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**Research Report**

## Patent examination and legal fictions: How rights are created on feet of clay

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**58**

# **PATENT EXAMINATION AND LEGAL FICTIONS: HOW RIGHTS ARE CREATED ON FEET OF CLAY**

Carlos M. Correa





## **RESEARCH PAPERS**

**58**

### **PATENT EXAMINATION AND LEGAL FICTIONS: HOW RIGHTS ARE CREATED ON FEET OF CLAY**

**Carlos M. Correa**

**SOUTH CENTRE**

**DECEMBER 2014**



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## I. INTRODUCTION

Industry's demands and political pressures exerted by developed countries to expand and strengthen patent protection worldwide<sup>1</sup> have been based on the argument that patents promote innovation and thereby contribute to achieve social, political and economic well-being, independently of the level of development of the country where they are granted and enforced<sup>2</sup>. This view ignores the fact that patents do not have the same impact in countries with different industrial base, R&D capabilities and availability of capital to finance innovation, among other characteristics. Significantly, there is a growing body of academic studies challenging the belief that patents are essential to incentivize innovation, even in advanced countries,<sup>3</sup> or to enhance economic growth.<sup>4</sup> While many scholars call for a substantial reform of the patent system,<sup>5</sup> others go as far as suggesting its abolition. Boldrin and Levine have argued that

In spite of the enormous increase in the number of patents and in the strength of their legal protection we have neither seen a dramatic acceleration in the rate of technological progress nor a major increase in the levels of R&D expenditure ... there is strong evidence, instead, that patents have many negative consequences. Both of these observations, the evidence in support of which has grown steadily over time, are consistent with theories of innovation that emphasize competition and first-mover advantage as the main drivers of innovation and directly contradict 'Schumpeterian' theories postulating that government granted monopolies are crucial in order to provide incentives for innovation.<sup>6</sup>

The role of the patent system is, hence, controversial, particularly in developing countries. This paper focuses on another, less studied aspect of such system: some of the elusive legal grounds on which patents are normally granted.

In the last 25 years, much emphasis has been put on the concept of intellectual property as 'truly property'.<sup>7</sup> Different variants of natural-rights-based approaches<sup>8</sup> have been

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<sup>1</sup> See, e.g. Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, (Cambridge Studies in International Relations 2003).

<sup>2</sup> E. Richard Gold, 'Patents and Human Rights: A Heterodox Analysis', (2013) *The Journal of Law, Medicine & Ethics* 41 (1) <<http://onlinelibrary.wiley.com/doi/10.1111/jlme.12013/pdf>>.

<sup>3</sup> See, e.g., the literature quoted in Carlos Correa, 'Innovation and Technology Transfer of Environmentally Sound Technologies: The Need to Engage in a Substantive Debate' (2013) *Review of European, Comparative and International Environmental Law (RECIEL)* 22(1) Blackwell Publishers, Oxford, pp. 54-61.

<sup>4</sup> Using aggregate data for 60 countries for thirty years (1960-1990), Park and Ginarte found that intellectual property rights had no independent effect on growth above and beyond that contributed by investment and R&D. See WG Park and JC Ginarte, 'Intellectual Property Rights and Economic Growth' (1997) *Contemporary Economic Policy* XV, pp. 51-61.

<sup>5</sup> For instance, Gary Becker, a Nobel Prize of Economics, has argued that '[T]he current patent length of 20 years (longer for drug companies) from the date of filing for a patent can be cut in half without greatly discouraging innovation', (21-7-13) <<http://www.becker-posner-blog.com/2013/07/on-reforming-the-patent-system-becker.html>>. See also D L Burk and M A Lemley, *The Patent Crisis and How the Courts Can Solve It* (University of Chicago Press, 2009), (advocating that courts tailor the patent law, through interpretations and applications, to suit the needs of various types of industries).

<sup>6</sup> Michele Boldrin and David K. Levine, *The Case Against Patents*, Working Paper 2012-035A (Federal Reserve Bank of St. Louis, 2012), available from <http://research.stlouisfed.org/wp/2012/2012-035.pdf>, p. 1.

<sup>7</sup> See James Bessen and Michael J. Meurer, 'Of Patents and Property' <<http://object.cato.org/sites/cato.org/files/serials/files/regulation/2008/11/v31n4-4.pdf>>.

articulated to justify developed countries' relentless efforts to increase the scope and levels of intellectual property protection, notably for patents. The idea that patents are a piece of property has provided ideological support for an expansion of the protectable subject matter<sup>9</sup>, the extension of the term of protection<sup>10</sup>, the reinforcement of the exclusive rights,<sup>11</sup> and the strengthening of enforcement measures.<sup>12</sup>

Patents confer exclusive rights. They limit the use of knowledge – a public good by its very nature<sup>13</sup> – and competition – which promotes consumer well-being and innovation.<sup>14</sup> Nobody can produce or commercialize the protected invention during the lifetime of the patent, unless authorized by the patent holder or under compulsory licenses, which are rarely granted.<sup>15</sup> Given the exclusionary effects of patents, they have often been characterized as 'monopolies'.<sup>16</sup>

Yet, the rights conferred by patents are based on partial and often imperfect factual determinations. The examination process does not allow patent offices to reach definitive

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<sup>8</sup> For a critical analysis, see, e.g. P Drahos, *A Philosophy of Intellectual Property* (Dartmouth 1996).

<sup>9</sup> Including over life forms and genetic information. See, e.g., G S Nijar, *Patenting life forms* (University of Malaya Press 2012). In some jurisdictions, such as the USA, computer programs and business methods are also held patentable.

<sup>10</sup> The TRIPS Agreement requires a minimum term of 20 years, but this term can be further extended in accordance with some national laws. For instance, a patent term extension was introduced in the USA in 1984, to compensate delays in regulatory review, by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. 355(b), (j), (l); 35 U.S.C. 156, 271, 282) (also known as the 'Hatch-Waxman Act'). The provisions of several free trade agreements (FTAs) also contain obligations to extend the patent term to compensate delays in patent grant proceedings or the marketing approval of medicines. See, e.g., Cynthia Oh, 'Current controversies concerning patent rights and public health in a world of international norms' in Toshiko Takenaka (ed.), *Patent Law and Theory: A Handbook of Contemporary Research* (Edward Elgar 2008) p. 700.

<sup>11</sup> Such as through the extension of the protection to the products directly obtained by a patented process (article 18.1(b) of the TRIPS Agreement).

<sup>12</sup> See, e.g., X Li and C Correa (eds.), *Intellectual property enforcement. International perspectives* (Edward Elgar-South Centre 2009).

<sup>13</sup> See, e.g., Carlos Correa, 'Managing the Provision of Knowledge: The Design of Intellectual Property Laws', in Inge Kaul, Pedro Conceição, Katell Le Goulven, and Ronald U. Mendoza (eds.), *Providing Global Public Goods: Managing Globalization* (Oxford University Press 2003).

<sup>14</sup> 'Competition can stimulate innovation. Competition among firms can spur the invention of new or better products or more efficient processes. Firms may race to be the first to market an innovative technology...' (Federal Trade Commission, 'To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy' (2003) <[www.ftc.gov/os/2003/10/innovationrpt.pdf](http://www.ftc.gov/os/2003/10/innovationrpt.pdf)> p. 1).

<sup>15</sup> Except perhaps in the USA where a large number of patents has been subject to compulsory licenses or government use. See Jerome H. Reichman and Catherine Hasenzahl, 'Non-voluntary Licensing of Patented Inventions. Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA', (ICTSD 2003) <[http://www.ictsd.org/downloads/2008/06/cs\\_reichman\\_hasenzahl.pdf](http://www.ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf)>.

<sup>16</sup> The US courts have referred to the 'patent monopoly' in many decisions. In *Federal Trade Commission V. Actavis, Inc., et al*, June 17, 2013, for instance, it was stated that '[T]he Court was willing to presume that the single-patentee practice approved in General Electric was a "reasonable restraint" that "accords with the patent monopoly granted by the patent law"' (Federal Trade Commission v. Actavis, inc., et al (2013) *Certiorari* to the United States Court of Appeals for the Eleventh Circuit No. 12-416 <[http://www.supremecourt.gov/opinions/12pdf/12-416\\_m5n0.pdf](http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf)>) See, also the decision of the European Court of Justice in *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEVE* ("a medicine is protected by a patent which confers a temporary monopoly on its holder") ([2008] ECR I-7139, § 64, ECJ, C-468/06 to C-478/06). The use of the term 'monopoly' in relation to patents, however, has been contested in the context of antitrust regulations. See, e.g., Sven Bostyn and Nicolas Petit, 'Patent monopoly – A legal fiction' <<http://ssrn.com/abstract=2373471>>.

judgments on patentability.<sup>17</sup> There is uncertainty regarding the validity of patents as well in the boundaries of what is protected under individual patents.<sup>18</sup> The patent claims are in many cases ambiguous and it is unclear what the actually protected subject matter is: '[P]atents, unlike blocks of land, do not come with settled boundaries'.<sup>19</sup> Thus, it is fuzziness rather than definitiveness that characterizes patent grants.<sup>20</sup> This is not accidental, but deliberately sought by patent applicants to discourage competitors.<sup>21</sup> In addition to imprecise disclosures of what is deemed to be the invention, courts interpret patent claims with different theories and methodologies<sup>22</sup> that lead to diverse outcomes with regard to what is deemed protected and eventually infringed.<sup>23</sup> The breadth and generality of the patent statute make the outcomes of particular disputes on patents unpredictable.<sup>24</sup> Uncertainty about the scope of patent claims may deter innovation and investment in new products and processes and distort competition, since competitors 'cannot discern in advance which technologies carry the cost of patent royalties and negotiate those royalties before they incur sunk costs based on the patented technology'.<sup>25</sup>

The establishment of courts specialized in intellectual property matters (as was notably the case in the USA)<sup>26</sup> may contribute to a pro-patent interpretation of the law.<sup>27</sup>

<sup>17</sup> The EPO decision T 270/90 (OJ EPO 1993), for instance, stated that the [EPO] Board decisions need not, and in deed, in most cases could not, be based on absolute conviction, but has, instead, to be arrived at on the basis of the overall balance of probability'. See, e.g., 'Recommendations for Improving the Patent System 2012 Statement' EPO Economic and Scientific Advisory Board <[http://documents.epo.org/projects/babylon/eponot.nsf/0/835DA6DA218CB760C1257B2C004E809E/\\$FILE/ES\\_AB\\_statement\\_en.pdf](http://documents.epo.org/projects/babylon/eponot.nsf/0/835DA6DA218CB760C1257B2C004E809E/$FILE/ES_AB_statement_en.pdf)>.

<sup>18</sup> Thambisetty, Sivaramjani, *Why Patent Law Doesn't Do Innovation Policy* (November 13, 2013). LSE Legal Studies Working Paper No. 20/2013, available from SSRN: <http://ssrn.com/abstract=2328173>, p. 7.

<sup>19</sup> Peter Drahos, 'Trust me: Patent offices in developing countries' (2008) Centre for Governance of Knowledge and Development working paper <[www.cgkd.anu.edu.au](http://www.cgkd.anu.edu.au)>.

<sup>20</sup> On the need to change laws and institutions to address this problem, see, e.g., J Bessen and MJ Meurer, *Patent Failure: How Judges, Bureaucrats and Lawyers Put Innovators at Risk*, Princeton University Press 2008.

<sup>21</sup> See, e.g., Bronwyn H. Hall, Christian Helmers, Mark Rogers, Vania Sena, 'The Choice between Formal and Informal Intellectual Property: A Literature Review' (2012) NBER Working Paper No. 17983, p. 17.

<sup>22</sup> See, e.g., Christopher A. Cotropia, 'Patent Claim Interpretation Methodologies and Their Claim Scope Paradigms', 47 (1) Article 3, William and Mary Law Review <<http://scholarship.law.wm.edu/cgi/viewcontent.cgi?article=1220&context=wmlr>>. One example, is the determination of 'infringement by equivalence' (as opposed to literal infringement), which significantly varies among different jurisdictions. See, e.g., Ray D. Weston, Jr., 'A Comparative Analysis Of The Doctrine Of Equivalents: Can European Approaches Solve An American Dilemma?' (1998) IDEA: The Journal of Law and Technology (39 J.L. & TECH. 35).

<sup>23</sup> See, e.g., Anderson, Jonas and Menell, Peter S., 'Informal Deference: A Historical, Empirical, and Normative Analysis of Patent Claim Construction' (September 3, 2013). 108 *Northwestern University Law Review* 1 (2014). Available from SSRN: <http://ssrn.com/abstract=2150360>.

<sup>24</sup> See, e.g., PM Janicke, 'On the Causes of Unpredictability of Federal Circuit Decisions in Patent Cases' (2005) 3 *Northwestern Journal of Technology and Intellectual Property*, 2005 vol 3:2.

<sup>25</sup> Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice and Remedies With Competition*, Washington DC, 2011, available from <http://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf>, p. 4.

<sup>26</sup> See, e.g., A. Jaffe and J. 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).

<sup>27</sup> In Japan, however, the establishment of an Intellectual Property High Court led, at least when it started functioning, to an 'anti-patent storm' with a significant increase in the rate of patents considered invalid. See Yoshiyuki Tamura, 'IP-Based Nation: Strategy Of Japan', in Frederick Abbott, Carlos Correa and Peter Drahos, *Emerging Markets and the World Patent Order*, Edward Elgar, 2013.

‘the constraints of lower specialist courts and greater decision-making resources available to higher generalist courts can lead to different assessments’ since a ‘restrictive heuristic’ does not bind an appellate generalist court.<sup>28</sup>

Another fundamental problem with the patent regime is that it operates on the basis of a limited capacity to examine the patentability of claimed inventions and on a number of legal fictions created by legislators, patent offices or courts. Such legal fictions are often dogmatically applied, without a critical assessment of their justification and implications. This paper discusses, first, limitations of the examination process and, without attempting to be exhaustive, some examples of the legal fictions that underpin the grant of patents.

## II. THE EXAMINATION PROCESS

A patent is granted in most countries after a substantive examination is conducted to determine whether they meet the patentability standard established by national laws which generally require novelty, inventive step (or nonobviousness) and industrial applicability (or utility)<sup>29</sup>. However, some countries (e.g. Luxembourg, South Africa) confer patents without such a substantive examination<sup>30</sup> or without assessing inventive step (e.g. Switzerland, France<sup>31</sup>).

The depth of the analysis of patentability undertaken by patent offices is limited by a large number of factors, such as institutional incentives to grant rather than to reject applications<sup>32</sup> and the trouble and constraints to carry out accurate searches of the prior art<sup>33</sup>, including overreliance on previously granted patents<sup>34</sup>, insufficient qualified staff and linguistic barriers. In addition, examiners cannot generally take tacit knowledge<sup>35</sup> into account to substantiate an objection to a patent claim. Thus, an objection based on the lack of inventive step cannot be done if a written document is not found showing that the claimed

<sup>28</sup> Thambisetty, Sivaramjani, *Why Patent Law Doesn't Do Innovation Policy*, op. cit., p. 8.

<sup>29</sup> The TRIPS Agreement mandates WTO members to grant patents for inventions that meet these standards (article 27.1). However, it does not define them thereby leaving room for WTO members to do so in accordance with their own criteria. See, e.g. Carlos Correa, ‘Is Section 3(d) Compatible with the TRIPS Agreement?’ (2013), *Economic and Political Weekly*, XLVIII (32).

<sup>30</sup> In the case of Spain, the applicant may opt for submitting or not its application to substantive examination. See Diego Solana, ‘El anunciado fin de las patentes sin examen previo’ <<http://www.cremadescalvosotelo.com/blog/2013/12/el-anunciado-fin-de-las-patentes-sin-examen-previo/>>.

<sup>31</sup> In France, the patent office can reject a patent application on grounds of lack of novelty but not of inventive step, which is judged by courts in case of litigation. See, e.g., Cabinet Beau de Loménie ‘The French Patent System’ <[http://www.bdl-ip.com/upload/Etudes/uk/bdl\\_the-french-patent-system.pdf](http://www.bdl-ip.com/upload/Etudes/uk/bdl_the-french-patent-system.pdf)>.

<sup>32</sup> This is notably the case when the operation of the patent offices is funded by the fees they collect, rather than by general budgetary allocations. See, e.g., Peter H. Feindt, ‘Biopatents – A Threat to the Use and Conservation of Agricultural Biodiversity?’ (2010) Position Paper of the Advisory Board on Biodiversity and Genetic Resources at the Federal Ministry of Food, Agriculture and Consumer Protection, BMELV <[http://www.bmelv.de/SharedDocs/Downloads/EN/Ministry/Biopatents.pdf?\\_\\_blob=publicationFile](http://www.bmelv.de/SharedDocs/Downloads/EN/Ministry/Biopatents.pdf?__blob=publicationFile)>.

<sup>33</sup> See Drahos, 2008, op. cit.

<sup>34</sup> Many patent offices in developing countries lack sufficient funding to pay for journal subscriptions. The search of prior art, hence, in non-patent literature is limited or absent.

<sup>35</sup> See, e.g., Jeffrey Cummings, *Knowledge Sharing: A Review of the Literature*, World Bank, 2003, available from [http://ieg.worldbank.org/Data/reports/knowledge\\_eval\\_literature\\_review.pdf](http://ieg.worldbank.org/Data/reports/knowledge_eval_literature_review.pdf).

invention is obvious in the light of the prior art, even if the claimed invention was obtained by applying common knowledge in a particular technical field (for instance, by finding various crystalline forms of a chemical substance, characterizing them and choosing that the form best suited for pharmaceutical use).<sup>36</sup> As noted by one commentator, unlike the courts, the patent office is an administrative agency that operates overwhelmingly on documentary evidence via internal processes that are difficult to scrutinize. The ‘judges’ in patent offices are technically qualified to examine patents. However, procedural expertise in legal reasoning, such as evidence sifting or weighting of arguments that may be routinely expected from judges of national courts, is rare.... Conservative patent offices, that rely only on formally documented prior art, risk granting patents that ought not to be granted, which in turn can further entrench notions of average skill in the art and related legal standards.<sup>37</sup>

Moreover, in many cases patent offices stretch the interpretation of the applicable rules to allow for the grant of patents that should otherwise be rejected. Thus, the EPO’s narrow interpretation of the exclusion of animal varieties (thereby allowing for the patentability of genetically modified animals), the admissibility of computer programs (explicitly excluded by the European Patent Convention) ‘as long as the patent description incorporates ‘technical’ components as banal as servers or other general-purpose equipment’ and of diagnostic methods provided that ‘at least one step in the process of diagnosis is practised away from the human or animal body’ reveal ‘a decision-making heuristic that direct the EPO away from granting the right kind of patents to merely granting patents’.<sup>38</sup>

The increase in patent applications (stimulated by the low standards applied by many patent offices)<sup>39</sup> and the growing diversity and complexity of the issues at stake, have put patent offices under great strain. A few initiatives to increase the ‘patent quality’ implemented by the patent offices in some developed countries, seem to focus more on procedural aspects than on applying rigorous standards and criteria to exam a patent application.<sup>40</sup> Legislative changes were made in Australia with the same purpose<sup>41</sup> but it is unclear the extent to which they have achieved their intended purpose.

One indicator of the difficulties facing the patent offices is the backlog of unexamined patent applications.<sup>42</sup> In order to speed up the examination process, some patent offices have

<sup>36</sup> See, e.g., Rahul Purohit and P. Venugopalan, «Polymorphism: An Overview», *Resonance*, September 2009, available from <http://www.ias.ac.in/resonance/Volumes/14/09/0882-0893.pdf>.

<sup>37</sup> Thambisetty, Sivaramjani, *The Learning Needs of the Patent System: Implications from Institutionalism for Emerging Technologies Like Synthetic Biology* (June 1, 2013). LSE Legal Studies Working Paper No. 18/2013, available from SSRN: <http://ssrn.com/abstract=2272980>, pp. 6 and 29.

<sup>38</sup> Thambisetty, *Why Patent Law Doesn't Do Innovation Policy*, op. cit., p. 6.

<sup>39</sup> An OECD survey indicated in 2003 that 75% of firms had reported that they sought patents that ‘they would not have thought to patent ten years ago’ (OECD, *Preliminary results of OECD/BIAAC Survey on the use and perception of patents in the business community*, Paris, 2003. This trend has probably intensified since then.

<sup>40</sup> For instance, the EPO launched the ‘Raising the Bar’ program based on the belief that ‘patents must support innovation and, by extension, the economy, demanding in turn that resources are not squandered on systematically avoidable procedural matters and that the balance between the teaching of the patent specification and the benefits of private monopoly is redressed. That is why it is in the interest of all stakeholders (and certainly every applicant with a creditable idea) that more stringent measures are put in place to ensure applications are drafted in accordance with EPC standards from the outset – and that fewer opportunities exist to circumvent efficient examination procedures’ (<<http://www.epo.org/about-us/annual-reports-statistics/annual-report/2008/focus.html>>). This program, introduced in 2007, has been discontinued.

<sup>41</sup> Intellectual Property Laws Amendment (Raising the Bar) Bill 2011.

<sup>42</sup> For instance, the backlog in the US Patent and Trademark Office (USPTO) is over half a million applications. See, e.g., <<http://www.pharmapatentsblog.com/2013/09/19/a-look-at-the-uspto-backlog-dashboards/>>. The world backlog is estimated at over 10 million unexamined patents. See EPO, ‘Scenarios for the Future, How

opted to accept the results of the examination made by a foreign patent office (even if subject to a different substantive law)<sup>43</sup> or to apply the patentability requirements in a lax manner. Thus, the USPTO performance in deciding whether to grant or refuse an application has been reported to have slightly improved in the last five years but at the price of further relaxing the criteria applied to grant a patent.<sup>44</sup>

While patent offices in developing countries (except China) receive a number of patent applications much lower than developed countries, some (e.g., Argentina, India, Thailand) have introduced legislative or other regulatory changes to tighten the application of the patentability requirements and reduce, through a rigorous examination, the proliferation of patents, particularly in the pharmaceutical field.<sup>45</sup> This may, in turn, diminish the number of applications filed, especially if the patent offices' fees and other costs for registration and maintenance are high.

The intervention of patent offices through substantive examination in the process of creating patent rights gives them an appearance of validity. However, such intervention offers no guarantee in this respect and the public and uninformed business actors may be grossly misled<sup>46</sup>. The US Federal Trade Commission noted one decade ago that once a patent application has been submitted the patent is presumed to be granted unless the examiner can provide proof to the contrary, and that the USPTO methods and procedures were not adequate to assume this responsibility; it warned that '[T]hese circumstances suggest that an overly strong presumption of a patent's validity is inappropriate... It does not seem sensible to treat an issued patent as though it had met some higher standard of patentability'.<sup>47</sup>

While the substantive examination of patent applications, where it exists, does not offer legal certainty about neither the validity of the granted patent nor the boundaries of the protected inventions, having such an examination, particularly if well managed, is a superior policy option as compared to the absence thereof. The case of South Africa, where, as noted, no substantive examination is currently made, is illustrative. Thousands of patents have been registered in South Africa to cover minor or trivial developments that can block local production or importation of lower-priced generic medicines.<sup>48</sup> The government of South

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Might IP Regimes Evolve by 2025? What Global Legitimacy Might Such Regimes Have?' (2011) p. 16.

<sup>43</sup> For instance, through Resolution 263/2003 (January 2004) the Argentine patent office was authorized to grant patents without examination in cases where a patent with the same or a narrower scope had been granted by a foreign patent office.

<sup>44</sup> See Christopher Anthony Cotropia, Cecil D. Quillen, Jr. and Ogden H. Webster, *Patent Applications and the Performance of the U.S. Patent and Trademark Office* (2013), Richmond School of Law Intellectual Property Institute Research Paper No. 2013-01 <http://ssrn.com/abstract=2225781> or <http://dx.doi.org/10.2139/ssrn.2225781>.

<sup>45</sup> See Joint resolution 118/2012, 546/2012, and 107/2012, *Guidelines for the Examination of Pharmaceutical and Chemical Patent Applications* (Argentina); Office of the Controller General of Patents, Designs and Trademarks, 'Draft Guidelines for examination of patent applications in the field of pharmaceuticals' <[http://ipindia.nic.in/iponew/Guidelines\\_Pharma\\_PatentApplication\\_28February2014.pdf](http://ipindia.nic.in/iponew/Guidelines_Pharma_PatentApplication_28February2014.pdf)> 17 (India); Thailand updated patent examination guidelines for pharmaceuticals in September 2013 (see <<http://www.worldipreview.com/news/thailand-updates-patent-examination-guidelines>>).

<sup>46</sup> Due to this false appearance, the substantive examination system was qualified as a 'public calamity'. See P Di Guglielmo, *La Invención patentable: comentario de la Ley 111 y el subdesarrollo industrial de la República* (Víctor P. de Zavalia, 1968) p. 123.

<sup>47</sup> Federal Trade Commission (FTC), 'The Proper Balance of. Competition and Patent Law and Policy. A Report by the Federal Trade Commission' (2003) pp. 8 and 10.

<sup>48</sup> See Yousuf Vawda, 'Country Case Study: South Africa', in Carlos Correa (ed.) *Pharmaceutical innovation, incremental patenting and compulsory licensing* (South Centre 2013).

Africa recently announced, however, its intention to introduce a system of substantive examination, at least for pharmaceutical patents.<sup>49</sup>

This proposal raised stiff opposition from pharmaceutical multinational companies, which were eventually found to finance a covered lobbying operation aimed at derailing the government's initiative<sup>50</sup>. One of the arguments of the opponents was that implementing substantive examination will take several years and will be too costly. While the preference of the major users of the patent regime for a mere registration system is not surprising,<sup>51</sup> the arguments about the difficulties that the government would face to put the substantive examination into practice have been grossly exaggerated.

On the one hand, it is to be expected that the introduction of such a system would discourage patent applications that may not survive a serious substantive analysis; hence, the number of applications will presumably diminish over time, especially if fees are established at a level that discourages speculative patenting.<sup>52</sup>

On the other, the available information on patent offices in other developing countries suggests that the number of examiners required to review pharmaceutical patent applications is manageable for South Africa even if it opted to rely on internal examiners only.<sup>53</sup> But many patent offices in developing countries rely totally or partially on external examiners. For instance, in Chile there are a few internal examiners and about 80 external examiners from universities and research institutions; in Bolivia the examination of patent applications is made by external professionals; in Ecuador, the work of 11 internal examiners (4 in the area of pharmaceuticals) is supplemented by 25 external examiners (8 in pharmaceuticals).<sup>54</sup> The Intellectual Property Office of Singapore 'either accepts the examination results of certain major patent offices, or outsources the patent examination function for domestically filed patent applications to the patent offices of Australia, Austria and Denmark to conduct patent

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<sup>49</sup> 'South Africa wants to undertake substantive search and examination of patents so as to have strict rules that frustrate granting weak patents as is the case currently through the "Depository System". Weak patents frustrate accessibility and affordability of medicines and technologies. With regard to the aforementioned, we are considering going the substantive search and examination route' (Media Statement by Minister Rob Davies on the National IP Policy and Removal of Adverse Credit Information (2013) <<http://dontradeourlivesaway.wordpress.com/2013/11/11/media-statement-by-minister-rob-davies-on-the-national-ip-policy-and-removal-of-adverse-credit-information/>>).

<sup>50</sup> See, e.g. 'The new drug war continued. Leaky pharma' *The Economist* (January 27 2014) <<http://www.economist.com/blogs/schumpeter/2014/01/new-drug-war-continued>>.

<sup>51</sup> In Spain where, as noted, substantive examination is optional, less than 10% of the applicants reportedly opt for it. See Solana, op. cit.

<sup>52</sup> An EPO-sponsored workshop recommended to consider fees not 'only as a way of funding an office, but also as a way of steering patent applicant behaviour, setting high quality standards, and reducing the numbers of patents'. It recommended to develop a policy of 'fee management' to increase patent quality: higher initial fees for examination, rewards for higher-quality patents, and fees for faster examination offset by lower renewal fees. See EPO Economic and Scientific Advisory Board, *Report Workshop on Patent Thickets* (2012), available from [http://documents.epo.org/projects/babylon/eponot.nsf/0/B58781F239B083CEC1257B190038E433/\\$FILE/works\\_hop\\_patent\\_thickets\\_en.pdf](http://documents.epo.org/projects/babylon/eponot.nsf/0/B58781F239B083CEC1257B190038E433/$FILE/works_hop_patent_thickets_en.pdf).

<sup>53</sup> A study for some Asian countries found the following *total* number of patent examiners: Indonesia 72; Malaysia 62; Philippines 43; Thailand, 29; Vietnam, 19. See Kenan Institute Asia (K.I.Asia), the International Intellectual Property Institute (IIPI), and the Chulalongkorn University Intellectual Property Institute (CUIPI), 'Comparative Assessment Study of Patent and Trademark Offices in Southeast Asia', (2007). In the case of Argentina the total number is 59 examiners; 20 for chemicals and pharmaceutical inventions. See S Piatti, *Patentes y Salud Pública. La Dimensión Técnica de las Políticas de Patentabilidad: El caso de las patentes farmacéuticas en Argentina*, Tesis de Maestría, (FLACSO 2007).

<sup>54</sup> See Piatti, op. cit.



examinations'.<sup>55</sup> Cooperation agreements may be established with patent offices that apply relatively rigorous standards to assess pharmaceutical patent applications, such as those from Argentina, Egypt and India.

The appropriate training of patent examiners is crucial and takes time. The already quoted IPI/CUIPI report notes that:

Ideally, patent examiners should have appropriate training, which can take many years of both academic and professional training. A patent examiner should have at minimum an undergraduate degree in a scientific or engineering field, although master's degrees or higher are preferable; indeed, some highly specialized technical areas such as genetic engineering may require an MS or PhD. In order to maintain their technological knowledge, examiners should regularly attend conferences and seminars in their technological fields and regularly share their examination experiences with colleagues... Patent examiners should also receive extensive training in the industrial property law of their country and in examination practices and procedures.<sup>56</sup>

In accordance with these recommendations, examiners' training should only be for technical capacitation. However, it should include another dimension: make the examiners conscious that the decisions they take can have drastic effects in the society where they live, as is the case when patents on trivial developments are used to block legitimate competition leading to high prices for medicines and limitations to access thereto. Unfortunately, many patent offices have tended to work under the assumption that their role is to grant as many patents as possible, and to decide in favour of the applicant in case of doubt.<sup>57</sup> Applicants are often treated as 'clients'. As noted by Foray,

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.<sup>58</sup>

In many cases examiners have more incentives (e.g. higher remuneration if more patents are granted, annual bonuses, increased prospect of moving to better paid positions in

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<sup>55</sup> Kenan Institute Asia (K.I.Asia), the International Intellectual Property Institute (IPI), and the Chulalongkorn University Intellectual Property Institute (CUIPI), op. cit., 17. It is worth noting that a reform of the patent law enacted in 2012 tightened the requirements to obtain a patent in Singapore. Thus, a foreign patent on which an application in Singapore is relied upon is examined to determine whether it fully complies with certain particular requirements of Singapore's patent law. The so-called "self-assessment" system was abolished; hence patents can no longer be granted if there is an examination report with outstanding objections, as it was possible before the reform. See Cantab IP, *Guide to the Singapore Patents Act Amendments*, available from <http://guides.cantab-ip.com/singapore-patent-amendments>.

<sup>56</sup> IPI/CUIPI Report, op. cit., p. 11.

<sup>57</sup> For instance, in Australia, in accordance with a long-standing principle (based on *Microcell v The Commissioner of Patents* (1959) 102 CLR 232), the applicant was given the "benefit of doubt" during examination with respect to novelty and inventive step. This principle was changed for a test of "balance of probabilities" by the Patents Amendment Act 2001. See 'Removal of Benefit of Doubt in Patent Examination' *Australian Official Journal of Patents* (2002) <<http://www.ipaustralia.gov.au/about-us/news-and-media/official-notices-listing/removal-benefit-doubt>>.

<sup>58</sup> Dominique Foray, 'The patent system and the dynamics of innovation in Europe' (2004), *Science and Public Policy* 3 (6), p. 450.

the private sector<sup>59</sup>, etc.) to grant rather than to reject patent applications. Thus, in the USA a study found that examiners are essentially rewarded for granting patents:

Patent examiners at the U.S. Patent and Trademark Office (USPTO) receive a bonus that depends on the number of applications processed. But because a rejection is more time – consuming than a grant, the bonus introduces a bias towards granting patents. Such a compensation scheme is puzzling. Apart from biasing the grant decision, it does not seem to give examiners good incentives to exert effort. Rejecting an application requires the examiner to come up with evidence that the claimed invention already exists or would have been obvious to someone skilled in the art. Granting a patent is much less demanding: the examiner can simply report not having found such evidence...<sup>60</sup>

In the case of the EPO, the Administrative Council agreed to award a bonus of tens of millions of 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 patents.<sup>61</sup>

These policies are clearly incompatible with the basic role of patent offices as custodians of the integrity of the public domain against attempts of private appropriation. As emphasized by the FTC,

The patent office should function 'as a steward of the public interest, not as a servant of patent applicants. The PTO must protect the public against the issuance of invalid patents that add unnecessary costs and may confer market power...<sup>62</sup>

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<sup>59</sup> For instance in relation to the USPTO it was noted that '[I]ndeed, during the economic boom of the late '90s, the agency lost hundreds of examiners to the more lucrative private sector. In the year 2000 alone, 437 examiners left their jobs, while just 375 were hired. Yet between 1996 and 2000, patent applications grew over 50 per cent. And the office was caught flat-footed when a federal court in 1998 upheld a patent for a computerized method of calculating share prices for mutual funds. Following the ruling, the patent office was flooded by applications for business methods, such as Amazon's controversial "one click" checkout system for online ordering. Short on M.B.A.'s, the office was forced to hire more business-qualified examiners' (Megan Barnett, 'Patents pending' [U.S. News & World Report 2002]).

<sup>60</sup> See Florian Schuett, 'Patent Quality and Incentives at the Patent Office' (2012) <<http://www.econtract.nl/uploads/document/Patent%20Quality%20and%20Incentives%20at%20the%20Patent%20Office.pdf>>.

<sup>61</sup> See 'EPO Staff To Get Disputed €28M Bonus, Despite Protest' (2013) <<http://www.ip-watch.org/2013/01/10/epo-staff-to-get-disputed-e28m-bonus-despite-protest/>>.

<sup>62</sup> FTC (2003) p. 14.

### III. SOME LEGAL FICTIONS

While, as noted, patents are understood to confer ‘property’ rights – the violation of which may even lead, in some jurisdictions, to criminal sanctions –<sup>63</sup> the grant of such rights relies on a number of legal fictions.

The most important legal fiction under patent law is, perhaps, the notion of a ‘person skilled in the art’ whose knowledge is to be considered in order to establish whether a claimed invention meets the standard of inventive step or non-obviousness. Of course, such a person is hypothetical,<sup>64</sup> and the depth and scope of his/her knowledge is determined by the patent offices or courts. In some cases, patent offices’ practices are such that the ‘person skilled in the art’ is somebody with ordinary knowledge, to whom trivial developments would appear as ‘inventive’. Thus, Burk and Lemley noted that

The courts have endowed the PHOSITA [person having ordinary skill in the art] with mediocre personality traits; she is conceived of as an entity that adopts conventional approaches to problem solving, and is not inclined to innovate, either via exceptional insight or painstaking labour.<sup>65</sup>

There have been attempts in some countries, by the administration or courts, to correct the distorted use of the concept of a person skilled in the art. In the USA, the Supreme Court had stated in *KSR Int'l Co. v. Teleflex, Inc.* (550 U.S. 398, 2007), that [‘A] person of ordinary skill is also a person of ordinary creativity, not an automaton’.<sup>66</sup> In *re Kubin*, the US Court of Appeals for the Federal Circuit argued that establishing obviousness only requires a reasonable expectation of success from previous teachings.<sup>67</sup> Nevertheless, the rate of allowance (that is, of approval of patent applications) of the USPTO has risen in the last years despite a decline between 2001 and 2009.<sup>68</sup>

Although the concept of a hypothetical person skilled in the art is useful to adapt decision-making to different fields of technology, its application to establish inventive step or nonobviousness suffers from a fundamental problem of indeterminacy. Three factors have been identified as its main cause:

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<sup>63</sup> See, e.g., C Geiger (ed.), *Criminal enforcement of intellectual property. A handbook of contemporary research* (Edward Elgar 2012).

<sup>64</sup> See Office of the Controller General of Patents, Designs and Trademarks ‘Draft Guidelines for examination of patent applications in the field of pharmaceuticals’, op. cit., p. 17.

<sup>65</sup> Dan L. Burk and Mark A. Lemley, ‘Biotechnology’s Uncertainty Principle’ (2004) *Case Western Reserve Law Review*, 54 (3) p. 21.

<sup>66</sup> The Indian Intellectual Property Appellate Body similarly held that ‘the skilled person is not a dullard and has certain modicum of creativity’, quoted in the Office of the Controller General of Patents, Designs and Trademarks, op. cit., p. 17.

<sup>67</sup> *Re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). See, e.g., Eric Wu, ‘In re Kubin 561 F.3d 1351 (Fed. Cir. 2009)’ (USF\_IPLB\_15-1\_WU\_SURVEY, 2011) <[http://www.iplb.org/assets/pdfs/Volume15/Surveys/USF\\_IPLB\\_15-1\\_Wu\\_Survey.pdf](http://www.iplb.org/assets/pdfs/Volume15/Surveys/USF_IPLB_15-1_Wu_Survey.pdf)>.

<sup>68</sup> Timothy B. Lee, ‘Study suggests patent office lowered standards to cope with backlog. The “allowance rate” sharply increased during Obama’s first term’ (2013) <<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, op. cit.

a failure to identify the quantum of innovation necessary to satisfy the standard, a failure to define the baseline level of ordinary skill against which to measure an innovation, and the epistemic infeasibility of requiring a technologically lay decision maker to judge from the perspective of a more highly trained and educated person of ordinary skill in the art...Due to the “curse of knowledge,” individuals are cognitively incapable of accurately making judgments from other individuals’ perspectives. ..These indeterminacy and epistemic problems cause nonobviousness decisions to be inconsistent and unpredictable.<sup>69</sup>

As a result of these difficulties, decisions about patentability are subjectively determined leading to inconsistency and unpredictability in the application of a key concept under patent law.<sup>70</sup>

### III.1 Biotechnological Inventions

A telling example of the legal fictions applied to allow for the grant of patents is the way in which genes and microorganisms have been treated by some patent offices. It has been noted in this regard that

[A]nother legal fiction is that patent law grants rights in new inventions, so how can scientists claim rights to genes they did not invent? The scientist certainly did not invent the gene, and it already exists in the human body. Yet patent law allows scientists to claim rights over genes that have been isolated. If we lose sight of the artificial constructs and assumptions involved in creating scientific theory, we lose the ability to ask whether these scientific theories fit the legal issues properly as they unfold in cases.<sup>71</sup>

A large number of patents have been granted in the USA on the ground that the prior knowledge on gene sequences or protein sequences is not destructive of novelty of each other:

In US law structural dissimilarity between gene sequences and the protein sequences they code for can deem one or the other of them novel and inventive even though we now know that a PSA [person skilled in the art] can decode one from the other. This technological misconception has worked in favour of inventors and increased the patenting of genomic inventions (which has consequently reduced their incentive to litigate the ruling).<sup>72</sup>

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<sup>69</sup> 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), pp. 57 and pp. 59-60. See also Kelly Casey MULLALLY, ‘Legal (Un)Certainty, Legal Process, and Patent Law’, *Loyola of Los Angeles Law Review*, Vol. 42, 1109, 2010, available from SSRN: <http://ssrn.com/abstract=1739948>.

<sup>70</sup> Paul M. Janicke ‘On the Causes of Unpredictability of Federal Circuit Decisions in Patent Cases, *Northwestern Journal of Technology and Intellectual Property*, Volume 3, Issue 2 Spring (‘obviousness an imaginary mental state, hence nearly always a subjective evaluation’), available from <http://scholarlycommons.law.northwestern.edu/cgi/viewcontent.cgi?article=1030&context=njtip>, p. 96.

<sup>71</sup> Alex R. Hess, ‘Review of The Role of Science in Law by Robin Feldman’ *Journal of High Technology Law Suffolk University Law School* <[http://www.suffolk.edu/documents/jhtl\\_book\\_reviews/hess10.pdf](http://www.suffolk.edu/documents/jhtl_book_reviews/hess10.pdf)>.

<sup>72</sup> Thambisetty, Sivaramjani, *The Learning Needs of the Patent System: Implications from Institutionalism for Emerging Technologies Like Synthetic Biology*, op. cit., p. 24.

The USPTO has also granted thousands of patents based on an artificial differentiation between ‘natural’ and isolated’ genes. However, in *Association for Molecular Pathology v Myriad Genetics* (569 U.S. 12-398, 2013) the US Supreme Court correctly ruled that naturally occurring isolated is not a valid patentable subject matter.<sup>73</sup> The case referred to a set of patents on BCRA genes the presence of which is associated with an increased risk of hereditary breast and ovarian cancer. However, the court made a distinction between DNA and cDNA, that is, a form of synthesized DNA used in genetic engineering to produce gene clones, and argued that the latter is patentable.<sup>74</sup> But cDNA contains the same information found in a natural DNA although it omits portions (introns) within the DNA segment that do not code for proteins: a cDNA molecule housing the DNA of a naturally occurring protein is not “markedly different” from anything found in nature just as “isolated and purified DNA” is not. Both are artificial, but neither are inventions’.<sup>75</sup>

In the practice and jurisprudence of the EPO, patents on genes are admissible.<sup>76</sup> Moreover, according to EPO practice gene patents may be granted with a broad scope, including aspects that the applicant was unaware of.<sup>77</sup> The patent owner, hence, is deemed to have ‘invented’ what was actually unknown to him.

Legal fictions have proliferated in EPO practices relating to patentability in the field of biotechnology.

In the *Oncomouse* case, for instance, the EPO considered whether the exclusion of ‘animal varieties’ contained in Article 53(b) of the European Patent Convention (EPC) amounted to an exclusion of animals **as such**. The final decision was in favour of patentability, on the argument that if the exclusion only applied to claims that were to a specific species of animal or a specific sub-species or sub-sub-species of animal, and not to a higher level of classification (e.g. a genus), then the invention was not excluded.<sup>78</sup> However, it has been observed that

to regard the claim as not being a patent on a species or lower classification by virtue of being a patent worded in terms of being on a member of a genus, is at least a fiction (and is surely a contradiction, as it is not the term that is being patented but the animal). What undoubtedly drives this is the general policy operated by patent law that exceptions to patentability are to be construed as narrowly as possible, so that if there is any interpretation possible that evades the exception then that interpretation must be given.<sup>79</sup>

<sup>73</sup> Laurence Gostin, ‘Who Owns Human Genes? Is DNA Patentable?’ (2013) *JAMA* 310:791. 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).

<sup>74</sup> As a result of this reasoning, the US Supreme Court decision may not drastically affect the possibility of appropriating basic genetic information. *Myriad Genetics*, for instance, holds other BRCA-related patents that have not been invalidated, including claims to cDNA.

<sup>75</sup> Adam Liptak, ‘Supreme Court Rules Human Genes May Not Be Patented’ (2013) <[http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html?\\_r=0](http://www.nytimes.com/2013/06/14/us/supreme-court-rules-human-genes-may-not-be-patented.html?_r=0)>.

<sup>76</sup> See, e.g., Technical Expert Working Group (TEWG) on Genetic Sequence Data, ‘Final Report to the PIP Advisory Group’ (2014) WHO <[http://www.who.int/influenza/pip/advisory\\_group/PIP\\_AG\\_TEWG\\_Final\\_Report\\_15May2014.pdf](http://www.who.int/influenza/pip/advisory_group/PIP_AG_TEWG_Final_Report_15May2014.pdf)>.

<sup>77</sup> See e.g. decisions T 301/87 and T 923/92.

<sup>78</sup> See decision *T19/90 Oncomouse/HARVARD*, O.J. E.P.O. (1990).

<sup>79</sup> Mike Adcock and Deryck Beyleveld, ‘Purposive Interpretation and the Regulation of Technology: Legal Constructs, Legal Fictions, and the Rule of Law’.

Article 53(b) of the European Patent Convention (EPC) determines the non-patentability of ‘plant or animal varieties or essentially biological processes for the production of plants or animals’ but it provides that ‘this provision shall not apply to microbiological processes or the products thereof’. The exception contained in this subparagraph has been interpreted as providing the basis ‘to permit cell-lines (whether of animal or human tissue) as well as types of fungi to be patented’.<sup>80</sup>

A microorganism is an **organism** not perceptible by the naked eye, including bacteria, fungi, archaea, and protists.<sup>81</sup> The scientific meaning of the term does not encompass cells or its components. However, the EPO jurisprudence (as well as the practice of other patent offices) has expanded the concept, so as to include human, animal and plant cells.<sup>82</sup> This is odd ‘because it requires cell-lines and fungi to be construed as animal or plant varieties or essentially biological processes for the production of plants or animals’.<sup>83</sup>

This legal fiction may have important implications. Article 27.3(b) of the TRIPS Agreement allows WTO members to exclude the patentability of plants and animals, but mandates the patentability of ‘microorganisms’. If this concept were broadly understood, WTO members’ obligation would be unjustifiably expanded. Such an obligation is actually limited to the protection of microscopic or sub-microscopic organisms, and does not include cells or sub-cellular parts. Importantly, bacteria, fungi, etc. can also be excluded from patentability whether claimed in their natural form, isolated or genetically modified.

The EPC Rule 26 (5) also provides a good example on how legal concepts may distort technical realities. It states that ‘[A] process for the production of plants or animals is essentially biological if it consists **entirely** of natural phenomena such as crossing or selection’.<sup>84</sup> Obviously, crossing and selection are not **natural** phenomena, as noted by the EPO Enlarged Board of Appeals itself: in Decision G 1/08 it recognized that crossing and selection required the intervention of a breeder in order to achieve certain desired results: ‘crossing and selection are not natural phenomena but are method steps which generally involve human intervention’. Based on this observation, the Board found that ‘the wording of R 26(5) is ambiguous, if not contradictory’. The fundamental problem is, however, that those activities can only be considered as natural phenomena by way of a legal fiction.<sup>85</sup>

### III.2 Second Use of a Known Product

In accordance with the TRIPS Agreement, patents must be granted when the patentability requirements are met, in relation to products and processes (article 27.1). However, in many countries patents are issued in respect of the **use** of a known product, on the basis of a fiction on novelty.

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*Medical Law International* 2007, 8: 305 <<http://mli.sagepub.com/content/8/4/305>> p. 317.

<sup>80</sup> Ibid., p. 318.

<sup>81</sup> Although viruses are generally considered to be a ‘microorganism’, this categorization is controversial.

<sup>82</sup> In accordance with the EPO Guidelines the definition of ‘microorganism’ encompasses ‘bacteria and other generally unicellular organisms (...), including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and, moreover, human, animal and plant cells’ (EPO Guidelines, Part G, Chapter II, Section 5.5.1).

<sup>83</sup> Mike Adcock and Deryck Beyleveld, op. and loc. cit.

<sup>84</sup> Emphasis added.

<sup>85</sup> See Oliver Randl, ‘G 1/08 – Leave Mendel Alone’, available from <http://k-slaw.blogspot.ch/2010/12/g-108-mendel-set-free.html>.

Under article 54(5) of the European Patent Convention (EPC), for instance, a product which was known in a particular field could be protected **as such** under a patent if a new use were found in another field.<sup>86</sup> This provision did not allow the EPO to consider novel a product that was already disclosed for use in the same field of technology, a limitation that had particular implications in the area of pharmaceuticals, where finding a new therapeutic use for a known medicine often opens up lucrative markets. While the identification of the **first** medical indication of a known product was sufficient to obtain a patent on a medicine, the Convention excluded the possibility of granting a patent in relation to the **second** use of a medicine.

A basic objection to the patentability of such a second use was found in the prohibition contained in the EPC to grant patents on ‘methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body’ (article 53(c)). In fact, a claim on the use of a medicine is equivalent to a claim on a method of medical treatment, as the only contribution made by the ‘inventor’ is to indicate how to administer a known drug to achieve certain therapeutic results:

‘[T]here is no real difference between patent claims relating to a use of a substance and those relating to a therapeutic procedure: in both cases a new medical activity is patented, i.e. a new way of using one or more known products. Thus the difficulties in European patent law of protecting a new medical indication for a known substance are due to the combination of the novelty requirement (which impedes products claims) and the ban on patents for medical procedures (which impedes use claims)’.<sup>87</sup>

Importantly, a claim on the use of a medicine lacks industrial applicability (or technical effect as required under European law<sup>88</sup>), since the effects of the use take place in the body of the patient. Therefore, even in the absence of a specific exclusion from patentability of methods of medical treatment, such a claim would not be admissible in countries where industrial applicability (or technical effect) is required.

These limitations were overcome by the EPO with another legal fiction.

In decision G5/83, the Enlarged Board of Appeal considered that, if worded in accordance with the so-called ‘Swiss claim’, a patent on a second medicinal use could be granted. The Swiss claim reads: “compound X for the manufacture of a medicament for therapy Y”. In order to adopt this approach, the EPO had to consider that a second medical use claim could **derive** industrial applicability from the use of a substance for the manufacture

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<sup>86</sup> Interestingly, the United States adopted a more restrictive approach, confining patents on uses to a particular “method-of-use” that did not encompass protection of the product as such. See, e.g., Werner Stieger, ‘Article 54 (5) of the Munich Patent Convention: An Exception for Pharmaceuticals’ (1982) *International Review of Industrial Property and Copyright Law* 13 (2).

<sup>87</sup> See B Domeij, *Pharmaceutical Patents in Europe* (Kluwer Law International/Norstedts Juridik 2000), p. 178.

<sup>88</sup> Although the EPC does not specifically spells out a requirement of technical effect, this character is generally required as an essential requirement for its patentability under European law. The EPO, for instance, held in decision T 154/04 (OJ 2008, 46) that “technical character” was an implicit requisite of an “invention” within the meaning of article 52(1) of the EPC. However, this requisite has been diluted by admitting the patentability of subject matter otherwise excluded by the EPC on the argument that there is no requirement for a technical feature to dominate in an invention; the presence of technical aspects ‘would allow a mixed invention to escape the exclusion’ (Thambisetty, Sivaramjani, *The Learning Needs of the Patent System: Implications from Institutionalism for Emerging Technologies Like Synthetic Biology*, op. cit., p. 14).

of a medicament and **derive** novelty and inventive step from the new found therapeutic application of a product, regardless of the fact that the product and method for its manufacture were known.<sup>89</sup> This amounts to a significant departure from basic principles of patent law:

The novelty requirement is met with aid of disclosure of a new indication, while the technical effect requirement is met, and the medical procedure ban avoided, by the feature “production of a pharmaceutical”. Only with such a construction of the claims is it possible simultaneously to meet the novelty requirement and avoid the ban on patents for medical procedures. This solution, however, is contrary to an established principle of patent law. The new technical features in the claims are deemed to be those which are to be taken into consideration when assessing whether the invention constitutes a medical method.<sup>90</sup>

As a result, the objections based on lack of novelty and technical effect, and on the non-patentability of medical methods, could be bypassed just by redrafting a medical method claim in the form of a ‘Swiss claim’. As noted by one commentator in relation to the novelty requirement, ‘the “Swiss formula” suffers from “the logical objection that it lacks novelty, since it claims the use of the compound for preparation of a medicament, and normally the medicament itself will be the same as that already used for the first pharmaceutical indication’.<sup>91</sup>

The ‘Swiss claim’ formulation not only allowed pharmaceutical firms to claim hundreds of new uses of known medicines in Europe, but also to do so in a large number of developing countries that, through EPO’s technical assistance, were induced to grant patent on such uses, probably in violation of the national laws that require industrial applicability or, even more specifically, that prohibited patents over methods of medical treatment.

In 2000, an amendment to Article 54(5) of the EPC allowed for the patenting as such of new uses of substances or compositions used in a method of medical treatment. The ‘Swiss claim’ format became unnecessary once the EPC amendment entered into force in 2007. The irony is that after the amendment, the EPO decided that ‘[W]here 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’.<sup>92</sup> This means that, while the Swiss claim format is not acceptable any more in Europe, it may still provide in countries that followed EPO’s advice, a basis to bypass the industrial applicability requirement as well as, in many cases, a direct ban on methods of medical treatment.

Importantly, nothing in the TRIPS Agreement prevent those countries to review their practice or regulations and reject patents based on the ‘Swiss claim’, nor to revoke patents

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<sup>89</sup> A similar legal fiction has been applied by some patent offices, including the EPO to accept patents on the so-called ‘analogue processes’, that is, processes which themselves would otherwise not involve an inventive step, are nevertheless patentable insofar as they provide a novel and inventive product. In this case the process, which is not patentable, derives its presumed attributes from the product. See *Guidelines for examination in the European Patent Office*, Part C, Chapter IV, (9.) Inventive step, (9.12) Dependent claims; claims in different categories.

<sup>90</sup> Domeij, op. cit., p. 183.

<sup>91</sup> P Grubb, *Patents for chemicals, pharmaceuticals and biotechnology. Fundamentals of global law, practice and strategy* (Clarendon Press, Oxford 1999) p. 221.

<sup>92</sup> Decision G 0002/08 (Dosage regime/ABBOTT RESPIRATORY) of 19.2.2010, available from <http://www.epo.org/law-practice/case-law-appeals/recent/g080002ex1.html>.



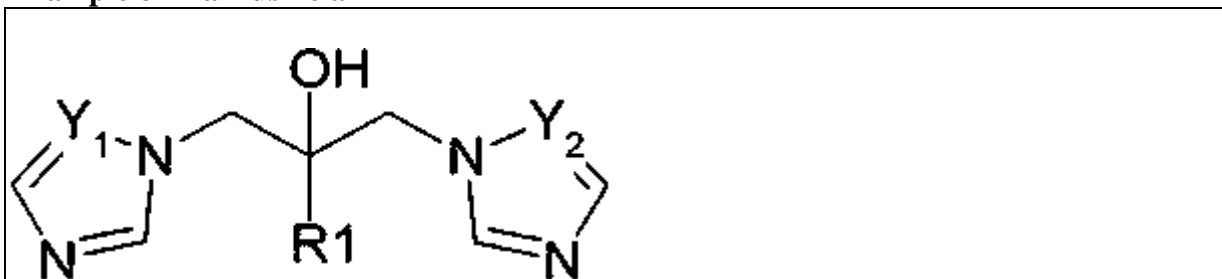
which were granted in violation to their law. As mentioned, said Agreement only mandates the grant of patents on products and processes.<sup>93</sup> The refusal of patents on second uses would not only be consistent with patent law principles and the TRIPS Agreement. It would also be important from a public health perspective, as patents on second medical uses are often applied for in order to ‘evergreen’ pharmaceutical patents and thereby exclude the competition from cheaper generic medicines. The implications for public health may be particularly serious when the second use is the most important indication of a medicine. For instance, AZT (Zidovudine), a drug effective in both the treatment of AIDS and the reduction of mother-to-child transmission, was first developed in 1964 by the National Cancer Institute in Detroit, USA, for cancer treatment. 11 years later its antiretroviral activity was recognized in studies also conducted at the National Cancer Institute. Burroughs Wellcome laboratories carried out subsequent clinical trials and first patented in 1985 the antiretroviral use of AZT, which became the first breakthrough in AIDS therapy. Prices for AZT were significantly higher in countries where patent protection was obtained than in those where generic competition was possible.<sup>94</sup>

### III.3 Markush Claims and Selection Patents

The so-called ‘Markush claims’ refer to patent claims on chemical structures that may include multiple entities in one or more parts of the compound which are claimed to be functionally equivalent (see example in Figure 1). Markush claims may, on the basis of a general chemical formula and a list of alternatively useable elements, cover millions of possible compounds. The use of Markush claims has become increasingly common in the pharmaceutical sector, where a large number of patent applications are filed, and approved, with this format.<sup>95</sup>

Figure 1

#### Example of Markush claim



Patent GB 2,078,719 claiming compounds of the above formula wherein  $R_1$  is alkyl, cycloalkyl, aryl or aralkyl any of which may be optionally substituted,  $Y_1$  and  $Y_2$  are =CH- or =N-, and their acid addition salts, metal complexes, ethers and esters.

<sup>93</sup> See the decision of the Andean Tribunal of Justice available from <http://www.comunidadandina.org/canprocedimientosinternet/DetalleExpediente1.aspx?IdExp=2049&IdProced=7&CodExp=TJCA+89-AI-00>.

<sup>94</sup> Catrin Schulte-Hillen, ‘Study concerning the availability and price of AZT. An MSF report’ (1999) <[http://www.haiweb.org/campaign/novseminar/schulte\\_text.html](http://www.haiweb.org/campaign/novseminar/schulte_text.html)>.

<sup>95</sup> See the country studies in C. Correa (ed.), *Pharmaceutical innovation, incremental patenting and compulsory licensing* (South Centre 2013).

Patent laws generally require that inventions be precisely and clearly defined in the claims and that the specifications enable the execution of the invention.<sup>96</sup> Markush claims can hardly comply with these requirements. In general, patent applicants only include in the specifications a few examples of the different compounds that may be obtained through a number of combinations of the listed elements. As a result, these patents allow the patentee to control a large number of compounds that have not been actually obtained and whose properties have not been tested, but only theoretically inferred from the possible equivalence with other compounds covered by the same general formula.<sup>97</sup>

In addition, the search of prior art for millions of compounds to establish novelty and inventive step is virtually impossible. As noted by the USPTO,

In certain circumstances, however, a Markush group may be so expansive that persons skilled in the art cannot determine the metes and bounds of the claimed invention. For example, a Markush group that encompasses a massive number of distinct alternative species may be indefinite under § 112, ¶2 if one skilled in the art cannot determine the metes and bounds of the claim due to an inability to envision all of the members of the Markush group. In such a circumstance, an examiner may reject the claim for indefiniteness under § 112.2.<sup>98</sup>

In order to avoid an exorbitant coverage of patents based on Markush claims it is recommendable to require that test conducted for each embodiment is provided<sup>99</sup> or at least to demonstrate that, with the substitution of any member within the same family class, the same disclosed result would be obtained, thereby limiting the protection to what is actually enabled by the disclosure in the specification.<sup>100</sup>

While Markush claims are granted on the grounds that all its elements are effectively disclosed, many patent offices, including the EPO, apply another legal fiction to allow that one or a sub-group of the elements contained in such claims be subsequently selected and claimed as novel in a separate patent. In order to issue ‘selection patents’ patent offices consider that the novelty requirement is complied with, despite the fact that the selected elements were disclosed in the original patent and, hence, lack novelty.<sup>101</sup> This is another common strategy for ‘evergreening’ patents that unduly extend the protection for compounds after they have fallen into the public domain as a result of the expiry of a prior Markush claim patent. Patent offices, however, do not need to apply the fiction of novelty that underpins the grant of selection patents.<sup>102</sup>

Patent regimes should ensure that there is a balance between exclusive rights and competition. This can be achieved by appropriate legislation and policies aiming at curbing the grant of invalid or overbroad patents that disrupt that balance ‘by discouraging follow-on

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<sup>96</sup> For instance, 35 U.S.C. section 112, ¶2, requires that claims particularly describe and distinctly claim the subject matter that the applicant regards as his invention.

<sup>97</sup> See Carlos Correa, ‘Guidelines for the examination of pharmaceutical patents: developing a public health perspective’ (2006) Working Paper, WHO, ICTSD and UNCTAD <[www.ictsd.org](http://www.ictsd.org)>.

<sup>98</sup> *Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications*, Federal Register/ vol. 76, no. 27 / 9 February 2011 / Notices.

<sup>99</sup> See Office of the Controller General of Patents, Designs and Trademarks, op. cit., p. 7.

<sup>100</sup> See Carlos Correa, 2006, op. cit., p. 12.

<sup>101</sup> Ibid., p. 15.

<sup>102</sup> Ibid., p. 13.

innovation, preventing competition, and raising prices through unnecessary licensing and litigation'.<sup>103</sup>

#### IV. CONCLUSIONS

Patents are often presented as an absolute property, comparable to property over land. This simplification overlooks that patent rights are conferred without a solid determination of the factual conditions required for such rights to arise out. The examination process of patent applications faces substantial limitations, even in the case of large patent offices, to determine whether a claimed invention actually meets the patentability standards, however defined. Such an examination does not offer a guarantee regarding the validity of the titles granted nor, in many cases, ensure a clear delimitation of the boundaries of the protected invention. Despite this, an examination system is a better option than a mere registration system, as the latter creates legal monopolies without a minimal analysis of what is claimed.

Patents are granted on the basis of a number of legal fictions that reveal how precarious the basis for the grant of such rights often is. Importantly, however, no country is obliged under the TRIPS Agreement or any other international instrument to apply such fictions or to accept certain types of claim formulations. Nor can they be prevented from changing their previous policies by introducing more rigorous standards under which certain claims would be disallowed.<sup>104</sup>

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<sup>103</sup> Federal Trade Commission, 2011, op. cit. p. 1.

<sup>104</sup> This is precisely what Eli Lilly, a US pharmaceutical company, is attempting to do through a complaint, based on alleged investors' rights, against a Canadian decision to revoke a patent on grounds of lack of utility. See, e.g., Carlos Correa, 'Investment Agreements: A New Threat to the TRIPS Flexibilities?' South Bulletin, No. 72, 13 May 2013, available from <http://www.southcentre.int/question/investment-agreements-a-new-threat-to-the-trips-flexibilities/>.





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