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Tackling the proliferation of patents: How to avoid undue limitations to competition and the public domain

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TACKLING THE PROLIFERATION OF PATENTS: HOW TO AVOID UNDUE LIMITATIONS TO COMPETITION AND THE PUBLIC DOMAIN

Carlos M. Correa

RESEARCH PAPERS

52

TACKLING THE PROLIFERATION OF PATENTS: HOW TO AVOID UNDUE LIMITATIONS TO COMPETITION AND THE PUBLIC DOMAIN

Carlos M. Correa

SOUTH CENTRE

AUGUST 2014

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South Centre
Ch. du Champ d'Anier 17
POB 228, 1211 Geneva 19
Switzerland
Tel. (41) 022 791 80 50
Fax (41) 022 798 85 31
south@southcentre.int
www.southcentre.int

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I. INTRODUCTION

The steady increase[1] in patent applications and grants that is taking place in developed and some developing countries (notably in China[2]) is sometimes hailed as evidence of the strength of global innovation and of the role of the patent system in encouraging it. However, such an increase does not correspond to a genuine augmentation in innovation.[3] It points instead to a major deviation[4] of the patent system away from its intended objective: to reward those who contribute to technological progress by creating new and inventive products and processes. Firms are increasingly using patents for strategic purposes.[5] As noted in a report of the UN Secretary-General,

> Arguably, the [patent] system in many countries has moved from its original objective of stimulating innovation through the provision of incentives to innovators, to preventing new domestic and foreign market entrants, an increasing number of which are from developing countries.[6]

The increase in the number of patents reflects, to a large extent, the low requirements of patentability applied by patent offices and courts. Patents granted despite the absence of a genuine invention detract knowledge from the public domain and can unduly restrain legitimate competition.

The problem of proliferation of patents of low or no inventive step affects various sectors. For instance, Nokia is reported to hold around 30,000 patents relating to mobile phones, a large part of which are likely to be invalid,[7] while Samsung holds more than 31,000 patent families.[8] Google took over the Motorola's mobile branch in 2011 in order to get control over around 17,000 patents and avoid costly litigation.[9] A study covering various fields of clean energy technologies, including solar photovoltaic, geothermal, wind, and

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[1] Patent filings grew by 9.2 per cent in 2012, representing the fastest growth in the past 18 years. See WIPO, "World Intellectual Property Indicators – 2013 Edition", 2013, available at http://www.wipo.int/ipstats/en/wipi/index.html.

[2] China is the main driver of global growth in patent applications. In 2012, residents of China accounted for the largest number of patent applications filed throughout the world; the Chinese patent office was the largest recipient of patent filings. See WIPO, 2013, op. cit.

[3] See, e.g., Adam B. Jaffe and Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to do About It*, Princeton University Press, 2004.

[4] See, e.g., John H. Barton, "Reforming the Patent System", *Science*, vol. 287 no. 5460, 17 March 2000, p. 1933-1934 ('The costs of the intellectual property system in the United States are growing significantly faster than the amount of research', p. 1933).

[5] See, e.g. Cohen, W.M., 2010. "Fifty years of empirical studies of innovative activity and performance", in Hall B., Rosenberg H., eds. *Handbook of The Economics of Innovation*, vol. 1, p. 129-213.

[6] United Nations, General Assembly, *Options for a facilitation mechanism that promotes the development, transfer and dissemination of clean and environmentally sound technologies. Report of the Secretary-General*, A/67/348, 2012.para. 21.

[7] See online.wsj.com/article/SB10001424052702303822204577468251129110174.html.

[8] See, e.g., Reuven Brenner, "Must All Patents Last for 20 Years? A flexible system that recognizes the needs of different industries might lead to less legal conflict", April 23, 2013, available at http://online.wsj.com/article/SB10001424127887324504704578413154212218668.html.

[9] See, e.g. http://www.nytimes.com/2013/01/05/technology/in-google-patent-case-ftc-set-rules-of-engagement-for-battles.html.

carbon capture, found nearly 400,000 patent documents.[10] Another study estimated that there are around 215,000 existing patents with a main focus on renewable energy applications.[11] 262 patent families of patents relating to environmental stress tolerance in plants (such as drought, heat, flood, cold, salt) were identified (including 1,663 patent documents published worldwide), 77 percent of which were held by a handful of big bio-science companies.[12]

Low standards of patentability encourage a large number of applications that would not be otherwise made, leading to a world backlog estimated at over 10 million unexamined patents.[13]

The proliferation of patents is particularly high and problematic in the pharmaceutical sector, where large companies actively seek to acquire broad portfolios of patents in order to extend patent protection beyond the expiry of the original patents on new compounds.[14] These evergreening strategies allow them to keep generic producers out of the market and charge prices higher than those that would otherwise exist in a competitive scenario.[15] For example, the basic patent for paroxetine, an antidepressant, expired in the late 1990s, whereas 'secondary' patents will extend up to 2018.[16] One example of how large pharmaceutical manufacturers 'push the bounds'[17] of the non-obviousness requirement is the patent obtained

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[10] United Nations Environment Programme (UNEP), European Patent Office (EPO) and ICTSD, "Patents and Clean Energy: Bridging the Gap Between Evidence and Policy-making", UNEP, EPO and ICTSD, 2010, available from: <http://www.unep.ch/etb/events/UNEP%20EPO%20ICTSD%20Event%2030%20Sept%202010%20Brussels/Study%20Patents%20and%20clean%20energy_15.9.10.pdf>.

[11] Copenhagen Economics, "Are IPR a Barrier to the Transfer of Climate Change Technology?", Copenhagen Economics A/S and the IPR Company Aps, 2009, found at: <http://trade.ec.europa.eu/doclib/docs/2009/february/tradoc_142371.pdf>.

[12] ETC Group, "*Gene Giants Stockpile Patents on "Climate-Ready" Crops in Bid to Become Biomassters"***,** 2010, found at: http://stopogm.net/webfm_send/405. See, more generally, on this issue Carlos Correa, "Innovation and Technology Transfer of Environmentally Sound Technologies: The Need to Engage in a Substantive Debate"**,** *Review of European, Comparative and International Environmental Law (RECIEL)*, vol. 22(1), Blackwell Publishers, Oxford, UK, 2013, pp. 54-61.

[13] See EPO, "*Scenarios for the Future, How Might IP Regimes Evolve by 2025? What Global Legitimacy Might Such Regimes Have?"*, 2011, p. 16; "*Recommendations for Improving the Patent System, 2012 Statement by the EPO Economic and Scientific Advisory Board"*, available at <http://documents.epo.org/projects/babylon/eponot.nsf/0/835DA6DA218CB760C1257B2C004E809E/$FILE/ESAB_statement_en.pdf.

[14] With this strategy, generally called 'evergreening', 'technology producers, using serial secondary patents and other mechanisms, keep their product sales protected for longer periods of time than would normally be permissible under the law' (Sandeep K. Rathod, "Ever-greening: A status check in selected countries", *J Generic Med* 7, pp. 227-242, July 2010).

[15] See, e.g., M. Tornvall, *The Use and Abuse of Patents – Evergreening in the Pharmaceutical Sector*, LL.M. Thesis submitted to the Faculty of Law, Lund University, 2013; S. Kumar, N. Shukla and T. Sangal, "Evergreening of Patents and the Indian Patent Law", *SSRN*, No. 1420003, 2009; E. Hore, *Patently Absurd: Evergreening of Pharmaceutical Patent Protection under the Patented Medicines (Notice of Compliance) Regulations of Canada's Patent Act*, CGPA, 2004; R. Chalmers, "Evergreen or Deciduous? Australian Trends in Relation to the 'Evergreening' of Patents", *MULR*, vol. 30, 2006.

[16] Mike Hutchins, "Using Interlocking Additional Early Stage Patents to Improve and Extend Patent Protection", *International Journal of Medical Marketing, 3, 2003, p.* 212-215. For other examples, see A. Kapczynski, C. Park and B. Sampat, "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents", *PLoS ONE*, vol. 7, Issue 12, e49470, 2012. T. Amin and A.S. Kesselheim, "Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could Be Extended For Decades", *Health Affairs*, vol. 31, no. 10, 2012.

[17] Aaron S. Kesselheim, "Intellectual Property Policy in the Pharmaceutical Sciences: The Effect of Inappropriate Patents and Market Exclusivity Extensions on the Health Care System", *The AAPS Journal* 2007, 9 (3) Article 33, p. E308.

by Astra Zeneca on a purified s-isomer (esomeprazole) of its popular drug omeprazole (Prilosec). The patent was granted for what can be considered 'an obvious subsequent development step..[and despite] the similar efficacy of these 2 molecules, the company used its marketing resources to promote the more expensive s-isomer when omeprazole, the original product, faced loss of its patent protection'.[18]

Over 800 patents were filed since the initial PCT application WO1994014436 to protect different aspects of ritonavir, an HIV/AIDS drug, and its methods of use.[19] Evergreening strategies by one company often force others to follow the same pattern as a defensive approach.[20] The proliferation of 'secondary' or 'spurious' patents can impose significant costs on patients and public health systems.[21]

This paper discusses some of the measures that can be applied at the national level in order to avoid the proliferation of patents on trivial developments. The measures considered here may be implemented in full consistency with the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), since they fall within the policy space that WTO members have retained to design and apply their patent laws. The paper does not consider policies and measures, extensively addressed by recent literature, which may be adopted in the context of competition laws.[22]

II. MEASURES TO REDUCE THE PROLIFERATION OF PATENTS

II.1 Raising the Standards for Patentability

The most important policy that governments may implement to prevent patent proliferation is the rigorous application of the requirements of patentability, based on a thorough examination of patent applications. The TRIPS Agreement neither defines the concept of 'invention' nor how such requirements need to be interpreted[23]. Thus, national laws may differentiate

[18] Ibid.

[19] See WIPO, "Patent Landscape Report on Ritonavir", available from http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/ritonavir.html.

[20] 'The more innovator formulation (and molecular form) patents that are granted with seemingly insignificant incremental innovations over the prior art, the more generic firms are pushed to develop alternative formulations and protect their R&D investment by patenting these. The lack of certainty over the final outcome of these late-filed formulation patents due to varying patent quality within and across patent offices around the world is a significant problem from a generic developer's perspective and prevents true generic competition post active ingredient expiry' (Leighton Howard, "Formulations patents in pharmaceutical development", *Journal of Generic Medicines*, 5, 2008, 365-370, p. 369).

[21] See, e.g., N. Vernaz, G. Haller, F. Girardin, B. Huttner, C. Combescure, P. Dayer, D. Muscionico, J. Salomon and P. Bonnabry, "Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis", *PLoS Med*, 10(6), 2013.

[22] See, e.g., UNCTAD, "Competition Policy and Exercise of Intellectual Property Rights", 2008, available at http://unctad.org/en/docs/c2clpd68_en.pdf; European Commission, "Preliminary Report on Pharmaceutical Sector Inquiry", 2008, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf; Josef Drexl, *Research Handbook on Intellectual Property and Competition Law*, Edward Elgar Publishing, 2008; Carlos Correa, *Intellectual Property and Competition Law: Exploration of Some Issues of Relevance to Developing Countries*, ICTSD, Geneva, 2010, available at http://ictsd.org/i/publications/11376/.

[23] Article 27.1 of the TRIPS Agreement stipulates that patents "shall be available for any inventions … provided that they are new, involve an inventive step and are capable of industrial application". It leaves WTO Members

inventions and discoveries, and require that the former result from an inventive *activity*, thereby excluding pre-existing subject matter that is merely found, such as natural substances. For example, patent legislation can consider that naturally occurring isolated DNA is not valid patentable subject matter, as the US Supreme Court did in *Association for Molecular Pathology v Myriad Genetics* 569 U.S. 12-398 (2013).[24] Likewise, particular crystalline forms of known chemical compounds such as pharmaceutical active ingredients[25] may be considered non-patentable[26]. In addition, national laws may consider novelty at the local or universal level,[27] and determine that the novelty requirement is not met when a claimed invention is disclosed in a prior document even if not described *expressis verbis*,[28] or where novelty can be derived from a combination of publications[29] Patent offices may also apply the "doctrine of inherency", which – as developed under the USPTO patent examination practice – takes into account "inherent disclosures" in determining novelty. As a result, a feature or an element of claimed invention which already exists in the prior art cannot be novel regardless of whether its presence was expressly stated, known, or even whether it would have been recognizable.[30]

While some patent offices grant patents on the basis of legal fictions on novelty, there is no reason to follow such practices in other jurisdictions. An example of this practice by some patent offices is to admit what are known as 'selection patents' whereby one of more items that were previously disclosed (e.g. under a 'Markush claim'[31]) are independently claimed. This type of patents provide an effective means of evergreening, since protection can be extended for the full length of a new patent, i.e. normally twenty additional years, despite the fact that novelty was actually lost when such items were first disclosed.

Applying a rigorous standard of inventive step is crucial to ensure that patents are granted if and when a genuine technical contribution has been made. As discussed

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leeway to interpret and define, in good faith, within their legal systems, the concept of 'invention' and the patentability requirements.

[24] LO Gostin, "Who Owns Human Genes? Is DNA Patentable?", *JAMA* 310: 791, 2013. For example, the 1996 Brazilian Industrial Property Code (No. 9.279, 14 May 1996) excludes from patentability living beings or "biological materials found in nature", even if isolated, including the "genome or germplasm" of any living being (article 10.IX).

[25] Differences in the crystalline forms found in chemical compounds have led to an explosion in the patenting of polymorphs. See, e.g., Rahul Purohit and P. Venugopalan, "Polymorphism: An Overview", *Resonance*, September 2009.

[26] See, e.g., Carlos Correa, "Guidelines for the examination of pharmaceutical patents: developing a public health perspective", Working Paper, WHO, ICTSD and UNCTAD, available from www.ictsd.org, Geneva, 2006.

[27] In fact, the USA defended this 'flexibility' before the Council for TRIPS, as its patent law contained a hybrid local and universal standard. The USA held that in the TRIPS Agreement there was 'no prescription as to how WTO Members define what inventions are to be considered "new" within their domestic systems' and, hence, that its legislation was 'perfectly consistent with the provisions of the TRIPS Agreement' (IP/Q3/USA/1, May 1, 1998).

[28] See, e.g. Philip Grubb, *Patents for chemicals, pharmaceuticals and biotechnology. Fundamentals of global law, practice and strategy*, Clarendon Press, Oxford, 1999.

[29] In general, patent offices require disclosure in a single document to consider that novelty has been destroyed. The combination of publications is suggested by the *EAC Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation*, 2013, available at http://www.cehurd.org/wp-content/uploads/downloads/2013/05/EAC-TRIPS-Policy.pdf.

[30] See, e.g., Schering Corp. v. Geneva Pharmaceuticals, 339 F.3d 1373 (Fed. Cir.2003).

[31] 'Markush claims' are broadly drafted claims covering a family of a large number (sometimes millions) of possible compounds through the definition of a chemical structure with multiple functionally equivalent chemical entities allowed in one or more parts of the compound. See Carlos Correa, op. cit., 2006.

elsewhere,[32] there is ample room under the TRIPS Agreement to define[33] and apply the inventive step standard in a manner that prevents the patenting of trivial developments. While some large patent offices, such as the US Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the Chinese Patent Office (SIPO)[34], seem to apply a lax inventive step standard thereby allowing for the grant of a large number of 'low quality' patents, there are strong public interest arguments to follow a different approach, particularly in developing countries.[35]

A strict application of the industrial applicability/usefulness requirement, when provided for by the national law, may also contribute to prevent the grant of unwarranted patent rights. This is the case, in particular, for claims on new medical uses, which are equivalent to claims over methods of treatment that have no industrial application or technical effect. The lack of industrial applicability may be a sufficient ground to reject such claims. Interestingly, while the EPO accepted since 1983 claims on new uses for known medicines, – based on the so-called 'Swiss claims' formulation[36] – this policy was in contradiction with the European patent law requirement of a new technical effect of a product or process as a basis for patentability.[37] In addition, the information described in patent applications is often not sufficiently complete and clear for a person skilled in the art to execute the claimed invention. Patent applications should not be admitted in these cases, as they would grant a monopoly without correspondingly disclosing the protected subject matter for use by others after patent expiry. For instance, lack of descriptive sufficiency has been – together with lack of novelty – one of the main grounds for rejection of patent applications by the Agência Nacional de Vigilância Sanitária (National Agency for Sanitary Surveillance – ANVISA) in Brazil.[38] Canadian courts have also revoked 18 patents for failing to meet the "usefulness" requirement on the basis of what has been termed the "promise doctrine" established by the Canadian Federal Court of Appeal.[39] This doctrine requires the patent applicant to demonstrate, or

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[32] See, e.g., Carlos Correa (editor), *A Guide to Pharmaceutical Patents*, South Centre, Geneva, 2008.

[33] 'It may be that no legal term as significant as nonobviousness' is as poorly defined' (G MANDEL, 'The Non-Obvious Problem: How the Indeterminate Non-obviousness Standard Produces Excessive Grants', University of California, 42 *U.C. DAVIS L. REV*. 57, 88 (2008), p. 88).

[34] On the case of China, see Wei Zhuang, "Evolution of the patent system in China" in F Abbott, C Correa and P Drahos (editors), *Emerging Markets and the World Patent Order*, Edward Elgar, London, 2013.

[35] See Padmashree Sampath, "Promoting Local Pharmaceutical Capacity in Developing Countries: A Discussion on Inventive Step and Compulsory Licensing", in Carlos Correa (editor), *Pharmaceutical innovation, incremental patenting and compulsory licensing*, South Centre, Geneva, 2013.

[36] 'The use of a substance X for the manufacture of a medicament for the treatment of disease Y'.

[37] See B Domeij, *Pharmaceutical patents in Europe*, Kluwer Law International, New York, 2001, p. 183; Carlos Correa (editor), *A Guide to Pharmaceutical Patents* (editor), South Centre, Geneva, 2008, p. 138. The European Patent Convention (EPC) was amended in year 2000 to allow for purpose-related product claims for a new medical use of a known substance ('product X for use in Y-new therapeutic use''). The new Article 54(5) EPC as amended reads: 'Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art'. On February 19, 2010, the European Patent Office Enlarged Board of Appeals held in In re Abbott Respiratory, G 0002/08, that 'Where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83'.

[38] Submission by Antonio Carlos Da Costa Bezerra (ANVISA) at the Foro Latinoamericano de la Industria Farmacéutica, 2013, available from http://www.asinfar.com/Archivos/alifar/Forum_Latino_Americano_da_Industria_Farmaceutica_2013-Antonio_Carlos_Da_Costa_Bezerra.pdf. See also below, Section II.4.

[39] See Michelle Wein, "Is it Useful? A Drug Patent Enigma", October 21, 2013, available from http://www.innovationfiles.org/is-it-useful-a-drug-patent-enigma/.

soundly predict, what is the "promise" of a claimed drug and not merely to state what it can be useful for.[40]

Given the policy space left to WTO Member countries by the TRIPS Agreement to adopt their own definitions of the patentability standards, and to do so consistently with their legal systems and practices,[41] governments can follow different methods to ensure that patents are granted only when there are sufficient merits under the applicable law.

Governments may introduce specific standards in the patent laws themselves. A notable case is the Indian Patent Act, as amended in 2005, which incorporated in section 3(d) specific standards to assess patent applications in the field of chemicals and pharmaceuticals. While section 3(d) specifies subject matter that may be deemed as not constituting an 'invention', it has also been understood as tightening the patentability requirements (inventive step and/or utility).[42] In a case brought by Novartis (a Swiss pharmaceutical company) against the rejection of its patent application relating to a beta crystalline form of imatinib mesylate, the Indian Supreme Court held that the claimed invention failed 'in both the tests of invention and patentability as provided under clauses (j),(ja) of section 2(1) and section 3(d) respectively' (para. 195)'. [43]

The Philippines patent law, as amended in 2008, introduced a section similar to the referred section 3(d) in the Indian Patent Act, but the guidelines adopted by the patent office may lead to a less rigorous application of the patentability requirements than in India[44]. While in the latter the concept of enhanced efficacy – as a condition of patentability – is understood to allude to the "therapeutic efficacy" of a drug, in Philippines it may encompass 'any of the "advantageous properties" (e.g. bioavailability, stability, solubility among others) exhibited by the new form of a known substance'.[45] With the purpose of heightening the standards for obtaining a patent, Australia adopted in 2012 the 'Raising the Bar Act' which, *inter alia*, raised the requirements for patentability and disclosure, and expanded the grounds for re-examination of a granted patent to all substantive grounds considered during examination.

The definition of the standards of patentability can also be made through regulations, including patent offices' guidelines.[46] A good example is provided by the guidelines on the

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[40] Eli Lilly, a major US pharmaceutical company, has notified an investment complaint against Canada arguing that the a Federal Canadian court decision to invalidate, five years before its expiry, a patent it had obtained in Canada on the basis of the 'promise doctrine' violate the company's investor's rights. See Carlos Correa, "Investment Agreements: A New Threat to the TRIPS Flexibilities?", *South Bulletin*, Issue 72, 13 May 2013.

[41] See article 1.1 of the TRIPS Agreement.

[42] See Carlos Correa, "The Novartis Decision by India's Supreme Court: a good outcome for public health", *South Bulletin*, Issue 75, 7 October 2013.

[43] The court, however, emphasized that 'in whichever way section 3(d) may be viewed, whether as setting up the standards of "patentability" or as an extension of the definition of "invention", it must be held that on the basis of the materials brought before this Court, the subject product, that is, the beta crystalline form of Imatinib Mesylate, fails the test of section 3(d), too, of the Act' (para. 190).

[44] A UNDP report has noted, however, that several patents have been granted in India that would not strictly comply with section 3(d). See UNDP, "Five years into the product patent regime: India's response", New York, 2010. See also Bhaven N. Sampat and Tahir Amin, "How Do Public Health Safeguards in Indian Patent Law Affect Pharmaceutical Patenting in Practice?", available from http://www.columbia.edu/~bns3/trips_april.pdf.

[45] Section 4.2 of the 'Examination Guidelines for Pharmaceutical Patent Applications Involving Known Substances', available at http://ipophil.gov.ph/index.php/patents.

[46] See some examples of adopted guidelines in http://www.wipo.int/patents/en/guidelines.html.

patentability of pharmaceutical products and processes adopted by the Argentine government[47] in 2012 to limit the evergreening of pharmaceutical patents.

In the USA there have been some initiatives to improve the examination process and limit the grant of unwarranted patents,[48] but with limited success. The USPTO is reported to grant 95-97 per cent of all patent applications, a policy that 'sets a dangerous precedent, as the USPTO is probably issuing a number of bad patents that do not represent true innovation'.[49] The US Federal Trade Commission proposed in 2003, among other measures, to tighten the non-obviousness standard.[50] While the number of applications approved by the USPTO declined steadily from 2001 to 2009, there was thereafter 'a sharp reversal, with a 2012 allowance rate about 20 percent higher than it was in 2009'.[51]

The EPO launched in 2007 a process aiming at 'Raising the bar on patent quality'.[52] However, little progress has apparently been made, as the EPO is reported to grant (like the Japanese patent office) 60-80 per cent of the patent applications.[53] The EPO granted 66,700 patents in 2013, the highest number ever in its history and 1.6 per cent more than in 2012. The EPO Administrative Council agreed to award a bonus of tens of millions euros to EPO staff at the end of 2012, thereby linking the staff's income to the Office's surplus and providing incentives to grant more, rather than less patents.[54]

Courts also have an important role in determining how the concept of invention and the patentability standards are applied. In some cases – as illustrated by the 'promise doctrine' of Canada and the 'doctrine of the inherency' in the US – courts define how such standards are to be implemented. Particular trends are often identifiable in the way courts deal with patent issues. In Japan, for instance, courts were responsible of an 'anti-patent storm' which has somehow calmed down recently. [55] In the US, it is widely recognized that the

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[47] Joint Resolution of the Ministry of Industry, Ministry of Health and Instituto Nacional de la Propiedad Industrial 118/2012, 546/2012 y 107/2012.

[48] See, e.g., US Government Accountability Office, "Intellectual Property: Assessing Factors That Affect Patent Infringement Litigation Could Help Improve Patent Quality", August 2013, p. 39 et seq., available from http://www.gao.gov/assets/660/657103.pdf.

[49] EPO, *Report.* "Workshop on Patent Thickets", *EPO Economic and Scientific Advisory Board*, Leuven, 26 September 2012, p. 10, available from http://documents.epo.org/projects/babylon/eponot.nsf/0/B58781F239B083CEC1257B190038E433/$FILE/workshop_patent_thickets_en.pdf.

[50] See Federal Trade Commission, "To Promote Innovation: The Proper Balance of Competition and Patent Law and policy", Washington DC, 2003.

[51] Timothy B. Lee, "Study suggests patent office lowered standards to cope with backlog. The 'allowance rate' sharply increased during Obama's first term", 7 April 2013, available from http://arstechnica.com/tech-policy/2013/04/study-suggests-patent-office-lowered-standards-to-cope-with-backlog/. See also Christopher Cotropia, Cecil Quillen Jr. and Ogden Webster, "Patent Applications and the Performance of the U.S. Patent and Trademark Office", *Intellectual Property Institute, Richmond School of Law*, 2013, available at: http://ssrn.com/abstract=2225781.

[52] See https://www.epo.org/about-us/annual-reports-statistics/annual-report/2007/focus.html.

[53] EPO, op. cit., p. 10. See also Peter H. Feindt, "Biopatents – A Threat to the Use and Conservation of Agricultural Biodiversity?" Position Paper of the Advisory Board on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV 2010), available at http://www.bmelv.de/SharedDocs/Downloads/EN/Ministry/Biopatents.pdf?__blob=publicationFile (arguing that the financing model of the EPO, mainly by procedural and maintenance fees, creates incentives to grant patent applications in case of doubt).

[54] See "EPO Staff to Get Disputed €28M Bonus, Despite Protest", 10 January 2013, http://www.ip-watch.org/2013/01/10/epo-staff-to-get-disputed-e28m-bonus-despite-protest/.

[55] Yoshiyuki Tamura, "IP-Based Nation: Strategy of Japan", in F. Abbott, C. Correa and P. Drahos (editors), op. cit.

establishment of a specialized appeal court for intellectual property cases induced a deep relaxation[56] of the patentability requirements in the country.[57] However, in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), the US Supreme Court reminded that '[A] person of ordinary skill is also a person of ordinary creativity, not an automaton'. Similarly, a report has noted that since 2007, the number of patents invalidated by the Federal Circuit has remained consistently higher than in the years prior and that '[t]his new trend by the Federal Circuit may be due to the increased scrutiny of the US Supreme Court into the outcome of patent cases'[58]. It has also been noted that it has become increasingly difficult in the US to get a patent granted on a polymorph[59] – one of the ways of evergreening pharmaceutical patents – and to defend it if challenged in courts.[60]

Finally, it is worth noting that in applying the patentability standards, patent offices can differentiate, in line with the TRIPS Agreement,[61] among fields of technology in order to take into account particular features of specific sectors and public policies objectives, for instance in relation to the promotion of generic drugs. The 'Declaration on Patent Protection: Regulatory Sovereignty under TRIPS' issued by the Max Planck Institute for Innovation and Competition in April 2014 notes in this regard that:

> Every technology is more or less unique with regard to its exposure to market failure, its susceptibility to patent protection, and its socio-economic implications. It follows that the demand for legal protection, and the effects of that protection on both the operation of competition and the attainment of other public policy goals may differ according to the technology at issue…Measures to accommodate these differences cannot be considered contrary to Article 27(1) of the TRIPS Agreement… Differentiation that serves to level the actual conditions of competition across all fields of technology is not discriminatory but rather the opposite. It constitutes a necessary response to the diversity of technologies and, consequently, a condition sine qua non for an intrinsically balanced system of protection that remains neutral in its effects on competition…Differentiation may relate to the requirements of patentability, patent eligibility and disclosure…[62]

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[56] In 1941, the US Supreme Court had defined a high standard of non-obviousness: 'A new device, to be patentable, must reveal a flash of creative genius' (Judge Douglas in *Cuno Engineering Corp.*, 314 U.S. 84, 51 U.S.P.Q. 1, 1941).

[57] See Adam B. Jaffe and Josh Lerner, op. cit.

[58] White Paper Report, "United States Patent Invalidity Study 2012", available at http://www.morganlewis.com/pubs/Smyth_USPatentInvalidity_Sept12.pdf, p. 1. For instance, in *Pfizer, Inc. v. Apotex, Inc*. F.3d, 2007 WL 851203 (Fed. Cir. 2007) the US Court of Appeals for the Federal Circuit deemed invalid a patent on amlodipine besylate on the argument that unpredictability cannot be equated to patentability, and that 'obviousness cannot be avoided simply by showing of some degree of unpredictability in the art so long as there was a reasonable probability of success'.

[59] Polymorphs are different crystalline forms of a molecule which keep the same chemical properties but may differ with regard to solubility, stability and melting point.

[60] See, e.g., P. Vure, "Polymorph patents; how strong they are really?" *Int. J. of Intellectual Property Management*, vol.4, no.4, 2011, 297-306.

[61] In a WTO case between the EC and Canada, the panel held that "Article 27 prohibits only discrimination as the place of invention, the field of technology, and whether products are imported or produced locally. Article 27 does not prohibit bona fide exceptions to deal with problems that may exist only in certain product areas. Moreover, to the extent the prohibition of discrimination does limit the ability to target certain products in dealing with certain of the important national policies referred to in Articles 7 and 8.1, that fact may well constitute a deliberate limitation rather than frustration of purpose" (WT/DS114/R, 17 March 2000, para 7.92).

[62] Available at http://www.ip.mpg.de/en/pub/news/patentdeclaration.cfm.

II.2 Pre and Post-grant Opposition

Once a patent is granted it is generally presumed to be valid until otherwise decided by the courts. Substantial resources (both financial and technical) are necessary to invalidate a patent. This is a difficult or impossible task for small and medium companies, non-governmental organizations or individuals (e.g. patients) that may be directly affected by wrongly granted patents. In addition, invalidation procedures may take years[63] during which the patent can be legally enforced. Hence, it is in the public interest to establish mechanisms that limit to the fullest extent possible the grant of wrong patents.

Pre and post-grant oppositions by third parties are one of such mechanisms[64]: '[O]ne of the main objectives of the opposition system is to provide a simple, quick and inexpensive mechanism that ensures the quality and validity of granted patents by allowing an early rectification of invalid patents'.[65] Opposition procedures may be *ex-parte* when the person who initiates it has limited opportunity to submit evidence and be heard in the process (for instance, he/she may be allowed to make a written presentation but not to attend oral hearings nor to be informed of the applicant's further comments or rebuttal). However, they may also be *inter partes* so as to allow the opponent to take part more actively in the proceedings.

Many patent laws provide for the possibility of filing observations or an opposition before a patent application is granted ('pre-grant opposition), based on the non-compliance with any of the patentability requirements and insufficiency of disclosure[66]. The advantage of this method is that it may *prevent* the grant of a patent altogether. The work of examiners is facilitated by the information and arguments submitted by opponents. Patent laws normally specify a term within which an opposition can be filed. If the term is too short (e.g. three months as provided, for instance, in some Latin American countries), interested third parties may be unable to complete the often complex technical analysis needed to articulate an opposition. This may be particularly the case when the full application is not published (but only a summary thereof or some claims) and when the patent applicant conceals information that is necessary to understand what the invention actually is about. In the case of pharmaceuticals, patent applications very often do not include the known International Non-Proprietary Name (INN) attributed by WHO to a particular drug. In Argentina, for instance, the generic name of the medicine was not mentioned in the information published by the patent office for 80 per cent of the granted patents.[67]

One limitation of pre-grant opposition proceedings is that, at the time such proceedings need to be initiated, potential opponents may not yet know the market value of the claimed invention to decide whether it is worthwhile opposing the grant of a patent. In many countries *post-grant* re-examination mechanisms are established either as an alternative

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[63] This may notably the case in many developing countries, where the judicial systems are slow. But even in the USA -a country deemed to have an efficient judicial system- invalidating the so-called 'Enola patent' (a patent granted on yellow colored beans obtained from Mexico by a US breeder) took almost nine years. See Sangeeta Shashikant and Asmeret Asghedom, "The 'Enola Bean' dispute: patent failure & lessons for developing countries", *Third World Network*, 12 August 2009, available at http://www.twnside.org.sg/title2/wto.info/2009/twninfo20090811.htm.

[64] It is worth noting that the TRIPS Agreement is silent on opposition procedures, thereby leaving WTO members freedom to decide on the matter.

[65] See WIPO, Opposition Systems, Document prepared by the Secretariat, Geneva, SCP/17/9, October 31, 2011.

[66] Some laws admit other grounds, such as inventorship. See, e.g., WIPO, 2011, op. cit. p. 6.

[67] See Carlos Correa, *Pharmaceutical innovation, incremental patenting and compulsory licensing* (editor), South Centre, Geneva, 2013, p. 19.

or a supplement (as in the case of India) to pre-grant procedures. Oppositions may be filed within specified time frames. In the case of the EPO, for instance, they must be filed within nine months from the publication of the mention of grant of the European patent in the European Patent Bulletin. In the US, post-grant re-examination procedures had been rarely used.[68] The 'America Invents Act' that amended in 2011 the US Patent Act aimed, *inter alia*, to boost the use of such procedures. Among other changes, the USPTO Director can now institute re-examination on his own initiative on the basis of prior art cited during another re-examination. A new proceeding, called 'post grant review', was also introduced to allow more broadly based challenges to a patent during the nine months after grant or reissue.[69] These new procedures 'are designed to be quick, less costly and use more technically-trained adjudicators than the US Federal court system. These procedures may provide welcome relief to litigants facing protracted litigation and sky-rocketing discovery expenses'.[70] The cost and length of post-grant procedures would normally be substantially lower than those of judicial litigation[71], and may open up the opportunity for challenges to the validity of patents that otherwise would not be pursued.

The rate of patent oppositions (as a percentage of total patents granted) is relatively low in the case of EPO: around 5 per cent to 6 per cent (data for 1980-2005) of the European patents granted are opposed. However, about two thirds of the opposed patents were revoked or amended to survive the challenge.[72]

The use of pre and post-grant procedures is particularly intense in areas of high patenting activity, such as pharmaceuticals. Patents granted for pharmaceuticals are opposed at a higher rate than the average for all patents granted by EPO:

> …granted patents classified under A61K, the International Patent Classification code representing Preparations for Medical Use, were opposed on average over the past four years at a rate that is twice that of the EPO average for a given year. These data also show that one in ten patents granted by the EPO in the field of formulations are of questionable validity to the extent that an observer has sought to challenge the grant decision. When reviewing the results of such challenges, an average of 70 per cent of opposed patents in the field resulted in either revocation or amendment of the patent

[68] Since the establishment of the *ex-parte* reexamination system (and until September 2012), the USPTO received 12874 requests (a small proportion of the patents granted in that period), 69 per cent of which filed by third parties. All claims were cancelled in 11 per cent of the submitted cases and claims changed in 66 per cent cases. See http://www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2013.pdf. On the other hand, 1919 request of *inter partes* reexamination were filed since 1999, leading to cancelation of claims in 45 per cent of the cases and to claims' amendments in 43 per cent of the cases. See http://www.uspto.gov/patents/stats/inter_parte_historical_stats_roll_up_EOY2013.pdf.

[69] See, e.g., John Richards, "US Patent Law Reform 2011", available at http://www.ladas.com/BULLETINS/2011/New_US_Patent_Law.shtml.

[70] White Paper Report, "United States Patent Invalidity Study 2012", available at http://www.morganlewis.com/pubs/Smyth_USPatentInvalidity_Sept12.pdf. p. 1.

[71] The cost of an opposition procedure before the EPO may be in between €6000 and €50,000 (including patent lawyers) (see Malwina Mejer and Bruno van Pottelsberghe de la Potterie, "Economic Incongruities in the European Patent System", ECARES working paper 2009-003, January 2009), while a court case may cost more than one million Euros. See also, with regard to the USA, James Bessen and Michael Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk*, Princeton and Oxford, Princeton University Press, 2008.

[72] Aalt van de Kuilen, "Successful European oppositions: Analysis for the patent information professional", *World Patent Information (Elsevier)*, vol. 35, issue 2, 2013, p. 126-129; Malwina Mejer and Bruno van Pottelsberghe de la Potterie, op. cit.;

> claims…, casting considerable doubt on the ability of the EPO to examine these patents with a high degree of quality in the first instance.[73]

In Argentina, 25 patent oppositions were submitted by domestic companies including for the HIV medicines efavirenz, ritonavir, lopinavir, raltegravir, elvitegravir and the fixed-dose combination TDF/FTC/EFV, as well as medicines to treat other conditions like heart disease, diabetes, and arthritis[74]; many of the opposed patent applications were finally rejected.[75] In India, 25 out of 34 oppositions that were filed by local companies or non-governmental organizations against pharmaceutical patent applications filed between 2005 and 2008 resulted in rejections, i.e. a significantly high ratio of 73.5 per cent.[76] Médicins sans Frontières (MSF) has created and operates a database to share information on patent oppositions relating to pharmaceuticals and thereby facilitate the challenge by local firms or civil society of patent applications in different jurisdictions.[77].

II.3 Easing Legal Challenges to Patents of Questionable Validity

Patents are granted, even in countries where substantive examination takes place, without any guarantee about the utility of the invention or the validity of the patent. [78] Granted patents are often invalidated when challenged in post-grant opposition proceedings or before the courts. A study estimated that at least 28 per cent of current patents would be found invalid by the courts in the US.[79]

In only 39 out of 283 cases where patent validity was questioned before a US Federal District Court between 2007 and 2011, the claims that were challenged were found to be valid and enforceable.[80] When the lower court invalidated a patent, the Federal Circuit affirmed that decision more than 70 per cent of the time over the years examined.[81]

Despite that 'secondary' patents for pharmaceuticals are often found invalid by courts, in accordance with industry advisers it is still worthwhile to obtain and defend them:

> Even where the final outcome of proceedings is that the patent is held invalid, the effect of the litigation will have been to delay the generics' entry to the

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[73] Howard, op. cit., p. 369.

[74] See MSF, "New resources from Argentina now available on PODB", available at http://news.patentoppositions.org/.

[75] As a result of the new guidelines for pharmaceutical inventions adopted in 2012 and opposition to various applications, the Argentine patent office only granted 55 pharmaceutical patents in that year. See CILFA, "Análisis de patentes farmacéuticas concedidas en 2012», 12-4-2012, available at http://www.cilfa.org.ar/index.php?modulo=index&accion=sitio_articulos&idarticulos=129187&idarticulos=129187&idcategoria1=19&idcategoria2=141&idcategoria3=97901&idcategoria4=129184&ajax=1&modulo2=articulos&accion2=sitio_ver&idioma=sp#sitio_top.

[76] See Shamnad Basheer, "Patent Oppositions in India: The 'Efficacy' of Section 3(d)", September 16, 2009, available from http://spicyip.com/2009/09/patent-oppositions-in-india-efficacy-of.html ('...20 out of the 25 rejections above were based on section 3(d),… indicating the "efficacy" of this controversial section').

[77] See http://patentoppositions.org/.

[78] Despite this limitation, it is advisable for countries (e.g. South Africa) that do not have a substantive examination system to introduce it, so as to limit the number and scope of granted patents.

[79] Shawn P. Miller, "Where's the innovation? An analysis of the quantity and qualities of anticipated and obvious patents", February 10, 2012, available at SSRN: http://ssrn.com/abstract=2029263 or http://dx.doi.org/10.2139/ssrn.2029263.

[80] White Paper Report, op. cit.

[81] Ibid.

> market. Fighting the litigation may also have 'warned off' other generic competition. In any event, for a successful product, the benefit of even a short time of additional proprietary sales may easily outweigh the costs of patent litigation.[82]

As noted, pursuing the invalidation of a patent is generally costly and takes a long time. Significant technical and financial resources are needed. Often there is little incentive for local companies to challenge a patent and bearing the corresponding costs, since once invalidated the market will remain open to any other company despite not having borne the risk and cost of the invalidation procedures. It has been noted in this regard that

> A patentee's incentive to defend his patent grossly exceeds an alleged infringer's incentive to challenge it. Where there are multiple infringers, patent invalidity judgments result in patents being turned into public goods, removing the ability of a patent attacker to exclude others from appropriating the benefits of a successful attack.[83]

In order to provide an incentive for invalidation, the US law stipulates that the first generic company to successfully challenge a patent on a drug will enjoy a 180-day exclusivity period in which no subsequent abbreviated new drug application (ANDA) could be approved for that drug (21 U.S.C. §355(j)).[84]

In Australia, a panel established by the Parliamentary Secretary for Innovation discussed the lack of incentives for generic manufacturers to challenge the validity of pharmaceutical patents. It observed that

> …the incentive available to generic manufacturers to challenge patents in the courts is low due to a number of factors. The Australian market is relatively small compared with the US, Europe and Japan and the profit margins of generic manufacturers are lower than originators. This is exacerbated by the lack of special reward or period of market exclusivity for a successful challenger. Because its margins over production cost are slimmer than the originator, a generic manufacturer 'internalises' only a small proportion of the benefits of successfully challenging a patent. Therefore it is often in a competitor's interest to wait and hope that another competitor incurs the cost and risk of a challenge.[85]

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[82] Michael Burdon and Kristie Sloper, "The Art of Using Secondary Patents to Improve Protection", vol. 3, *International Journal of Medical Marketing*, 2003, p. 228.

[83] Sivaramjani Thambisetty, *The Learning Needs of the Patent System: Implications from Institutionalism for Emerging Technologies Like Synthetic Biology* (1 June 2013). LSE Legal Studies Working Paper No. 18/2013, available from SSRN: http://ssrn.com/abstract=2272980, p. 11. See also M Carrier, 'Solving the Drug Settlement Problem: A Framework for Presumptive Illegality' (2009) 108 *Michigan Law Review* 37; J Farrell and RP Merges, 'Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Review Might Help' (2004) *19 Berkeley Technology Law Journal* 943.

[84] The implementation of this provision has been considered in several court cases. See, e.g., Tony V. Pezzano, "United States: The Drug Approval Process: What's The 'Hatch' With The One Hundred Eighty-Day ANDA Exclusivity Period?", 2001, available at http://www.mondaq.com/unitedstates/x/24779/Life+Sciences+Biotechnology/The+Drug+Approval+Process+Whats+The+Hatch+With+The+One+Hundred+EightyDay+ANDA+Exclusivity+Period.

[85] Australian Government, *Pharmaceutical Patents Review. Draft Report*, April 2013, p. 155, available at http://www.ipaustralia.gov.au/about-us/ip-legislation-changes/review-pharmaceutical-patents/.

The Panel's arguments would certainly apply to developing countries with manufacturing capacity in pharmaceuticals. It considered that 'some form of extra incentive may be necessary to provide competitors with sufficient encouragement to challenge potentially invalid patents, without removing all the risk for challengers and thereby creating inefficiencies and a litigation industry',[86] and suggested the following possible mechanisms[87]:

- 'making it a mandatory condition of being granted an injunction for pharmaceutical cases that the patentee undertakes to repay any damages to the Government;
- providing the challenger of a patent with a portion of the damages obtained by the Government from an undertaking by the patentee;
- providing a challenger with a combination of guaranteed and conditional subsidies or negotiating some other arrangement;
- requiring the patentee to repay to the Government an amount based on the lost reduction in PBS (Pharmaceutical Benefits Scheme) subsidy due to the delayed entry to the market of generics; or
- requiring the patentee to pay a portion of its profits for the product during the injunction period to a successful challenger'. [88]

Other legal measures can be adopted in order to ease legal challenges to wrongly granted patents. One of such measures refers to the calibration of the presumption of validity conferred to granted patents. While rebuttable, the challenging party normally has the burden to produce convincing evidence to support a non-validity claim[89]. However, as indicated by the US Federal Trade Commission, the circumstances in which patents are granted "suggest that an overly strong presumption of a patent's validity is inappropriate" and that "it does not seem sensible to treat an issued patent as though it had met some higher standard of patentability."[90] The strength to be recognized in the patent validity presumption has been discussed in the US and other countries[91]. In the US, for instance, the Federal Trade Commission has recommended to replace the standard of proof applied requiring the challenger to produce "clear and convincing" evidence, by the softer standard based on a "preponderance" of evidence of invalidity.[92] In accordance with Samuelson,

> U.S. patent law says that "patent[s] shall be presumed valid," but it doesn't say how strong such a presumption of validity should be. The effect of the presumption is to put onto anyone who contests the validity of a patent (say, on obviousness grounds) the burden of proving invalidity… The law puts the patent examiner to the task of identifying reasons why the patent shouldn't issue to an applicant, not on the applicant to prove he is entitled to it.

[86] Ibid.
[87] It is worth noting that the proposed measures would be consistent with Part III of the TRIPS Agreement.
[88] Ibid. p. 157-158.
[89] See, e.g., Bernard Remiche and Vincent Cassiers, *Droit des brevets d'invention et du savoir-faire: Créer, protéger et partager les inventions au XXIe siècle*, Éditions Larcier, Bruxelles, 2010.
[90] Federal Trade Commission, 2003, op. cit. p. 8.
[91] See, e.g. Carlos Correa (editor), *Medidas cautelares en el régimen de patentes*, LexisNexis, Buenos Aires, 2006.
[92] See Federal Trade Commission, 2003, op. cit.

> Moreover, patent examiners have heavy caseloads and a limited number of hours within which to conduct examinations of each application. The PTO's own decisions about patents are made on a preponderance standard, so it makes sense that the presumption in favour of the patent is no greater than this. [93]

One option would be to distinguish between the presumption of validity of the administrative act by which a patent is granted (issuance in accordance with the prescribed procedures) and that referred to the compliance with the patentability requirements, which is more difficult to establish *a priori* given the limitations of the substantive examination, even if conducted by large patent offices, such as the USPTO with almost 8.000 patent examiners.[94]

II.4 Involving other Public Authorities in Examination or Litigation

While patent offices have the main responsibility in examining patent applications,[95] and courts in finally deciding on validity issues in cases of dispute, national laws may provide for the intervention of other authorities in order to improve the quality of patent examination and avoid abuse of the system. Two examples can be mentioned in this regard.

As a result of concerns about the issuance of patents that could unduly block the commercialization of generic medicines in Brazil, the Provisional Presidential Decree Nº2006/1999 (later confirmed by Law No. 10,196 of February 14, 2001) determined that any patent application related to pharmaceuticals had to be subjected to the 'prior consent' of ANVISA. Consequently, the patent office (Instituto Nacional da Propriedade Industrial – INPI) can only grant a patent after such consent is given.

The implementation of this law revealed significant differences between the pro-public health approach adopted by ANVISA in examining patent applications, and that of the patent office more inclined to follow the criteria and practices developed by patent offices of industrialized countries. Such differences became evident with regard to two typical modalities of evergreening; claims relating to polymorphs and to second uses of known medicines, which were deemed non-patentable by ANVISA.[96] The controversy[97] led to the

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[93] Pamela Samuelson, "Legally Speaking: Why Reform the U.S. Patent System?", available at http://people.ischool.berkeley.edu/~pam/papers/cacm%20patent%20reform.pdf. More radically, judge Posner has argued for the elimination of the presumption that patents are valid once they are issued by the USPTO. See Ryan Davis, "7th Circuit's Posner Calls For Crackdown On Patent Proliferation", *Law360*, 14 May 2013, available at http://www.law360.com/articles/439755/7th-circ-s-posner-calls-for-crackdown-on-patent-proliferation.

[94] See USPTO, "*Performance and Accountability Report*", FY 2012, available at http://www.uspto.gov/about/stratplan/ar/USPTOFY2012PAR.pdf. The FTC noted in its 2003 report that 'the courts have interpreted the patent statute to require the PTO to grant a patent application unless the PTO can establish that the claimed invention does not meet one or more of the patentability criteria. Once an application is filed, the claimed invention is effectively presumed to warrant a patent unless the PTO can prove otherwise. The PTO's procedures to evaluate patent applications seem inadequate to handle this burden' (FTC, 2003, op. cit. p. 9).

[95] In some countries (e.g. Luxembourg, South Africa) there is no substantive examination of patent applications; they are registered after a mere formal examination.

[96] Eduardo Guimarães and Marilena Corrêa, "Intellectual property and public health: the role of the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária – ANVISA) in pharmaceutical patenting in Brazil", RECIIS – R. Eletr. de Com. Inf. Inov. Saúde, Rio de Janeiro, vol.6, no.3, September 2012, available from http://www.reciis.icict.fiocruz.br/index.php/reciis/article/viewArticle/612/1230.

[97] The constitutionality of ANVISA's role in patent examination was judicially challenged by pharmaceutical

intervention of other governmental bodies,[98] and to an attempt to cut down the scope of ANVISA's examination.[99] Finally, the role of ANVISA was confirmed and clarified by Resolução da Diretoria Colegiada RDC 21/03[100], in accordance to which ANVISA will examine patent applications in 'the light of public health' in cases where the claimed products present a health risk or are of interest to the Unique Health System (Sistema Único de Saúde – SUS).

While consent was denied – in most cases due to lack of novelty or inventive step – [101] by ANVISA for only 12 per cent of the 1484 patent applications it examined until 15/5/12, a much larger number of applications have been amended as a result of the Agency's observations.[102]

Another interesting example of governmental intervention (beyond the patent office) is provided by sections 26C and 26D of the Australian Therapeutic Goods Act 1989 (as amended), in accordance to which the Commonwealth Attorney-General is given the authority to join an application for an injunction by a brand name patent holder against a generic medicines manufacturer and to claim damages where the injunction has caused a price rise under the PBS. [103]

II.5 Applying Penalties and Additional Damages

All patent laws sanction the infringement of patents, generally through civil remedies.[104] But liability should be triggered not only for the violation of conferred patent rights. The misconduct by patent applicants and holders should also be legally sanctioned in order to ensure a balance of rights and obligations and protect the public interest.[105] Australia has developed a system to curb the abuse of patents in the pharmaceutical field that works as described below.

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companies (see Eduardo Da Gama Camara Jr, "Brazil: Prosecution Of Pharmaceutical Patents In Brazil: Tensions Between The Brazilian Patent Office And ANVISA", 22 July 2013, available at http://www.mondaq.com/article.asp?articleid=253068) albeit unsuccessfully. It is worth noting that the TRIPS Agreement is silent about which governmental body is competent to review and approve or refuse patent applications. ANVISA's intervention is unobjectionable under that Agreement.

[98] In 2008, the Interministerial Intellectual Property Group (Grupo Interministerial de Propriedade Intelectual – GIPI) was called on to give an opinion on the patentability of polymorphs. Eight of the eleven agencies of the Federal Public Administration that participated in the GIPI voted in favor of the position adopted by ANVISA. See Eduardo Guimarães and Marilena Corrêa, op. cit.

[99] The Federal Attorney General determined in 2009 that ANVISA was not empowered to evaluate patentability requirements,' except when (i) the new invention could cause harm to population health and (ii) it found that the effectiveness of the invention was questionable' (Eduardo Guimarães and Marilena Corrêa, op. cit.).

[100] Available at http://portal.anvisa.gov.br/wps/wcm/connect/800267004fb78790ac99fd9a71dcc661/RDC+21.13+Altera+a+RDC+45.pdf?MOD=AJPERES.

[101] Presentation by Antonio Carlos Da Costa Bezerra, op. cit.

[102] In the period 2001-2008, 36.6 per cent of the original patent applications underwent changes pursuant to ANVISA's intervention. See Eduardo Guimarães and Marilena Corrêa, op. cit.

[103] See next sub-section.

[104] Some national laws provide for criminal sanctions in developing countries. However, the TRIPS Agreement only obliges members to provide for such sanctions 'in cases of willful trademark counterfeiting or copyright piracy on a commercial scale' (Article 61).

[105] Notably, article 41 of the TRIPS Agreement provides that 'T]hese procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse'.

A generic manufacturer seeking to rely on data previously provided to the drug authority by an 'originator' company must provide a certificate ('s.26B certificate') stating that:

- the applicant, acting in good faith, believes on reasonable grounds that it is not marketing, and does not propose to market the therapeutic goods in a manner or circumstances that would infringe a valid claim of a patent that has been granted in relation to the therapeutic goods (section 26B(1)(a) of the Therapeutic Goods Act 1989); or

- a patent has been granted in relation to the goods, and that the applicant proposes to market the therapeutic goods before the end of the patent, and that the applicant has notified the patentee accordingly (section 26B(1)(b) of the Therapeutic Goods Act 1989)[106].

If the patent owner intends to initiate patent infringement proceedings against a generic company that has provided an s.26B certificate, the former must provide, in turn, a certificate ('s.26C certificate') to the Therapeutic Goods Administration (TGA) and to the generic company stating that 'the proceedings are to be commenced in good faith, have reasonable prospects of success, and will be conducted without unreasonable delay. A penalty of up to $10 million [Australian dollars] may be ordered for providing a s.26C certificate where the certificate contains false or misleading particulars, or where an undertaking given in the certificate is breached'.[107]

In addition, in accordance with section 26D of the Therapeutic Goods Act 1989, where a generic company has provided a certificate under section 26B(1)(b) and the patentee (or its licensee) has been granted an interlocutory injunction restraining the company from marketing the allegedly infringing products, if the infringement proceedings are subsequently discontinued or dismissed, or the court finds that the patentee did not have reasonable belief that final relief would be granted, or that the proceedings had no reasonable prospect of success, the court may award compensation to the applicant, the Commonwealth and/or a State or Territory – for losses sustained as a result of the injunction.[108]

To date 'generic companies rarely notify an originator of their intention to enter the market by filing a certificate pursuant to s.26B(1)(b)',[109] and there is no evidence so far about the application of the penalty under section 26C, or of any action being undertaken in relation to section 26D.[110] Nonetheless, these provisions indicate the clear intention of the Australian government to introduce anti-evergreening safeguards in response to the tightening of intellectual property protection for pharmaceuticals imposed by the US-Australian Free Trade Agreement that entered into force in January 2005.

Of particular interest are the Australian rules establishing that damages need to be paid to the Government when a patentee has obtained an interlocutory injunction and the patent

[106] Australian Government, Pharmaceutical Patents Review. Draft Report, April 2013, p. 159, available at http://www.ipaustralia.gov.au/about-us/ip-legislation-changes/review-pharmaceutical-patents/.,. Providing a false or misleading 's.26B certificate' is an offence which incurs a fine of $170,000 (Australian Dollars) and/or imprisonment for 12 months.
[107] Ibid. p. 171.
[108] Ibid.
[109] Ibid., p. 160.
[110] Ibid. p. 171.

has finally been found invalid. This recognizes that the enforcement of wrongly granted patents not only affects the particular parties alleged to infringe them, but the consumers and government, or social security services forced to pay monopoly prices as a result of the patentee's action. In the case of Australia, such damages can include 'the foregone savings to the PBS [Pharmaceutical Benefits Scheme] budget resulting from delay in generic entry into the market and reduction in the Government subsidy. Damages can total in the millions of dollars, depending on the value of the product and the period of the injunction'.[111] The Australian Department of Health and Ageing sought compensation from the patentees in two cases where injunctions were granted for PBS-listed products – clopidogrel (Plavix) and venlafaxine (EFEXOR XR) – and the patents were subsequently being revoked.[112]

The safeguards against evergreening and patent abuse were questioned by the US Trade Representative (USTR), who in a letter to the Australian Trade Minister stated:

> We also remain concerned about recent amendments to sections 26B(1)(a) 26C and 26D of the Therapeutic Goods Act of 1989. Under these amendments, pharmaceutical patent owners risk incurring significant penalties when they seek to enforce their patent rights. These provisions impose a potentially significant, unjustifiable and discriminatory burden on the enjoyment of patent rights, specifically on owners of pharmaceutical patents. I urge the Australian Government to review this matter, particular in the light of Australia's international legal obligations. The US reserves its rights to challenge the consistency of these amendments with such obligations.[113]

The referred to safeguards have never been challenged under the WTO dispute settlement mechanism and, in fact, it would be hard to prove that they are inconsistent in any manner with the TRIPS Agreement or other obligations under the WTO rules.

In summary, as illustrated by the Australian legislation, nothing prevents ministries of Health or other authorities from claiming compensation in cases of unwarranted injunctions that allowed patentees to keep generics out of the market. To this end there is no need to introduce specific legislation, as such claims can be based on general principles governing the intervention of third parties in legal proceedings[114] and the award of damages. There is also no need to introduce a system of certificates as the one developed under Australian law.[115]

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[111] Ibid. p. 154.
[112] Ibid. p. 154.
[113] See item 6 (Pharmaceutical Patents) of Letter from Robert Zoellick to Mark Vaile, 18 May 2004 Department of Foreign Affairs and Trade <http://www.dfat.gov.au/trade/negotiations/us_fta/final-text/letters/ip_zoellick_vaile.pdf> accessed July 2005.
[114] For example, the Ministry of Health of Argentina was accepted as a third party in 2007 in a case where a preliminary injunction had been granted at the request of Bristol Myers Squibb based on a patent (AR017747B1) covering a formulation for the slow release of didanosine (a drug that was in the public domain). The injunction prevented the Ministry from acquiring and distributing didanosine to HIV/SIDA patients until the preliminary injunction was dismissed on appeal. In 2013, the appeal court found that there was no infringement (decision of 18 June, 2013, Sala I de la Cámara en lo Civil y Comercial Federal). See https://www.cilfa.org.ar/archivos/File/Bolet%C3%ADn%20PI/año%202%20nº%203/CCCFed%20I%202013-6-18%20-%20Bristol%20Myers%20Squibb%20Company%20s-cautelares%20-%20expte%201412-2007.pdf.
[115] The possible effectiveness of the certification system has been put into question : 'In the scheme of the overall system, the 'anti-evergreening' provisions seem a pyrrhic victory, useful as a media stunt but not achieving any fundamental reform to the system. It is hard to envision these provisions, with their multiple qualifications and standards, ever being effectively used against a drug company to impose a significant penalty,

However, such a system may be useful in providing the basis for the implementation of other measures, such as monetary sanctions in case of misleading or false allegations, for instance, when a patentee alleges infringement beyond any reasonable interpretation of the patent claims.

II.6 Marketing Approval of Generic Drugs

In some countries where the laws or regulations establish a 'linkage'[116] between patent protection and the marketing approval of generic medicines, some measures have been adopted to curb evergreening.

In the US, patent owners can obtain court injunctions and delay the marketing approval of generic products for up to 30 months, on the basis of patents listed in the 'Orange Book'. In 2002, an inquiry by the US FTC found that while 75 per cent of new drug applications by generic producers were blocked by patent owners, there was a high rate of invalidity or non-infringement.[117] Upon a recommendation by the FTC, the *Medicare Prescription Drug Improvement and Modernisation Act 2003*[118] established that only one injunction against a potential generic market entrant would be permitted per product. In addition, the rules for the submission of patents to the 'Orange book' were tightened to help prevent unfair competition. The type of patents that must be submitted to the FDA (patents on active ingredients, drug formulations, compositions and on approved uses of a drug) was clarified, while indicating also those (e.g. for packaging) that cannot be submitted. False statements can lead to criminal charges.[119]

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though they may result in greater internal scrutiny by a patentee of the merits of its case — in particular, in relation to which of its claims it will seek a remedy' (CHALMERS, op. cit. P. 46).

[116] This practice prevents a drug regulatory authority from granting marketing approval to a generic medicine if patents on the respective product are still in force. See, e.g., T Faunce and Joel Lexchin, "'Linkage' pharmaceutical evergreening in Canada and Australia", *Aust New Zealand Health Policy*, 4: 8, 2007.

[117] See Federal Trade Commission, "*Generic Drug Entry Prior to Patent Expiration: An FTC Study*", 2002. The FTC found that 'there were cases involving several brand-name drugs between 1994 and 2000 in which repeated 30-month stays of approval delayed access to generic drugs. Access to generic drugs has sometimes been delayed from four to 44 months when drug companies have used various methods to get repeated 30-month stays. Often the patents were for minor matters that did not affect the drug product's effectiveness or safety' (FDA, "Greater Access to Generic Drugs. New FDA Initiatives to Improve the Drug Review Process and Reduce Legal Loopholes", A Special Report From the *FDA Consumer Magazine* and the FDA Center for Drug Evaluation and Research Fourth Edition / January 2006, available from http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143545.htm).

[118] In describing the objective of the new legislation, President Bush stated: 'When a drug patent is about to expire one method some companies use is to file a brand new patent based on a minor feature such as the color of the pill bottle or a specific combination of ingredients unrelated to the drug's effectiveness. In this way the brand name company buys time through repeated delays called automatic stays that frees the status quo as the legal complexities are sorted out. In the meantime, the lower cost generic drug is shut out of the market. These delays have gone on in some cases for 37 months or 53 months or 65 months...Today I'm taking action to close the loopholes, to promote fair competition and to reduce the cost of prescription drugs in America. …These steps we take today will not undermine patent protection. Instead, we are enforcing the original intent of a good law. Our message to brand name manufacturers is clear; you deserve the fair rewards of your research and development. You do not have the right to keep generic drugs off the market for frivolous reasons. Over the next three years about 200 drug patents are set to expire. By cutting out delays and maneuvering, our reforms will yield cost savings of more than $3 billion a year'. See Transcript. CNN LIVE EVENT/SPECIAL, President Makes Address About Prescription Drugs, October 21, 2002 – 08:32, available at http://transcripts.cnn.com/TRANSCRIPTS/0210/21/se.01.html.

[119] FDA, op. cit.

In Canada, the Commission on the Future of Health Care established by the Prime Minister noted the pharmaceutical industry's practice of evergreening to delay 'the ability of generic manufacturers to develop cheaper products for the marketplace and it is a questionable outcome of Canada's patent law'.[120] It recommended the federal government to 'immediately review the pharmaceutical industry practices related to patent protection, specifically, the practices of evergreening and the notice of compliance regulations'.[121]

In accordance with the Canadian Notice of Compliance Regulations (NOC)[122] the Minister of Health has to maintain a Patent Register which contains the patents informed by innovator companies in respect of drugs (including formulations, dosage forms and uses of drugs) for which marketing approval is sought. The Minister may refuse to add, or may delete, patents from this Patent Register. In 2006, the Canadian government adopted measures aimed at preventing the use of evergreening patents to block the registration of generic products[123]. The new regulations prevent an innovator company from obtaining an order to prohibit the registration of a generic product for a period of 24 months (or upon resolution of the court application, whichever is sooner) as otherwise allowed by the Canadian regulations, in the case of patents listed *after* a generic company submits an application for approval of its product. The new Regulations also make it clear that patents covering matters without direct therapeutic application, such as processes or intermediates, cannot be used to delay the marketing approval of generics.[124]

The problem of evergreening of pharmaceutical patents has been specifically addressed in several court cases in Canada. In *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61, for instance, the Supreme Court stated: '[E]vergreening is a legitimate concern and, depending on the circumstances, strategies that attempt to extend the time limit of exclusivity of a patent may be contrary to the objectives of the Patent Act'.[125]

The experiences of the US and Canada may be illustrative for other countries that have adopted (often as a result of requirements under free trade agreements)[126] a 'linkage' between patent protection and drug marketing approval. In the absence of appropriate measures, patents on polymorphs, salts, enantiomers, formulations, etc., if granted, may be used to unduly delay the entry of generic products into the market[127]. Importantly, linkage provisions

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[120] Commission on the Future of Health Care in Canada, «*Building on Values: The Future of Health Care in Canada*», 2002, p. 209, available at http://publications.gc.ca/collections/Collection/CP32-85-2002E.pdf.
[121] Ibid. p. 208.
[122] Available at http://www.wipo.int/wipolex/en/text.jsp?file_id=222609.
[123] See Regulations amending the patented medicines (notice of compliance) regulations. Canada Gazette Part II (Government of Canada) 140 (21), 5 October 2006.
[124] Rathod, op. cit.
[125] In a previous case the Supreme Court referred to the 'commercial strategy of the innovative drug companies to evergreen their products by adding bells and whistles to a pioneering product even after the original patent for that pioneering product has expired' (*AstraZeneca Canada Inc. v. Canada (Minister of Health),* (2006) 2 S.C.R. 560, 2006 SCC 49).
[126] See Public Citizen, "Comparative Table of Patent Linkage Provisions in U.S. Free Trade Agreements and the U.S. Proposal to the Trans-Pacific Partnership (TPP) Agreement", available at http://www.citizen.org/documents/patentlinkagetablewclauses.pdf.
[127] In the USA it was found that independent formulation patents add an average of 6.5 years of patent life, independent method of use patents add 7.4 years, and independent patents on polymorphs, isomers, prodrug, ester, and/or salt claims add 6.3 years, and that late-filed independent secondary patents are more common for higher sales drugs. See Anthony Crasto and Ann Newman, "How to Handle Drug Polymorphs… Case Study of Trelagliptin Succinate", available at http://newdrugapprovals.org/2014/02/05/how-to-handle-drug-polymorphs-case-study-of-trelagliptin-succinate/.

– where provided for – should only be applied in relation to patents covering the active ingredients. [128]

II.7 Limiting Divisional Applications

A 'divisional' patent application is a patent application that includes some part of the subject matter claimed in a prior application (generally called 'parent application'). In examining a divisional application, the filing date of the parent application and, if invoked, its priority, will be taken into account, thereby reducing the risk of rejection on grounds of lack of novelty or inventive step.

When liberally allowed, divisional applications can be misused to keep pending for long periods the decision on the grant of a patent, thereby generating uncertainty for potential competitors. In addition, it has been observed in the US that

> There are a number of different ways to re-file applications, with names like File Wrapper Continuations, Continued Prosecution Applications, Requests for Continued Examination and Continuation-In-Part Applications. But in all cases, the upshot is the same: the applicant gets another shot at convincing examiners to grant him a patent… [129]

In Australia, the Raising the Bar Bill 2011 introduced 'stricter conditions for filing divisional applications and extensions of time to prevent exploitation of the system and thereby, public uncertainty'.[130] Before the reform, a divisional application could be filed at any time until the grant of the parent application, including during the opposition proceedings, thereby allowing the applicant to obtain a safeguard in case the opposition was successful.[131] Moreover, 'it was previously possible to convert a standard patent application into a divisional application so long as the application to be converted could have been filed as a divisional of the nominated parent on its original filing date. This resulted in a situation where an application could be converted into a divisional after grant of the parent'.[132]

While article 4(G) of the Paris Convention for the Protection of Industrial Property (which is binding on all WTO members in accordance with the TRIPS Agreement) provides for the applicant's right to file, under certain circumstances, a divisional application, it clearly states that '[E]ach country of the Union shall have the right to determine the conditions under which such division shall be authorized'.

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[128] See, e.g., Carlos Correa, "Vinculación de patentes y registro de productos agroquímicos y farmacéuticos: una solución contraria al interés público", in S. Gastaldi (editor), *Ciencia, Técnica y Poder Judicial. El pensamiento científico y poder judicial. Biotecnología, Bioética, Productos Farmacéuticos y Acceso a la Salud II*, La Ley, Buenos Aires, 2012.
[129] Timothy B. Lee, op. cit.
[130] Australian Government, op.cit., p. 145.
[131] See Jacinta Flattery-OBrien and Kieran Williams, "Changes to divisional applications deadlines in Australia – is there a need for precautionary filings?", available from http://www.shelstonip.com/news_story.asp?m=5&y=2013&nsid=274.
[132] Ibid.

II.8 Increasing Registration and Maintenance Fees

Low standards of patentability encourage the filing of numerous 'secondary' patents. The incentive to do so increases if fees to obtain and maintain a patent are low and affordable to large companies, as is generally the case in developing countries. [133]

Patent examination and maintenance fees can be used as an instrument to avoid the proliferation of patents. Thus, a group of experts convened by the EPO has recommended the use of higher initial fees for examination to reduce 'strategic behaviour' and the number of claims and thereby improve 'patent quality', particularly with regard to patent 'thickets'.[134] Higher renewal fees were also recommended.[135] Ecuador provides an example of this policy. Examination and registration fees, as well as maintenance fees for patents were drastically increased recently,[136] elevating the cost of obtaining a patent to more than U$S 100,000, except for certain categories of applicants (such as small companies and universities). These fees – probably the highest in the world – are likely to substantially reduce the number of patent applications.

III. FINAL CONSIDERATIONS

The proliferation of patents granted on the basis of lax or wrongly implemented patentability requirements can prevent the use of knowledge that should otherwise remain in the public domain. The evergreening strategies of pharmaceutical companies illustrate well this problem. The analysis made above discusses some of the measures that governments can adopt to address it.

Acting at the pre-grant phase through a rigorous examination process is likely to be the most effective measure that can be implemented to ensure that patents are applied for and granted when an inventive activity has actually taken place. As noted in an OECD study, '[T]he social cost of filing patents could also be reduced by discouraging both applications for minor or economically unimportant inventions and strategic patenting'.[137]

In the USA it has been argued that the cost of a thorough examination is too high and that, hence, such examination should be left to the courts in cases where challenges to validity are filed.[138] While this may be an argument for an over-burdened patent office like the USPTO, developing countries (with the exception of China) receive a fraction of the thousands of patent applications filed in developed countries and can implement examination systems that protect the public and competitors against evergreening and other patenting strategies. This is within the reach of most countries, whether on the basis of internal

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[133] See Martín Bensadón and Iván Poli, 'Crisis en el sistema de patentes argentino', Revista del Derecho Comercial y de las Obligaciones, 260 Abeledo Perrot, Buenos Aires.
[134] EPO, op. cit., pp. 12 and 16.
[135] Ibid., p. 12.
[136] See Resolución No. 001-2013 CD-IEPI, available at http://www.propiedadintelectual.gob.ec/wp-content/uploads/2013/08/reformas_tasas_2013.pdf.
[137] OECD, "*Patents And Innovation: Trends And Policy Challenges*" Paris, 2004, available from http://www.oecd.org/science/sci-tech/24508541.pdf, p. 29.
[138] See M. A. Lemley, "Rational Ignorance at the Patent Office", *Northwestern Law Review*, 95, 2001, p. 1495.

examiners or relying on experts from research institutions and universities. The establishment and operation of regional offices may help to address limitations in financial and human resources at the national level. In any case, patent offices, national or regional, should be conscious that their role is not to satisfy patent applicants as if they were their 'clients'.[139] Through the implementation of rigorous standards of patentability they should function 'as a steward of the public interest, not as a servant of patent applicants...[and] protect the public against the issuance of invalid patents that add unnecessary costs and may confer market power…'.[140]

It has also been argued that raising the standards of patentability in developing countries would make it more difficult or impossible for local companies to obtain patents. But the society does not benefit from the appropriation of knowledge through patents, whether owned by foreign or local companies. The wide diffusion of knowledge can, instead, enhance competition and contribute to local development. In addition, low standards of patentability are likely to mostly benefit the large foreign companies that are well prepared to exploit any window left by the patent system, rather than small and medium companies much less inclined and able to use patents to pursue their business objectives.[141] The use of intellectual property rights is correlated with the basic economic characteristics of firms, their activities and industry environment.[142] In particular, given the cost of acquiring, maintaining, monitoring and defending the conferred rights, the main users of the patent system are large firms.[143]

A rigorous examination process may be enhanced by pre and post-grant opposition proceedings. Both of them present some advantages and limitations, but there is no need to opt for only one of them. As in the case of India, patent laws may provide for both mechanisms. Importantly, any person, including, for instance, patients, should be allowed to file an opposition and to later participate in the proceedings (*inter-partes*). The term for filing a pre-grant opposition should be sufficient to assess the application and elaborate possible observations. The effectiveness of pre-grant opposition mechanisms will depend to a great extent on the scope and quality of the information published regarding the patent applications filed. In particular, patent offices should require that all patent applications (and their summaries) related to pharmaceuticals include the INN, where it is already known.

As discussed above, the presumption of validity of patents, as recognized in some jurisdictions, needs to be reviewed in the light of the limitations of the procedures that lead to their grant, even if based on a substantive examination. Challenges to patent validity should

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[139] 'Patent offices have become extremely pro-patent since the early 1980s…the applicant, formerly considered with suspicion, has become a 'client', whose needs must be satisfied by quick, cheap procedures. The result is a total deterioration of examination procedures' (Dominique Foray, "The patent system and the dynamics of innovation in Europe", *Science and Public Policy,* vol. 3, no. 6: 449-456, 2004, p. 450).

[140] Federal Trade Commission, "To promote innovation: the proper balance of competition and patent law policy", available at htpp://www.ftc.gov, 2003, p. 14.

[141] See, e.g., Carlos Correa, "Do small and medium enterprises benefit from patent protection?", in Carlo Pietrobelli and Árni Sverrisson (eds.), *Linking Local and Global Economies. Organisation, Technology and Export Opportunities for SMEs*, Routledge, London and New York, 2003. Interestingly, a study revealed that US small and medium firms that knew that their rights were violated did not enforce them due to the cost and time of litigation. See Graziela Zucoloto, "Propiedade intelectual em debate", *Radar. Teconologia, Producao e Comércio Exterior,* No. 29, IPEA, 2013.

[142] *Economics of Innovation and New Technology,* "The Use of Intellectual Property Rights and Innovation by Manufacturing Firms in Canada», *Taylor & Francis Journals*, vol. 17(4), pp. 285-309.

[143] See, e.g., Bronwyn H. Hall, Christian Helmers, Mark Rogers and Vania Sena, "The Choice between Formal and Informal Intellectual Property: A Literature Review", *NBER Working Paper,* No. 17983, April 2012.

be eased or encouraged (as in the US in respect of pharmaceuticals). The recommendations of the Australian panel quoted in sub-section 3 may provide a useful guidance for action at the national level.

The intervention in patent examination by ANVISA of Brazil provides a useful example that other countries may follow.[144] Similarly, the participation of the government in patent litigation (as provided for in Australia) and the possibility for the government and other affected parties (e.g. social security organizations) to claim compensation in cases of baseless allegations of patent infringement may also act as deterrent of strategic litigation. Specific penalties may also be instituted for cases of legally baseless actions aimed at block competitors.

In countries where some form of 'linkage' between patents and drug registration is implemented (often as a result of requirements imposed in FTAs with the US), the negative impact of such mechanism may be somewhat attenuated by limiting the number of situations in which an injunction can be obtained as well as the patents that can be invoked. For instance, only patents relating to an active ingredient as such could be admitted for that purpose.

Countries can establish various limitations to the filing of divisional patents, for instance, to allow for only one divisional application to be submitted before the substantive examination of the parent application starts, and only in cases where the divisional application is justifiable to overcome a problem of unity of invention. Limiting the number and circumstances under which a divisional application is admissible may help to reduce uncertainty and market distortions.

Higher registration, assignment and maintenance fees, with exceptions for individuals, small companies and research or teaching institutions, is another measure that may be adopted to discourage strategic patenting policies by large companies.

Finally, while this paper has focused on measures actually adopted and implemented to deal with the proliferation of patents, other options may be considered, such as limiting defensive patenting by 'setting up a credible public domain alternative: for example, encouraging firms to publicise their inventions on dedicated Internet sites at low cost when the only purpose for patenting is to avoid others patenting first'.[145]

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[144] Such as in the case of regulations adopted in Paraguay and Bolivia.
[145] OECD, op. cit. p. 29.

Chemin du Champ d'Anier 17
PO Box 228, 1211 Geneva 19
Switzerland

Telephone: (41 22) 791 8050
Fax: (41 22) 798 8531
Email: south@southcentre.int

Website :
http://www.southcentre.int

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