how to apply this requirement to inventions concerning a modified form of known substances. For TRIPS compliance, it does not matter how the legislature or the courts understand the domestic rule. What is relevant is only whether the things the provision refers to fall under the categories of subject matter that may be excluded from patent protection pursuant to TRIPS provisions.¹⁰⁸

In this respect, three justifications are abstractly possible for the exclusion. One could indeed argue that “new forms of known substances that do not result in an

¹⁰² *Id.*

¹⁰³ See BERTHOLD, *supra* note 46, at 176.

¹⁰⁴ See BERTHOLD, *supra* note 46, at 176 *et seq.* with further references; see also SHEETAL THAKUR, PATENTING IN INDIA, 317 *et seq.* (2015).

¹⁰⁵ See Shamnad Basheer, *India's Tryst with TRIPS: The Patents (Amendment) Act 2005*, 1 IND. J. OF L. & TECH., 15, 24 *et seq.* and 43 *et seq.* (2005).

¹⁰⁶ See *Novartis AG v. Union of India & Ors.*, Decision of 1 April 2013, Civil Appeal Nos. 2706-2716, 2728, and 2717-2727, ¶ 192 (India) [hereinafter *Novartis Supreme Court Decision*], available at <http://judis.nic.in/supremecourt/imgs1.aspx?filename=40212>. See on this judgment Stefano Barazza, *Incremental pharmaceutical innovation in India: the Supreme Court's judgment in the Novartis Gleevec case*, 8 J. OF INTELL. PROP. L. & PRACTICE, 776 *et seq.* (2013).

¹⁰⁷ Rajarshi Sen & Adarsh Ramanujan, *Pruning the Evergreen Tree or Tripping Up over TRIPs?—Section 3(d) of the Indian Patents Act, 1970*, 2 INT'L REV. INTELL. PROP. & COMPETITION L. 2010, 170 *et seq.*; Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CALIF. L. REV. 1571, 1597 (2009).

¹⁰⁸ See BERTHOLD, *supra* note 46, at 176.

improvement in the known efficacy of the substance” either (i) are not inventions pursuant to Article 27(1) of TRIPS; or (ii) fall under one of the exceptions of Article 27(2) or 27(3) of TRIPS; or (iii) are not inventive within the meaning of Article 27(1) of TRIPS.

The first argument would be clearly untenable. The wording of TRIPS makes it clear that chemical or pharmaceutical products can also be the subject of an invention in the field of technology. This is confirmed *inter alia* by the transitional provisions, such as Article 70(8) of TRIPS, which specifically consider pharmaceutical products as a subject matter eligible for protection within the meaning of Article 27(1) of TRIPS.¹⁰⁹ The new form of a chemical substance may fulfill this notion. Whether the claimed product is a completely new entity or a derivative from known compounds has no relevance for the issue of whether or not it constitutes an invention. Article 27 of TRIPS clearly separates the concept of patent-eligible invention from the requirements for its protection.¹¹⁰

The second argument would fail as well. According to the predominant view, Article 27(2) of TRIPS requires the Member States to prohibit the commercial exploitation of inventions for which no patent might be granted for policy or moral reasons.¹¹¹ This would imply that the Indian or Brazilian legislature should prevent domestic companies from selling substances comprised by Section 3(d) IPA 2005 or Article 3 of Bill No. 5402/13 in order to successfully invoke Article 27 TRIPS as justification for patent exclusion, which would likely defeat the very purpose of the provision. Against this background, Article 27(2) of TRIPS is hardly relevant for assessing the TRIPS-compliance of the exclusions concerned.

The only way to justify the norm is therefore by referring it to the inventive step (Article 27(1) TRIPS).¹¹² The rule could be intended as an attempt to clarify when an inventive step exists and when it does not with respect to chemical compounds for

¹⁰⁹ See also *Daiichi Sankyo Co. Ltd., et al. v. DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon*, ECJ Case no. C-414/11 (July 18 2013), points 65 *et seq.*, where the ECJ states:

Article 27(1) of the TRIPs Agreement provides that any invention, whether a product or a process, which is new, involves an inventive step and is capable of industrial application is patentable, provided only that it belongs to a field of technology. As regards that condition, it is clear that pharmacology is regarded by the contracting parties to the TRIPs Agreement as a field of technology within the meaning of Article 27. That follows in particular . . . from Article 70(8) of the TRIPs Agreement, a transitional provision dealing with the situation in which ‘a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical . . . products commensurate with its obligations under Article 27’ which provides that, in that situation, the WTO member in question must at least provide, as from that date, ‘a means by which applications for patents for such inventions can be filed.’ As follows from the wording of that provision, Article 27 of the TRIPs Agreement includes the obligation to make inventions of pharmaceutical products patentable.

¹¹⁰ A technical teaching remains an invention within the meaning of Article 27 TRIPS if it is anticipated or rendered obvious by the relevant prior art and for this reason not patentable.

¹¹¹ See Carlos M. Correa, *The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection*, EUR. INTELL. PROP. REV., 327, 328 (1994); DE CARVALHO, *supra* note 39, at 313.

¹¹² Amy Kapczynski, *supra* note 107, at 1597; see also Zoe Lynn Turrill, *Finding the Patent Balance: The Novartis Glivec Case and the TRIPS Compliance of India’s Section 3(d) Efficacy Standard*, 44 GEO. J. INT’L L. 1555, 1581 *et seq.* (2013).

which a structural obviousness can be presumed, since they are merely a modified form of substances already known in the prior art. This reading would be consistent with the understanding that “technical advance”¹¹³ may be regarded as an (optional) part of the inventive step test under Article 27 (1) of TRIPS. The “enhanced efficacy” would represent the technical advance required for the new form of a known substance to be patented.

When considering the TRIPS conformity of the provision, it might be useful to check how the competent patent offices in Europe and in the U.S. would assess similar situations under Article 56 of the European Patent Convention¹¹⁴ or U.S. Code § 103.¹¹⁵ If one accepts that the practices of the EPO and the U.S. Patent and Trademark Office (“USPTO”) are TRIPS-compliant,¹¹⁶ then potential examination by a WTO panel would likely concentrate on the differences of the rules adopted and of the practices governed by them.¹¹⁷

In Europe, the examiner would regard the new form of the known substance as being patentable when either the preparation of the compound implies an inventive step¹¹⁸ or the properties disclosed by the applicant are unexpected. These properties might be different from those indicated in the prior art or they might be the same, but enhanced. If surprising, they could make the product claim valid. By contrast, if the new form indeed presented an enhanced efficacy but such an improvement was foreseeable, this would represent a motivation to modify the prior art as proposed in the patent application. Under the problem-solution approach, the technical advance over the prior art is an ambiguous element for the purpose of patentability. If predictable indeed, it is an argument against and not for the existence of an inventive step.

Before the USPTO, the situation would be similar. If the product is structurally similar to a class of known compounds, then it would be considered *prima facie* obvious. To overcome an objection under U.S.C. § 103, the applicant must show in this case either that the prior art does not “disclose or render obvious a method for making the substance”¹¹⁹ or that the substance has unexpected and superior properties.¹²⁰

¹¹³ See discussion *supra* Part III, Paragraph A (1), of this article.

¹¹⁴ See EPC, *supra* note 24, Art. 56 (inventive step).

¹¹⁵ Conditions for Patentability; Non-obvious Subject Matter, 35 U.S.C. § 103 (1999).

¹¹⁶ For such an approach see also Du, *supra* note 38, at 244; Lee, *supra* note 94, at 309.

¹¹⁷ See Lee, *supra* note 94, at 309.

¹¹⁸ See T 595/90, Decision of 24 May 1993, OJ EPO 1994, at 695, Reasons for the Decision no. 5 (according to which a “product which can be envisaged as such with all characteristics determining its identity together with its properties in use, i.e. an otherwise obvious entity, may become nevertheless non-obvious and claimable as such if there is no known way or applicable (analogy) method in the art to make it and the claimed methods for its preparation are therefore the first to achieve this in an inventive manner”). See also EPO, *supra* note 61, at 220; German Federal Supreme Court (Bundesgerichtshof, BGH), 10 September 2009—Xa ZR 130/07—“Escitalopram”; House of Lords, Generics (UK) Limited and others (Appellants) v H Lundbeck A/S (Respondents) [2009] UKHL 12 on appeal from: [2008] EWCA Civ 311.

¹¹⁹ *In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 597, 601 (CCP A 1968); see also U.S. PAT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, Manual of Patent Examining Procedure, Ch. 2100, § 2144.09 [hereinafter MPEP].

¹²⁰ See MPEP, *supra* note 119, Chapter 2100, Section 2145.

The provisions of Section 3(d) of the IPA 2005 and Bill No. 5402/13 are therefore not entirely unlike these regional or national practices.¹²¹ However, they do differ from them in two main respects:

- (i) for the new form to be protected, the claimed product must show an enhancement in the known efficacy. New effects which manifest themselves by inventive uses are not relevant to pass the test under Section 3(d) of the IPA.¹²² If the new form may be purified or produced only through an inventive method, then the latter does not matter either for the validity of the product claim.
- (ii) According to the Supreme Court of India,¹²³ the term efficacy, in the field of pharmaceutical invention, is said to comprise only therapeutic efficacy.¹²⁴ Other advantages presented by the new form—e.g. better biodegradability or stability—are irrelevant.

On the basis of these differences, two WTO-law challenges against the regulation are abstractly possible.

First, one could argue that the provision implies a discrimination against specific pharmaceutical inventions. However, this reasoning would not be persuasive. Section 3(d) IPA 2005 applies to all chemical substances. Thus, even if the explanatory note refers to new forms which are the subject matter of patent applications more frequently in the pharmaceutical field than in others, the main provision applies to all chemical sectors. Of course, a WTO-complaint would likely raise the issue in the form of a *de facto* rather than a *de jure* discrimination. But in this form, the claims would not be convincing. The requirements for finding a discrimination *de facto* under Article 27(1) of TRIPS as specified by the WTO-case law are very strict. The adverse effects of the provision contested should be limited to the allegedly discriminated sector. Further, the differential disadvantage imposed by the challenged measure must be without justification.¹²⁵ None of these two cumulative elements of the concept seems to recur with respect to the proposed Brazilian legislation or the followed Indian model. There is no evidence indeed that the applicability of the proposed “Section 3(d)”-like provision to chemical products other than pharmaceutical ingredients would be a “sham.”¹²⁶ There is no reason to assume that the improvement—required by the provision in order to grant a valid patent for a new form of a known compound—is not also necessary for granting a valid patent for other types of new (but structurally obvious) products.¹²⁷ Since Bill

¹²¹ See the analysis by Rajarshi Sen & Adarsh Ramanujan, *supra* note 107 at 170, 173 *et seq.*; Adarsh Ramanujan & Rajarshi Sen, *Pruning the Evergreen Tree: Section 3(d) of the Indian Patents Act 1970*, EUR. INTELL. PROP. REV., 135, 140 *et seq.* (2009).

¹²² See Basheer, *supra* note 105, at 24 *et seq.*

¹²³ See *Novartis* Supreme Court Decision, *supra* note 106, at ¶ 180.

¹²⁴ See also Controller General of Patents, Designs and Trademarks of India, GUIDELINES FOR EXAMINATION OF PATENT APPLICATIONS IN THE FIELD OF PHARMACEUTICALS, October 2014, 10.5 *et seq.*

¹²⁵ See Canada—Patent Protection of Pharmaceutical Products, Report of the Panel WT/DS114/5 (circulated November 12, 1998), 7.101 *et seq.*

¹²⁶ *Id.* at 7.104.

¹²⁷ In Europe, for instance, if the invention consists not in creating a new device with a new functionality, but in modifying a specific pre-existing device—e.g. modifying a straightening machine for filigates by replacing the mechanical cylinders with hydraulic ones with a resulting increase in efficiency—the modified device may be regarded as new. It will be considered

No. 5402/13 intends to codify technical progress as a general requirement for protection in all technical fields, a discrimination complaint would be, as reshaped by the reform in the Brazilian legal context, even more unjustified than the followed Indian normative model.

As a second challenge, one could argue that the provision creates additional criteria for patentability. It may indeed prevent product protection for substances which may be novel and inventive within the meaning of Article 27 of TRIPS.¹²⁸ Nevertheless, this argument also seems questionable.

Article 27 of TRIPS requires patent protection for all inventions which are novel, inventive, and industrially applicable. If the invention consists of a product, it is the product which must meet these requirements, not the method for its manufacture or the uses made possible by its properties.¹²⁹ It may be true that in some regional or national practice the inventive character of a structurally obvious substance can be borrowed from its unexpected effects when used for a specific purpose or from the method for making it. So under European and U.S. case law, even if the existence and the properties of an enantiomer were foreseeable, a product claim for it may be allowed for it if the prior art does not indicate any obvious method for resolving the racemate.¹³⁰ This practice is not, however, imposed by WTO obligations. As long as

non-obvious if the modification implies some unpredictable improvement over the closest prior art. In most cases, this improvement regards the efficiency of the device—i.e., its ability to produce increased or equivalent effect with minor energy, time, or effort.

¹²⁸ This is apparently the opinion of the European Commission, Director General for Trade, Letter of 20 March 2014, Ref. Ares(2014)824810 in commenting the Draft Guidelines of the Indian Patent Office; *see also* on the same subject Pharmaceutical Research and Manufacturers of America (PhRMA), *Comments by the Pharmaceutical Research and Manufacturers of America (PhRMA) on August 12, 2014, Revision to Draft Guidelines For Examination Of Patent Applications In The Field Of Pharmaceuticals*, p. 3, where the following remarks may be found:

TRIPS outlines three substantive criteria for patentability—novelty, inventive step, and capability of industrial application—and does not permit WTO Members to impose additional requirements for patentability of inventions beyond these three criteria. The additional requirement under Section 3(d) of the Patents Act thus contravenes TRIPS, as it deprives innovators of patent protection for new forms of known substances that fully meet the TRIPS requirements of novelty, inventive step, and capability for industrial application.

(Both opinions are *available at* http://www.ipindia.nic.in/iponew/comments_PharmaceuticalGuidelines/FeedBack_Pharmaceuticals.htm). For a similar view, *see also* the written Testimony of Roy F. Waldron, Chief Intellectual Property Counsel of Pfizer Inc., before the House Committee on Ways and Means, Subcommittee on Trade, on the occasion of the Hearing in US-India Trade Relations: Opportunities and Challenges (March 13, 2013) where it is observed that:

This provision [Section 3(d) of the India Patent Act of 1970] requires certain types of inventions to show ‘enhanced efficacy’ which limits substantially the ability to obtain a patent. Not only is this term unclear, but it goes beyond the specific requirements of patents under the WTO’s Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement including novelty, inventive step, industrial applicability, and sufficient disclosure for carrying out the invention.

For similar conclusions, *see also* Susan Fyan, *Pharmaceutical Patent Protection and Section 3(D): A Comparative Look at India and the U.S.*, 15 VA. J. OF L. & TECH. 198, 199, 224 (2010); BERTHOLD, *supra* note 46, at 181.

¹²⁹ *See* KRÄBER, PATENTRECHT, 6th ed., Munich 2009, 141 and 235 *et seq.*

¹³⁰ *See* Jonathan M. Spenner, *Obvious to Try: Obviousness of Chemical Enantiomers in View of Pre and Post KSR Analysis*, 90 J. PAT. & TRADEMARK OFF. SOC’Y 469, 487 *et seq.* (2008).

the structure and the existence of the product are obvious, Article 27 of TRIPS does not require any legal protection for it in the form of a product patent.

Section 3(d) of the IPA 2005 regards only substances which represent a specific new form of a known class of molecules. The existence of these substances will generally be predictable. Their structure may be considered obvious against a prior art including the substance from which they are derived. Member States are not obliged—following the European practice—to consider a compound inventive because of the difficulties overcome to make it or because of the surprising effects it displays when used for a specific purpose. Despite that, a Member State may decide to do so (e.g., consider inventive a structurally obvious compound when some surprising effects are shown). If they do so, there is no evident logical or legal argument under Article 27 of TRIPS as to why they should not be allowed to select at the same time—for policy-related considerations—which types of surprising effects or improvements may justify the grant of a valid patent, as long as such requirement applies uniformly to all product inventions.¹³¹ Bill No. 5402/13, like the Indian normative model from which it is inspired, seems to have adopted such a selection. The legislature decided that the properties of the compound may matter for patent protection, but only when they imply an increase in the known efficacy. Indian case law defines efficacy under Section 3(d) of the IPA 2005 to mean the therapeutic effect where pharmaceutical inventions are concerned.¹³² Against this background, the possible effect of the provision—in the pharmaceutical field—is to direct private investment versus research of (i) new chemical entities with any useful properties, or (ii) new forms of existing compounds implying a specific technical advance over the prior art, and (iii) to discourage investment (or at least patent applications) directed to new forms of known compounds that do not present an improvement of the efficacy predictable on the basis of the closest prior art.¹³³ Such a choice does not seem to be constrained by Article 27 of TRIPS. A mandate to consider all properties and advantages of the claimed structure, as predicated by *In Re Papesch*,¹³⁴ is not to be inferred from Article 27 of TRIPS, regardless of how reasonable such an approach might be.¹³⁵ Further, the Member States are not obliged to grant a product patent for an obvious subject matter only because the method of making it involves an inventive step. In this case, the availability of a method claim is sufficient to comply with Article 27 of TRIPS. Section 3(d) IPA 2005 does not limit the patentability of a new and inventive method for obtaining the substances to which the exclusion itself applies.

The provision may give rise anyway to the following problem: the wording of Section 3(d) of the IPA 2005 might end up preventing a grant when the applicant has disclosed for the first time surprising new properties and effects of a new form of a

¹³¹ *Contra Du*, *supra* note 38, at 244.

¹³² See *Novartis* Supreme Court Decision, Civil Appeal Nos. 2706-2716, 2728, and 2717-2727, 172.

¹³³ See Amy Kapczynski, J.D., *Engineered in India—Patent Law 2.0*, 369 *NEW ENG. J. MED.* 497, 498 (2013).

¹³⁴ *In re Application of Viktor Papesch*, 315 F.2d 381 (C.C.P.A. 1963).

¹³⁵ See generally Harold C. Wegner, *Post-KSR Chemical Obviousness in Light of Pfizer v. Apotex* (2007), available at http://www.patenthawk.com/blog_docs/070613_PostKSRChemicalObviousness.pdf. Wegner weighs in on the approach in *Papesch*, by examining the patentability of structurally obvious compounds, and on the judgment in *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007), which seems to question this approach.

known substance that allows a use other than the use predictable on the basis of the properties of the class of known compounds.¹³⁶ If this is the case, it could be argued that Section 3(d) of the IPA 2005 excludes protection for an invention which is new and inventive within any possible meaning under Article 27 of TRIPS. Such cases may be a rare occurrence with respect to the substances described in Section 3(d) of the IPA 2005 and Article 3 of Bill No. 5402/13. Nevertheless, by interpretation through the courts or by amendment through the legislative process, such an outcome ought to be avoided based on the principle of equal treatment to which every inventor is entitled according to Article 27 of TRIPS.

b. Practical Aspects

The Indian literature has addressed the difficulties to which the application of Section (3)(d) of the IPA—in light of its explanatory clause—could give rise. Some of them are worth mentioning.

The first concern comes from the fact that the rule should apply to derivatives from known substances. However, the concept of derivatives is not clarified in the Indian legislation. This holds true also for Bill No. 5402/13. The same substance can be considered to derive from several crystalline forms of the same class of compounds, which in turn may present a different degree of efficacy or no efficacy at all. As a consequence, the claimed compound may be considered a significant or less significant improvement depending on which substance is used as *tertium comparationis*.¹³⁷

Second, the provision makes patentability conditional upon enhancement in the known efficacy. Nonetheless, for the same substance, the prior art may indicate different technical effects. It is not clear how the rule is to be interpreted when the effect indicated for the known compounds in the prior art is different from the effect indicated in the later patent application for the new forms.¹³⁸

Third, at the priority date, evidence for therapeutic efficacy may not exist at all. It is unclear whether further evidence may be submitted during the grant procedure and whether post-published dates may be considered.¹³⁹

By addressing these practical aspects one should consider that for novelty, inventive step, or patentability the Brazilian Patent Office can rely on the practice elaborated on by other countries, as well as on preliminary reports on patentability prepared for PCT applications. The provision discussed here, if enacted, would have no equivalent in the PCT rules or in European or U.S. legislation. The only practice

¹³⁶ See BERTHOLD, *supra* note 46, at 183.

¹³⁷ See Shamnad Basheer & T. Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5 SCRIPTED 232, 240 (2008), available at <http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.pdf>; THAKUR, *supra* note 104, at 317 *et seq.*

¹³⁸ See BERTHOLD, *supra* note 46, at 183. The same interpretative problem exists when the prior art does not suggest any technical effect for the known substances to which the compounds claimed in the pending patent application or in the granted patent are compared.

¹³⁹ See also Du, *supra* note 38, at 251 *et seq.*

to which a reference could be made would be that of the Indian Patent Office and imitating countries, such as Argentina¹⁴⁰ or the Philippines.¹⁴¹

5. Policy Considerations

The purpose of Section 3(d) of the IPA 2005 is—according to the case law and the literature—to foster incremental innovation and to prevent so called “evergreening.” Under this notion a part of the literature and case law understands the attempt of originator companies through the filing of subsequent patent applications for new forms of a known compound, specific selection of a known chemical formula or more specific uses of an already known application to prolong the exclusivity for a specific and already patented product, mostly commercially successful drugs.¹⁴²

With the aim of preventing this practice, the Indian provision, as well as the Brazilian Proposal, ban patents for the following categories of inventions: (1) all new uses of substances already known; (2) new forms of known substances, even if a new use and surprising new effect are shown; and (3) new uses of known processes unless such process results in a new product or employs at least one new reactant. Against this background and by considering the subject matter concerned, three objections might be brought against the exclusions provided under Section 3(d) of the IPA 2005 and proposed under Bill No. 5402/13.

¹⁴⁰ In Argentina, the Patent Act was not amended; however, exclusions similar to those provided under Section 3(d) of the IPA were framed in the guidelines for the examination of the Argentinian Patent Office through three joint Resolutions of the Ministerio de Industria, the Ministerio de Salud, and the Instituto Nacional de la Propiedad Industrial. See Resolución Conjunta 118/2012, 546/2012 y 107/2012—Apruébanse las pautas para el examen de Patentabilidad de las solicitudes de Patentes Sobre Invencciones Químico Farmacéuticas, Law No. 24.425, 32.392 B.O. 17-19, (May 8, 2012).

¹⁴¹ Section 22 of the Philippines Intellectual Property Code reads as follows:

Discoveries, scientific theories and mathematical methods, and in the case of drugs and medicines, the mere discovery of a new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant. For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Intellectual Property Code of the Phillipines (Republic Act No. 8293, 1997), as amended by Act No. 9502 (2008).

¹⁴² Kate S. Gaudry, *Evergreening: a common practice to protect new drugs*, 29 NAT. BIOTECHNOL. 876 *et seq.* (2011); for an analysis or a criticism of the term evergreening in the field of patent rights see John Thomas, *Patent “Evergreening”: Issues in Innovation and Competition*, CRS Report for Congress Prepared for Members and Committees of Congress; MONICA DONGHI, PATENT STRATEGY IN PHARMACEUTICAL INDUSTRY: ARE ADDITIONAL PATENTS VALUABLE? 43 (2014); Scott Parker & Kevin Mooney, *Is ‘Evergreening’ a Cause for Concern? A Legal Perspective*, 13 J. COM. BIOTECH. 235 *et seq.* (2007); Sarah B. Myers, *A Healthy Solution for Patients and Patents: How India’s Legal Victory Against a Pharmaceutical Giant Reconciles Human Rights with Intellectual Property Rights*, 10 VAND J. ENT. & TECH. L. 763, 774 (2008); Zoe Lynn Turrill, *supra* note 112, at 1557-1559; Du, *supra* note 38, at 238 *et seq.*

The first objection concerns the consistency between the purposes and the effect of these exclusions. Some of the inventions which Section 3(d) of the IPA 2005 excludes from patent protection constitute exactly the incremental innovations the development of which the provision intends to foster.¹⁴³ This seems particularly true for new uses of known compounds. The disclosure of a new medical or non-medical use for a known compound may enrich the public even more than the development of new substances. The investment required and the risks connected may be as significant as in the case of a completely new class of compounds.¹⁴⁴

Second, granting a patent for the new use of a known compound or new forms of known compounds does not imply “evergreening” if, under this concept, the prolonging of protection for an embodiment already disclosed in a previous patent is understood.¹⁴⁵ Such a situation is, in principle¹⁴⁶, not possible under the EPC,

¹⁴³ See Aditya Kant, *Section 3(d): ‘New’ Indian Perspective*, 14 J. INTELL. PROP. RTS., 285, 290 (2009).

¹⁴⁴ See KRABER, *supra* note 129, at 249; Neurim Pharmaceuticals (1991) Ltd v. Comptroller-General of Patents, Court of Appeal, London, UK, (March 8, 2011, Case no. [2011] EWCA Civ 228); *see also* Opinion of Advocate General Trstenjak delivered on May 3, 2012, Case C-130/11, Rn. 48, available at <http://curia.europa.eu>.

¹⁴⁵ See MONICA DONGHI, PATENT STRATEGY IN PHARMACEUTICAL INDUSTRY: ARE ADDITIONAL PATENTS VALUABLE? 43 (2014); Scott Parker & Kevin Mooney, *Is ‘Evergreening’ a Cause for Concern? A Legal Perspective*, 13 J. COM. BIOTECH. 235 *et seq.*; Du, *supra* note 38, at 238 *et seq.*

¹⁴⁶ Exceptions are indeed possible. If a patent covers a general chemical formula (hereinafter: genus patent), the subsequent filing for a selection of the compounds comprised in the claimed genus (hereinafter: species patent) may certainly result in the term of protection for the species being extended. On an abstract level, a company might decide not to disclose the information about the superior properties of specific compounds falling under the claimed genus in the first patent application, thus leaving room for subsequent applications claiming the specific compounds falling under the claimed genus; *see* HYEWON AHN, SECOND GENERATION PATENTS IN PHARMACEUTICAL INNOVATION 109 *et seq.* (2014). But such a strategy involves some risk for the originator. Eventually, competitors might also discover the useful and superior properties of the selected compounds and file their own patent applications. Furthermore, such a strategy would hardly be compatible with the best mode requirement provided under U.S. patent law; *see also* BERTHOLD, *supra* note 46, at 127. Even though the best mode requirement is no longer a ground for invalidating a granted patent under U.S. law, it is still a ground for rejecting the application. The applicant interested in protection in the U.S. and other jurisdictions should tailor the content of the patent specification to the strictest legal jurisdiction for which protection will be sought already in the first national filing. Otherwise the chance of claiming a valid priority of the first deposit in that legal jurisdiction might be at risk. Another situation where an extension in the term protection theoretically might arise is when a first patent has been granted for a pro-drug and a subsequent patent for the metabolite. This is true only when case law takes the view that the patent for the metabolite is valid and infringed by the marketing of a pro-drug already known at the time of filing of the patent application for the metabolite. So far, no court decision has reached such a conclusion; *see* Richard Li-dar Wang and Pei-Chen Huang, *Patent Protection of Pharmacologically Active Metabolites: Theoretical and Technological Analysis on the Jurisprudence of Four Regions*, 29 SANTA CLARA COMPUTER AND HIGH TECHNOLOGY L. J. 489, 493 *et seq.* (2013). Lastly, a borderline situation exists when a patent has been granted for polymorphs, whilst an older patent discloses another crystalline form of the same compound less stable than the one later patented. If it is no longer possible to produce the older form without the presence of the patented new polymorphs since seeds of said new polymorphs have spread in the environment, the patentee could take the stance that practicing the prior art would necessarily result in the younger patent being infringed under the so called disappearing polymorphs theory. In any case, as shown *infra* in the text, provisions similar to those in Section 3(d) of the Indian Patent Act are not necessary to properly handle the situations mentioned in this footnote.

although it allows patents on new uses or new forms of known substances. On the basis of a patent for a new form of an existing substance, the patentee may prevent others from using the new form, but not the older basic compound.¹⁴⁷ On the basis of a patent for new uses, the patentee may prevent others from using the substance for the new purpose, but not for purposes already known. Under the EPC, no patentee may prohibit others from using a technical teaching which was already disclosed in prior art published before the critical date of the asserted patent, or which derives from it in an obvious way.

This does not mean that pharmaceutical companies might not be successful in prolonging their market positions with respect to specific products even after the patent on the chemical entity concerned has expired. Such situations, however, are the result of factors other than the mere granting of so called secondary patents. In the pharmaceutical field, they may arise from a restrictive notion of generics in the applicable regulatory legislation¹⁴⁸ or from the ability of the patentee to induce prescribing doctors to switch to (patented) follow-up drugs before the original basic compound becomes patent-free.¹⁴⁹ If the purpose of the Reform were only to prevent “evergreening,” other measures would be more efficient and less radical.

For instance:

- (i) A general prior art defense according to which (a) no one may be refrained from performing an activity which fully corresponds to what was done before the filing or priority date of the asserted patent; or (b) no patent may restrict anyone from practicing technology included in the prior art available to the public prior to the priority date of the patent or resulting from it in an obvious manner. Both defenses are not coextensive: the first excludes, for instance, that, on the basis of a patent for a metabolite, the commercialization of the pro-drug may be prevented, even if the patent asserted remains valid, since the pro-drug was not available to the public under the applicable patent law. The second argument is a “classic” practicing prior art defense, which applies even when the embodiment accused of infringing the patent is not anticipated, but made obvious by the prior art. In this way, it would be legally clear for every company that no patent on dosage or administration or specific patient group indication may

¹⁴⁷ See also AHN, *supra* note 146, at 225 *et seq.*

¹⁴⁸ This case may occur when a company files a first patent application for a new chemical entity and later a further patent application for a specific crystalline form of the substance. If the patentee pursues the regulatory approval only for the crystalline form and not for the chemical entity that is the subject of the first patent application, and if the applicable medical law does not allow for the generic companies to refer—by requesting the approval for the original substance which has become patent free—to the later patented crystalline form, the generic companies will likely refrain from entering the market. The approval of the original chemical entity, which the patentee has omitted to do, would incur costs that normally none of the generic competitors are prepared to bear. For these examples, see BERTHOLD, *supra* note 46, at 130 *et seq.*; PHILIP W. GRUBB, PATENTS FOR CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY: FUNDAMENTAL OF GLOBAL LAW, PRACTICE AND STRATEGY 243 (4th ed. 2010).

¹⁴⁹ For an analysis of this phenomenon from the perspective of European competition law, see Bengt Domeij, *Anticompetitive Marketing in the Context of Pharmaceutical Switching in Europe*, 273 ff., in JOSEF DREXL & NARI LEE, PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW: A TRILATERAL PERSPECTIVE (2013).

prevent a competitor from using the basic substance for purposes or indications already disclosed.

- (ii) With respect to selection inventions, a rule according to which a prior art reference disclosing a general formula in principle anticipates all the compounds comprised by said formula—even in absence of “an individualized disclosure”—if these compounds may be produced on the basis of the method described in the reference concerned.
- (iii) A broad definition of generics in regulatory law,¹⁵⁰ so that even if a patentee has obtained patent protection for a new form of a known substance and the authorization only for this specific new form, the generic competitor remains free to refer to the dossier concerning this new form of the substance to obtain an authorization for the basic compound already disclosed in the prior art.
- (iv) A legislative clarification in antitrust law of the situations where “product hopping” represents an abuse and where it does not.

Lastly, a third objection against the reform might be based on the effects which the patent exclusions discussed could produce on indigenous innovation. It might be argued that denying patents for new forms or uses of known compounds could adversely affect the domestic industry. They constitute a type of innovation with respect to which emerging industrial countries may be more active. Such a statement was made for the corresponding exclusion in the Indian Patent Act,¹⁵¹ and it might also be relevant to Bill No. 5402/13. Brazilian pharmaceutical innovators are likely to be more successful in discovering new uses and new forms of known substances than creating new chemical entities.¹⁵² Despite that, there is no basis for assuming that such a reform will negatively or positively affect the pace of innovation in Brazil or any other country adopting similar rules. Changes in municipal patent legislation do not necessarily translate into modifications in the behavior of domestic companies. This holds true even in those fields—such as the pharmaceutical sector—where there seems to be a causal link between patents and innovation. Indeed, after the significant growth of free trade in the last thirty years, the functions that the patent system is supposed to perform should be viewed in a global context.

Assuming that, at least in the pharmaceutical field,¹⁵³ patent protection can prevent a market failure and enable investment in research and development that

¹⁵⁰ See the analysis by BERTHOLD, *supra* note 46, at 128 *et seq.* and 238 *et seq.*

¹⁵¹ See Mueller, *supra* note 87, at 558 (commenting on Section 3(d) of the IPA and the exclusion for use claim as follows: “In its zeal to prevent pharmaceutical product patent holders from extending their monopolies through follow-on process patents, India may have suppressed an important means of stimulating indigenous innovation.”); see also Basheer, *supra* note 105, at 24; Du, *supra* note 38, at 254 *et seq.*

¹⁵² See Kenneth C. Shadlen, *The Politics of Pharmaceutical Patent Examination in Brazil*, in KNOWLEDGE GOVERNANCE: REASSERTING THE PUBLIC INTEREST 139, 156 *et seq.* (Leonardo Burlamaqui *et al.*, eds., 2012); see also KUNISAWA, *supra* note 11, at 127 *et seq.*

¹⁵³ The effects of patent protection on innovation are still unclear. The literature seems to agree that the patent system works differently in the various technical sectors and that at least for the chemical and pharmaceutical industry the patent protection is needed to prevent a market failure. This opinion—supported by some empirical evidence—is based on the specific features of the pharmaceutical market: the high costs of developing a marketable product—that is, an authorized drug—and the low costs of reproducing industrially the drug and eventually getting an

would otherwise be prevented by free-riding, patent exclusions in this sector can indeed deter innovation efforts. More specifically, they can reduce the outlays in the development of the type of inventions excluded from patentability. Whether or not a patent act providing for such exclusions might have such an effect on the companies located in either the territory to which said patent act applies or abroad depends on the economic significance of those markets for the companies concerned. The following example may be cited to clarify this obvious¹⁵⁴ assumption.

The U.S. and the EU are still the world's two largest pharmaceutical markets.¹⁵⁵ If patents are available in the EU and the U.S. for a specific category of inventions, this legal protection will foster innovative efforts by all companies operating in the field and for which the U.S. and the EU represent a significant¹⁵⁶ source of revenue from sales or licensing. Where these companies are located—in Europe, in the U.S., or in South America—is less relevant. For these reasons, the fact that specific medical applications of known compounds, patentable abroad, are not eligible for protection in Brazil, might not affect the behavior of Brazilian innovators. This holds true at least for those pharmaceutical companies located in Brazil for which the EU and the U.S. markets are a sufficient source of revenue to justify continuing to invest in such incremental innovations. Therefore, while the exclusions proposed in Bill No. 5402/13 could not harm indigenous innovators, they could benefit indigenous manufacturers. If other countries imitate Indian legislation in this respect, the exclusions enacted would give domestic Brazilian generic manufacturers the opportunity to also export to those markets drugs falling under the provisions corresponding to Section 3(d) of the IPA. Patent exclusions for first, second, and further medical indications could not only help keep down prices of pharmaceutical products in the internal market, but also promote the domestic generic industry without harming domestic originators.¹⁵⁷

authorization for it as a generic copy once the medicine has been brought to the market. See Bruce Lehman, *The Pharmaceutical Industry and the Patent System*, International Intellectual Property Institute, Washington, at 7 *et seq.* (2003), available at http://users.wfu.edu/mcfallta/DIRO/pharma_patents.pdf; D. Lakdawalla & N. Sood, *Incentives to Innovate*, OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 143 (2012); ADAM B. JAFFE & JOSH LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT 40 (2007). At the same time, economic studies suggest that stronger patent protection in the pharmaceutical fields might be related to faster innovation, but only in countries with higher levels of economic development; see Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection, 1978-2002*, 89 REV. ECON. & STAT., 436, 450 (2007).

¹⁵⁴ See EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 110 *et seq.* (1951); see also Nuno Pires de Carvalho, *The Rule of Patent Law (RPL) as Established by the TRIPS Agreement and Its Role in Promoting Trade Rather than Invention*, in PATENT LAW IN GLOBAL PERSPECTIVE (Ruth L. Okediji & Margo A. Bagley eds., 2014), 673, 675.

¹⁵⁵ See IMS Pharmaceutical World Review, 2013.

¹⁵⁶ Significant means high enough not only to recover the investment made but also to adequately remunerate it.

¹⁵⁷ This assumption seems to be reasonable at least when the market affected by the patent exclusions is of limited significance compared to the foreign markets where similar patent exclusions do not apply.

At the same time, this strategy of “sharing the benefit without sharing the cost”¹⁵⁸ of patent protection, if imitated by other countries, in the long term might delay the development of new pharmaceutical uses for known compounds. The incentive effect of the patent system depends on the revenues that it can guarantee in the market. The broader the potential market that might be covered by a family of valid patents, the stronger the incentive should be. It follows that if more countries ban patents on pharmaceutical inventions, the stimulus to invest in these innovations could become weaker.¹⁵⁹ This assumption would hold true for all companies operating in the field, irrespective of their geographical location.¹⁶⁰

Nevertheless, it might be argued that this was also true at the time when Switzerland,¹⁶¹ Germany,¹⁶² Italy,¹⁶³ or the Netherlands¹⁶⁴ denied product protection or even any patent protection to chemical or pharmaceutical inventions. These Western countries make use of broad patent exclusions as long as they regard this as being useful for their development.¹⁶⁵ They benefited from the patent system existing abroad and from a free imitation regime on the home market.¹⁶⁶

The counterargument might be that the world has radically changed since then.¹⁶⁷ At that time, the innovative countries could respond through protectionist measures against products from those countries which denied adequate patent protection for their citizens and industries.¹⁶⁸ That is not the case under today’s WTO regime. In addition, international free trade has increased significantly since the 19th Century.¹⁶⁹

¹⁵⁸ See FRITZ MACHLUP, AN ECONOMIC REVIEW OF THE PATENT SYSTEM 79 (1958).

¹⁵⁹ See Du, *supra* note 38, at 254.

¹⁶⁰ The assumption is a logical one: evidence of the influence of foreign IP protection on the innovation in large industrialized countries, such as the U.S. or the EU, is inconclusive. See, e.g., Larry D. Qiu & Huayang Yu, *Does the Protection of Foreign Intellectual Property Rights Stimulate Innovation in the US?*, 18 REV. INT’L ECON., 882, 883 (2010); the authors of this contribute did not find evidence that making patent protection available in foreign markets has affected the innovation rate in the United States; as consequence, they argue that the U.S. market is large enough to offer sufficient incentives for originators to invest in pharmaceutical innovation.

¹⁶¹ See Barbara Dölemeyer, *Wege der Rechtsvereinheitlichung. Zur Auswirkung internationaler Verträge auf europäische Patent- und Urheberrechtsgesetze des 19. Jahrhunderts*, in ASPEKTE EUROPÄISCHER RECHTSGESCHICHTE. FESTGABE FÜR HELMUT COING ZUM 70. GEBURTSTAG. EUROPÄISCHES RECHTSDENKEN IN GESCHICHTE UND GEGENWART 65, 83 (Horn *et al.* eds., 1982).

¹⁶² On the patent exclusion for chemical substances in Germany, see GEISSLER, DER UMFANG DES STOFFSCHUTZES FÜR CHEMISCHE ERFINDUNGEN: EINE RECHTSVERGLEICHENDE UNTERSUCHUNG ANHAND DER RECHTSLAGE IN FRANKREICH, DEN USA, SKANDINAVIEN UND DEUTSCHLAND, 3 *et seq.* (1972).

¹⁶³ See F.M. Scherer & S. Weisburst, *Economic Effects of Strengthening Pharmaceutical Patent Protection in Italy*, 26 INT’L REV. INTELL. PROP. & COMPETITION L. 1009 *et seq.* (1995).

¹⁶⁴ Netherlands abolished the patent system in 1869, and reintroduced a patent protection for nationals and foreigners in 1912. See ERIC SCHIFF, INDUSTRIALIZATION WITHOUT NATIONAL PATENTS: THE NETHERLANDS, 1869-1912; SWITZERLAND, 1850-1907, 19 *et seq.* (1971).

¹⁶⁵ See Yi Qian, *supra* note 153, at 450.

¹⁶⁶ See JAKKRIT KUANPOTH, PATENT RIGHTS IN PHARMACEUTICAL IN DEVELOPING COUNTRIES: MAJOR CHALLENGES FOR THE FUTURE, at 100 (2011).

¹⁶⁷ See GRUBB, *supra* note 148, at 57.

¹⁶⁸ The limitations to the patentability of chemical and pharmaceutical compounds in Switzerland were eliminated in 1907, after Germany threatened to introduce higher tariffs on Swiss imports. See MACHLUP, *supra* note 158, at 5; PENROSE, *supra* note 154, at 16; WALTHER STUBER, DIE PATENTIERBARKEIT DER CHEMISCHEN ERFINDUNGEN 26 *et seq.* (1907).

¹⁶⁹ GRUBB, *supra* note 148, at 57.

Again, this line of reasoning is based on a questionable equivalency. The WTO regime limits the option to enact import restrictions and adopt unilateral retaliations for developed as well as developing countries. There is no reason to see these limitations as a trade concession by developed countries to less developed ones. It is clear that any further inquiry into these political and economic questions would go beyond the purpose of this paper and likely the skills of its author.

IV. PATENT TERM

A. Abolition of Minimum Term of Protection Under Article 40, Sole Paragraph of Law No. 9279/96

As in most jurisdictions, Brazilian law provides patent protection for a term of twenty years. At the same time, it includes a compensation mechanism that has no counterpart in EU or U.S. law. Pursuant to the Sole Paragraph of Article 40 of Law No. 9279/96, if the examination of the application and the patent grant takes more than ten years, then the patent will last ten years from the issue date. The effect of the rule is that the exclusivity right conferred by any patent in Brazil, irrespective of the filing date and the applicant's behavior, has a term of at least ten years, either because the patent was granted before the ten-year pendency of the application or because it was granted later, and Sole Paragraph of Article 40 of Law No. 9279/96 therefore applies.

The reform intends to abolish this provision.¹⁷⁰ If the Bill is enacted, all patents granted by INPI will expire twenty years from the filing date.¹⁷¹

The purpose of Sole Paragraph of Article 40 of Law No. 9279/96 is to compensate the patent owner for delays in the grant procedure.¹⁷² This is a serious matter affecting several jurisdictions, and not necessarily caused by inefficiencies on the part of the competent patent office. Patent applications have grown in number and size over the last twenty years.¹⁷³ After the economic downturn between 2007 and 2012, this is likely to continue.¹⁷⁴ Indeed, other Asian and non-Asian countries—apart from Japan, China, Taiwan, and South Korea—are stepping up their

¹⁷⁰ See Bill No. 5402/13, Art. 2 (Braz. 2013).

¹⁷¹ Utility models will reach the end of their term 15 years from the filing date. See *id.*

¹⁷² See Fernando Eid Philipp & Guilherme Toshihiro Takeishi, *Legal Consequences of Backlog Patent*, 114 *Revista da ABPI* 35, 40 (2011).

¹⁷³ See Bruno van Pottelsberghe, *Lost property: The European patent system and why it doesn't work*, at p. 21 (2009), available at <http://www.bruegel.org/publications/publication-detail/publication/312-lost-property-the-european-patent-system-and-why-it-doesnt-work/>.

¹⁷⁴ With the exception of 2002 and 2009 the number of patent applications filed worldwide has increased steadily since 1978 and totaled 2.35 million in 2012. In the same year, 195,308 PCT applications were filed. Even though the latest data is twice the number published by the WIPO for 2000, the number of PCT applications filed annually remains relatively small with respect to the number of applications filed worldwide with regional and national offices. For the reported data and comparisons, see WIPO, *World Intellectual Property Indicators*, at § A, p. 43 *et seq.* (2013). On possible reasons for the relatively limited interest in PCT filings, see MARKETA TRIMBLE, *GLOBAL PATENTS—LIMITS OF TRANSNATIONAL ENFORCEMENT* 27 *et seq.* (2012).

international filings. Furthermore, the subsidy policy pursued by China¹⁷⁵ might foster imitators, even though such practice still has to pass the scrutiny of WTO rules. This would contribute to a further increase in global filing data.

Delays in examination affect not only—and not in every case—the applicants, who in specific fields seem to be more interested in maintaining pendency of the application than obtaining a decision on it quickly,¹⁷⁶ as the limited use of the PACE Program¹⁷⁷ by EPO applicants seems to demonstrate.¹⁷⁸ Delays create legal uncertainty for competitors, too. They cannot always base their entrepreneurial decisions on the assessment given by other patent offices for other members of the same patent family. In the majority of jurisdictions, the applicant is entitled to amend and limit the claims of the pending application, and could in this way possibly obtain a patent on a different legal basis even if similar applications have been rejected abroad.

In Brazil, where patent and utility models are subject to examination, delays are significant. An examination, on average, takes more than eight years.¹⁷⁹ Despite that, in view of the arbitrary character that affects the uniform term of protection granted by Article 33 of TRIPS, the intention to abolish the Sole Paragraph Law of Article 40 of No. 9279/96 seems reasonable for three reasons.

First, the rule as drafted does not treat all patentees equally because the needs of the technical sectors and the applicants concerned are different. For some of them, it is convenient to maintain pendency of an application for several years¹⁸⁰ and to have ten years of full protection after the products covered by the patent issued are brought to market. This is true, for instance, in the case of patent applications for products subject to administrative authorization. For other applicants, it might be of no value to have the term extended because the time to bring the products to market

¹⁷⁵ In China, the central government and local authorities provide different programs for subsidizing the costs of foreign patent applications filed by domestic companies; see Haijun Jin/Yuli Tu/Shutong Wang, *Government—Backed Patent Funds in China*, Tech Monitor, Oct-Dec., 24 *et seq.* (2013).

¹⁷⁶ See, with reference to U.S. filing practices, Warren K. Mabey Jr., *Deconstructing the Patent Application Backlog: . . . A Story of Prolonged Pendency, PCT Pandemonium & Patent Pending Pirates*, 92 J. PAT. & TRADEMARK OFF. SOC'Y 208, 232, 236 *et seq.* (2010).

¹⁷⁷ PACE is the acronym for the “Programme for accelerated prosecution of European patent applications” introduced by the EPO in 1997. This programme made it possible for applicants to have the application examined within shorter deadlines than otherwise provided by requesting the EPO to issue the search report together with the opinion under Rule 62(1) EPC and the first examination report; see Notice from the European Patent Office dated May 4, 2010 concerning the program for accelerated prosecution of European patent applications—“PACE,” OJ EPO 352 (2010).

¹⁷⁸ Apparently, only 7-8% of the applicants every year request accelerated prosecution, even though it does not involve additional fees or costs. See EPO, *IP5 Statistics Report 2012 Edition*, at p. 7 (2013).

¹⁷⁹ See Barbosa, *supra* note 10, at 142 (reporting data of 2011).

¹⁸⁰ See Mabey, *supra* note 176, at 232, 236 *et seq.*; see also Eugenio Hoss, *Delays in Patent Examination and Their Implications under the TRIPS Agreement*, MIPLC Master's Thesis Series (2010/11), <http://www.miplc.de/research/>, available at <http://ssrn.com/abstract=2166853>, p. 49. The situation is different for pharmaceutical inventions, where the time to bring a product to market is longer than the time needed to process a PCT application and get protection in the different designated regional and national jurisdictions.

is short, the technology in question becomes outdated more quickly, and protection is therefore most important in the first few years after the filing date.¹⁸¹

Second, the rule is inefficient.¹⁸² It grants a compensation which *de facto* may go beyond the loss the applicant has incurred for the pendency, but *de jure* falls short of what would be necessary to avoid a violation of international law.¹⁸³ Indeed, after the patent application has been published, serious competitors might refrain from using the claimed technology because of the risk of being subject to a compensation claim after the patent is issued. This holds particularly true when members of the same patent family have been granted abroad after examination. By the same token, commercial operators might refrain from ordering the claimed items from competitors of the owner of the patent application. Indeed, in the post-grant phase, use of the claimed products, if not delivered with the consent of the applicant, would infringe the patent.¹⁸⁴

De facto, the patent applicant in several cases might enjoy the advantages the grant would ensure despite the absence of an exclusivity right. *De jure*, this is not relevant from the perspective of a WTO consultation. WTO rules require that a formal right to exclude be bestowed within a reasonable period of time.¹⁸⁵

Third, there are other ways to compensate applicants for pendency of the application without creating legal uncertainty with respect to the term of the patent right. I am not referring to the general task of improving the efficiency of the Patent Office and reducing the pendency of patent applications. These are tremendous undertakings requiring hiring efforts, cooperation agreements with other national or regional Patent Offices, and a change in filing patterns that no single government

¹⁸¹ *Id.* at 49. Hoss observes that “[f]or some industries, especially in high technology fields, the timely examination of patents is crucial, because they often refer to products with short life-cycles. Those industries do not need a long period of protection, but a quick one.” See also Mabey, *supra* note 176, at 232, 243 *et seq.* (2010); Harold C. Wegner, “Three Track” TRIPS Treaty Violations, Testimony to the USPTO (July 27, 2010), <http://www.ip-watch.org/weblog/wp-content/uploads/2010/07/Wegner-ThreeTrack-July27.pdf>. Wegner observes that for some technologies not granting a patent in the first few years after filing amounts effectively to “a denial of patent protection altogether.”

¹⁸² See also Fabrício de Souza Oliveira, *Comparative Analysis of the Extension Mechanisms of Medicine Patent: a criticism of the Brazilian system*, *International Journal of Medicine and Pharmacy*, 2 (1), 29 *et seq.* (2014).

¹⁸³ See also Ctr. for Strategic Stud. & Debates, *supra* note 1, at 70, *et al.*

¹⁸⁴ Consider the case of a steel plant operator and a tender for a new plant. If a steel plant maker takes part in the tender and proposes a new plant to the operator including a technology covered by one or more patent applications still pending and owned by a competitor—for instance, a specific rolling mill or process solution to roll the laminates—it would be very risky from a legal point of view for the operator to accept this offer, even with a significant indemnification clause in the event of infringement. Indeed, operating the plant—after the patent application has been examined and the patent eventually granted—would involve an infringement of the product or process claims. As far as the product claim is concerned, the product or device has not been placed on the market with the consent of the patent owner. Therefore, no exhaustion doctrine applies and the operation of the rolling mill is in violation. Obviously, the problem described above does not have any significance for end products to be bought by private consumers and not commercial companies, because the former would be entitled to continue to use the product—even after the grant of the patent—because of the limitation of the right of the patent provided under Article 43(I) of Law No. 9279/96. Similar exemptions for the private and non-commercial use of patented items are provided for under the law of almost all WTO Members.

¹⁸⁵ See de Carvalho, *supra* note 39, 667 *et seq.* See also Part VI, Paragraph B (2) of this article.

can really handle on its own. Further, Brazilian law has already adopted some of the measures proposed by the specialized literature to handle the backlogs, such as deferred examination¹⁸⁶ or hiring efforts.¹⁸⁷ One way might be to provide the applicant—after the patent application has been published—with a full right and not merely an indemnification claim. This solution has already been adopted by countries such as Italy,¹⁸⁸ Poland,¹⁸⁹ San Marino,¹⁹⁰ and—to a certain extent—France.¹⁹¹ It would first require the patent applicant to be able to initiate litigation based on the published application, file a claim, and obtain a preliminary injunction if equitable. At the same time, it would require that a competitor, sued on the basis of a published patent application, be able to challenge the patentability of the invention covered by the asserted claim before the Court grants the preliminary injunction. From the point of view of fairness, attribution of a *jus excludendi alios* and a full damage claim before the patent has been issued does not raise concerns in those legal systems where utility models are accepted and registered as *property rights on technical inventions* without examining the prior art. In fact, no difference would exist between the right to exclusivity arising from a published patent application or that resulting from a utility model.

In this regard, Brazil moreover is an exception internationally. Utility models are subject to full examination on their merits. Whether the examination is imposed by constitutional constraints is unclear to foreign observers.¹⁹² If the question is to be answered in the negative, the solution proposed above would be available, and might eventually be combined with a reform of the utility model grant procedure.¹⁹³

¹⁸⁶ See Law No. 9279/96, *supra* note 2, Art. 33.

¹⁸⁷ Between 2004 and 2010 the number of examiners at the INPI increased from 150 to more than 400, see INPI, *Balance and Perspectives—INPI in Transformation*, at p. 13, http://www.inpi.gov.br/images/stories/downloads/pdf/INPI_Relatorio_Comunicacao_ingles.pdf.

¹⁸⁸ See Article 120.1 & Article 52.1, *Codice dei diritti di proprietà industriale* (Industrial Property Code, hereinafter *cpi*) (Italy). According to the mentioned provisions, it is possible to obtain a preliminary injunction based on a published patent application and to lodge an infringement proceeding on the merits. Moreover, the Court is entitled to grant the definitive injunction only after the patent has been granted. See Roberto Romandini, *La durata del brevetto e dell'esclusiva*, in *DIRITTO INDUSTRIALE ITALIANO 703 et seq.*, 708 (Mario Franzosi & Massimo Scuffi eds., 2014).

¹⁸⁹ See EPO, *National Law Relating to the EPC*, at Chapter IIIA (2013).

¹⁹⁰ See Article 228, Industrial Property Law (June 30, 2000, San Marino).

¹⁹¹ In France, the right to exclusivity takes effect after the patent application has been published or notified to a third party if the claims have not been amended between the publication of the application and grant of the patent. This implies that the applicant may lodge an infringement proceeding. However, pursuant to Article 615-4 IPC, the court in charge has to stay the proceeding until the grant of the patent. See Laurence Petit, *The Enforcement of Patent Rights in France*, in *PATENT ENFORCEMENT WORLDWIDE: A SURVEY OF 15 COUNTRIES: ESSAYS IN HONOUR OF DIETER STAUDER 147* (Christopher Heath & Laurence Petit eds., 2005).

¹⁹² Designs are granted under Brazilian law without examination of novelty and individual character, and this might argue *prima facie* for the assumption that *jus excludendi* granted without an examination on the merits is not in conflict with Brazilian constitutional principles. At the same time, the impact on free competition of a design right is considered far less relevant than the impact resulting from a patent or a utility model. This is seen from compulsory licenses, which are available for patents and utility models, but not for designs.

¹⁹³ See *infra* Part VI, Paragraph, B (2) of this article.

B. TRIPS Compliance

From the perspective of TRIPS, the proposal to abolish the minimum term of protection provided by the Sole Paragraph of Article 40 of Law No. 9279/96 does not give rise, *per se*, to any issues. Article 33 of TRIPS only requires a term of protection for twenty years from the filing date. Admittedly, one could argue for a systematic reading of Article 33 of TRIPS in conjunction with Article 62(2) of TRIPS, and in this case try to maintain that the former requires the Member States to provide the patent holders with a term of “*effective protection*,” minus a period of time for processing the application which must be reasonable under Article 62(2) of TRIPS. However, such a reading of Article 33 has already been rejected by a WTO panel¹⁹⁴ and by a WTO appellate body.¹⁹⁵ Both came to the conclusion that Article 33 lends no support “to the notion of an ‘effective’ term of protection as distinguished from a ‘nominal’ term of protection.”¹⁹⁶ This conclusion is worthy of approval. The Treaty clearly differentiates between the “*term of protection*” (Article 33 of TRIPS) and the “*period of protection*” (Article 62(2) of TRIPS),¹⁹⁷ and takes into account that the latter, because of the grant procedure, may be shorter than the former.

Consequently, where the law of a country provides for a term of protection that is shorter than twenty years, that situation is non-compliant with Article 33 of TRIPS even if the grant procedure is so fast that the effective term of protection in that country is longer than that of the majority of WTO Members. Conversely, if the law of the country provides for a term of protection of 20 years from the filing date, this situation is consistent with Article 33 of TRIPS even if the grant procedure in that country systematically takes more than ten years and the applicants, under the same national law, were entitled only to a compensation claim—but not to injunctive relief against acts of exploitation committed before the grant of the patent—with the result that, for most of the patent’s life, the inventions were protected by a liability rule and not a property rule.¹⁹⁸

Nevertheless, in a similar situation other provisions of the TRIPS Agreement might call for action on the part of the Member State concerned.¹⁹⁹

¹⁹⁴ See *Canada—Term of Patent Protection*, Report of the Panel WT/DS170/R (circulated May 5, 2000).

¹⁹⁵ See *Canada—Term of Patent Protection*, Report of the Appellate Body WT/DS170/AB/R, AB-2000-7 (circulated Sept. 18, 2000).

¹⁹⁶ See *id.* at 95.

¹⁹⁷ Two other authentic versions of the Treaty—the Spanish and the French—use two different expressions for the formal term of protection pursuant to Article 33 of TRIPS and the effective period of protection referred to in Article 62(2) of TRIPS. See, respectively, in French the expressions *Durée de la protection* and *période de protection*, and in Spanish *Duración de la protección* and *período de protección*. The Portuguese version distinguishes between *vigenza de proteção* and *prazo de proteção*. By contrast, the German official translation of the Treaty uses in both Article 33 of TRIPS and Article 62(2) of TRIPS the expression *Schutzdauer*. The German version, in any case, is not an authentic text.

¹⁹⁸ According to Hoss, however, “there might be some particular cases where an excessive delay could be considered a violation of Article 33 TRIPS, e.g., if the delay is so long that it goes beyond the term protection.” Hoss, *supra* note 180, at 40.

¹⁹⁹ See *infra* Part VI, Paragraph B(2) of this article.

V. GOVERNMENT USE

A. Premise

Various TRIPS Member States allow government use of patented inventions.²⁰⁰ By contrast, Law No. 9279/96 does not expressly regulate this power of the executive branch. This does not mean that government uses of patented inventions are not possible under Brazilian law. Pursuant to Article 71 of Law No. 9279/96, “in cases of national emergency or of public interest, as declared in an act of the Federal Executive Power, and provided the patent holder or his licensee does not fulfill such need, a temporary and non-exclusive compulsory license for exploiting the patent may be granted, *ex officio*, without prejudice to the rights of the respective title holder.”²⁰¹

According to the literature, this provision may cover cases such as the use of the invention by a public administration contractor or by a public agency to perform a public function, which in another legal system would fall under an exception of use by the crown. However, the procedure is more burdensome. The authorization is only possible when the patentee is not able or willing to fulfill the public need. According to some commentators,²⁰² such requirements make negotiations with the patent holder necessary prior to granting the compulsory license.²⁰³ Furthermore, the use must not only be public and non-commercial, but must also serve the public interest. Hence, the regulation is considered stricter than what TRIPS would require.

Whatever the shortcomings of the regulation in force, the declared purpose of Bill No. 5402/13 is to streamline the procedure for the government to engage the use of patented technologies. Thus, Bill No. 5402/13 proposes that Law No. 9279/96 should be supplemented with a new rule, entitled Article 43A, which would provide as follows:²⁰⁴

²⁰⁰ For a brief comparative overview of the government use in other jurisdictions, see Celeste C. Yang, *Crown Use and Government Use*, in COMPULSORY LICENCING—PRACTICAL EXPERIENCES AND WAYS FORWARD 398 *et seq.* (Hilty Reto & Kung-Chung Liu eds., 2014) (proposing a distinction between crown and government use); Ana Paula De Freitas Cosenza, *O Uso Governamental das Patentes—Uma possibilidade para a Saúde Pública no Brasil*, Ph.D. Thesis, at 17 *et seq.* (Braz. 2010), available at http://www.ie.ufrj.br/images/pos-graduacao/pped/defesas/10-Ana_Paula_de_Freitas_Cossenza.pdf; Blake Evan Reese, *Do As I Say, Not As I Do: An International and Comparative Study of Governments’ Rights to “Infringe” Patents in Light of the Federal Circuit’s Recent Interpretation of 28 U.S.C. § 1498 and a Call for Congress to Modernize the Statute*, 4 BUFFALO INTELL. PROP. L.J. 84, 106 *et seq.* (2006); ADVISORY COUNCIL ON INTELLECTUAL PROPERTY (ACIP), *REVIEW OF CROWN USE PROVISIONS FOR PATENTS AND DESIGNS*, 13 *et seq.* (Nov 2005).

²⁰¹ The requirements provided under Article 71 of Law No. 9279/96 have been specified in Decree No. 3,201, of October 6, 1999, lastly amended by Decree No. 4830/2003 of September 3, 2003.

²⁰² See De Freitas Cosenza, *supra* note 200, at 27.

²⁰³ See MARISTELA BASSO ET AL., *INTELLECTUAL PROPERTY LAW IN BRAZIL* 95 (2010).

²⁰⁴ This proposal for reform is inspired by a previous proposal submitted by an authoritative Brazilian Scholar, Denis Borges Barbosa, in *Proposta para introduzir o uso público não comercial das patentes no direito brasileiro*, 2010, available at http://www.denisbarbosa.addr.com/arquivos/200/economia/proposta_uso_patentes.pdf (last visited Aug. 8, 2014).

The Government, by Ordinance from the Minister of State concerned, may use the subject matter of a patent or of a patent application, for non-commercial purposes, without consent or authorization from the patent holder or patent applicant, directly or upon contract or authorization to third parties, for public interest purposes, including national defense and social interest.

- § 1 Should the invention be a process, the public non-commercial use of the patent or the patent application shall include the use in relation to any product that may be obtained by the process that is protected by the patent or the patent application;
- § 2 The Government shall notify the patent holder or patent applicant upon public non-commercial use;
- § 3 Public non-commercial uses shall meet the following conditions:
 - I—not hinder the full exercise of the other rights of the patent holder or patent applicant;
 - II—be non-exclusive, and not admit sub-licensing;
 - III—be undertaken exclusively to serve the goals of the Ordinance that authorized it, resting assured that any other use that, without the character of public non-commercial use, would constitute an infringement of Article 42 of this Act, is hereby prohibited;
- § 4 The remuneration for public non-commercial use shall be set by the Government, taking into account the circumstances of each use, and shall take into account the percentage that would customarily incur upon a voluntary license between independent parties, applied over the cost for the Government resulting from the use of the subject matter of a patent or patent application, and weighed according to the collaboration supplied by the patent holder in the transfer of technology;
- § 5 In the case of patent applications, the remuneration shall be legally deposited until the granting of the patent;
- § 6 The Judiciary shall not, in regard to public non-commercial use, decide whether public interest purposes apply;
- § 7 Public non-commercial uses shall not be lifted, limited, or interrupted by legal appeal over the appointed remuneration.

The proposed Article 43A is not intended to replace Article 71 of Law No. 9279/1996, and therefore, both provisions would co-exist. This provision also presents slightly different wording from the definition of government use provided in Law No. 11484/2007 on the protection of Topographies of Integrated Circuits, for which a public interest is not required.²⁰⁵ Whether the difference is relevant for the application of Article 43A will depend upon how the courts interpret

²⁰⁵ Pursuant to Article 47 of Law No. 11.484 of May 31, 2007 “the Public Authorities may make public, non-commercial use of protected topographies, directly or by contracting or authorizing third parties, observing the provisions of items III to VI of the main body of Article 49 and the provisions of Article 51 of this Law.” See the English translation of the Law No. 11.484/2007 available at http://www.wipo.int/wipolex/en/text.jsp?file_id=272285.

the term “public use.” If the latter only includes uses for public functions, then a public interest, in this case, would exist as well, and the difference between the proposed Article 43A and Article 47 of Law No. 11484/2007 would be only of a stylistic nature.

B. TRIPS compliance

Article 31 of TRIPS expressly allows government use of patented inventions but subjects them to the same procedural guarantees provided for other not authorized uses. The only exception concerns the need for prior negotiations with the patentee. In this regard, the Treaty distinguishes between public commercial uses and public non-commercial uses of the patented subject matter. The signatories may allow the latter without requiring the public agency to first obtain a license with reasonable commercial terms from the patentee.²⁰⁶

Bill No. 5402/13 reproduces the conditions specified under Article 31 of TRIPS, but with three deviations.

First, the proposed Article 43A does not provide that the use of the invention shall predominantly serve the supply of the domestic market, and hence does not follow Article 31(f) of TRIPS. Second, the provision excludes the existence of a public interest purpose from judicial review, and hence seems to go beyond Article 31(i) of TRIPS. Third, for determining remuneration, the rule makes relevant the circumstance of whether the patentee cooperated or not with the authority transferring know-how material for using the invention, and hence, considers relevant a circumstance which Article 31 of TRIPS does not factor.

The first divergence—the silence over the predominantly domestic destination of the outcome resulting from the authorized use—is only apparent. Indeed, government use is to be granted pursuant to Article 43A only when a public interest exists. It appears rather straightforward that the public interest, to which the proposed legislation refers, is the one existing in the patent-granting country. Because the ordinance, pursuant to Article 43A, must determine the goals for which the use is to be undertaken, the purpose thereby indicated can be reasonably assumed to satisfy the specific interest that justifies the enactment of the ordinance, and therefore fulfills a specific social or technological need within the Brazilian Federation. Thus, the language of the proposed Article 43A does not indicate *per se* a TRIPS violation. Another conclusion is possible if ordinances based on Article 43A—should the provision be legislated—are adopted to allow public companies to exploit patented technologies with the purpose of strengthening their competitiveness and to allow them to export in patent-free countries. However, in this case, the use in question would likely be of a commercial nature within the meaning of Article 31 of TRIPS. The borders defined by Article 43A would have been crossed anyway.

The prong of the proposed Article 43A that prevents the courts from examining whether a public interest exists at the basis of the authorization²⁰⁷ is more

²⁰⁶ See TRIPS Agreement, Art. 31(b).

²⁰⁷ Article 43A § 6, *see* Bill No. 5402/13, at Art. 3.

problematic.²⁰⁸ Article 31(1)(i) of TRIPS mandates judicial review of the decision authorizing the use of the invention and does not admit any exceptions. With respect to the proposed new Article 43A, one could argue that, for government use, TRIPS does not require any condition, including that use of or on behalf of the public agency should be “non-commercial” and “public.” These two requirements apply only when the government intends to exploit the patented technology without first trying to get a license on reasonable terms from the patentee. Consequently, a WTO-Member attempting to make government use dependent upon further conditions—not requested by TRIPS—while at the same time excluding any legal challenges based on their alleged absence could be legitimate. Such reasoning is possible, but not convincing. The TRIPS Agreement has not limited the ability of Member States to determine the reasons for granting compulsory licenses to private parties,²⁰⁹ but the Treaty requires two conditions for the signatories: (1) they must first codify—i.e., formally list in a law or decree—the cases in which an unauthorized use may be allowed (*where the law of a Member State allows for other use*, TRIPS Article 31(1)); and (2) they must allow judicial review over the validity of the decision granting the authorization (Article 31(1)(i)).

It would contravene at least TRIPS Article 31(1)(i) to formally allow for such a review, while at the same time exempting from the inquiry the issue of whether the legislative reason for the authorization existed in the specific case.²¹⁰

The last deviance, which implies a lower remuneration for the patentee in cases in which the patentee does not cooperate or transfer the know-how for practicing the technology covered by the patent, does not meet significant objections. In cases of infringement, a possible criterion for determining compensation—recognized by all

²⁰⁸ In the prudent Proposal of Professor Denis Borges Barbosa (see *supra* note 204), which inspires Bill No. 5402/13, such limitation to judicial review is absent. The mentioned proposal provides only that a judgment by the judiciary may not interfere with the public use as long as it did not become *res judicata*. Therefore, on the basis of the wording proposed by the Brazilian scholar, the patentee was entitled to challenge the decision to make public use of the invention with the argument that no public interest requires such use. On the question whether this limitation of the judicial review provided in the Bill is consistent with the division of powers under Brazilian constitutional law, see Marcelo Lauer Leite, *Uso nao comercial do objeto ou pedido de patente pelo estado brasileiro—Criticas ao PL 5402/13*, p. 13 et seq., available at http://www.ij.fd.uc.pt/publicacoes_estudos_en.html.

²⁰⁹ See Paragraph 5 of the *Declaration on the TRIPS Agreement & Public Health*, WT/MIN(01)/DEC/2, adopted on November 14, 2001) [hereinafter Doha Declaration], stating that “each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.” On the interpretative Status of Doha Declaration under Article 31 of the Vienna Convention of the Law of Treaties see the analysis by James Thuo Gathii, *The Legal Status of the The Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J. OF L. & TECH., 292 et seq. (2002); see also Max Planck Inst. for Innovation & Competition, *supra* note 6.

²¹⁰ By the same token, the judicial review is possible for the “public” and “not commercial” character of the use. For the literature, the term “public” can have a double meaning. First, it “implies a collective purpose, one in the public interest.” Second, it means that the “operation is carried out, supervised or controlled by a public entity.” See DE CARVALHO, *supra* note 39, at 406. Against this background, if the authorized use is of a public nature within the meaning of Article 31 of TRIPS, it will likely serve a public interest as well. If in practice the Courts by teleological interpretation refrain from examining whether or not the authorized use is public because such examination would imply assessing the existence of a public interest, then the provision and the related practice will likely infringe upon Article 31 of TRIPS.

TRIPS Member States—consists of the reasonable royalties that a voluntary licensee would have paid for using the patented subject matter. In these cases, even if the infringer paid exactly the same fees as the hypothetical (or real) volunteer licensee, the burden for both is not the same. The volunteer licensee usually has an implied right to assistance and to the transfer of information instrumental to the use of the invention. The royalty fees practiced in that sector or agreed in the license take into account these ancillary duties of the patentee. In contrast, the infringer does not benefit from the assistance of the rights-holder by exploiting the protected technology.

In the case of a compulsory licensee, the use of the invention is legal and the licensee is not an infringer. Therefore, it is justifiable to detract from the remuneration due to the additional costs that incur because of the refusal of the patentee to transfer information or give necessary or useful instructions for the exploitation of the claimed technical teaching.

Furthermore, the wording of TRIPS does not require the patentee to be put in the same condition as if the authorized use had not taken place.²¹¹ Such an interpretation means an implicit restriction for reasons for which the compulsory license may be granted. Indeed, it would not be possible to use the compulsory license as a tool to reduce the price of the patented products.²¹² A compulsory license would remain meaningful only in cases in which the patent owner is either unable or unwilling to satisfy domestic needs.²¹³ However, such limitations on the possible reasons for a compulsory license were not agreed upon.²¹⁴ Therefore, it would be in conflict with this understanding of the Agreement, accepted by the Member States, to derive such a limitation through interpretation of the term “adequate remuneration” in Article 31 of TRIPS. The wording of the latter provision does not endorse such a reading. It mandates indeed an “adequate remuneration” that takes into account the

²¹¹ *But see* Martin J. Adelman, *Compulsory Licensing of Drugs: TRIPS Context*, Paper Presented at ATRIP Annual Meeting in Tokyo, Japan (Aug 4 2003). According to Adelman:

Thus the TRIPS agreement permits compulsory licensing under conditions defined in Article 31, but only if the licensee pays a royalty equal to adequate damages. The actual language of Article 31(h) is the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization. If these words are taken literally, then actual damages caused by the grant of a compulsory license is the measure of adequate remuneration (any other measure is by definition inadequate and arbitrary). Under such conditions compulsory licensing is only useful when the patent owner is unwilling or unable to provide a sufficient supply of a needed patented drug.

Id. at 4. *See also* Martin J. Adelman, *The Role of Patents in the Quest for Affordable Access to Drugs*, Presentation to the World Bank in Washington, D.C. (June 2, 2003).

²¹² *See* Samuel Mark Borowski, *Saving Tomorrow from Today: Preserving Innovation in the Face of Compulsory Licensing*, 36 FLA. ST. U. L. REV. 275, 301 *et seq.* (2009) (arguing that basing “adequate remuneration on a lost profits standard as determined by full market value would defeat the very purpose of compulsory licensing within the TRIPS Regime,” i.e. “promote the public health through lower medicine costs” because “when royalties are based upon lost profits, no subsequent price reduction follow.”). *See also* F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations*, 5 J. INT’L ECON. L. 913, 921 (2002).

²¹³ This is the conclusion that Professor Adelman draws from the understanding of Article 31 of TRIPS as mandating a remuneration equivalent to damage award. *See* Adelman, *supra* note 211.

²¹⁴ *See supra* note 209.

“*economic value of the authorization.*” A definition of both terms is lacking in the Agreement. It seems clear, however, that the terms “*adequate remuneration*” and compensation of losses or lost profits are not co-extensive, and that the expression “*value of the authorization*” does not refer to the value which the patent or the compulsorily licensed technology has for the patentee.²¹⁵

As long as Article 43A does not sanction the patentee with the loss of any reasonable compensation in cases in which the patentee refuses to cooperate or transfer know-how, the rule seems to not only be TRIPS-compliant but even advisable. It creates an incentive for the rights-holder to assist the public authority under whose supervision or interest the public use will occur.

VI. PROCEDURAL NORMS

A. *Premise*

Bill No. 5402/13 provides, *inter alia*, for two modifications to the patent grant procedure. First, it intends to adopt a pre-grant opposition system. Second, it intends to confirm and specify the role of the *Agência Nacional de Vigilância Sanitária* (ANVISA) in the examination of the patent applications. While the model for the first legislative measure is provided by the Indian Patent Act of 1970, to which the study supporting the reform expressly refers,²¹⁶ the role of ANVISA in the grant procedure is already provided for under Brazilian law. The reform is motivated by the domestic case law questioning such role.

B. *Creation of a Pre-Grant Opposition Procedure*

1. *Third-Party Participation in the Grant Procedure*

The aim of an examination system is to prevent the grant of patents that do not satisfy the requirements for protection under applicable law. The examiner alone is not always in a position to guarantee such an outcome. This is particularly true when the relevant patent act considers any information made accessible to the public in any language, and in any form anywhere in the world, as prior art capable of being cited against the invention claimed. Today, this is the rule provided in the vast majority of patent systems, including those of Europe²¹⁷ and Brazil.²¹⁸

The reasons for these shortcomings in examination are well known. Beyond human failure, a patent office does not have access to all pieces of information that

²¹⁵ See Xiuqin Lin, *Prior Negotiation and Remuneration for Patent Compulsory Licensing: Practice, Problem, and Proposal*, in COMPULSORY LICENCING—PRACTICAL EXPERIENCES AND WAYS FORWARD 165, 182 *et seq.* with further references (Hilty Reto & Kung-Chung Liu eds., 2014).

²¹⁶ See Ctr. for Strategic Stud. & Debates, *supra* note 1, at 70, *et seq.*

²¹⁷ See EPC, *supra* note 24, at Art. 54(1)-54(2).

²¹⁸ See Law No. 9279/96, *supra* note 2, Art. 11 § 2. In contrast to European law, Brazilian law provides for a grace period. See *id.* Art. 12.

would constitute prior art under such a legislative model. Information published in writings other than patent applications or articles contained in databases accessible to the office are rarely available to the examiner. Moreover, prior uses and oral disclosures can hardly be taken account of in the examination. The same holds true for some online publications. Even patent literature, if published in languages not known to the examiner, may be ignored or misunderstood because of the inadequacy of automatic translations.²¹⁹ With the growing importance of Asian technical publications, the purpose of any examination system—to prevent the grant of patents which turn out to be invalid in revocation procedures—may be better served only with the cooperation of the public, or, more precisely, with the cooperation of those entities (not only competitors) operating in the field of the invention.

In this regard, third-party participation in proceedings before the grant authority serves two complementary purposes. On the one hand, it supplements the examiner with information not available to or overlooked by him.²²⁰ On the other hand, it shows the office which patents or patent applications really matter to the public.²²¹ In this way, the system should be capable of not only reducing the likelihood of patents being granted that later turn out to be invalid, but also of performing this function while paying specific attention to those patents or patent applications which competitors consider relevant for their activities.

It is not surprising, therefore, that almost all patent systems providing for a substantive examination also provide for third-party participation. From a diachronic and synchronic perspective, three primary models have been seen so far.

The first one is based on a pre-grant opposition model in which any third party has the right to challenge the patentability of the invention prior to the grant of the patent. After the grant, any party—including former, but unsuccessful, opponents—would be able to initiate a revocation procedure, without *res judicata* or *estoppel* arising from the opposition lodged in the grant procedure. This system was dominant in examination countries up to the 1980s. Since then, it has gradually given way to the post-grant opposition model. Today, only a few jurisdictions, among them Australia²²² and Israel,²²³ contemplate a pre-grant opposition.

The second model is based upon a post-grant opposition procedure. In this variant, it is possible to file an opposition before the granting authority, but only after the latter has issued the patent. Before the patent is granted, third parties are usually entitled to provide the examiner with information and documents, but

²¹⁹ On the problems surrounding machine translations of prior art, see T 1343/12 of Oct 10, 2014, margin numbers 4.7.8 (unpublished)—Dust adsorbing oil/UNI-CHARM.

²²⁰ See Michael A. Carrier, *Post-Grant Opposition: A Proposal and a Comparison to the America Invents Act* (September 21, 2011), 45 UC DAVIS LAW REV 103, 116 (2011).

²²¹ With respect to the European opposition system, see Bronwyn H. Hall and Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System—Design Choices and Expected Impact*, 19 Berkeley Tech. L.J. 989, 1006 (2004) (observing that “opposition at the EPO has a screening property: particularly valuable patents are more likely to be opposed than low value ones”); Mabey, *supra* note 176, at 232, 268 (noting that “the vast majority of patents are never used, never commercialized, never asserted, and never challenged” and is therefore likely not relevant for the public). See also the data quoted by Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1497 (2001) (only 2% of all patents granted are litigated in the United States).

²²² On the opposition system in Australia, see the analysis by Kimberlee Weatherall *et al.*, *Patent Oppositions in Australia: The Facts*, 34 UNSW L.J., 93 *et seq.* (2011).

²²³ See Patent Law, 5727-1967 (consolidated as of 2014), Articles 3 & 30 (Isr. 1967).

without a right to be heard. This model is adopted by the EPC²²⁴ and was reintroduced in Japan²²⁵ in 2014.

Lastly, the third model is found in Indian law. It combines pre-grant²²⁶ and post-grant²²⁷ opposition procedures²²⁸ before the patent office with a trial invalidation procedure before the courts.²²⁹ In the pre-grant as well as post-grant procedures, the opponent has a right to be heard under Section 25(1) of the India Patent Act of 1970.

While Brazil had a pre-grant opposition system for a long time,²³⁰ the law in force resembles the situation under the EPC. Before the grant, third parties may file documents with the office without becoming parties to the procedure.²³¹ After the grant, they may initiate an administrative procedure for revocation before the INPI²³² and a revocation proceeding before the Federal Courts.²³³ The reform intends to create a further option—i.e., the filing of pre-grant opposition. The proposed provision reads as follows:

Article 31. From the publication of the patent application until the end of the examination, any interested party may file an opposition.

§ 1 The applicant shall be notified of the opposition through publication in the official gazette, and may respond within 60 days from the publication of the opposition.

§ 2 In cases where an opposition to a patent application is filed, the Brazilian Patent Office may commission technical opinions from the Public Administration, from organizations recognized by the Government as consultancy bodies, and from university professors and students.

§ 3 After the opposition is filed, the examiner may, upon justified demand, apply for any additional clarification he/she deems necessary, as well as the presentation of supplementary documents.

²²⁴ See EPC, *supra* note 24, Articles 99-105 & 115.

²²⁵ See Act on the Partial Revision of the Patent Act and Other Acts (Act No. 36 of May 14, 2014).

²²⁶ See § 25(1), Patents (Amendment) Act, 2005, No. 15, Acts of Parliament, 2005 (India).

²²⁷ See *id.* § 25(2).

²²⁸ On the Indian opposition system, see M.B. RAO & MANJULA GURU, PATENT LAW IN INDIA 176 *et seq.* (2010); Mueller, *supra* note 87, at 567 *et seq.*

²²⁹ An even broader model for pre-grant third-party challenges has been adopted by New Zealand in the Patent Acts 2013, 68/2013, approved on September 13, 2013. According to the new law, a third party can choose between (i) filing material and observation up to publication of the acceptance by the examiner; (ii) initiating a pre-grant opposition (Sections 92 of the Patents Act of 2013) within a period of three months from publication of the acceptance; (iii) requesting a re-examination (Sections 94 and 95 of the Patents Act of 2013) before or after the patent has been granted. After the patent has been granted, it is further possible to request (iv) a post-grant re-examination or file (v) a revocation application before the Controller of the Patent Office. Opposition and revocation are *inter partes* procedures, pre-grant and post-grant reexamination are *ex parte* procedures, since the third party has no right to influence the examination or to be heard by the Controller.

²³⁰ See Ctr. for Strategic Stud. & Debates, *supra* note 1, at 71, *et al.*

²³¹ See Law No. 9279/96, *supra* note 2, Art. 31.

²³² See *id.* Art. 50-51.

²³³ See *id.* Art. 56-57.

§ 4 The examiner shall mandatorily respond to each filed opposition, indicating the reason for which he/she accepts or rejects the arguments presented.

While the content and the impact of the regulation may be analyzed and predicted only by scholars familiar with the Brazilian prosecution practice, two remarks—from a European perspective—might nonetheless be stated at this stage.

According to the Report supporting Bill No. 5402/13, the pre-grant opposition should replace the “*input for examination*” model—that is, the option to submit information and documents to the examiner—provided by the current wording of Article 31 of Law No. 9279/96.²³⁴ Such a statement actually does not seem to find support in Bill No. 5402/13.²³⁵ In any case, from a European perspective, the abolition of the option provided by Article 31 of Law No. 9279/96 in force would be at odds with the reform’s purpose of increasing the quality of the granted patents by improving third-party participation in the grant procedure. Under the European patent system, the right to file information (Article 115 EPC) and the right to file an opposition (Article 99 EPC) are not deemed functionally equivalent,²³⁶ not only because the former is available before and after grant. Filing observations under Article 115 EPC does not incur costs and may be done anonymously.²³⁷ This matters because entities might be hesitant to challenge the patent where they are the licensor of the patentee for the same or other patents, or are in anyway contractually or economically bound to the patentee.²³⁸ Third parties—knowledgeable in the field

²³⁴ See Ctr. for Strategic Stud. & Debates, *supra* note 1, at 70 (“thus, we believe that the replacement of the input to examination institute for the pre-grant opposition institute provided by law in many countries such as India and China, for instance, can strengthen the participation of third parties in the process as well as, and most importantly, increase patent quality”).

²³⁵ Indeed, a new rule of Bill No. 5402/13 aims at strengthening the third-party participation system by requiring the INPA to establish “an intuitive electronic channel, of easy access, connected to the Internet, for any person to present, free of charge, evidence or proof of previous existence, in Brazil or abroad, of the related invention or state of the art.” This ability of a third person to submit evidence online is to persist even after the patent has been granted and especially during the opposition and the “post-grant opposition procedures.” See the proposed Sole Paragraph to Article 31-A, which reads as follows: “It shall be allowed the presentation of evidence or proof of prior existence, in Brazil or abroad, of the related invention or state of the art, even after a patent is granted, and especially during the opposition and the post-grant opposition procedures.” With the term “post-grant procedure” it is meant the administrative revocation procedure provided under Article 50 *et seq.* of Law No. 9279/96.

²³⁶ See the analysis by Teschemacher, *Einwendungen Dritter*, Commentary to Article 115 EPC, margin numbers 1 *et seq.* in EUROPÄISCHES PATENTÜBEREINKOMMEN (Friedrich K. Beier, *et al.*, eds., 2004).

²³⁷ On the possibility of filing anonymous third-party observations, see the Decision of the President of the EPO of May 10, 2011, OJ EPO 2011, at 418; Notice from the EPO, May 11 2011, OJ EPO 2011, p. 420; on the compatibility of the Decision of the President of the EPO with Article 115 EPC see T 1336/09, Decision of 14 December 2011 (unpublished), margin number No. 2.2.

²³⁸ See the following comments by the USPTO in “Changes To Implement the Pre-issuance Submissions by Third Parties Provision of the Leahy-Smith America Invents Act. Final Rule,” 77 FR 137 42150-42174 (July 17, 2012), available at <http://www.gpo.gov/fdsys/pkg/FR-2012-01-05/pdf/2011-33811.pdf>:

The Office believes that providing anonymity would encourage small-entity third parties to submit prior art. Without such anonymity, there are situations where potential small third-party start-ups would be hesitant to make a third-party

of the invention—might refrain from confronting the owner of the patent applications with an opposition, but may be willing to exercise the option under Article 115 EPC.

The mechanism under Article 31 of Law No. 9279/96, instead of being abolished, might be reformed in order to allow anonymously filed observations, something that is possible in the PCT system,²³⁹ but (apparently) not under Brazilian law.²⁴⁰

Second, what differentiates a grant procedure with third-party participation from one with pre-grant opposition is that the latter, originally *ex parte*, after filing of the opposition becomes *inter partes*. This is the case, however, only when both parties are provided with a right to be heard. Such a right, at the moment, does not seem to be clearly articulated in the reform proposal.

2. TRIPS compliance

In the parliamentary report supporting the reform proposal, it is assumed that TRIPS is not relevant when it comes to choosing which administrative mechanism may be provided by the law to third-parties for opposing or revoking the grant of a patent.²⁴¹ This understanding of the Treaty is correct as far as the choice of whether or not third parties may challenge the patentability of the invention or the validity of the patent is concerned. However, it is not accurate with respect to the effects of the specific regulation adopted. Three TRIPS provisions are crucial in this context.²⁴²

The first one is laid down in Article 62(1) of TRIPS and reads as follows:

Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part. II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.

The other provision is encapsulated in Article 62(2) of TRIPS, and reads as follows:

submission, for example in a case in which the third party were concerned with damaging a valuable relationship with the larger applicant. Anonymity helps small start-ups in supplying prior art against applications submitted by large entities (not necessarily competitors) with whom they may have a relationship.

See also Harold C. Wegner, *Third Party Submissions: The Final Rule* (July 17 2012) (commenting on the remarks reported above by the Patent Office).

²³⁹ *See* Section 801(1)(i) of the Administrative Instructions under the Patent Cooperation Treaty, WIPO PCT/AI/14 REV, June 22 2014, according to which “the third party observation system shall provide a third party with the option to remain anonymous.” This option is provided only under the Administrative Instructions, and it is not expressly regulated (as well as not prohibited) by the Treaty and by the Implementing Regulation to the Treaty. Pursuant to Article 89(1) of the PCT Regulations, the Administrative Instructions are valid as long as they are not in conflict with the provisions of the PCT Treaty and PCT Regulations, or any agreement entered into by the International Bureau with an International Searching Authority, or an International Preliminary Examining Authority.

²⁴⁰ *See* Stéphanie Celaire, *Third Party Observations: a weapon to integrate into your IP strategy?*, p. 6 *et seq.* (2013), at 7, available at http://www.regimbeau.eu/REGIMBEAU/Web/Pages/Article.aspx?Language=EN&Article_Id=438.

²⁴¹ Ctr. for Strategic Stud. & Debates, *supra* note 1, at 73, *et al.*

²⁴² *See* DE CARVALHO, *supra* note 39, at 667 *et seq.*; *see also* Hoss, *supra* note 180, at 27 *et seq.*

Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

Lastly, Article 62(4) of TRIPS provides that:

Procedures concerning the acquisition or maintenance of intellectual property rights and, where domestic law provides for such procedures, administrative revocation and *inter partes* procedures as opposition, revocation and cancellation, shall be governed by the general principles set out in Article 41.2 and Article 41.3.

Of relevance for the present analysis is the former provision referred to by Article 62(4) TRIPS—i.e., Article 41(2) of TRIPS. This provision requires the procedures for the enforcement of IP rights under domestic law to be “*fair and equitable*,” not “*unnecessarily complicated or costly*,” and that they not “*entail unreasonable time-limits or unwarranted delays*.” Article 62(4) renders these principles binding also for the grant, opposition and revocation procedures.

It follows from a contextual reading of all the provisions mentioned that the procedures for the acquisition and maintenance of IP rights shall: (i) be reasonable (Article 61(1) of TRIPS); (ii) ensure the granting or registration of the right within a reasonable period of time (Article 61(2) of TRIPS); and (iii) avoid delays which are unwarranted (Article 61(4) in conjunction with Article 41(2) of TRIPS).²⁴³

As far as the first requirement is concerned, scholars consider a procedure to be reasonable within the meaning of Article 62(1) of TRIPS if it is aimed at assessing whether the claimed subject matter satisfies the requirements for protection which the Treaty itself expressly mandates or implicitly allows.²⁴⁴

As to the second limitation, the legislature must design the procedure in order to make the grant possible within a reasonable period of time “so as to avoid unwarranted curtailment of the period of protection.” It is controversial whether or not the expression “so as” qualifies the obligation to grant right under a reasonable period of time under Article 62 of TRIPS. If the expression does not qualify the obligation,²⁴⁵ a situation where the grant of the patent is not possible within a

²⁴³ See *id.*

²⁴⁴ See LAWSON, MALBON & DAVISON, *supra* note 100, at Art. 62, margin number 62.05 (2014); Nuno Pires de Carvalho, *From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent*, 17 WASH. U. J. L. & POL'Y 111, 125 (2005).

²⁴⁵ See DE CARVALHO, *supra* note 39, at 671. De Carvalho observes that:

It should be emphasized that paragraph 2 obliges WTO Members to adopt procedures for grant or registration that permit the acquisition of the rights in a speedy manner. This is important, because certain WTO Members find it easier to adopt measures that, being palliative, accord applicants a certain alleviation of the negative impact of excessive delays, but do not eliminate the delays.

reasonable period of time—even if examination is requested—would be in conflict with Article 62(2) of TRIPS, even if no curtailment of protection resulted from the delay.²⁴⁶ If the expression, by contrast, qualifies the obligation, then the Member States comply with Article 62(2) of TRIPS, even if the procedure does not ensure, upon request by the applicant, that the patent is granted within a reasonable period of time, provided that a protection sufficient for the TRIPS standard is bestowed on the applicant.²⁴⁷ The latter interpretation is the more convincing one. From a textual point of view, it gives an autonomous meaning to the clause introduced by “so as,” which would otherwise be superfluous. From a teleological point of view, it is consistent with the purpose of Article 62(2) of TRIPS, which seems to oblige the Member States to ensure within a reasonable period of time not the formal grant of a patent as such, but the grant of a legal protection that is consistent with the standard requested by Article 28 of TRIPS. It does not matter whether this protection is conferred by granting the patent after examination, by registering it without examination, or by attributing a *jus excludendi* before formal grant. TRIPS does not mandate the manner in which the exclusivity rights are created, but only their content and their term. For this reason, it is understood that Article 62(2) of TRIPS prohibits only delays that affect the protection requested.

Against this background, the proposed Article 31 for Law No. 9279/96 involves the following problem.

An opposition may be filed up to the end of the examination process. The examination process ends—according to Article 32 of the Normative Instruction No. 30/2013 of December 4, 2013—on the “date of the conclusive opinion report regarding patentability, or the thirtieth day prior to the publication of the decision of acceptance, rejection or definitive shelving, whichever of these is the last to occur.”²⁴⁸ According to the proposed Article 31 § 4, the “examiner shall mandatorily respond to each filed opposition, indicating the reason why he or she accepts or rejects the arguments presented.” Since the regulation proposed allows oppositions during the whole pendency of the application, the procedure is open to abuse. For example, it is possible for third parties to file serial and consecutive oppositions for as long as the final written report has not been issued, requiring the examiner to consider each of these one at a time. The regulation might therefore give rise to controversy under Article 62 of TRIPS. On the one hand, it could be challenged as unreasonable under Article 62(1) of TRIPS. Allowing serial and consecutive oppositions is not necessary for examining the patentability of an invention. On the other hand, if there is a delay in the grant, the regulation might be considered one factor contributing to a situation not consistent with Article 62(2) of TRIPS.

Id.

²⁴⁶ Indeed, no curtailment of protection could result if the published patent application confers exclusivity rights and the patent applicant may institute infringement action before the issuance of the patent.

²⁴⁷ See Hoss, *supra* note 180, at 49 *et seq.* (seeming to deem the interpretation exposed in the main text possible).

²⁴⁸ The provision quoted in the text reproduces the wording of Article 7.5 Ato Normativo 127/97—Dispõe sobre a aplicação da Lei de Propriedade Industrial em relação às patentes e certificados de adição de invenção; see the English translation of the Normative Act 127/97 available at http://www.wipo.int/wipolex/en/text.jsp?file_id=125407.

These remarks should be considered from the perspective that the reform intends to eliminate Sole Paragraph of Article 40 of Law No. 9279/96, and that published applications under Brazilian law do not confer exclusivity rights, and even do not allow for infringement actions to be lodged before the patent is granted.²⁴⁹ Furthermore, should the court nevertheless deem the statutory period of limitation for the indemnification claim under Article 225 of Law No. 9279/96 to commence from publication of the application and not from grant of the patent,²⁵⁰ the law would approve the possibility of a curtailment of protection because of the unilateral behavior of the opponents.

Against this background, two amendments seem to be opportune. A first rule should provide for the INPI to state an intention to approve the claims and grant the patent public. A second provision should fix a strict deadline for filing the opposition—two or three months—starting from the publication of the acceptance of the patent application. The formal grant would take place only after the expiration of such deadline or after the filed opposition has been unsuccessful.

This normative model is provided by the laws of Australia,²⁵¹ New Zealand,²⁵² and Israel,²⁵³ and was in force in Germany²⁵⁴ and the UK²⁵⁵ before these countries,

²⁴⁹ Indeed according to Article 44 of Law No. 9279/96 it is the patent proprietor and not the owner of the patent application that has the right to obtain a compensation for the use of the invention occurred after the publication of the patent application. From this provision the scholarship and the case law infer that the right to obtain the compensation comes to existence with the grant of the patent, but it has a retroactive application; see Denis Borges Barbosa, *A inexplicável política pública por trás do parágrafo único, do art. 40, da Lei de Propriedade Industrial*, http://www.denisbarbosa.addr.com/arquivos/200/propriedade/inexplicavel_politica_publica.pdf (last visited February 8, 2015), at 33 *et seq.*

²⁵⁰ The issue does not seem to have been clarified in the case law of the state courts so far. See Fernando Eid Philipp & Guilherme Toshihiro Takeishi, *supra* note 172, at 42 *et seq.* According to these two authors, the statute of limitations should not commence before the grant of the patent since the patentee is not in a position to exercise the right. For this reason, Article 199(1) of the Brazilian Civil Code applies, according to which the statute of limitations does not run “*pendendo condicao suspensiva*.” As both authors reported in the cited paper, this issue has yet to be settled by the Brazilian courts.

²⁵¹ In Australia, the opposition is to be lodged at the patent office “within three months from the day the notice of acceptance is published” in the Australian Official Journal of Patents. See § 59 Patents Act of 1990; Reg. 5.4 Patent Regulations (1991). See also Weatherall *et al.*, *supra* note 222, at 95 *et seq.*

²⁵² On the situation in New Zealand, see *supra* note 229.

²⁵³ In Israel, when the application has been accepted under Section 26 of Patent Act No. 5727-1967, the Registrar shall publish the fact of acceptance online. Pursuant to Section 30 of the Patent Act, “any person may—within three months after the date of publication of the application under section 26—oppose the grant of a patent by written notice to the Registrar” (the quoted translation of the Act is available at www.wipo.org). On pre-grant opposition under Israeli law, see ERAN LISS & DAN ADIN, *INTELLECTUAL PROPERTY LAW AND PRACTICE IN ISRAEL* 73 *et seq.* (2012); ORIT FISCHMAN AFORI ET AL., *INTELLECTUAL PROPERTY LAW IN ISRAEL* 104 *et seq.* (2013).

²⁵⁴ See Section 24 of the Patent Act (Patentgesetz) of April 7, 1891. On the historical development of the opposition system in Germany, see CHRISTIAN HAUGG, *DIE ENTWICKLUNG DES EINSPRUCHSVERFAHRENS IM DEUTSCHEN UND EUROPÄISCHEN PATENTRECHT* 16 *et seq.* (2000).

²⁵⁵ See Section 11 of the Patent and Designs Act of 1907, pursuant to which “any third party within a period of two months from the date of the advertisement of the acceptance by a patent office of the complete specification may give notice at the patent office of opposition to the grant of the patent.” The comptroller was required to advertise the acceptance of the patent, and from that date the application was to be open to the public for inspection pursuant to Section 9 of the Act.

influenced by the EPC,²⁵⁶ adopted a post-grant opposition. It has a clear advantage. The strict deadline for filing the opposition prevents serial and consecutive oppositions aimed at delaying the examination. It moreover reduces the room for challenging the regulation as unreasonable under Article 62(1) of TRIPS. Admittedly, delays resulting from examination of the prior art found by the examiner or submitted by an opponent remain possible and likely. However, this fundamental problem exists in Brazil just as in other countries regardless of whether or not a pre-grant opposition procedure is available.²⁵⁷ While it is not the purpose of this article to focus on this issue, it is questionable whether a mere change in domestic provisions (beyond moving to a pure registration system)²⁵⁸ could really resolve it. Nevertheless, the legislature could at least remove factors contributing to the backlogs of the INPI that are purely home-grown. For example, one peculiarity of the Brazilian system is that utility models undergo a full examination on their merits. It is worth considering whether this legislation might be reformed so as to ease the burden on the INPI.

The following cumulative measures are possible. The legislature could first extend utility model protection to all product inventions. Second, it could shift the utility system from an examination model to one in which there is no examination of novelty and inventive activity—such as in Italy, or China²⁵⁹—or is optional—such as in Australia²⁶⁰, Japan²⁶¹ and Portugal,²⁶²—or in which only a prior art search report must or may be issued—such as in Austria²⁶³ and Germany,²⁶⁴ respectively. Lastly,

²⁵⁶ See Kurt Härtel, *Die Entwürfe der Übereinkommen über ein europäisches System der Erteilung von Patenten und über ein Patent für den Gemeinsamen Markt*, Gewerblicher Rechtsschutz und Urheberrecht – Internationaler Teil [GRUR Int.], pp. 95, 99 (1970).

²⁵⁷ See also Barbosa, *supra* note 249; Hoss, *supra* note 180, at 49.

²⁵⁸ See the analysis and the proposal in the U.S. context by F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C. L. REV. 55 (2003).

²⁵⁹ In China (as in Italy), the National Patent Office SIPO examines only the absolute grounds for non-eligibility (i.e., grounds whose existence does not depend on the content of the prior art, as to whether the claimed subject matter is eligible for protection—process and chemical compounds are excluded from utility models—or whether the exclusion for immoral inventions applies). The SIPO does not carry out a search of the prior art, and does not examine novelty and non-obviousness; for details, see T. Mak, *Utility Models*, in PATENT LAW IN GREATER CHINA 369 *et seq.* (Stefan Luginbuehl & Peter Ganea eds., 2014).

²⁶⁰ Innovation patents are granted without examination. The examination is necessary if the owner of the patent wants to institute an infringement proceeding; see Advisory Council on Intellectual Property (ACIP), *Review of the Innovation Patent System—Final Report*, p. 3 *et seq.* (May 2014). According to this report, the absence of an examination is a cause of uncertainty, and therefore the Committee proposes to introduce such examination to be requested by the applicant three years from filing.

²⁶¹ Pursuant to Article 12, 29*bis* and 29*ter* of Utility Model Act n. 123 1959 any person may request a technical opinion over the registrability of the subject matter claimed in a pending application or over the validity of a registered utility model. The opinion does not bind the judge, if it is referred to a registered utility model, and does not bind the Patent Office, if it is referred to a pending application.

²⁶² See Article 131 of the Industrial Property Code (IPC), pursuant to which the examination may be requested before the grant (Article 131.1 of the IPC) and must be requested after the grant if the owner intends to start an infringement proceeding (Article 131.3 of the IPC).

²⁶³ See Gebrauchsmustergesetz (last amendment BGB1. I. Nr. 126/2009) (Utility Model Act) § 27 (Austria 1994).

the INPI could raise fees for patent applications that undergo examination and lower them for utility models granted without examination. These measures would likely free up resources which could then be allocated to the prosecution of patent applications.

The additional option created in this way—utility models without full and mandatory examination—would mostly benefit domestic applicants, as experience in China and elsewhere suggests.

3. *Practical Aspects*

Should Bill No. 5402/13 be enacted into law, competitors will have five possible ways to challenge either the patentability of an invention filed with, or the validity of a patent granted by, the INPI:

- (1) submitting data and information pursuant to Article 31 of Law No. 9279/96;
- (2) filing a pre-grant opposition;
- (3) instituting nullity proceeding before the INPI within a period of six months from the patent grant (Article 51 of Law No. 9279/96);
- (4) proposing judicial nullity proceedings during the life of the patent before the Federal Court (Article 57 of Law No. 9279/96);
- (5) raising an invalidity defense before the state courts in the infringement proceeding instituted by the patentee (Article 56 § 1 of Law No. 9279/96).²⁶⁵

²⁶⁴ Pursuant to Section 7 of the German Utility Model Act (*Gebrauchsmustergesetz*), the patent office is required, upon request, to perform a search of the prior art which is relevant for “assessing the registrability of the subject matter of the utility model application or the utility model”; see English translation of Utility Model Act (as amended September 2, 1994) available under http://www.wipo.int/wipolex/en/text.jsp?file_id=126190. Such “a request may be filed by the applicant or the registered proprietor or by any other party” before or after the registration in the utility model register; see Section 7 (2) of the Act.

²⁶⁵ In Brazil, the State courts have jurisdiction over infringement actions, whereas the Federal courts have jurisdiction over actions for the revocation of the patent, see Article 57 of Law No. 9279. The INPI shall participate in the revocation proceedings when it is not the plaintiff. As a consequence, the defendant in an infringement action can not file a counterclaim for revocation of the asserted patent before the State court sued by the patentee. Indeed the defendant in this case should add to the counterclaim the INPI, since the latter is a necessary joint defender in any revocation action. But this is not possible under current procedural law according to Brazilian scholars. However, according to the aforementioned Article 56 § 1 of Law No. 9279/96, “the nullity of a patent may be argued at any time as a matter of defense.” This provision for a long time was understood as allowing the defendant to contest the validity of the patent as a defense with effect inter partes in any infringement proceeding pending before a State court. However, the case law now seems to reject this interpretation. The Superior Court of Justice, in a decision of 13 March 2012 concerning design rights, but relevant also for patents, interpreted the rule as only allowing the defendant in an infringement proceeding to start a revocation proceeding—pending the infringement action—before the Federal courts. See Superior Tribunal de Justiça, RE no. 1.132.449 - PR (2009/0062354-4). By contrast, this judgment does not allow the question of invalidity to be raised as a defense against an infringement action before the State court. If this judgment becomes established case law, the Brazilian system will practically adopt a principle of separation as provided under German law. On this point and for the analysis of the case law I refer to the contribution of Filipe Fischmann, PATENT ENFORCEMENT IN BRAZIL, in CRISTOPHER HEATH (ed.), PATENT ENFORCEMENT WORLDWIDE—WRITINGS IN HONOUR OF DIETER STAUDER, 3 ed., 2015, 516, 530 *et seq.*

Bill No. 5402/13 is silent on the relationship among the different procedures. In particular, it does not address the issue of whether the same party remains entitled to initiate a trial invalidation procedure even if this procedure is based on the same invalidity grounds already invoked in a previous administrative pre-grant (or post-grant) *inter partes* procedure. The functionality of the system should require that no opponent should suffer drawbacks in subsequent litigation as a result of having challenged the patentability of the invention in the pre-grant-procedure.

C. Role of ANVISA in the Patent Grant Procedure

1. Scope of ANVISA's Prior Consent

The role of ANVISA in the Brazilian patent grant procedure is provided for under Article 229-C of the Law No. 9279/96. The rule, introduced in 2001,²⁶⁶ makes the grant of “patents for pharmaceutical products and processes” dependent “on the prior consent of the National Health Agency—ANVISA.”

The provision does not stipulate which aspects should be addressed by examination by the Health Agency, or the reasons why approval may be denied. This loophole has given rise to controversy before the Brazilian courts.²⁶⁷ The reform would remove this uncertainty by restating Article 229-C as follows:

Article 229-C. The granting of patents for pharmaceutical products and processes shall depend on the prior consent from the National Health Agency—ANVISA, which shall examine the object subject to the patent application in light of public health.

§ 1 A patent application shall be considered contrary to public health, according to further regulation, where:

I—the product or pharmaceutical process in the patent application presents a health risk; or

II—the patent application for a pharmaceutical product or pharmaceutical process is of interest to an access-to-medicines policy or to a pharmaceutical care program under the National Health System—SUS, and provided that it does not meet the patentability requirements and the other criteria established by this law.

§ 2 Following the prior consent examination and after the decision is published, ANVISA shall return the application to the Patent Office, which shall examine the approved application, and definitively archive the application that has not been approved.

²⁶⁶ See Law No. 9279/96, *supra* note 2, amended by Law No. 10196 February 14, 2001 [hereinafter Law No. 10196/2001]; see also Viviane Yumy Mitsuuchi Kunisawa, *Patenting Pharmaceutical Inventions on Second Medical Uses in Brazil*, 12 J. WORLD INTELL. PROP. 297, 298 (2009); L.L. Mueller & Costa Taketsuma, *Should ANVISA Be Permitted to Reject Pharmaceutical Patent Applications in Brazil?* 24 EXPERT OPINION ON THERAPEUTIC PAT. 1 *et seq.* (2014).

²⁶⁷ See BASSO ET AL., *supra* note 203, at 79 with reference to diverging decisions over the reach of ANVISA competence: see also KUNISAWA, *supra* note 11, at 105 *et seq.*

According to the amendment, the patent application still has to be filed with the INPI, but the substantive examination is to be performed by ANVISA first. If ANVISA deems the invention to be patentable, this opinion does not prevent the INPI from carrying out a second substantive examination and rejecting the application. Conversely, if ANVISA denies patentability, the INPI is bound by this opinion.

2. TRIPS Compliance

The role of ANVISA has already been challenged from the standpoint of the TRIPS Agreement. The provisions of Bill No. 5402/13 confirming this function of the agency will likely face similar objections. So far, there are two arguments that have been brought forward.

The first is that the regulation mandating the prior approval of the Health Agency does not comply with the prohibition of discrimination provided under Article 27(1) of TRIPS.²⁶⁸ As a result of this mechanism, some inventions are subject to dual examination while others are not.²⁶⁹

The second argument is that the involvement of an external agency for examining health risks and the resulting delay in the grant procedure is not reasonable pursuant to Article 62(1) of TRIPS.²⁷⁰ The grant of the patent does not give the right to use the invention under Article 27 of TRIPS, and therefore does not justify assessing the health risks resulting from the marketing of the invention.

As far as the prohibition of discrimination under Article 27(1) of TRIPS is concerned, the attack is unconvincing for two reasons. First, the prohibition of discrimination does not apply to inventions for which a protection may be outright denied because of an optional exception to patentability under Article 27(2) or 27(3) of TRIPS. Indeed, the power to exclude any protection for a specific subject matter—provided by Article 27(3) of TRIPS—includes the ability to admit a lesser protection than that required by Article 28 of TRIPS for the other inventions, or an equivalent protection but one subject to conditions in addition to those generally requested for the other inventions.²⁷¹ The use of a known compound for the treatment of a disease is a medical method within the meaning of Article 27(3) of TRIPS.²⁷² Therefore, it

²⁶⁸ See Pharm. Res. & Mfrs. of Am. (PhRMA), *Special 301 Submission*, 101 (2009) (observing, with regard to ANVISA intervention in the grant procedure: “This dual examination is incompatible with Brazil’s obligations under the antidiscrimination provisions of Article 27.1 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).”). The same opinion may be found in Innovative Pharm. Ass’n of S. Afr. (IPASA), *Comments on the Draft National Policy on IP*, 15 (Oct 2013), available at <http://ipasa.co.za/>; L.L. Mueller & Costa Taketsuma, *supra* note 266, at 3.

²⁶⁹ See Kunisawa, *supra* note 266, at 305 (specifically with respect to second medical use claims); KUNISAWA, *supra* note 11, at 118.

²⁷⁰ See Hoss, *supra* note 180, at 26 *et seq.*

²⁷¹ This is the argument by Thomas, invoking the maxim “*the greater includes the less*” by addressing the issue whether or not the limitation to the enforceability of medical-methods patents complies with Article 27(1) of TRIPS. See John R. Thomas, *Symposium: The Post-Industrial Patent System*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 3, 49 (1999).

²⁷² See *supra* Part III, Paragraph B (3) of this article.

may be made subject to procedural or substantive conditions possibly not admitted by Article 27(1) of TRIPS.

As for new chemical entities and processes for their manufacture, the situation is *prima facie* different. This category of subject matter may not be excluded from patent protection under Article 27(3) of TRIPS. However, as pointed out in the literature²⁷³ and in WTO case law,²⁷⁴ Article 27(1) of TRIPS does not prohibit differentiation in cases where objective grounds for them exist. If it can be reasonably argued that the participation of ANVISA in the grant procedure in the field of pharmaceutical inventions is necessary, because only this agency—in the specific administrative structure of the Brazilian State²⁷⁵—has the technical competence or the specific legal skills required to examine all or some of the requirements for protection in that field,²⁷⁶ the differential treatment might be defended before a WTO panel as justified. This consideration might be valid provided that the examination performed by ANVISA concerns prerequisites for patentability which TRIPS mandates or allows.

This brings us to the second point, namely what the subject of the examination of ANVISA should be from a TRIPS perspective in order to be reasonable within the meaning of Article 62(1) of TRIPS.

Under Article 27 of TRIPS, the patent applicant has a right to the grant of the patent. If the requirements for protection are met and no exception applies, the patent has to be issued. Any regulation affording room to exercise discretion in this respect would be inconsistent with the principles set out in Article 27(1) of TRIPS.²⁷⁷ According to some scholars, it would further challenge the principle of legacy governing administrative actions enshrined in several constitutions, which would likely include the Brazilian constitution.²⁷⁸

Bill No. 5402/13 is consistent with these premises. According to the proposed Article 229-C § 1 ANVISA may not deny its approval when the patentability requirements are satisfied and the invention is not dangerous to health. No discretionary power is granted to the administrative authority. Because TRIPS does not mandate the Member States to entrust only their patent offices with the

²⁷³ See Max Planck Inst. for Innovation & Competition, *supra* note 6, at 688; Graeme B. Dinwoodie and Rochelle C. Dreyfuss, *Diversifying Without Discriminating: Complying with the Mandates of the TRIPS Agreement*, 13 Mich. Telecomm. Tech. L. Rev. 445, 450 *et seq.* (2007).

²⁷⁴ See Canada—Patent Protection of Pharmaceutical Products, Report of the Panel WT/DS114/5 (circulated November 12, 1998), 7.94.

²⁷⁵ See TRIPS Agreement, *supra* note 5, Art. 1(1).

²⁷⁶ As reported by De Carvalho, the Brazilian representatives during the Trade Policy Review of Brazil in 2000 already argued that the requirement of the prior approval by ANVISA was lawful under Article 1 and Article 8 of TRIPS, maintaining that “INPI may lack the expertise to examine all the complex technological elements involved in pharmaceutical inventions,” and that therefore “ANVISA’s approval may contribute to ensure a more expeditious approval of pharmaceutical patents.” DE CARVALHO, *supra* note 39, at 79; WT/TPR/M/75 of Dec 6 2000, ¶ 65-66 (quoted again after De Carvalho).

²⁷⁷ Under TRIPS, more precisely, patents are private rights whose grant or bestowal is not subject to the exercise of a case-specific political discretion of the competent authority. See TRIPS Agreement, see *supra* note 5, Preamble (stating that the Member States recognize IP rights as private rights).

²⁷⁸ See Denis Borges Barbosa, *A Inconstitucionalidade da anuência da ANVISA no procedimento de concessão de patentes como manifestação discricionária da Administração Federal*, <http://denisbarbosa.addr.com/papelanvisa.pdf>. (last access December 2014).

examination,²⁷⁹ and because other countries allow consultation of external agencies in the prosecution of all or specific applications,²⁸⁰ the role attributed to ANVISA does not *per se* contravene any obligation under WTO law as far as the examination of the patentability requirements is concerned.

The legal assessment is more complex when it comes to the competence of ANVISA to deny approval in case of health risks provided by the first prong of the provision.²⁸¹ According to the comments of the parliamentary report supporting the reform, this rule should call for a refusal of the application only when the product has been previously rejected by ANVISA.²⁸² A resolution of ANVISA, which concerns the operation of Article 229-C of Law No. 9279/96 in force, stipulates that a patent application is contrary to public health only when it concerns a substance whose exploitation is already prohibited under Brazilian law.²⁸³

If the latter means that the grant of the patent is prevented only when the exploitation of the substance used or manufactured by the invention is absolutely prohibited—and not merely unauthorized—and if that is the meaning underlying the expressions used by the proposed Article 229-C, then the first prong of the provision will not really be relevant.²⁸⁴ Further, it will not meet with serious concerns from the perspective of international law. If the commercial exploitation of the substance used

²⁷⁹ See DE CARVALHO, *supra* note 39, at 285.

²⁸⁰ As far as biotechnological inventions are concerned, the patent offices in Italy and Norway are entitled to request the opinion of external agencies on questions relating to patentability. In Norway, pursuant to Section 15a of the Patent Act (Act no. 9 of December 15, 1967 on patents), if the Industrial Property Office “is in doubt whether a patent should be granted or refused based on Section 1b” then it “shall obtain an advisory statement from an ethics committee appointed by the King.” See translation of the Patent Act, *available at* <https://www.patentstyret.no>. Section 1b of the Norwegian Patent Act excludes patentability for inventions whose commercial exploitation is in conflict with public policy or morality. In Italy, pursuant to Article 170*bis* of the code of industrial property (cpi), the Patent and Trade Mark Office may consult the Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita (CNBBS). While in Norway the Ethical Committee should advise only in the case of doubts related to the applicability of the exclusion based on *ordre public* and morality, in Italy the CNBBS may be requested to issue an opinion on any issue related to patentability. Otherwise, the Norwegian Patent Office may consult the Ethical Committee on any invention to which Section 1b of the Patent Act might apply. By contrast, the Italian Patent and Trade Mark Office may resort to the CNBSS only in cases of biotechnological inventions as defined by Article 2 of the Directive on the legal protection of biotechnological inventions, 98/44 CE. According to the Italian scholars, since Article 170*bis* cpi confers the ability but not the obligation to consult the CNBSS, the opinion of the latter would not bind the Patent Office. On Section 15a of the Norwegian Patent Act, see Kaja Veel Midtbø, *Amendments to the Norwegian Patents Act—Implementation of Directive 98/44/EC*, INT’L REV. INTELL. PROP. & COMPETITION L. 542, 544 (2005), and on article 170*bis* of the Italian code of Industrial Property, see Anna Colmano, *Commentary on Article 170 bis cpi*, in CODICE DELLA PROPRIETÀ INDUSTRIALE, at 1590 *et seq.* (Adriano Vanzetti ed., 2014).

²⁸¹ See Article 229-C § 1 I as redrafted by the Bill No. 5402/2013.

²⁸² Ctr. for Strategic Stud. & Debates, *supra* note 1, at 14.

²⁸³ See Resolution No. 21, §§ 1-2 (Apr 10, 2013).

²⁸⁴ According to the data published by the Center for Strategic Studies and Debates, ANVISA has denied its prior approval between 2001 and 2009 to 119 patent applications out of 1,346 forwarded by the INPI (denial rate of about 9%). Based on the data reported by the study, none of the patent applications were rejected because of a risk to public health. The main reasons were, instead, lack of novelty or inventive step (72.6% of cases), insufficient disclosure (16%), and exception for natural products (5.9%). See Ctr. for Strategic Stud. & Debates, *supra* note 1, at 262.

or produced by the claimed invention is prohibited, without exception, Article 27(2) of TRIPS allows patentability of the claimed technical solution to be prohibited as well.

Another conclusion is possible, by contrast, if the provision is interpreted as meaning that the Agency should examine the safety of the drug and deny the patentability if such safety is not proven under regulatory standards.

The wording of the proposed Article 229C § 1 does not exclude such an understanding.²⁸⁵ An exclusion thus made and applied in this way would go beyond Article 27(2) of TRIPS. The latter refers indeed to inventions whose commercial exploitation is contrary to the fundamental principle of the legal system of the WTO-Members,²⁸⁶ and is therefore in conflict with provisions embodying some fundamental values—provisions that usually do not admit any exception. Provisions, such as those concerning the approval of drugs which prohibit the commercial exploitation of a product only in the absence of an authorization by the competent authority, are not considered norms capable of excluding patentability within the meaning of Article 27(2) of TRIPS²⁸⁷ and Article 4quater of the Paris Convention.²⁸⁸ Against this background, if ANVISA were to exclude inventions based on the same criteria which it would apply to deny a market authorization, this could turn out to be problematic under WTO law.²⁸⁹

Historically, several legal systems actually did make the grant of a patent conditional upon the safety of the invention. In Italy, if the Patent Office held that the invention might be harmful to health, it had to ask—up until 1979—the Public Health Agency for an opinion.²⁹⁰ If the latter concluded that the invention was harmful, the Patent Office had to reject the patent application.²⁹¹

²⁸⁵ The interpretation assumed in the text, while allowed by the proposed wording, seems to be clearly rejected by the Report supporting Bill No. 5402/13, *see* Ctr. for Strategic Stud. & Debates, *supra* note 1, at 14 (stating that one of the purpose of the reform is to grant ANVISA “the duty to analyze, prior to the Patent Office, patent applications involving pharmaceutical/chemical i) products that have previously been rejected by the Agency, and thus present health risks”

²⁸⁶ *See* Straus, *supra* note 5, at 182; *see also* Rainer Moufang, *Patenting of Human Genes, Cells and Parts of the Body?—The Ethical Dimensions of Patent Law*, 25 INT’L REV. INTEL. PROP. & COMPETITION L. 487, 503 et seq. (1994).

²⁸⁷ *See also* THIERRY CALAME, *ÖFFENTLICHE ORDNUNG UND GUTE SITTEN ALS SCHRANKEN DER PATENTIERBARKEIT GENTECHNOLOGISCHER ERFINDUNGEN*, at 134 (Basel *et al.* eds., 2001).

²⁸⁸ According to Article 4quater of the Paris Convention (1967), the grant of a patent shall not be refused on the ground that the sale of the patented product is subject to restriction or limitations resulting from domestic law.

²⁸⁹ One way to defend the domestic situation might be to invoke the requirement for industrial applicability or utility. It might be argued that an invention that gives rise to a health risk or is not proven to be safe cannot be industrially applicable or useful within the meaning of Article 27(1) of TRIPS. However, such a reading of the requirement would be at odds with Article 27(2) of TRIPS, more specifically with the clarification contained therein that an invention does not contravene public policy and morality only because the exploitation is prohibited by statutory law. The latter condition would be obsolete if a Member State, in the case of a sales ban for products incorporating the invention, had sufficient grounds to exclude patent protection on the basis of the utility requirement. *See* CALAME, *supra* note 287, at 66.

²⁹⁰ *See* Royal Decree 1127/1932, Art. 32. This provision was abolished in 1979.

²⁹¹ On the binding character of the Health Agency opinions for the Patent Office, *see* Corte di Cassazione (Supreme Court), Sezioni Unite, April 15 1939 no. 1217, *Naturin Werke v. Ministero corporazioni*, Il Foro italiano, Rep. 1989, *Privative ind.*, no. 39; Corte di Cassazione, Sezioni unite, August 1 1942, no. 2312; *Soc. Schering v. Ministero Corporazioni*, Il Foro Italiano, Vol. 68, I, 1943, p. 217 ff.

In the U.S., some inventions were excluded from patent protection for lack of utility when they were held to be dangerous for human health.²⁹² The reason cited for this practice was, *inter alia*, that the patent grant might be misunderstood as proof of the safety and functioning of the patented technology. The risk of such a misunderstanding was said to be particularly serious in the pharmaceutical field and therefore had to be prevented.²⁹³

Gradually, though, all these systems came to reject safety as a criterion for patentability.²⁹⁴ Three reasons were mentioned for this development.

First, the examination of an invention's safety requires time and skill. The delay and costs caused by the examination would be disproportionate to any benefit gained. The grant of the patent does not authorize the use of patented technology, and, conversely, the refusal of the application does not prevent its exploitation.²⁹⁵

Second, the specification of a patent application does not contain the data necessary to assess whether or not the invention is safe. The information needed, in the case of pharmaceuticals, usually does not become available during the prosecution but only several years after the examination has begun.²⁹⁶

²⁹² See *In re Application of William C. Anthony*, 414 F.2d 1383, 1398-99 (C.C.P.A. 1969) (with references to prior decisions). See also CALAME, *supra* note 287, at 108.

²⁹³ See *Isenstead v. Watson*, 157 F. Supp. 7 (D.D.C. 1957). The risk that the patent grant might be understood as *imprimatur* was also one of the reasons brought by the former Sub-Alpine Parliament in Italy to exclude the patentability of pharmaceutical inventions. See Corte Costituzionale, Decision of 9. March 1978, INT'L REV. INTELL. PROP. & COMPETITION L. 1979, 246—"Pharmaceuticals."

²⁹⁴ See CALAME, *supra* note 287, at 108.

²⁹⁵ See *In re Application of William L. Hartop, Jr.*, 311 F.2d 249 (C.C.P.A. 1962) (where the Court of Customs and Patent Appeals observed: "It is an elemental principle of patent law that a patent grants no more than the legal right to exclude others from making, using or selling the thing patented. It is no guarantee of anything and gives no one a right to make, use or sell anything. The public, therefore, is in no way protected either by the granting or withholding of a patent."). See also CALAME, *supra* note 287, at 108 *et seq.*

²⁹⁶ See the remarks of the Board of Appeal of the EPO in T 0356/93, Decision of 21 February 1995, OJ EPO 1995, 545, Reasons for the decision no. 18.4—Plant cells/PLANT GENETIC SYSTEMS:

In most cases, potential risks in relation to the exploitation of a given invention for which a patent has been granted cannot be anticipated merely on the basis of the disclosure of the invention in the patent specification. Typical examples are patents granted for chemical compounds with a pharmaceutical use. In this particular technical field, patents are generally granted on the basis of preliminary *in vitro* or animal data before any human clinical data become available. In fact, the actual approval (or disapproval) by the competent authorities of the exploitation of pharmaceutical products is often obtained only after the grant of the patent. This is because a realistic assessment of therapeutical operability requires a comprehensive and time-consuming programme of testing and evaluation of the products. The results of such tests are usually not available to patent offices during the prosecution of a case. During this time, the exploitation of the claimed products is most likely to be in the initial phase when risk and safety assessment by the competent authorities or bodies has either not yet taken place or not yet been completed. The same holds true for many other products the exploitation of which is subject to approval by the competent authorities or bodies, such as herbicides, insecticides, etc. These specialised authorities and bodies are in a position to carry out a realistic

Third, the purpose of a patent system is to stimulate “the investment of additional capital needed for the further development and marketing of the invention.”²⁹⁷ For this reason, the rejection of a patent application on the grounds that further research is necessary to prove that the invention is safe and ready for marketing “would effectively defeat that objective of the patent system.”²⁹⁸

Even in Europe, where the patent system is not morally neutral,²⁹⁹ safety is not a general criterion for patentability. Absence of its proof and doubts as to its existence—save exceptional cases—do not prevent the patent from being granted.

It is likely that not all the arguments cited against an assessment in the grant procedure of whether the invention is safe are cogent.³⁰⁰ Nevertheless, the Brazilian legislature could take account of these experiences in Europe and in the U.S., and consider whether the concerns being voiced there against safety control through the national or regional patent offices are also relevant for the Brazilian context.

3. *Some Practical Considerations*

The dual examination prescribed by Bill No. 5402/13 might lead to additional delays in the procedures by the INPI. Since Brazilian law does not contemplate supplementary certificates of protection for pharmaceutical inventions, and since Article 40, Sole Paragraph of Law No. 9279/96 should be abolished, the reformer ought to consider whether alternative measures—providing for the requested role of ANVISA, but avoiding a duplication of procedures—are possible. One way to simplify the situation might be to entrust only one agency with examination of the patent applications. For this purpose, a patent department consisting of officials from both authorities could be established by INPI or by ANVISA. While the INPI might receive and formally review the application, this patent department would then be the only entity to conduct the substantive examination. Based on the outcome of the examination, the INPI could formally grant the patent or reject the application.

The reform might pave the way for such cooperation. The main reason why the intervention of ANVISA is controversial in Brazil seems to be—beyond the delays

assessment of risks or even hazards on the basis of the regulations in force, of objective criteria and of scientifically valid parameters.

Id.

²⁹⁷ *In re Anthony*, 414 F.2d at 1383 (C.C.P.A. 1969), (quoting REPORT OF THE PRESIDENT'S COMMISSION ON THE PATENT SYSTEM, TO PROMOTE THE PROGRESS OF THE USEFUL ARTS, S. Doc. No. 5, 90th Cong., 1st Sess. (1967)); CALAME, *supra* note 287, at 109.

²⁹⁸ *Id.*

²⁹⁹ See Article 53(a) EPC and Article 6 of the *Directive on the Protection of Biotechnological Inventions*, 98/44 CE, Official Journal L 213, July 30, 1998, p. 13. Patents have been denied and patent claims have been objected in the practice of the EPO because of moral concerns related to commercial exploitation of the subject matter claimed. See T 0866/01, Decision of 11 May 2005, unpublished—Euthanasia Compositions/Mich. St. Univ.).

³⁰⁰ For instance, the mere fact that the patent does not confer the right to use the invention is not sufficient to reject any position advocating an indirect regulatory function of the patent system. Indeed such an argument might be used against the exclusion based on the *ordre public* and morality as well, which, by contrast, is adopted by the EU Member States and is admitted by TRIPS; see CALAME, *supra* note 287, at 166.

caused in the prosecution—the different approach to patentability adopted by the Health Agency. More precisely, while the INPI considers patent claims for new uses and derivatives admissible in principle, ANVISA does not.³⁰¹ Since the reform is intended to legislate in this field—irrespective of the content of the provisions that are finally enacted—it will likely limit the scope for divergent interpretations. As already observed in the literature,³⁰² India entrusts the examination of Section 3(d) of the Patent Act of 1970 to the Patent Office and not to the Central Drugs Standard Control Organization, the Indian counterpart to ANVISA. This apparently has not affected the relevance of the patent exclusion in practice.

VII. FINAL REMARKS: THE ISSUE OF USE CLAIMS

It has been suggested that the shift in global economic power might affect the norm-setting process within the WTO system. According to this theory, emerging countries, formerly passive rule-takers, will increasingly experiment with innovative regulatory frameworks.³⁰³ Bill No. 5402/13, if enacted with the current wording, would be in line with this prediction. At the same time, the passage of Bill No. 5402/13 would deepen the existing division in the patent policy of the emerging economies.

On one side of the divide stand China and other countries who share Western-level patent protection standards, an effective utility model system, and an understanding of IP rights as strategic weapons which nationals are encouraged to accumulate at home and abroad. On the other side are India and Brazil, both with a more critical attitude towards patents,³⁰⁴ the absence of utility models granted without examination,³⁰⁵ and skepticism about the ability of domestic actors to compete against foreign companies in acquiring relevant IP assets.³⁰⁶

In comparison to existing research on these political aspects of lawmaking within and beyond the WTO system, the purpose of this paper was by far more modest. It intended to show that the TRIPS Agreement, with some reservations, leaves sufficient room for adopting the Proposal for reform. Admittedly, it would be inaccurate to assume that the Member States are completely free under WTO law to set an autonomous standard of patentability and design the granting procedure. TRIPS, however, allows for denial of product protection for structurally obvious

³⁰¹ See Kunisawa, *supra* note 266, at 299 *et seq.*; Mueller & Taketsuma, *supra* note 266, at 1 *et seq.*; Kenneth C. Shadlen, *The Political Contradictions of Incremental Innovation: Lessons from Pharmaceutical Patent Examination in Brazil*, 39 POL. & SOC'Y 143, 154 (2011).

³⁰² See Shadlen, *supra* note 152, at 158.

³⁰³ See Susan K. Sell, *The geo-politics of the world patent order*, in EMERGING MARKETS AND THE WORLD PATENT ORDER 46, 47 (Frederick M. Abbott *et al.* eds., 2013).

³⁰⁴ The most visible legislative signs of this are limitations to patent-eligible subject matter, local working requirements, an effective compulsory license regime, and the existence of multiple options for preventing or removing the grant of a patent even at the cost of efficiency.

³⁰⁵ India does not provide for utility model protection. Brazil, as mentioned in the paper, provides for utility models, but subjects their issue to a full examination.

³⁰⁶ See Ctr. for Strategic Stud. & Debates, *supra* note 1, at 42 *et seq.*

compounds, even if these have unexpected properties.³⁰⁷ It permits denial of protection for medical uses of known compounds, even if they are novel and inventive. It does not limit the reasons for granting compulsory licenses.³⁰⁸ Also, it finally allows the Member States to provide third parties with multiple options for preventing and removing granted patents.³⁰⁹

Whether or not making use of all the mentioned options constitutes good policy is an entirely separate question. The uncertainty surrounding the effects of the patent system prevents the author from even speculating whether the Chinese model or the Indian approach would work better for Brazil or other countries. But it is possible that the effects of the national patent system—in promoting or hindering domestic development—are overstated. The size of the markets, the regulatory environments, the infrastructures, and the efficiency of the administration are likely far more influential factors in attracting or deterring investments. Furthermore, global trade has grown significantly in the last thirty years. No national patent system—beyond those of the EU, China, and the U.S.—can likely claim to be controlling the decisions in research and development of domestic actors.

Nevertheless, national markets, if sufficiently broad, are often the first source of revenue for domestic firms. The availability of patent protection for specific categories of subject matter might be relevant for domestic innovators. Therefore, if one accepts the premise that, at least in the pharmaceutical field, a state of under-protection is as problematic as a state of over-protection, the legislative proposal to ban any use claims—as enshrined in Bill No. 5402/13 and adopted elsewhere—deserves further examination.³¹⁰ This exclusion indeed does not comprise only what some economists define as secondary patents. The exclusion would, by contrast, prevent any legal protection for the first (medical or non-medical) use of any known substance.³¹¹ It would avoid the granting of patents for completely different uses from the applications of the known compound already established.³¹² The rule would deny protection to a new medical indication for substances described

³⁰⁷ *A fortiori*, the Treaty permits the national legislator or case law to select which of the unexpected properties might matter for patentability, as Section 3(d) of the IPA 2005 does with respect to substances listed therein. See *supra*, Part III Paragraph B (4) of this article.

³⁰⁸ See Max Planck Inst. for Competition & Innovation, *supra* note 6, at 679 *et seq.*

³⁰⁹ This is the case, as long as legal protection remains available—at the request of the applicant—within a “reasonable period of time.” Article 62(2) TRIPS. See *supra*, Part VI, Paragraph B (2) of this article.

³¹⁰ With respect to Indian law, see the observations by Mueller, *supra* note 87, at 491, 550 *et seq.*

³¹¹ For instance, if the patent application concerns pyrrolidine derivatives, which are already described in a previous publication, but have never been described in prior art as being pharmacodynamically active as therapeutic agents, their use would not be eligible for protection under the Bill No. 5402/13, even if novel and inventive. The example for this first medical use of a known compound is freely borrowed from T 128/82, Decision of 12 January 1984, OJ EPO 1984, 164—Pyrrolidine-Derivatives/Hoffman-La Roche. See, on the first medical indication claim under the EPC, RAINER MOUFANG, *PATENTABILITY OF PHARMACEUTICAL INNOVATIONS: THE EUROPEAN PERSPECTIVE, IN PHARMACEUTICAL INNOVATION, COMPETITION AND PATENT LAW—A TRILATERAL PERSPECTIVE* 54, 66 *et seq.* (Josef Drexler & Nari Lee eds., 2013).

³¹² For instance, if the compound is described as a colorant in prior art, and a later inventor discloses that it may be used as a lubricant, no protection would be allowed under the Bill No. 5402/13. Again, if prior art describes the ability of the substance to lower blood pressure, and a second inventor discloses that the same substance may be used to treat depressive disorders, the use claim would not be admissible.

as therapeutic agents in prior art, but for the treatment of a different illness. Some of the inventions affected might constitute a medical or technical breakthrough.³¹³

Against this background, the Brazilian legislature may ponder whether an intermediate solution is possible between the EPO approach, which admits a use claim under Article 54 of the EPC—even if the only new feature is the patient class,³¹⁴ the dosage regimen,³¹⁵ or the technical effect³¹⁶—and the Indian approach. This could consist of granting patents only for methods of use which differ in at least one step from prior art. A mere “*novelty of purpose*”³¹⁷ would not make the claimed use patentable. In the medical field, this approach would include issuing patents only for new indications—i.e., for using the compound in treating a disease which has not previously been treated with that substance.³¹⁸

This approach would likely counter the proliferation of use patents for the same class of compounds within the same indication. At the same time, it would allow protection for relevant innovations, as the first medical use of a known substance or the inventive repositioning of existing drugs. The latter field is of great medical utility,³¹⁹ and is one where not only established foreign originators, but also small companies, start-ups, and newcomers may be highly competitive.³²⁰

³¹³ In most of these cases, there are no qualitative differences between the inventor of a novel compound and the inventor of a novel use, beyond the accidental existence or absence of a document in prior art describing the chemical structure of the substance indicated in the patent claim—in a way enabling its synthesis or production. This is why absolute product protection was under attack in Europe in recent years, and was finally rejected by the ECJ in the field of gene sequences. See the analysis of a leading authority in European Patent Law, KRABER, *supra* note 129, at 139 *et seq.*

³¹⁴ See T 0019/86, Decision of 15 October 1987, OJ EPO 1989, 24—DUPHAR/Pigs II.

³¹⁵ G 2/08, Decision of 19 February 2010, OJ EPO 2010, 456—Dosage regime/ABBOTT RESPIRATORY.

³¹⁶ On this issue, see T 290/86, Decision of 13 November 1990, OJ EPO 1992, 414, 424, Reasons for the Decision no. 6—Cleaning plaque/ICI; see also the case law examined by Moufang, *supra* note 311, at 61 *et seq.*

³¹⁷ See GRUBB, *supra* note 148, at 249.

³¹⁸ As a consequence, patent claims for the uses of the known substance for curing the same illness as in prior art, where the novel feature is the method of administration, the dosage, the patient class, or the mechanisms of action, were not admissible. For a similar approach proposed as interpretation of Article 54 EPC 2000, see Dieter R. Schneider, *Patenting of Pharmaceuticals—Still a Challenge?* INT’L REV. INTELL. PROP. & COMPETITION L. 511, 523 (2008); Peter Meier-Beck, *Patentschutz für die zweite medizinische Indikation und ärztliche Therapiefreiheit*, Gewerblicher Rechtsschutz und Urheberrecht [GRUR] 300, 304 (2009).

³¹⁹ See also Opinion of advocate general Trstenjak delivered on May 3, 2012 (1) Case C-130/11 Neurim Pharmaceuticals (1991) Ltd v. Comptroller-General of Patents *quoting* KRABER, *supra* note 129, at 249; see GRUBB, *supra* note 148, at 249.

³²⁰ See Richard B. Smith, *Repositioned Drugs: Integrating Intellectual Property and Regulatory Strategies*, 8 DRUG DISCOVERY TODAY: THERAPEUTIC STRATEGIES, 131, 201 (2011) (discussing drugs repositioning and the reasons why in this field—because of the reduced risk and cost for the development—start-ups and small companies can attract venture capital more easily).