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**EMERGING ISSUES: NEW USES, WHETHER THREAT OR CHANCE,  
WHAT IS THE CURRENT AND APPROPRIATE LEGAL TREATMENT?**

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**Abstract**

*Legal status of the new detected uses for old patents as an independent invention is a problematic issue that gives rise to basic legal challenges regarding patent's promotion standards of protection, in particular the prolongation of the patent monopoly's term. International instruments, uncertainties, and a variety of treatments within different national and regional jurisdictions have increased the complexities of patentability of new uses. These uncertainties, especially in Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), the most important covenant on commercial aspects of intellectual properties toward new uses, have resulted in dividing various jurisdictions into contradictory of both proponent and opponent positions. In this article, a comparative framework has been employed for analyzing these contradictory treatments, which are mainly founded on "being novel" and "lack of novelty" through a different sense, i.e. proving act of "creation" via fulfillment the constructive essentials of "process invention" based on patent law's principles. Within that context, we employ a framework has been designed for comparison at three levels: the*

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*international level (TRIPS), regional (European Patent Convention and Andean Union) and national level (emphasizing on United States' law because of its most consistency with our sense). In this regard, we are trying to propose an exhaustive and prescriptive criterion that, while satisfying the essentials of customary patent law, meets the interests of both proponent and opponent parties. The criterion lies in adjusting the border of constitutional elements of the process based on desires and interests.*

## **I. Introduction**

Patent law has different and practical legal subjects that are an important portion of industrial property law. Discovery of new uses for old inventions is one of the most problematic relative issues on the ground. The legal status of new uses, with regard to its direct and indirect influences on the scope of legal protection of patents and subsequently on economic revenues of technological innovations, has drawn the attention of many countries in recent years. Today, at the international level and its modern order, countries can be relatively divided into consumers (Southern countries) and producers (Northern countries) of technological intellectual properties. On one hand, the producer countries seek to keep their position, and on the other hand, the consumer countries seek to lessen the cost of using these products and restrict the producer countries exclusiveness. In that course, both groups have applied some efforts to meet their individual interests. The LDCs and some developing countries without productive capacities as consumers are invoking human right rules, like right to health<sup>1</sup> and, right to development<sup>2</sup> to achieve their aims. Meanwhile, the developed countries are trying to meet the extravagant

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<sup>1</sup> World Health Organization, World Intellectual Property Organization and World Trade Organization “Promoting Access to Medical Technologies and Innovation Intersections Between Public Health, Intellectual Property and Trade,” 42 (2013).

<sup>2</sup> See for example U.N. HRC, high-level task force on the implementation of the right to development, 6th Sess., U.N. Doc. A/HRC/15/WG.2/TF/2/Add.2. (2010). “Right to development criteria and operational sub-criteria.”

expenditures which they have incurred in the way of producing those products. Subsequent to the Uruguay round and establishment of TRIPS agreement, the producer member's efforts amounted to a follow that so-called “TRIPS\_plus”. One of the important examples of TRIPS\_plus, especially through the Free Trade Agreements (FTAs)<sup>3</sup>, and regional trade agreements<sup>4</sup>, is to provide patent protection for the discovery of secondary applications for known inventions as an *independent* patent in order to prolong the term of protection of patents by preventing expired patents from falling into the public domain. These initiatives are known as a kind of “*evergreening*” process and particularly in relation to pharmaceuticals (First/second medical indications) as a kind of “patent clusters”.<sup>5</sup>

The Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) defined “*evergreening*” in regard to pharmaceutical products as such: “When, in the absence of any apparent additional therapeutic benefits, patent holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term.”<sup>6</sup>

Determining what kinds of new uses, within meaning of TRIPS-plus, are consistent with customary and essential rules of patent law and TRIPS provisions is one of the questions which will be answered in this article.

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<sup>3</sup> See for example Jan. 11, 2006, Free Trade Agreement, U.S. – Bahrain, chapter 14, Art. 14.8.

<sup>4</sup> See for example Trans-Pacific Agreement, United States Proposal, Art. 8.1.

<sup>5</sup> For the purpose of delimitation, debating on the legal status of old products or processes that have no physical or chemical change occurred concerning the original invention which for the subservient uses have presented, is what has been concentrated on. Hence, it does not comprise other similar topics or other examples of evergreening flow like “incremental innovations” in pharmaceuticals patents *e.g. new forms* of old medicaments. See for example Novartis attempts in India to patent an anti-cancer medicament “Gleevec” which is beta crystalline form of imatinib mesylate.

<sup>6</sup> World Health Organization (WHO), Commission on Intellectual Property Rights Innovation and Public Health (CIPRH), “Public Health, Innovation and Intellectual Property Rights”, (Geneva 2006).

This paper will analyze the various treatments toward new use patents within different levels (i.e. international, regional, and national) via a comparative frame aimed to gain a comprehensive picture of the subject and arriving at a conclusion which aims at demarcates an applicable line between relevant contradictory and various positions that have been taken. This is intended to give a harmonized, legal approach by setting forth the foundations of patent law. The following sections will deal with different legal stances that have been taken for the treatment of claimed new uses in regard medical and non-medical subject-matters in TRIPS agreement, European Patent Convention and its parallel case law, Andean Union. At the national level, the emphasis will be on United States' law due to its resemblance to the ultimate conclusion of this article regarding the necessity of introducing concept of “use patent” within legal concept of “process patent” through *adjusting* the borders of constitutional elements of the “process invention” within territorial jurisdictions.

## **II. International Instruments as the Main Directive Sources**

There is no special procedural or substantive regulation concerning new use patents in international conventions, treaties and other respective international instruments in relation to the patent law that obliges the members to protect them or exclude them from protection.<sup>7</sup> Moreover, there is no accepted international doctrine on this matter. The TRIPS agreement as the exhaustive instrument that plays significant legal and economic role concerning intellectual property subjects has been preferably selected to be surveyed in this matter.

### **A. TRIPS Agreement**

There is no contractual condition that explicitly or implicitly includes or excludes the protection of new use patents in TRIPS. Then, at first glance, it seems that the members are free

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<sup>7</sup> Watal, “Intellectual Property in the WTO and Developed countries “,104 ( Kulwer law international 2001).

to determine their own approach. However, when we refer to Art. 27(1) of the agreement, this notion is complicated by the requirements set out for conferring patents. In other words, despite of Art. 1(1) of TRIPS, which introduces the TRIPS provisions as the minimum standards for protecting the IPRs and leaves the members free to expand their protection beyond these minimum standards; it simultaneously stipulates that members could not contravene what TRIPS uncontestably requires. Whereupon the patentability of new uses could be debated only as far as the requirements and terms of TRIPS patent provisions allow. Hence the fundamental question is: if the requirements stated in Art. 27(1) are met by the nature of definition of the new use patents, the conclusion is the protectable contrivance based on the TRIPS requirements, or not?

## **B. TRIPS's Patent General Provisions**

In regards to the methodology behind the interpretation of the international instruments through the international law, it is well-recognized by the International Court of Justice (ICJ), and in particular in relation to TRIPS through WTO's Panels and the Appellate Body, that TRIPS and other respective instruments within WTO's jurisdiction, should be construed based on the general rules of interpretation of the "Vienna Convention on the Law of Treaties" Arts. 31 and 32<sup>8</sup> as a part of "customary international law".<sup>9</sup> Therefore, considering Art. 31 of the Vienna Convention the contexture of TRIPS as the primary interpretative material must be interpreted in

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<sup>8</sup> See India Patent Protection for Pharmaceutical and Agricultural Chemical Products-United State, WT/DS50/AB/R, (Dec. 19, 1997) at para. 45; "...The duty of a treaty interpreter is to examine the words of the treaty to determine the intentions of the parties. This should be done in accordance with the principles of treaty interpretation set out in Art. 31 of the Vienna Convention..."

<sup>9</sup> The ICJ in several cases has held that those articles considering Art. 38 of the Statute of the International Court of Justice (SICJ) are part of customary international law. For example, Kasikili/Sedudu Island (Botswana v. Namibia), 1999 (Dec. 13) at para. 18.

“good faith”, in conformity with the “ordinary meaning” to be given to the terms and its “context” and in consideration of its “object and purpose”.<sup>10</sup>

Accordingly, the law first directs us to Art. 27(1) which addresses the basic requirements of patentability: “Patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application...”. By a plain reading, it is obvious that Art. 27(1) requires the triple requirement of novelty, inventive step, and industrial application, while it also restricts the range of patentable inventions to “*process*” and “*product*.” In other words, the primary and fundamental prerequisite for protecting an invention is being in the format of “process” or “product” and that condition must be proven prior to the novelty, inventive step, and industrial application. Nonetheless, the definitions of “process” and “product” have been left without any specific meaning that members have agreed on. Therefore, for the purpose of determining the patent eligibility of new uses from the TRIPS perspective, the first step before assessing novelty, non-obviousness, and industrial application must be to determine whether new uses as intellectual achievements belong to those entities i.e. “process” or “product” within the meaning of Art. 27(1) or not. This problem by itself depends on understanding the intended meaning of these two terms with all other terms harmoniously, contemplating the principle *effectiveness* in treaty interpretation (*ut res magis valeat quam pereat*).<sup>11</sup>

From a legal and practical view (and bearing in mind the object and subject of Art. 27(1)) absence of any evidence which indicates a specific meaning of those two terms in

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<sup>10</sup> Matsushita, Schoenbaum, & Mavroidis, “The World Trade Organization: Law, Practice and Policy” 35 (Oxford University Press 2006).

<sup>11</sup> See Appellate Body Report, Japan Taxes on Alcoholic Beverages-United States WT/DS8/AB/R (Oct. 4, 1996). See also Yearbook of the International Law Commission (ILC), Vol. II, at No. 6, U.N Doc. A/CN.4/SER. A/1966/Add. 1 Sales No. 67.V.2 (1966).

competent WTO body jurisprudences, decisions or even in *travaux préparatoires* of TRIPS (As the supplementary material for interpreting) shows the drafters and subsequently the members did not intend a meaning beyond the wellknown and prevalent notion of those terms.

On the other hand, unlike the examples of “product patents,” which are related to tangible, objective and physical entities, quiddity of detecting new uses is some kind of subjective knowledge and cognition of matters. It is uncontested that the subject matter of new use patents cannot inherently be represented as a “product”. Moreover, avoiding admixture with the concept of “discovery”, when we could name someone as an “inventor” that outcome of his intellectual activities give raises to “creativity”.<sup>12</sup> Thus, the detector of a new use should prove “*creation*” of a novel, inventive and useful “process.”

Accordingly, from the TRIPS perspective, the only supposable chance for protecting new uses is *incorporating* the concept of “use patent” within meaning of “process patent”. This necessity arises from the nature of the detecting of new uses is understandable from experiences of jurisdictions that have protected new uses within their territorial jurisdictions. For example, in United States and European Patent Office (hereinafter EPO) they just can formulates this as “use patents” and specifically as the “method of use” and “process of use” patents which both are categorized as the “process patents” within their jurisdictions.<sup>13</sup>

Nevertheless, being that the term “process” in Art. 27(1) in a state that has not been clearly agreed upon places it in a position wherein it could be interpreted with a broader meaning than what legally and literally means. This can result in imposing more onerous tasks on

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<sup>12</sup>Drahos, “ A philosophy of intellectual property” , 29 (Dartmouth1996).

<sup>13</sup> As will be explained in the following parts, it could be deduced as a general rule from EPC's provisions and EPO's procedures that the new discovered uses must be drafted as “process/use patent”. The exception to that rule is first and second/further medical indications in Art. 54(4) and (5) of EPC 2000. The Swiss-type claims for second/further indication also is subject of general rule. (See *infra* discussion No. 3.1.1).



members than what TRIPS requires. Whereupon, in the context of Art. 1 wherein the provisions of TRIPS are introduced as the minimum standards and considering *in dubio mitius* principle, the provision should be construed in a *restrictive* manner that involves its ordinary meaning, which would impose less onerous obligations to the parties. From a textualism angle, where applying the linguistics materials is “the starting point for determining the ordinary meaning of the terms”<sup>14</sup> the term “process” must be interpreted in a way that provides minimal level of covered obligations meeting the restrictive principle, which also provides meaningful a face of that term in favor of the principle of *effectiveness*. For instance, the Oxford Dictionary defines the term “process” as “A series of things that are done in order to achieve a particular result”.<sup>15</sup> Nevertheless, via the standards' promotion policies, members could have recourse to the TRIPS flexibilities applying a particular definition of the term “process” which broadly extends the protectable items beyond what the term “process” ordinarily means; *inter alia* “new uses” as *one step* activity.<sup>16</sup>

Therefore, based on what the Art. 27(1) addresses, members are required to protect new use patents, provided that a claimed new use fulfills the constructive elements of the “process” plus proving the triple requirements i.e. novelty, inventive step and industrial application. Hence the mere detection of new uses for old contrivances, without providing a *creative* intellectual steps or in other words without being in the form of “process”, irrespective of what is their nature (discovery and etc.) should not be considered as a protectable subject-matter.

When an application is posed as a process it must be *independently* examined in relation to its previous invention or rather the invention from which the new process was derived. From

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<sup>14</sup> Panel Report, United States Certain Measures Affecting Imports of Poultry-China, WT/DS392/R, Sec. VII, 7.259, (Sep. 29, 2010).

<sup>15</sup> “Oxford Advanced Learner’s Dictionary of current English”, A S Hornby (8th ed. 2010)

<sup>16</sup> Domeij, “Pharmaceutical Patents in Europe”, 130 (Kluwer Law International 2000).

here, the relationship between the prior and the newly discovered application will be cut and subsequently one new, absolute, and protectable invention will be created as the outcome. It is the affiliation between new detected application and prior patent that truly will result in claiming the lack of novelty, due to existence in prior art.

Through this approach the monopoly will be restricted to the new discovery made by inventor. Therefore there will nothing objectionable in granting patent.<sup>17</sup> In other words allocating rights of each proprietor of the original patent and patentee of the new uses, and isolating the original invention from its subsequent uses could refute the arguments that have been articulated supporting contrast between protection of new uses and the TRIPS Anti-competitive provisions. The core of those arguments emerges where the discoverer of new uses and proprietor of original invention are the same. They argue that it will block the rival producers (e.g. generic producers of pharmaceuticals) from entry into the market by prolonging the patent protection term.<sup>18</sup> A response to this concern is that: in the legal sense, irrespective of the *executive* difficulties<sup>19</sup>, *substantively* the independence of the original patent from its subservient uses means that rivals are able to produce the same patented product or use the same patented process for new uses within the originator's monopoly period and similarly, at the

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<sup>17</sup> Colston & Galloway, "Modern Intellectual Property Law", 180 (Routledge 2010).

<sup>18</sup> Musungu & Oh, "The use of Flexibilities of TRIPS By developing countries: Can they Promote Access to Medicines?" 36 (Commission on Intellectual Property Right Innovation And Public Health,(CIPIH), Geneva, 2005).

<sup>19</sup> Each of new use or original patent's right holders must where they are claiming the infringement of their rights prove that litigant have infringed his rights by exploiting the same product/process. In the realm of medical and pharmaceutical products and in particular prescription of medicaments to the active ingredient rather than brand of originator, these executive difficulties have intensified by issues like "off-label use" and "cross label use" of drugs. See Radley et al. "Off-label Prescribing Among Office-Based Physicians", 166 JAMA Internal Medicine (2006).

patent's expiration date, to produce or use the original invention for its old uses without any possibility of right infringement or free riding.

### **C. TRIPS and Patents for First/Second or Further Medical Indications**

There are no special features in pharmaceutical inventions which distinguish them from other inventions that are protectable under the Art. 27(1). In other words the terms of this article have embodied pharmaceutical inventions. However, Art. 27(3)(a) has given an option to members to “exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals” from patentability.<sup>20</sup> A little scrutiny will show that there is some significant and conceptual association between Arts. 27(1) and 27(3)(a). As explained above, on one hand the wording of Art. 27(1) insinuates that new use patents could be protected, if they formulated as “process”. On the other hand, Art. 27(3)(a) provides the possibility of excluding diagnostic, therapeutic and surgical methods for treatment. Therefore, logically, the inevitable conclusion of these two presuppositions is that if each member uses the flexibility given in Art. 27(3)(a), it has implicitly ruled a prohibition on protecting pharmaceutical new use patents within its internal law.<sup>21</sup> This is an inevitable result of applying the option given in the Art. 27(3)(a); irrespective of

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<sup>20</sup> It is not clear that whether these optional exceptions in general sense involve the in vitro process and prophylactic medical products or not; however it literary seems that Art. 27(3)(a) could be applied for these procedures as far as they are related to the treatment via therapeutic, diagnostic or surgical methods.

<sup>21</sup> Apart from the probable lexical differences between “method” and “process”, it seems there is no substantial difference between ordinary meanings of those terms, from TRIPS perspective, as those are in United States patent law. The arrangement of Art. 27 which based on it, the part 3(a) (Option of excluding of diagnostic, therapeutic and surgical methods) comes following to the part (1) (Requirements of granting the patent and being one of product or process) is indicating those specified methods are some kinds of content of part (1) of Art. 27 i.e. “process”. It is obvious that “method” cannot be categorized as the subset of “product” inventions, attending to its lexical and real nature of the term “method”.

whether it complies with members' interests that have adopted it, or not. However, for countries which have no sophisticated pharmaceutical R&D, this may be advantageous.<sup>22</sup>

Given the above, in this regard, the United States' performance, as a member of TRIPS in its respective legislations is most commensurate with Art. 27 of TRIPS. In the United States, the “therapeutic, diagnostic and surgical” method of treatment have not been excluded from protection, while their protection has been suspended on formulating their claims within meaning of “process.”<sup>23</sup>

The European countries' approach regarding “diagnostic, therapeutic and surgical methods” in European Patent Convention (hereinafter EPC) where in the majority of its member states are also members of TRIPS is interesting.<sup>24</sup> Generally, in spite of exclusion, these method of protection by the EPC's provisions, the protection of medical new uses (Including first and second medical indications), by means of complicated jurisprudences (Purpose-related product), has been provided for. The remarkable point in this regard is that the current procedure of the European Patent Office (EPO) for protecting non-medical new uses and its previous procedure for protecting medical second indications (Swiss type claim)<sup>25</sup> both require that new uses must be claimed within the *process* format. This is unlike the current EPC's approach (Purpose-related product patent) wherein second medical indications just like first indications are patented as *product* rather than *process*.<sup>26</sup>

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<sup>22</sup> Drahos, “Developing Countries and International Intellectual Property Standard-Setting”, 23 (Commission on Intellectual Property Rights (CIPR), Geneva, 2002 ).

<sup>23</sup> UNCTAD-ICTSD Project on IPR and Sustainable Development, “Resource Book on TRIPS and Development”, 384 (Cambridge University Press, 2005).

<sup>24</sup> There are only three countries including Monaco, San marino and Serbia that are EPC's member whilst have not acceded to WTO.

<sup>25</sup> See discussion *infra* 3.1.1.1.

<sup>26</sup> See the case, T 1099/09 Coloplast /device for treatment of urinary incontinency, (Jan. 12, 2012).

Such a verbatim reading of relevant TRIPS regulations that restrict the protection's scope of pharmaceutical new uses in essentials of customary patent law, considering the proven adverse influences of protecting of mere discovered pharmaceutical and therapeutic new uses on produce capacities for traditional medicines, preservation of bio-resources<sup>27</sup>, access to medicines<sup>28</sup>, medicines price<sup>29</sup>, and subsequently on public health. This is more commensurate with "Doha declaration" (Declaration on TRIPS Agreement and Public Health)<sup>30</sup> as an instrument which essentially has been agreed upon, to be applied for interpreting and implementing the requirements of TRIPS in a way that improves members' public health. Paragraph (4) of this declaration states: "...we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

### **III. The Regional Instruments**

In regard to the number of obligators, the regional instruments of intellectual properties, after internationals, could have a significant importance in opening ways to harmonize various national treatments toward subjects concerning patent law. There are many regional instruments in particular that concern patents that do not oblige their members to protect new uses. For

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<sup>27</sup>Correa, "A Guide to Pharmaceutical patent", 138 (South Centre 2008).

<sup>28</sup> Gaëlle, "New trends in IP protection and health issues in FTA negotiations" in: Coriat, "The Political Economy of HIV/AIDS in Developing Countries. TRIPS, Public Health Systems and Free Access", 56 (Edward Elgar Inc. Cheltenham, UK & Northampton, MA, USA 2008).

<sup>29</sup> The Case of price growth of depression medicament "Fluoxetine" subsequent to patent its second application treatment premenstrual dysphoric disorder. See supra note at 130. See also Vernaz et al. "

Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis", PLOS Medicine,(2013).

<sup>30</sup> World Trade Organization (WTO), Ministerial Declaration of 14 November 2001 WT/MIN(01)/DEC/1, 41 I.L.M 746 (2002).TRIPS on Agreement and Public Health(Doha Declaration), Nov. 14, 2001, Para. (6),.

instance, the “EPC” as a regional convention, and the “Andean Union”<sup>31</sup> and “Gulf Cooperation Council” (GCC)<sup>32</sup> as regional unions are the only regional entities which have responded to the issue of new use patents within their jurisdictions.

### **A. European Patent Convention (EPC)**

There is a bifurcation concerning new use patents in the EPC and its parallel judicial precedent in EPO based on subject matter of contrivances. Hence, the protection regime for pharmaceutical new uses (including first and second medical indications) has been separated against non-pharmaceutical new uses and has special conditions. That dualism dealing with medical and non-medical new uses, has emanated from the revision of the EPO's procedures and also the EPC 1973 in 2000, which amounted to creating two independent and equal legal processes.

#### **1. Medical New Uses (First/Second or Further Medical Indications)**

Within EPC's jurisdiction, the rules toward medical new uses can be divided into two periods of before and after the revision of the EPC. Because the revision of the EPC was in reaction to previous gaps and loopholes that existed in EPC 1973 and also existed in the unrevised EBA regulations concerning second medical indications (Swiss type claim) was an indirect inspiration for law of some non-European jurisdictions like Japan,<sup>33</sup> Australia,<sup>34</sup> New

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<sup>31</sup> The Andean Community as a customs union which comprises the South American countries, Bolivia, Colombia, Ecuador, and Peru. The trade bloc was called the Andean Pact until 1996 and came into existence with the signing of the Cartagena Agreement in 1969.

<sup>32</sup> Gulf Cooperation Council (GCC) as a political and economic union which comprises the States of United Arab Emirates, Kingdom of Bahrain, Kingdom of Saudi Arabia, Sultanate of Oman, and State of Qatar. Established on 25 May 1981.

<sup>33</sup> Supreme court of Tokyo, Heisei, 10 (Gyō Ke) 401, 2001, April 25.

<sup>34</sup> Bristol-Myers Squibb Co v. F H Faulding & Co Ltd (2000) 41 I.P.R.467 (Fed.ct.Aus.,TD).

Zealand,<sup>35</sup> Philippine,<sup>36</sup> Canada,<sup>37</sup> China,<sup>38</sup> Israel,<sup>39</sup> and Singapore<sup>40</sup> and at the regional level GCC<sup>41</sup>. As a result it is important to analyze both forgoing periods.

### **a) EPC 1973: The Primary Ban and Making a Standard Solution**

The EPC 1973 did not have any provision that endorsed the patentability of the second medical indications, unlike the first indications. Hence, the EPO would frequently show its distaste of patenting second/further indications through literal interpretation of Art. 52(4) of EPC 1973, which had excluded methods for treatment of any human or animal bodies by surgery or therapy, and diagnostic methods practiced on the human or animal body.<sup>42</sup> This stipulation had been based on ethical or moral reasons.<sup>43</sup> At the highest level, legal problems associated with the patentability of claims to the new use of a known compound, provided the subject matter for the first seven Decisions to be issued by the Enlarged Board of Appeal, namely G 1-7/83.

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<sup>35</sup> Pharmaceutical Management Agency Ltd v. Commissioner of Patents [2000] 2 NZLR 529 (Pharmac).

<sup>36</sup> Intellectual Property Office of the Philippines (IPHL), Examination Guidelines For Pharmaceutical Patent Applications Involving Known Substances, Part 9

<sup>37</sup> Canadian Intellectual property Office (CIPO), Manual of Patent Office Practice (MOPOP), Chapter 12, Sec. 12.06.08 & 12.06.08d.

<sup>38</sup> State Intellectual property Office of the People's Republic of China (SIPO), Guidelines for Patent Examination (2010), Part II, Chapter 10, Sec. 4.5.2.

<sup>39</sup> Israel Patent Office, 1993, Directive No. 38 and No 40.

<sup>40</sup> Singapore's Patents Act (Revised Edition 2005, as amended up to the Statutes (Miscellaneous Amendments) Act 2014), Sec. 14 (7).

<sup>41</sup> GCC Patent Office, patent no. GC 0001215, claim 27, "Use of the compound defined in any one of claims 1 to 23 for the treatment or prophylaxis of a disease modulated by LXR alpha and/or LXR beta agonists", published in GCC patent gazette no. 14. 30 September 2010. See also supra note 33.

<sup>42</sup> Ventose,"Patent Protection for Second and Further Medical Uses Under the European Patent Conventio", 6 SCRIPTed 7(2009).

<sup>43</sup> United Nation Conference on Trade and Development (UNCTAD) and International Center for Trade and Sustainable Development(ICTSD) Project on IPR and Sustainable Development, "Resource Book on TRIPS and Development", 384 (Cambridge University Press, 2005).

Historically, making an appropriate legal action was initiated toward first indications, in *HOFFMANN-LA ROCHE/Pyrrolidine derivatives*.<sup>44</sup> The claimed subject matter was to apply a non-medical substance as an active substance to combat cerebral insufficiency and improve intellectual ability. The technical board of appeal (hereinafter TBA) held that, "the principle of equal treatment would require that an inventor who for the first time makes a known compound available for therapy should be correspondingly rewarded for his service with a purpose-limited substance claim under Art. 54(5) EPC to cover the whole field of therapy".<sup>45</sup>

The TBA also observed that, in first medical indications, novelty will not only be destroyed by existence of same specific therapeutic effects in prior art, but also by existence of any other therapeutic application that would be disclosed. By that policy a monopoly was made over whole therapeutic applications that first medical indications might have contained and subsequently the novelty for second/further uses that could be discovered in the future was destroyed. In the case *G 5/83 (EISAI/Second Medical Indication)*, which was issued after the TBA'S referred question<sup>46</sup>, the patentability of first and second medical indications, in view the prohibitions of the Art. 52(4) EPC 1973 had legally been challenged. The core of the question was: "Can a patent with claims directed to the use be granted for the use of a substance or composition for the treatment of the human or animal body by therapy?"<sup>47</sup>

The EBA's response included two parts; the major part was concerned with second/further medical indications and minor part dealt with first indications. For first

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<sup>44</sup> T 0128/82.

<sup>45</sup> Id, at para. 10.

<sup>46</sup> T 0017/81, Bayer/Nimodipin.

<sup>47</sup> G 05/83, EISAI/Second medical indication, at para. 1.



indications the EBA confirmed that under Art. 54(5) EPC 1973(Now Art. 54(4)EPC)<sup>48</sup>, “The inventor of a first medical indication can obtain purpose-limited product protection for a known substance or composition, without having to restrict himself to the substance or composition when in a form technically adapted to a specified therapeutic purpose. The appropriate protection for him is, therefore, in its broadest form, a purpose-limited product claim.<sup>49</sup> In fact, the EBA made it a possibility for inventing the second/further medical indications for pharmaceutical products, which had been previously protected as first medical indications. This was not possible based on former TBA's jurisprudence. The case *Bayer/Pyrrolidine-Derivatives* had provided a monopoly over all existed but not still discovered medical applications in relevant substances and compositions.<sup>50</sup>

The bridge between provisions of first and second medical indications in the EBA's decision was that both had to be formulated as a “use claim” which is not constitutionally different from “method claim”.<sup>51</sup> Non-substantial differences between “method” and “use” claims made a big obstacle for protecting of second indications through the direct contradiction to the prohibition that ruled against protection of therapeutic, surgical and diagnostic methods; unlike the first indications. Thereby, claims which were directed as “Use of a substance or composition for the treatment of the human or animal body by therapy”<sup>52</sup> had an identical legal effect in comparison with claims were directed as method for treatment of the human or animal

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<sup>48</sup> The Art. 54(4) EPC 2000(The former 52(5) in EPC 1973) expresses: Paragraphs 2 and 3 [Requirements concerning novelty of novelty] shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 53(c)[ therapeutic, surgical, diagnostic ], provided that its use for any such method is not comprised in the state of the art.

<sup>49</sup> Supra note 46, at para. 15.

<sup>50</sup> Supra note 43, at para. 10.

<sup>51</sup> Supra note 46, at para. 11.

<sup>52</sup> Id, at para. 12.

body by therapy and subsequently were contrary to the Art. 52(4). The EBA had to contemplate the benefits of second medical protection while it also had to consider the barriers of EPC. Hence, the solution that could satisfy both of those interests should be devised. From a legal perspective, the EPO was faced with two basic problems. First, the problem of proving “novelty” just for a “use” in medical products which existed in prior art, bearing in mind the absolute definition of “novelty” which had been provided in Art. 54(1),(2) and (3).<sup>53</sup> Second, the confliction between second medical indications as use/method claims with specified methods in Art. 52(4). The EBA’s solution emanated from the Swiss Federal Office for Intellectual Property statement of practice regarding “use claims.”<sup>54</sup> The Swiss solution model led to birth the of the “Swiss type claim,” which was directed as “the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application”. By Swiss formulation, which was no less than an ingenious circumvention, both foregoing legal difficulties were solved. By that formulation the impediment of required “novelty” was met by extracting it from *special purpose* of use of the relevant substance or composition. Thereby, the relationship between claimed subject-matter and the existence thereof in prior art was discontinued by constituting new and independent novelty (i.e. one which is derived from *new therapeutic purpose* of use not from *method of use or the substance or composition per se.*) Hence, the claim must be directed to a known medicament to treat a malady not previously

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<sup>53</sup> Art. (54):

(1): An invention shall be considered to be new if it does not form part of the state of the art.  
(2): The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way before the date of filing of the European patent application.  
(3): Additionally, the content of European patent applications as filed, of which the dates of filing are prior to the date referred to in paragraph 2 and which were published under Art. 93 data shall be considered as comprised in the state of the art.

<sup>54</sup> Legal Advice from the Swiss Federal Office for Intellectual Property, OJ 1984, 581.

treated via that substance or composition. In its decision, the EBA justified through analogy the requirement for novelty of first medical indications.<sup>55</sup> The EBA stated that the content of Art. 54(5) 1973 toward protection of first indications does not mean that alternative i.e. second/further medical indication has been excluded and that this kind of interpretation i.e. “*expressio unius (est) exclusio alterius*” is not applicable here.<sup>56</sup> Thereby the EBA extended the notion of novelty provided for in former Art. 54(5) EPC 1973 to apply to each further medical use.

The next essential element of the Swiss-type claim was devised for resolving the conflict between the second/further indications as a plain use/method claim with Art. 52(4) 1973, “use for manufacture of a medicament”.<sup>57</sup> In practice, if a claim simply is formulated as the use or method of applying of a known medical substance or composition for therapy, it would be in direct conflict with the exclusion of methods of treatment; unless the substance or composition's new and direct therapeutic use or method of use could be transformed into indirect therapeutic use or method of use via a proviso of “*manufacture.*” For that purpose the way of using substance or composition for manufacture/preparation must be explained in the claim as indicating “*the sequence of steps being implied*”<sup>58</sup> for manufacturing a “*prophylactic*” or “*curative*”<sup>59</sup> “*chemical substance or composition,*”<sup>60</sup> which is used for treatment of a disease or

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<sup>55</sup> Supra note 46, at para. 21.

<sup>56</sup> Supra note 46, at para. 22.

<sup>57</sup> T 0138/02, Kanegafuchi Kagaku Kogyo Kabushiki Kaisha/ Adsorbent for removing interleukins and tumor necrosis factor, and process for removing the same, at para. 2.6; (Jun. 27, 2006).

<sup>58</sup> Supra note 46, at para. 11.

<sup>59</sup> T 0019/86, Pigs II, at para. 7; (Oct. 15, 1987).

<sup>60</sup> T 0004/98, Liposome Compositions, at 8.1; (Aug 9, 2001).

disorder within meaning of treatment by “*therapy*.”<sup>61</sup> For that purpose the claimed medicament “[must be] brought into contact with the body in order to deliver and apply a substance or composition in an effective form and dose for it to develop its therapeutic effects within the patient's body.”<sup>62</sup>

After establishing this preliminary legal framework for second medical indications within the meaning of (*EISAI/Second Medical Indication*) the breadth of items that can be brought up as protectable second medical indication was expanded to the subjects like new route of medication administration<sup>63</sup>, treating the same disease in a new way by using known product (New dosage regimen/method of administration)<sup>64</sup> treatment of the same receptors for the same disease by the same medication for a group of those with different physiological or pathological status<sup>65</sup>, and different technical effect which is leading to a truly new application.<sup>66</sup>

Finally, in 2010, the EBA stipulated that the Swiss type claim format is no longer the correct format for subject matter of claims that are rendered novel only by a new therapeutic use

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<sup>61</sup> For details in regard to meaning of “therapy” within EPO's jurisdiction, see supra 58 and infra 65.

<sup>62</sup> *Supra* note 56, at 2.5.

<sup>63</sup> T 0051/93, *HCG/SERONO*, (Jun. 8, 1994); related to “Use of HCG for the manufacture of a non- depot medicament for use in the treatment by subcutaneous administration of infertility or male sexual disorders.”

<sup>64</sup> T 1020/03, *Method of administration of IGF-I/GENENTECH INC.*, (29 Oct. 2004).

<sup>65</sup> T 0019/86, *Pigs II*, (Oct. 15, 1987); related to the therapeutic use of a vaccine (Attenuated Aujeszky-virus) which was known for treatment of sero-negative pigs for pigs that are sero-positive.

<sup>66</sup> T 0290/86, *Cleaning plaque*, (Nov. 13 1990); related to the two independent claims concerned with using same composition (Lanthanum salts) for same therapeutic purpose (Prevention of tooth decay) with different (New and inventive) technical effect, including using one of them for removing plaque and another for solubility of tooth enamel.

of a medicament.<sup>67</sup> The board was of the opinion that the loophole was existed in EPC 1973, has been closed, thus *ratio decidendi* “when the reason of the law ceases, the law itself ceases.”<sup>68</sup>

The recent TBA's decision in the *H.Maatalous Oy/food additive*<sup>69</sup> shows continuous endeavors to determine the extent of applying the G 5/83 (*EISAI/Second Medical Indication*) in new cases. In this case, the patent was within the veterinary science area and pertained to a feed additive which is prepared by hydrolytically treating a yeast raw material with an acid, for the prevention of intestinal diseases and/or promotion of growth. Subsequent to any opposition against the patent<sup>70</sup> and filing an appeal for opposition division's decision to maintain the patent in amended form<sup>71</sup>, the TBA considered and ruled in a milestone decision to apply the (*EISAI/Second Medical Indication.*)<sup>72</sup> The error that the board specified to be amended was in regard to a claim for both first and second/subsequent medical indications for the same subject-matter. A part of claim was directed as “The *procedure for preparing* a feed additive, to be used for the prevention of gastric disorders and intestinal diseases...”<sup>73</sup> which was in accordance with a form of a second medical use (*EISAI/Second Medical Indication*) and simultaneously, the claim was characterized as “Feed additive for the prevention of intestinal diseases ...” by analogy with Art. 54(5) EPC 1973. The board concluded that if the claimed subject-matter indeed relates to the first medical indication, then G 5/83 would provide no legal basis to additionally claim the same subject-matter in terms of a second medical indication. In other words, the legal fiction that

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<sup>67</sup> G 2/08, *Dosage regime/ABBOTT RESPIRATORY*, (Oct. 29, 2004).

<sup>68</sup> *Id.* at para. 7.1.2; “*cessante ratione legis, cessat et ipsa lex*”.

<sup>69</sup> T 1758/07, (Jun. 7 2010).

<sup>70</sup> Biotec Pharmacon ASA, field on 19 April 2005.

<sup>71</sup> *Supra* note 68, at para. III

<sup>72</sup> Whereas the patent what was the opposition had been filed against, granted before that EPC 2000 entered into force; therefore the EPC 1973 and relevant EPO's procedures was applied for consideration of the case.

<sup>73</sup> *Supra* note 68, at para. 3.2.

G 5/83, namely that the therapeutic treatment according to Art. 52(4) EPC 1973, is a limiting feature applies only if a therapeutic treatment is a second/further medical indication.<sup>74</sup>

### **b) EPC 2000: Eradication of the Legal Uncertainties**

After the EPC 1973 revision and the establishment of its 2000 version,<sup>75</sup> the legal status of second/further medical indications was determined unambiguously. Thereby, former Art. 54(5) EPC 1973 ("first use in a medical method") was renumbered to become Art. 54 (4) EPC and a new Art. 54(5) EPC was introduced enshrining the former judicial case laws to provide protection for each second/further medical uses. It expressly regulates:

Paragraphs 2 and 3 [Requirements concerning novelty of novelty] 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), [therapeutic, surgical, diagnostic] provided that such use is not comprised in the state of the art.

Unlike the Swiss type patent that was applied to process/method patents and for any medical methods in a way which provides broad (Generic) protection, the purpose limited product patents have been given only for the triple medical methods of Art. 53(c). Hence, the scope of items that Art. 54(5) of EPC 2000 covers will be restricted in comparison with the Swiss type claims which could be used for any kind of medical uses. In other words they provide equivalent legal protection as far as they overlap with each other toward medical methods within meaning of Art. 53(c). However, the extent of conferred rights and means of enforcement could be extended by changing the patent category from process patent into product patent through restrictions on the freedom of medical practitioners to prescribe or administer generics. Thereby by supposing (Legal fiction) that the detector of new second/further indication has initially invented the subject-matter as a product, which is specially used for specific medical applications

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<sup>74</sup> Id, at para. 3.3.

<sup>75</sup> EPC 2000 became into force in 13 December 2007.

the subject-matter will be separated from its prior existence. In other words, novelty is derived from the substance or composition itself and the new and inventive purpose of use will separate the subject-matter from its old identical existence. Accordingly, the legal status of first and second indications has currently been converged. Therefore, it could be said now that the same rationales that have been applied for justifying the first indications (Purpose-limited product) could be used for second/further.

By transforming the legal nature of the second medical indications i.e. from a process invention into product invention, enforcing the rights thereof has changed. Strictly speaking, irrespective of facts which could be varied from case to case, the person who has alleged violation, must prove a directly or contributory infringement for a product rather than a process, which has its special conditions, de jure.<sup>76</sup> In fact, since a patent will be issued subsequent to the inventor's creative act, the title of patent which determines the span of his/her rights must be in accordance to what he/she has created. Hence, even though issuing a "product patent" for first and second medical indications through purpose-limited product strategy seems legally justifiable, it is not within following the inventor's real creation i.e. "use."

Judicial bodies' decisions in the past have indicated a prudent treatment toward second/further medical indications. Since the context of paragraph (5) of Art. (54) is an exemption to prohibitions that are ruled in Art. 53(c) both are logically construed *Expressio unius* in relation to each other according to their strict text. This can be found from the

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<sup>76</sup> Art. 64(3) states: "Any infringement of a European patent shall be dealt with by national law". For example the UK legislature have provided that:

(a) Where the invention is a product, he makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise;...

(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise. (Patents Act 1977, Chapter 37, sec. 60)

preparatory documents of EPC 2000, in particular the Swiss delegation's proposal which was eventually adopted by the Diplomatic Conference and constitutes the current version Art. 54(5):

The decisive aspect of paragraph 5 of the Swiss proposal was that protection would only be granted for a “specific use” if it did not yet form part of the state of the art. The aim, therefore, was to provide narrow protection for the second medical indication and broad protection for the first indication.<sup>77</sup>

The TBA decision in *Coloplast* regarding a device for treatment of urinary incontinence<sup>78</sup> is a good example. In that case, the claimed subject-matter regarded an implantable device (Biocompatible material) designed for use in treatment of urinary incontinence in women. The TBA's narrow and literal interpretation restricted the range of Art. 54 (5) only in products which are *composition* and *substances*. The EBA clearly observed that “the distinction made by the legislature is not between substances and compositions but between products which are substances or compositions and products which are not.”<sup>79</sup>

## 2. Non-medical New Uses

There is no applicable regulation that determines the legal standing of nonpharmaceutical new use patents, whether it is in E.P.C 1973 or in E.P.C 2000. Those uncertainties were removed by case law and by the EBA in the case *Mobil/Friction*.<sup>80</sup> In that case the claim was the use of a known substance as a friction reducing additive in lubricants. The substance was already known to inhibit rust, and the application was therefore refused based on lack of novelty. Consequently “Mobil” decided to amend the application from the claim for a “*compound*” into the “*use of that compound in a composition for specified purpose*”, which was accepted by EBA. Finally, the EBA having regard to the importance of technological applicability of innovations within EPO's

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<sup>77</sup> Document CA/PV 81 e, para. 86.

<sup>78</sup> T 1099/09, (Jan. 12, 2012)

<sup>79</sup> *Id.* at para. 3.3.

<sup>80</sup> *Mobil/Friction reducing additive*, G2/88, (Dec. 11 1989).



jurisdiction,<sup>81</sup> held that if a claim was to the use of a known substance in a *new way (means of realization)*<sup>82</sup> for a *new purpose*, then it might be novel and inventive because the new way of using the substance created a *technical result (technical realization.)* In contrast, a claim for the use of a known substance in a *known way* to achieve a *new purpose* will not include any novel technical feature.<sup>83</sup> Clearly, the product claim could not succeed, as the substance was not new.<sup>84</sup>

The EBA affirmed this matter, stating:

There are basically two different types of claim, namely a claim to a physical entity (e.g. product, apparatus) and a claim to a physical activity (e.g. method, process, use) . . . . The technical features of a claim to a physical entity are the physical parameters of the entity, and the technical features of a claim to an activity are the physical steps which define such activity.<sup>85</sup>

In addition, within EPO's jurisdiction there are two different types of process claim, (i) The use of an entity to achieve a technical effect and, (ii) A process for the production of a product.<sup>86</sup> Whereupon, there is no constitutional difference between “use claim” and “method/process claim” and as EBA ruled, each of them can be formulated interchangeably, within EPO's jurisdiction. In actuality, a “method/process” implies an activity which consists of

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<sup>81</sup> For instance, what has been ruled at para. 7 of decision G2/88 shows the EBA's tendency, emphasizing on the background role of industrial susceptibility in determining novelty within meaning of Art. 57 EPC. It is stating "A claimed invention lacks novelty unless it includes at least one essential technical feature which distinguishes it from the state of the art. When deciding upon the novelty of a claim, a basic initial consideration is therefore to construe the claim in order to determine its technical features".

<sup>82</sup> *Supra* note 79, at para.10.2.

<sup>83</sup> Seville, “EU Intellectual Property Law and Policy“, 110 (Edward Elgar, Cheltenham, UK , Northampton, MA, USA 2009).

<sup>84</sup> *Supra* note 17.

<sup>85</sup> *Supra* note 79 at paras. 2.2 and 2.5.

<sup>86</sup> EPO Guidelines for Examination, Use claim (4.16). Available in [http://www.epo.org/law-practice/legal-texts/html/guidelines/e/f\\_iv\\_4\\_16.htm](http://www.epo.org/law-practice/legal-texts/html/guidelines/e/f_iv_4_16.htm). (Accessed on 21 Apr. 2014).

“*setting out a sequence of steps*” while a “use” implies an activity that involves “*a sequence of steps being implied.*”<sup>87</sup>

When those rules are pieced together like puzzle fragments, it is obvious that the new use claims should fall into physical activity claim types, wherein their technical features are the physical steps that define such activity within a sequence of steps which have been employed. In other words there should be a series of *objective* and *constructive* steps which amount to a *technical effect*, to constitute a patentable new use as subject-matter and subsequently to distinguish them from the concept of mere discoveries.

### **B. The “Andean” Experience**

The story began in the mid-1990s when the majority of the Andean member countries including Peru, Venezuela and Ecuador except Colombia decided to grant patents for newly discovered uses (Treatment male impotency) for cardiovascular medicament “*pyrazolpyrimidinones*” to an American multinational pharmaceutical corporation Pfizer. The Colombian authorities in “Superintendence of Industry and Commerce” rejected the Pfizer application through its specific interpretation from Art. 1 of Andean's decision 344 which states: “The Member Countries shall grant patents for inventions in all areas of technology, whether goods or processes, those are new, involve an inventive step and are industrially applicable.”

The Colombian authorities argued, that Art. 1 only involves “goods” and “processes” and does not permit the patent protection for “uses”. Eventually and subsequent to the presidential decree which permitted second-use patents in Peru, the Association of Pharmaceutical Industries of National Origin and Capital (ADIFAN,) fielded a compliant with the Andean General Secretariat. With the Secretariat's support, the case was submitted to the Andean Tribunal of

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<sup>87</sup> *Supra* note 46, at para. 11.

Justice (hereinafter ATJ).<sup>88</sup> The ATJ's verdict had the same result provided by the Colombian IP agency. The difference was in materials what ATJ had employed reasoning its judgment. The ATJ's judgment, which was based on Arts. 16 and 21 of Decision 486 that duplicated Arts. 2 and 16 of Decision 344, clarified the Peruvian decree and meanwhile other new use conferred patents by other members had violated Andean common intellectual property regime.<sup>89</sup> Art. 21 of Decision 486 requires the members:

Products or processes already patented and included in the state of the art within the meaning of Article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.

Art. 16 also defined the novelty requirement as:

An invention may be deemed new when not included in the state of the art. The state of the art comprises everything that has been made available to the public by written or oral description, use, marketing, or any other means prior to the filing date of the patent or, where appropriate, of the priority claimed.

Generally speaking, it could be understood that the ATJ's argumentation, alongside Art. 21, which references novelty's definition within meaning of Art. 16 and also existence of the former patent in Non-Andean community country, entails the acceptance of “*absolute novelty*” which was acknowledged in “pipeline patents” case.<sup>90</sup> In fact rejection the new use patents based on lack of novelty as the general rule without specifying geographical criteria for novelty, requires the original product or process not only in jurisdiction which the rule has been sought

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<sup>88</sup> Case 89-AL-2000 (Sep. 21, 2001).

<sup>89</sup> The only policy which can be supposed behind the context duplication of Arts. 16 and 2 of Decision 344 within Arts. 16 and 21 Decision 486 is emphasizing on community instance toward new use patents. The ATJ enjoyed this policy supporting its argumentations. *See* Action 89-AI-2000, para. 1; Action of Non-compliance lodged against Peru by General Secretariat of Andean community.

<sup>90</sup> Case 25-IP-2002, at 18 (May 8, 2002).

but also in any other jurisdictions have not been yet patented. Whereas, if it has already been patented it would be posited that the subject matter had been patented for all its uses.

Moreover, the Andean legislature, like many of other silent and opposed jurisdictions, has not clarified what kind of uses it intends and what fills the gap between “process” and “use” concepts. In other words, it has not specified any indicative criteria which would separate the concepts of “process” and “use”. For example, it is not clear whether a claim for a new use of an old invention could be directed in a manner in which the new use results from a series of steps, would be considered as a “process claim” or as a “use claim.”

Admittedly, extending the concept of processes in a manner that involves the uses works to “strengthen the industrial property rights” as permitted in Art. 143 of Decision 344. However, the ATJ's construction on Art. 143 in the “*pipeline patents*” forbids this conclusion by holding that the term “strengthen” must be interpreted in a teleological fashion that supportively complement regional IP system, not contradict it.<sup>91</sup>

#### **IV. National Laws' Treatments**

At this level, countries irrespective of their level of development could be divided into countries with silent, opponent and proponent domestic laws. The LDCs countries have totally fallen into the category of countries with silent laws. Studies show that in developing countries, in the majority (55%) of the laws reviewed, there is no specific exclusion regarding protecting new uses.<sup>92</sup> These countries include: Thailand,<sup>93</sup> Pakistan,<sup>94</sup> India,<sup>95</sup> Dominican Republic,<sup>96</sup>

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<sup>91</sup> R. Helfer, & J. Alter, “The Influence of the Andean Intellectual Property Regime on Access to Medicines in Latin America, to appear in *Balancing Wealth and Health: Global Administrative Law and the Battle over Intellectual Property and Access to Medicine in Latin America*”, Duke Law’s Scholarship Repository, 8 (2013).

<sup>92</sup> Supra note 18, at 35.

<sup>93</sup> Supreme Court of Thailand, case No. 7119/2552.

<sup>94</sup> Pakistan Patent Ordinance 2000, Art. 10(2).

Uruguay,<sup>97</sup> Philippines,<sup>98</sup> Mexico,<sup>99</sup> Oman Andean pact<sup>100</sup> (Bolivia, Colombia, Ecuador, and Peru) are part of developing countries' group with oppositional domestic laws. Some developing countries like Malaysia,<sup>101</sup> China,<sup>102</sup> South Africa,<sup>103</sup> pact GCC<sup>104</sup> have domestic laws just for second medical indications through Swiss-type claims and in some countries, like Chili<sup>105</sup> and Ukraine,<sup>106</sup> laws cover all claimed new uses (medical and non-medicals.)<sup>107</sup> The vast majority of developed countries recourse Swiss-type claim for protecting second medical indications and

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<sup>95</sup> The Indian Patent (Amendment) Act 2005, Sec. 3(d).

<sup>96</sup> Industrial Property Law of the Dominican Republic, Art. 2 (i).

<sup>97</sup> Regulating Right and Obligations Relating to Patents, Utility Models and Industrial Designs. 1999, Art. 15.

<sup>98</sup> Philippines Intellectual Property Code, Republic Act (R.A.) No 8293, as amended by RA No. 9502 , Part II, Chapter I, Sec. 21,(2008). Although through the Swiss-type claim the second/further medical indications are patentable; *see supra* note 27.

<sup>99</sup> Mexican Industrial Property Law (IPL), Art. 19 VIII, 1991, (Mex.).

<sup>100</sup> Industrial Property Rights and their Enforcement for the Sultanate of Oman, Royal Decree No. 67/2008, Part I, Sec. 2, 1(d). .Although it does not exclude new uses which satisfy the requirements of patent based on Sec. 1 of that statute.

<sup>101</sup> Malaysian Patent Act 1983, as amended up to Act No. A1264, 2006, Sec. 14(4).

<sup>102</sup> *See supra* note 29.

<sup>103</sup> Patent Act of Republic of South Africa 58 of 1978 as amended, 2002, Sec. 25.

<sup>104</sup> GCC Patent Office, patent No. GC 0001215, claim 27.

<sup>105</sup> Law No. 19.996 revising Law No. 19.039 on Industrial Property, 2005, Art. 37(e). In the Chilean's jurisdiction the new use patent is primarily not protectable unless it fulfills some special requirements *i.e.* solving a technical problem with no prior equivalent solution and the claimed subject matter physically be changed to achieve this solution.

<sup>106</sup> Resolution of the Ministry of Education and Science No. 223, April 14, 2005.

<sup>107</sup> The UK CIPR report specifically concerning pharmaceuticals and TRIPS flexibilities commented that “most developing countries should as a minimum take up the possibility allowed by TRIPS of excluding diagnostic, therapeutic and surgical methods for treatments of humans or animals from patentability, as well as new uses of known products (which, in essence, are equivalent to therapeutic methods). Since most developing countries are not in a position to develop such methods, they will have nothing to gain by not exploiting this flexibility”. Commission on Intellectual Property Rights ( CIPR), “Integrating Intellectual Property Rights and Development Policy” 49 (London, 2002). Available in : [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm). (Accessed on May. 6 2014).

some of them, like United States and Canada,<sup>108</sup> have identified legal protection for both of medical and non-medical new uses.

In the countries with silent domestic laws the factor that causes uncertainty is how they treat new uses, whether legally the “process” includes “uses,”<sup>109</sup> or more basically, whether “uses” are protectable subject-matters or not. Although, the common point of view for sanctioning the protection of new uses in opponent countries is absence of novelty.<sup>110</sup> In fact, despite of reasons like lack of novelty, inventiveness and industrial application which can be applied for treating some cases of new uses, it could be argued that this application could give rise to a non-comprehensive approach that does not account for all probable and potential cases that have been intended for prohibition. Similarly, in jurisdictions with proponent stances the plain protective laws without clear criterion for protecting new uses can place them in the same situation that may cause arbitrary results in extending the scope of protection beyond those jurisdictions’ legislative intent. By way of example, in the medical realm, presuming protectability of therapeutic methods where the claimed subject-matter is a new medical use that has been obtained by means of changing a specific dosage regimen, (Same dosage, for known medicament e.g. every 12 hours) the prime object that must be examined prior to the novelty, inventive step and industrial application is legal conformity between applicant’s chosen framework for claimed subject-matter and requirements of requested type of patent within relevant jurisdiction. In other words, when presented with a new use application, the first stage that the examiner in determining patentability has to consider is protect-ability of formulation

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<sup>108</sup> *Shell oil Co. v. commissioner of patent*, [1982] 2 S.C.R. 536, 67 C.P.R. (2d) 1 [cited to C.P.R.].

<sup>109</sup> *Supra* note at 26.

<sup>110</sup> The Pakistan’s law which states lack of industrial application as the reason for non-patentability of new uses is an exemption to that. *See* Pakistan Patent Ordinance 2000, Art. 10(2).

posed by the claim. In that case, the plain protection toward new uses without delineating the elements which legally constitute a “Process/Use invention” will amount to ambiguity in determining whether changing a schedule of doses of a therapeutic agent per unit of time as heuristics could constitute a protectable invention which is differentiable from an abstract idea. Similarly, plain opposition or opposition founded on the lack of each foregoing triple prerequisites does not determine whether a dosage regimen as a new use for old medical product is protectable subject-matter. Because the prime question here is not whether the dosage regimen is novel, inventive and industrially applicable, rather logically it is whether the claimed dosage regimen has met the “use/process” patent's legal essentials or not. When that conformity has been proven, examining for other requirements like novelty should be done at the next level of examination and in relation to the prior uses/processes included in respective prior art; not in association to the product which has claimed a new use. Therefore, when the conformity of chosen frame for claimed new use is done, the first phase of examination is accomplished, and examining the novelty and other requirements as second phase of examining the subject matter as what is independent from former inventions what it derives from will be begun.

In comparison to the EPO's experiences, the TBA's bewilderment regarding extension of Art. 52(5) in *Dosage regime/ABBOTT RESPIRATORY* toward meaning of “specific use” in relevant prior art is an example of plain protection that does not clearly specify the borders of protectable new uses. The TBA, in need of clarification, asked the EBA to determine the protectability of a claim that was directed to a novel and inventive method of therapeutic treatment (in that case specific dosage regimen) via using the same medicament which was known treating the same illness. In spite of the EBA's final positive response, which reasoned that Art. 52(5) requirement of “specific use” does not exclude using the same drug treating the same illness,

acknowledged “[I]t does not define any degree of distinctiveness the new use would be required to have in order to qualify as a specific use within the meaning of that article.”<sup>111</sup>

At this level, the legislature of United States has adapted the nearest approach to our point of view stating: “The term “process” . . . includes a new use of a known process, machine, manufacture, composition of matter, or material.”<sup>112</sup> In other words, if the new uses for known process, machine, manufacture, composition of matter, or material is not posed as “process” then it should not be considered protectable subject-matter.<sup>113</sup> This is what the United States Patent and Trademark Office's (USPTO) Manuel of Patent Examining Procedure (MPEP) categorizes as a separate subset for “process patent” with special requirements as “process of use patent.”<sup>114</sup>

Within precedent, this language could be traced back to the opinion of Privy Council in *Boulton v. Bull*,<sup>115</sup> wherein an inventor (David Hartley) had claimed using iron plates for securing buildings against fire. The Lord Eyre, C.J. said: “When the effect produced is no substance or composition of thing, the patent can only be for the mechanism, if new mechanism is used, or for the process, if it be a new method of operating, with or without old mechanism, by which the new effect is produced.”. While the Federal Circuit in *Atlas Powder Co. v. Ireco Inc.*<sup>116</sup> held that: “[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old

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<sup>111</sup> *Supra* note 66, at para. 5.9.1.

<sup>112</sup> 35 U.S.C. § 100 (b) (2007).

<sup>113</sup> *See Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, 676 (1972), at 787-788. *See also* *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).

<sup>114</sup> United States Patent and Trademark Office (USPTO), Manuel of Patent Examining Procedure (MPEP), Chapter 2100, Sec. 2112.02. Available in <http://www.uspto.gov/web/offices/pac/mpep/s2112.html>. Accessed on ( 5 Mar. 2014).

<sup>115</sup> *Boulton v. Bull*, 2 H. Bl. 463, 494 (1795).

<sup>116</sup> *Atlas Powder Co. v. Ireco Inc.* 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999).



*composition patentably new to the discoverer.*” On the other hand, in *In re Hack*<sup>117</sup> the Court of Customs and Patent Appeals ruled: “[I]t is obvious that such use can be nothing other than a method or process. As a matter of claim drafting, therefore, the discoverer of a new use must protect his discovery by means of process or method claims and not product claims.”

Therefore, claiming a new use, new function or unknown property which is inherently present in the prior art, does not necessarily make the claim patentable<sup>118</sup> unless it shows a “useful, concrete, and tangible” result<sup>119</sup> which is claimed in “process of using” format. However, when a claim cites the use of an old composition or structure and the “use” is directed to a result or property of that composition or structure, then the claim is *anticipated*.<sup>120</sup> In this regard, it is worth mentioning that it is unclear of how many of intellectual creative steps is required to be constitute a “process” within meaning of “process of use”. Nonetheless, it is uncontested that, through ordinary meaning, there must be a *series of steps taken* to introduce a special way to use the subject-matter to cause a result which be useful, non-obvious to a person who have ordinary skill in relevant art, and novel as to not be *anticipated* by other processes.<sup>121</sup>

## V. Conclusion

The purpose of this research was to provide a comparative study of the legal status of new use patents at international, regional and national levels, based on current and historical legal facts by questioning their appropriate treatments in hopes of arriving at a conclusion that posits that new uses, like other kinds of inventions, must involve the element of “*creativity*” as

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<sup>117</sup> *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957).

<sup>118</sup> *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

<sup>119</sup> *State Street Bank & Trust Co v. Signature Financial Group, Inc.*, 149 F. 3d 1368, 1373.

<sup>120</sup> *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978).

<sup>121</sup> Hansen & Hirsch “Protecting inventions in chemistry. Commentary on chemical case law under the European Patent Convention and the German Patent Law”, 120 (Wiley-VCH, Weinheim 1997).

the main core of contrivances. Proving the act of “creation” for new uses as key point in providing patent protection depends on applying an appropriate legal frame of patents. The essentials of customary patent law, quiddity of new uses, avoiding admixture with concept of “discovery” and the experiences of proponent jurisdictions are meant to address that the most appropriate legal format is applying the format of “*process*” proposing the new uses as an independent and patentable invention. Accordingly, providing a comprehensive approach which could cover all probable new use cases, not only for proponents but also for opponents, requires *adjusting* the legal definition of “process” to include “process of use” and “method of use” through *specifying* its constitutional elements. Hence, for the purpose of excluding the new uses, the opponent jurisdictions should define the term “process” *narrowly* and *full-conditionally* as far as it does not include the “uses”. In contrast, the proponents should define “process” as broad as to include the “uses” (e.g. one step processes) as far as they are intended; i.e. by *solidifying* or *softening* the terms of constitution.

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