

# TULANE JOURNAL OF TECHNOLOGY AND INTELLECTUAL PROPERTY

---

---

VOL. 3

SPRING 2001

---

---

## Public Health and Patent Legislation in Developing Countries\*

Carlos M. Correa<sup>†</sup>

I.	INTRODUCTION .....	2
II.	PATENTABLE SUBJECT MATTER.....	8
	A. <i>Products</i> .....	8
	B. <i>Substances Existing in Nature</i> .....	11
	C. <i>Uses</i> .....	14
	1. <i>First Indication</i> .....	14
	2. <i>Second Indication</i> .....	15
	D. <i>Methods for Treatment and Diagnostics</i> .....	16
	E. <i>Traditional Medicines</i> .....	17
III.	SCOPE OF CLAIMS.....	18
IV.	PATENTABILITY REQUIREMENTS .....	21
	A. <i>Novelty</i> .....	24
	B. <i>Inventive Step</i> .....	25
	C. <i>Industrial Applicability</i> .....	27
V.	SPECIAL CASES IN PHARMACEUTICALS .....	28
	A. <i>Selection Patents</i> .....	28
	B. <i>Prior Public Availability</i> .....	29

---

\* This Article presents a shortened version of a study prepared with the support of the Rockefeller Foundation. Earlier drafts of the study were reviewed and commented by: J.H. Reichman (Vanderbilt University, U.S.A.), Trevor Cook (United Kingdom), B.K. Keayla (India), & Ian Roberts (South Africa). Comments on the paper were also made by R. Kaukab (South Centre), S. Zarrilli (UNCTAD), B.L. Das (India), James Love (Consumer Project on Technology, Washington, D.C.), Bas van der Heide (Health Action International), Jayashree Watal (Institute of International Economics, Washington, D.C.), Joan Archer (UNDP), Sakiko Fukuda-Parr (UNDP), Richard O. Laing (Boston University School of Public Health), Frederick M. Abbott (University of California at Berkeley), and German Velasquez (WHO). The author is thankful for those comments but is solely responsible for the content of this Article.

<sup>†</sup> Director of the Centro Interdisciplinario de Estudios de Derecho Industrial y Economico (CEIDIE) of the University of Buenos Aires.

C. Polymorphism .....	29
D. Analogy Processes .....	30
E. Compositions .....	30
F. Optical Isomers .....	31
G. Active Metabolites .....	32
H. Prodrugs .....	32
VI. DISCLOSURE .....	32
VII. EXCEPTIONS TO EXCLUSIVE RIGHTS.....	34
A. Experimental Use.....	35
B. Early Working.....	36
C. Parallel Imports .....	37
D. Individual Prescriptions.....	41
VIII. CLAIMS INTERPRETATION.....	42
IX. COMPULSORY LICENSING.....	43
A. Grounds for Granting Compulsory Licenses.....	43
B. Imports/Exports.....	48
C. Registration .....	49
X. FINAL REMARKS.....	52

## I. INTRODUCTION

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) requires all World Trade Organization (WTO) member countries to adapt their laws to the minimum standards set forth by TRIPs, within established transitional periods. Conforming with TRIPs by recognizing or strengthening the protection of pharmaceutical products and processes through intellectual property rights (IPRs) has posed a special challenge for developing countries. The way in which the required legislative reform is made may have a significant impact on public health policies, and particularly on the population's access to drugs.

The basic premises of this Article are that, within the limits imposed by international obligations, notably the TRIPs Agreement<sup>1</sup>

---

1. See Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, RESULTS OF THE URUGUAY ROUND (1994) [hereinafter TRIPs Agreement]. For a general analysis of TRIPs and of the timing of its implementation under the specified transitional periods, see UNCTAD, *The TRIPs Agreement and Developing Countries*, New York and Geneva (1996); INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPs AGREEMENT (Carlos M. Correa & Abdulgawi Yusuf eds., Kluwer L. Int'l 1998); German Velásquez & Pascale Boulet, *Globalization and Access to Drugs: Perspectives on the WTO/TRIPs Agreement*, World Health Organization Action Programme on Essential Drugs, Health Economics and Drugs DAP Series, No.7, WHO/DAP/98.9 (1999); CARLOS CORREA,

of the WTO, developing country patent laws should be: (1) designed to serve the interests of all groups in the society and (2) responsive to health policy objectives and, in particular, to the needs of the poor.

There is broad recognition of the role that patents and IPRs can play in stimulating health-related research and development (R&D), especially in more advanced countries. Specifically, patents are considered important given the high costs and risks of R&D and the fact that this R&D may lead to inventions with potential utility to all countries.<sup>2</sup> It is also recognized that the level of protection conferred to inventions may influence foreign investment, technology transfer, and research (especially joint research programs and research to address local needs).<sup>3</sup> Patents work by providing government-sanctioned, limited-term monopolies as an incentive and reward for useful inventions.

But there are price and competition costs to IPRs. In the health sector, where denial of affordable access to treatment or pharmaceuticals can have life-or-death consequences, the conditions, including price, that determine access to medicines are critical matters, especially for the low-income segments of the population. While recognizing that IPRs are not the only relevant factor, it seems clear that the way in which IPRs are established and enforced may have a significant impact on the access to medicines; any IPR system must therefore strike a balance between creating incentives for innovation and protecting consumers' interest in the availability and access to the protected goods.

The TRIPs Agreement has introduced a new and important international framework for IPRs, which in turn has important implications for the health sector.<sup>4</sup> TRIPs sets forth detailed obligations in respect to the protection of inventions, including:

---

INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPs AGREEMENT AND POLICY OPTIONS (Zed Books Ltd. 2000).

2. On the little attention paid, however, in pharmaceutical R&D to the specific needs of developing countries, see, for example, ROBERT BEAGLEHOLE & RUTH BONITA, PUBLIC HEALTH AT THE CROSSROADS: ACHIEVEMENTS AND PROSPECTS 220 (Cambridge Univ. Press 1997); Jeffrey Sachs, *Helping the World's Poorest*, ECONOMIST, Aug. 14, 1999; ZAFRULLAH CHOWDHURY, THE POLITICS OF ESSENTIAL DRUGS: THE MAKINGS OF A SUCCESSFUL HEALTH STRATEGY: LESSONS FROM BANGLADESH (Zed Books Ltd. 1995).

3. The theoretical work and empirical evidence on such influence are, however, controversial and inconclusive. See UNITED NATIONS, INTELLECTUAL PROPERTY RIGHTS AND FOREIGN DIRECT INVESTMENT (New York 1993); Keith Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 DUKE J. COMP. & INT'L L. 109 (1998).

4. See H. Bale, *Uruguay Round Negotiations on Intellectual Property: A Step Forward?*, Third Annual Conference on International Trade, Washington College of Law of the American University, Oct. 3, 1991; Velásquez & Boulet, *supra* note 1.

(1) to recognize patents for inventions in all fields of technology, with limited exceptions; (2) not to discriminate with respect to the availability or enjoyment of patent rights; (3) to grant patents rights for at least twenty years from the date of application; (4) to limit the scope of exceptions to patent rights and to grant compulsory licenses only under certain conditions; and (5) to effectively enforce patent rights.<sup>5</sup>

The TRIPs Agreement, however, does not establish a uniform international law nor does it establish uniform legal requirements. WTO member countries are obligated to comply with the minimum standards of TRIPs, but they also have considerable room to develop their own patent and other intellectual property laws in response to their own legal systems and developmental needs. In implementing the TRIPs provisions, WTO member countries may legitimately adopt regulations that ensure a balance between the minimum standards of IPR protection and the public good. Moreover, they can adopt measures which are conducive to social and economic welfare, such as those necessary to protect public health, nutrition, and the public interest in sectors of vital importance for their socio-economic and technological development.<sup>6</sup> Countries can also adopt measures to prevent the abuse of intellectual property rights.<sup>7</sup>

It should be borne in mind that in the case of the countries that are bound to introduce patent protection for pharmaceuticals as a result of TRIPs, patents will only be available for products for which a patent application was filed after January 1, 1995. This means that other products, including those already applied for or patented in other countries, or commercialized before that date, will remain in the public domain, unless the national law admits (as in the case of Brazil) the retroactive protection of the so-called “pipeline” products.

Given diverse national objectives, it is not surprising that different countries’ patent systems diverge, in some cases significantly. There is no single “patent system.”<sup>8</sup> Moreover, the

---

5. See Stefano Sandri, *La Nuova Disciplina Della Proprietà Industriale Dopo I, in* GATT-TRIPs (Cedam 1996); Correa & Yusuf, *supra* note 1.

6. See TRIPs Agreement, *supra* note 1, art. 7.

7. See *id.* art. 8.1 & 8.2.

8. Thus, many developed countries in early phases of their development applied legal solutions (e.g., the nonpatentability of pharmaceutical products) more recently adopted by developing countries. See, e.g., EDITH PENROSE, *LA ECONOMÍA DEL SISTEMA INTERNACIONAL DE PATENTES* (Siglo Veintiuno Editores S.A. 1974); Alberto Bercovitz, *Evolución Histórica de la Protección de la Tecnología en los Países Desarrollados y su Relación con la Protección en los Países en Desarrollo*, año 12, *REVISTA DEL DERECHO INDUSTRIAL*, No.35 (1990); PAUL GOLDSTEIN, *COPYRIGHT, PATENT, TRADEMARK AND RELATED STATE DOCTRINES, CASES AND MATERIALS ON THE LAW OF INTELLECTUAL PROPERTY* (3d ed., Foundation Press 1993).

solutions adopted in particular countries have changed over time.<sup>9</sup> In the future, they may evolve further in order to better respond to equity considerations<sup>10</sup> and to the nature of innovation in “cumulative systems technologies.”<sup>11</sup>

Countries treat specific patent issues—including eligibility requirements, scope of protection, exceptions to exclusive rights, and compulsory licenses—in quite different ways. In developing their own IPR rules, policy and law makers in developing countries must recognize that, even within the general framework of international treaties, there is considerable room for devising and implementing their own solutions. Countries will be most successful in meeting their own needs if they are able to draw on the varied experience of national systems worldwide, meaning that a good knowledge of comparative law is valuable.<sup>12</sup>

Some countries—particularly developed countries—have opted for legal systems that confer strong patent rights to protect their technology-based revenue streams and to promote investment in technological innovation. Considerable debate exists in such countries, however, on the level and scope of protection, which are optimal to foster innovation without unduly restricting the free circulation of ideas and stifling competition.<sup>13</sup> A growing concern is voiced in some countries<sup>14</sup> on the shortcomings of the examination process and the proliferation of low quality patents.<sup>15</sup> Moreover, the economics of patent law is still an uncertain area, lacking empirical evidence and a strong theoretical framework.

Countries with less advanced technology may logically prefer to promote the transfer of technologies needed for development, and to preserve and enhance competition in order to secure access to goods, services, and technologies in the most favorable market conditions.

---

9. See, e.g., OVE GRANSTRAND, *THE ECONOMICS AND MANAGEMENT OF INTELLECTUAL PROPERTY TOWARDS INTELLECTUAL CAPITALISM* 17-54 (Edward Elgar, 1999).

10. See Lester Thurow, *Needed: A New System Of Intellectual Property Rights*, HARV. BUS. REV., Sept.-Oct. (1997); Sachs, *supra* note 2.

11. See ROBERT MERGES & RICHARD NELSON, *ON LIMITING OR ENCOURAGING RIVALRY IN TECHNICAL PROGRESS: THE EFFECT OF PATENT-SCOPE DECISIONS, THE SOURCES OF ECONOMIC GROWTH* (Harv. Univ. Press 1996).

12. See A. Samuel Oddi, *TRIPs—Natural Rights and a Polite Form of Economic Imperialism*, 29 VAND. J. TRANSNAT'L L. 415 (1996).

13. See F. Scherer, *Los Objetivos de la Concesión de Patentes*, ICE (Madrid 1981); MERGES & NELSON, *supra* note 11; Thurow, *supra* note 10.

14. See James Gleick, *Patently Absurd*, N.Y. TIMES, Mar. 12, 2000, at 44 (arguing that “the patent system is in crisis . . . . The [U.S.] patent office has grown entangled in philosophical confusion of its own making; it has become a ferocious generator of litigation; and many technologists believe that it has begun to choke the very innovation it was meant to nourish.”).

15. See *infra* Part IV.

Even in countries, which advocate and practice the strongest protection for IPRs, national laws provide for checks and balances to protect against the possible abuse of power conferred by intellectual property protection. The provision for compulsory licenses is one such example.<sup>16</sup>

In designing a national patent system, policy makers should consider cross-cutting issues—such as the protection of the environment<sup>17</sup> and public health, the promotion of competition<sup>18</sup> and technology transfer,<sup>19</sup> the protection of consumers and the support of small local inventors—while respecting inventors' rights to obtain a reward for contributions made to technical progress.

In addition, careful consideration should be given to other regulatory measures affecting public health, such as those relating to the approval and registration of medicines, in order to develop a consistent legal framework that enhances access to required medicines.

The protection of public health is one of the most pressing issues in developing countries. A large part of the world population still lacks access to essential drugs; in the poorest parts of Africa, for instance, over fifty percent of the population lacks access to necessary drugs.<sup>20</sup> An estimated 1.5 billion people are not expected to survive to age sixty, and more than 880 million people lack access to health care.<sup>21</sup> Of the more than 33 million HIV-positive people in the world, ninety-five percent live in developing countries, and most of them cannot afford drugs for treatment.<sup>22</sup> To deal with this dramatic situation, an integrated approach to the interrelated issues of national

---

16. See ALAN GUTTERMAN, *INNOVATION AND COMPETITION POLICY* (Kluwer L. Int'l 1997); INDUSTRY CANADA RESEARCH SERIES, *COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY* (Robert Anderson & Nancy Gallini eds., Univ. of Calgary Press 1998).

17. See *The Proposals for Amendment of the TRIPS Agreement by the Government of India*, submitted to the WTO Committee on Trade and the Environment, (Nov. 12, 1996).

18. See J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COL. L. REV. 2432, 2448-53 (1994) [hereinafter Reichman, *Legal Hybrids*]; J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPs Agreement*, Symposium, 29 N.Y.U. J. INT'L L. & POL. 11 (1997) [hereinafter Reichman, *From Free Riders to Fair Followers*].

19. See Carlos Correa, *Review of the TRIPs Agreement: Fostering the Transfer of Technology to Developing Countries*, 2 J. WORLD INTELL. PROP. 939 (1999).

20. See WORLD HEALTH ORGANIZATION, *THE WORLD DRUG SITUATION* (1988). The great majority of "essential drugs" as identified, for instance, by WHO, are off-patent and the access thereto will not be affected by the implementation of new patent policies. The considerations made in this paper are applicable to drugs, which are, or may be, protected in the future by patents or other IPRs.

21. See UNDP, *HUMAN DEVELOPMENT REPORT* (Oxford Univ. Press 1999).

22. See UNAIDS, *AIDS Epidemic Update* (Dec. 1998).

health policy, pharmaceutical policy, and patent policy is required. None of these policies can be framed or implemented in isolation.

This Article deals with patent issues from the perspective of *public health*. It focuses on issues relating to the *access* to medicines. It therefore concentrates on provisions and mechanisms in patent laws that may increase the *affordability* of medicines, including diagnostics, preventive and curative medicines, rather than those more relevant to the development of new drugs, or the production of pharmaceuticals, though the three issues are often interlinked. The purpose of this Article, however, is not to provide *specific* provisions for health-related inventions, but to suggest more *general* principles and rules instrumental in developing a health-sensitive national patent system.

One reason for this approach is that developing a public health-sensitive patent system requires consideration of many general aspects, such as the criteria for patentability. A second reason is that article 27.1 of TRIPs bans any discrimination, in either the recognition or exercise of patent rights, based on the field of technology. This means that both negative discrimination (e.g., reducing the rights available to pharmaceutical patent holders) and positive discrimination (broadening such rights) may be deemed inconsistent with TRIPs. In the latter case, broadening rights available to holders of pharmaceutical patents could be deemed inconsistent because it could discriminate against patent owners in *other* fields of technology.<sup>23</sup> However, differential treatment does not necessarily mean discriminatory treatment, because different technologies might require different treatment.

A health-sensitive approach could aim to address short-term emergencies to justify several types of temporary measures, such as the supply of medicines in cases of epidemics or catastrophe. In comparison, a health-sensitive approach could be devised as part of an integrated medium or long-term patent policy and strategy. In the latter case, attention should be given to the diversity of interests among developing countries, and to the possibility that countries with greater capacity for industry will want stronger patent rights than countries with less technological capacity. Less developed countries may wish, for instance, to develop a patent system that fosters cooperation with firms from more advanced countries.

---

23. Thus, a panel was requested by Canada against the European Union in the framework of the WTO dispute settlement mechanism, on the grounds that pharmaceutical patents can get an additional term of protection, in Europe, which is not conferred to other fields of technology (except agrochemicals). This request, however, has not been pursued so far.

In some instances, a country may, within the limits permitted by its international obligations, opt for different levels of protection in different areas of intellectual property depending on its respective competitive position and the expected role of national and foreign investors and technology suppliers. It may, for instance, be possible to emphasize protection in the area of information technologies through high levels of copyright protection for computer programs and databases, while recognizing more moderate levels of protection in areas where local industrial and technological capabilities are low and will not be significantly improved if there are high standards of protection for IPRs.

## II. PATENTABLE SUBJECT MATTER

### A. *Products*

When the Uruguay Round of Trade Negotiations for the General Agreement on Tariffs and Trade (GATT) was launched, more than fifty countries, including some developed countries, did not confer patent protection on pharmaceuticals.<sup>24</sup> While some regarded this absence of protection as necessary to promote access to drugs at competitive prices,<sup>25</sup> others criticized it as jeopardizing innovation and unfairly depriving inventors of the benefits generated by their contributions.<sup>26</sup>

Article 27.1 of TRIPs obliges all WTO members to recognize patents in all fields of technology.<sup>27</sup> When in force, this obligation will eliminate different patent policy approaches that previously existed.

---

24. See UNCTAD, *supra* note 1.

25. The specific implications of the patent system and, particularly, of the introduction of product patents in developing countries in the pharmaceutical field has been extensively discussed. See Julio Nogués, *Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries*, 24 J. WORLD TRADE 81 (1990); HEINZ REDWOOD, *NEW HORIZONS IN INDIA: THE CONSEQUENCES OF PHARMACEUTICAL PATENT PROTECTION* (Oldwicks Press 1994); Richard Rozek, *The Consequences of Pharmaceutical Product Patenting: A Critique*, 16 WORLD COMPETITION—LAW & ECONS. REV. 91 (1993); A. Subramanian, *Trade-Related Intellectual Property Rights and Asian Developing Countries: An Analytical View*, presented at the Conference on Emerging Global Trading Environment and Developing Asia, Manila, Philippines (May 1995); UNCTAD, *supra* note 1.

26. See Richard Rapp & Richard Rozek, *Benefits and Cost of Intellectual Property Protection in Developing Countries*, 25, No. 5, J. OF WORLD TRADE (1990).

27. According to article 27.1 of TRIPs, "patents shall be available for any inventions, whether products or processes, in all fields of technology." See Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, in FROM GATT TO TRIPs: THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS, 18 IIC Studies (F.K. Beier & G. Schrickler eds., VCH 1996).



Literally interpreted, article 27.1 of TRIPs does not permit the exclusion from patentability of medicines in general or, arguably, of specific groups thereof. Under this interpretation, WTO members could not exclude from patentability even the “essential medicines” listed by the World Health Organization (WHO).<sup>28</sup>

There are two areas in TRIPs under which pharmaceuticals might conceivably be excluded from patentability, but neither appear sufficient to justify such an exclusion, except in limited circumstances.

The first exception is *ordre public*, which is one of the recognized grounds for exceptions from patentability under TRIPs article 27.2. There is no universally accepted notion of *ordre public*,<sup>29</sup> leaving member countries some flexibility to define which situations are covered, depending upon their own social and cultural values. Article 27.2 itself indicates that the concept is not limited to “security” reasons; it also relates to the protection of “human, animal or plant life or health” and may be applied to inventions that may lead to “serious prejudice to the environment.”

Article 27.2 indicates that nonpatentability on grounds of *ordre public* is permissible if necessary to prevent commercial exploitation. In other words, it may not be possible to declare the nonpatentability of a certain subject matter while permitting at the same time its distribution or sale.<sup>30</sup>

However, the situation might be different if developing countries collectively decided to prohibit or suspend the patentability of certain pharmaceutical products on grounds of *ordre public*. Such a decision could produce a new “state practice” that WTO panels would have to

---

28. Currently Decision 344 of the Andean Group provides for such exception. Venezuela has submitted a proposal to review TRIPs in a possible future WTO Round in order to specifically allow for that exclusion. See WTO doc. WT/GC/W/282 (Aug. 6, 1999). However, it has been noted that most of the drugs in the WHO Essential Medicines List are off-patent, and that the list does not include high-priced drugs. Given the methodology applied for establishing that list, the nonpatentability of such drugs may not be a significant issue for developing countries. See MSF (Médecins Sans Frontières), HAI (Health Action International), and CPT (Consumer Project on Technology), *Open letter to the WTO Member Countries on TRIPs and Access to Health Care Technology*, Geneva, Nov. 12, 1999.

29. For instance, under the Guidelines for Examination of the European Patent Office *ordre public* is linked to security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behavior. See Guidelines for Examination, Part C, ch. IV, 3.1. Traditionally, *ordre public* in U.S. law referred to an invention that was “frivolous or injurious to the well-being, good policy, or sound morals of a society.” See DONALD S. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW 2.5 (1992). In the United States, “the trend is to restrict this subjective public policy approach to utility.” *Id.*

30. See Dan Leskien & Michael Flitner, *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System*, 6 IPGRI, ISSUES IN GENETIC RESOURCES (1997).

consider. If the grounds of such a decision were sufficiently compelling to warrant at least a temporary expansion of the *ordre public* exception beyond its traditional moorings, then it could also conceivably warrant an exception to the “non-commercial exploitation” rule contained in article 27.2, if such products were distributed on a not-for-profit basis. These matters are inherently speculative and to some extent contingent upon the still-to-be-determined meaning of the safeguard provisions set out in articles 7 and 8 of TRIPs.

A second exception that might authorize exclusion of pharmaceuticals from patentability is article 8.1 of TRIPs, which explicitly recognizes the right of WTO members to adopt policies in accordance with public health concerns. However, the adopted policies are subject to a test of “necessity” and of consistency with other obligations under TRIPs.

The “consistency” requirement may permit patentability exclusions in cases of distinct public health emergencies as defined by the national government, and as distinct from ordinary or everyday health and nutrition measures. Emergency cases could trigger the application of a different test of “inconsistency,”<sup>31</sup> or qualify as a situation not “conducive to social and economic welfare.”<sup>32</sup> In such a case, a suspension or exclusion from patentability might be linked to, and justified by, a specific emergency. Once the emergency subsides, the TRIPs requirement of patentability could be restored.

A key consideration is the purpose for which any subject matter exclusion is to be adopted. If, for example, the same objective could be obtained by imposing permissible compulsory licenses under article 31 of TRIPs, an exclusion of patentability could be seen as merely an attempt to circumvent the preconditions of article 31. However, if local situations posed such unusual problems as to merit a public interest exception, then these problems might also justify overriding or limiting other articles, such as article 31, in favor of some nonpermanent exclusion of subject matter, if that exclusion was necessary to solving the problem.

An issue that may merit further exploration is whether an exception to patentability may be justified under the general GATT exception to trade disciplines, article XX(b), when the exception is necessary to protect public health.<sup>33</sup> This article recognizes the

---

31. See TRIPs Agreement, *supra* note 1, art. 8.1.

32. See *id.* art. 7.

33. See General Agreement on Tariffs and Trade, Oct. 30, 1947, art. XX(b) [hereinafter GATT].

importance of sovereign nations being able to promote domestic health interests, even if contrary to their general obligations under the WTO agreements.<sup>34</sup> However, currently, article XX(b) has been interpreted and applied rather narrowly in GATT/WTO case law,<sup>35</sup> and it is doubtful whether GATT article XX(b) would apply in the TRIPs context. In the view of a panel, TRIPs has a relatively self-contained, *sui generis* status within the WTO, even though “it is an integral part of the WTO system, which itself builds upon the experience of over nearly half a century”<sup>36</sup> under GATT.

In sum, under the current TRIPs Agreement, a straightforward exclusion from patentability of pharmaceuticals, even the category of essential medicines, does not seem to be a viable option. The admissibility of exceptions based on *ordre public* will depend on the interpretation of both article 27.2 and articles 7 and 8, but it does not seem a promising basis for exclusion from patentability.<sup>37</sup> Exclusions to meet specific public health emergencies, especially if limited in time, might be justifiable if they are a necessary part of an overall strategy for addressing the emergency.

#### B. Substances Existing in Nature

Some pharmaceutical products are based on, or consist of, biological materials. These include compounds extracted from plants and algae as well as human proteins<sup>38</sup> obtained by extraction, or

---

Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: . . . (b) necessary to protect human, animal or plant life or health.

*Id.*

34. See JOHN JACKSON, *THE WORLD TRADING SYSTEM: LAW AND POLICY OF INTERNATIONAL ECONOMIC RELATIONS* 233 (2d ed. 1999).

35. See ERNST-ULRICH PETERSMANN, *THE GATT/WTO DISPUTE SETTLEMENT SYSTEM: INTERNATIONAL LAW, INTERNATIONAL ORGANIZATIONS AND DISPUTE SETTLEMENT* (Kluwer L. Int'l 1997); MICHAEL TREBILCOCK & ROBERT HOWSE, *THE REGULATION OF INTERNATIONAL LAW* 135-65 (2d ed. Routledge 1999) (1995).

36. See the Panel Report on *United States v. India—Patent Protection for Agricultural and Chemical Products*, WT/DS50/R, adopted on Jan. 16, 1998, para. 7.19.

37. It should also be noted that in many cases it may be difficult or impossible to anticipate *ordre public* considerations at the time of examination of an application, since such considerations may arise after the patent is granted (or the product is commercialized). In these cases, the granting of a compulsory license would be a logical option. See *infra* Part X.

38. For instance, a patent claim relating to a protein isolated from nature reads as follows: Homogeneous Erythropoietin Characterized By a Molecular Weight of About 34,000 Dalton on SDS PAGE, Movement as a Single Peak on Reverse Phase High Performance Liquid

through genetic engineering techniques (e.g., interferon, erythropoietin, and growth hormone). Plants, in particular, are an indispensable source of medicines.<sup>39</sup>

Whether biological materials are patentable depends in significant part on whether they are characterized as “inventions” (and therefore patentable) or “discoveries” (not patentable). Different patent law traditions treat this question differently.

If the philosophy underpinning patent law is that broad protection can foster inventive activity, then biological materials exceptions may seem unnecessary, or even counterproductive. Moreover, some developing countries may worry that excluding substances found in nature from patentability could conceivably hinder investment in some local activities, including activities that might otherwise lead to patents on products derived from traditional knowledge or specific local skill or expertise. The extent of any such disincentive, however, would depend on local industrial capabilities and on the existence of laws providing alternative forms of protection, including utility model laws or proposed laws to protect nonsecret expertise.<sup>40</sup>

Countries with scarce local research capabilities and countries prioritizing medicine affordability and access may prefer a different approach, choosing instead to place limitations on the patentability of substances existing in nature. Countries which deem patentability of such substances as contrary to basic cultural and ethical values<sup>41</sup> may similarly seek to limit the patentability of biological materials. The ability to do so will be limited, however, by TRIPs provisions, which require the patentability of microorganisms and of nonbiological and microbiological processes for the production of plants and animals.<sup>42</sup>

National laws vary considerably in characterizing biological materials as inventions or discoveries. In some jurisdictions, such as the United States, an isolated or purified form of a natural product, including genes,<sup>43</sup> is patentable.<sup>44</sup> The European Directive on

---

Chromatography and a Specific Activity of at Least 160,000 IU Per Absorbance Unit at 280 Nanometers. See U.S. Patent No. 4,677,195 (June 30, 1987).

39. See John Lambert, Jitendra Srivastava & Noel Viemeyer, *Medicinal Plants: Recuing a Global Heritage*, World Bank Technical Paper No.355, at 1 (Washington D.C. 1997).

40. See Reichman, *From Free Riders to Fair Followers*, *supra* note 18.

41. See Proposal for Review of Article 27.3.b of the TRIPs Agreement, submitted by Kenya on behalf of the African countries, (proposed Aug. 6, 1999).

42. See TRIPs Agreement, *supra* note 1, art. 27.3.b.

43. For example, a U.S. patent obtained by Amgen reads: “A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.”

44. See S.R. BENT, D. SCHWAB, CONLIN & D. JEFFREY, *INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE* 123 (Stockton Press 1991); PHILIP GRUBB, *PATENTS FOR*

Biotechnological Inventions<sup>45</sup> adopts a similar approach. The Directive, essentially a declaration of long standing law throughout much of Europe, establishes that “biological material” and substances isolated from nature, including new antibiotics, will be considered patentable.<sup>46</sup>

In many jurisdictions, gene patenting has become common practice. Claims often include natural DNA sequences without limitations.<sup>47</sup> The only condition on these patents is that genetic materials must be claimed in a nonnaturally-occurring form, that is, as an isolated or purified molecule. In the United States, for example, the *Re Deuel* doctrine<sup>48</sup> has paved the way for the patenting of DNA even when encoding known proteins on the grounds that—due to the degeneracy of the genetic code—their structure could not have been predicted. However, the principle set out in *Re Deuel* does not apply in Europe. Gene sequences, which code for a known protein, are generally now regarded as prima facie obvious, although such was not the case in the earliest days of molecular biology.

TRIPs does not define what an “invention” is; it only specifies the *requirements* that an invention should meet in order to be patentable. This leaves member countries considerable freedom to determine what should be deemed an invention, and to exclude from patentability any substance, which exists in nature.<sup>49</sup> In particular, DNA molecules may be regarded as building blocks of nature, which should be free for use by the scientific community and for any productive application.

---

CHEMICALS, PHARMACEUTICALS AND BIOTECHNOLOGY: FUNDAMENTALS OF GLOBAL LAW, PRACTICE AND STRATEGY 213 (Clarendon Press 1999). However, the extent of patentability of biological materials in the United States has not yet been addressed, by the U.S. Supreme Court.

45. See No. 96/9/EC (Mar. 11, 1996). “Biological material which is isolated from its natural environment or processed by means of a technical process may be the subject of an invention even if it already occurred in nature.” *Id.*

46. See GRUBB, *supra* note 44, at 213; see also Giuseppe Sena, *Directive on Biotechnological Inventions: Patentability of Discoveries*, 30 INT’L REV. INDUS. PROP. & COPYRIGHT L. 731, 736-38 (1999) (suggesting the use of compulsory licenses to remedy the possible negative effects on subsequent research that may result from the extension of patentability to simply isolated materials).

47. Patenting may relate to genomic DNA, a natural substance, or cDNA, that is, a DNA copy of mRNA that does not exist as such in nature. The U.S. Court of Appeals for the Federal Circuit has affirmed the validity of claims to full length DNA or genomic DNA molecules in the pharmaceutical field.

48. *In re Deuel*, 51 F.3d 1552 (Fed. Cir. Mar. 28, 1995).

49. TRIPs obliges member states to protect microorganisms but nothing in TRIPs can be interpreted as requiring the patentability of microorganisms found in nature and not “invented,” for instance, by alteration through genetic engineering.

### C. Uses

Pharmaceutical patents rarely relate to new chemical entities, that is, active ingredients that represent a fresh contribution to the stock of products available for medicinal use. Most pharmaceutical patents protect processes of manufacture, formulations, systems of delivery, and new *uses* of a known product.<sup>50</sup>

A “use” claim may be either a *product* claim or a *process* claim. In Europe, *first medical indications* have been dealt with as product claims, whereas *second medical indications* are treated as a process claim.

#### 1. First Indication

An important patent issue in the health sector arises when a new therapeutic use is found for a known product, which had no previous pharmaceutical use. Because patents protect inventions but not discoveries, the discovery of a new purpose for a product cannot render a known product patentable under general principles of patent law.<sup>51</sup> Therefore, the patentability of the *product as such* would be rejected.

Some jurisdictions, however, have adopted special rules for the protection of the *first indication* of a known product, expanding the scope of protection beyond its ordinary boundaries. In Europe, for example, a legal fiction allows the patentability of a known product for such an indication.<sup>52</sup> Under article 54(5) of the European Patent Convention, the identification of the first medical indication of a known product may suffice to obtain a patent on the product.<sup>53</sup> The United States, by contrast, has adopted a more restrictive approach,

---

50. See N. Zaveri, *Patents for Medicine: Balanced Patent Law—The Need of the Hour*, Indian Drug Manufacturers' Association 71 (1998).

51. Unless in connection with the new purpose the product is forced to be present in an amended new form. See BERND HANSEN & FRITJOFF HIRSCH, *PROTECTING INVENTIONS IN CHEMISTRY: COMMENTARY ON CHEMICAL CASE LAW UNDER THE EUROPEAN PATENT CONVENTION AND THE GERMAN PATENT LAW* 104 (VCH 1997).

52. See Werner Stieger, *Article 54(5) of the Munich Patent Convention: An Exception for Pharmaceuticals*, 13 INT'L REV. INDUS. PROP. & COPYRIGHT L. 137 (1982).

53. The European Patent Office Technical Board of Appeal has ruled that such claims should be deemed as covering all therapeutical uses of the product like in the case of claims on a pharmaceutical composition. Infringement of such claims would only take place when the product is commercialized for direct therapeutical use, and not in bulk. See GRUBB, *supra* note 44, at 218. The approach of granting patents for first medical indication of a known product may be deemed discriminatory vis-à-vis other sectors, although it may be justified as a limitation to the exclusion of the patentability of therapeutical methods. See *infra* Part II.

confining patents on uses to a particular “method-of-use.” Such method-of-use patents do not encompass protection of the product.<sup>54</sup>

Under TRIPs, countries are free to expand patent protection beyond the general principles of patent law, but they are under no obligation to do so. WTO member countries can decide whether or not to allow the patentability of products for *first indication*.

Countries concerned about “bio-piracy” may wish to exclude the patentability of the use of known products in order to prevent the appropriation under patent rights of biological products.

## 2. Second Indication

In some cases, a new use is discovered for a product that already has an existing pharmaceutical use.<sup>55</sup> Many national laws treat the new use as a *process* patent claim of one of two kinds: “use” claims, such as “the use of X as an antihistaminic,” or claims on one or more actual process steps.<sup>56</sup> The patenting of use inventions depends on whether the purpose of the use is novel and nonobvious. Method inventions may be judged independently of their purpose. Even if intended for a novel purpose, the key consideration in determining the patentability of a method invention is whether it could be anticipated by other methods.<sup>57</sup>

Patent applications on the second medical indication of a known product are usually written as instructions to the physician on how to employ a certain composition to treat a particular disease. Such applications are accepted in some countries. The European Patent Office (EPO) began granting such applications, when framed under the “Swiss formula,” in 1984.<sup>58</sup>

However, countries may deem an “invention” consisting of the second use of a substance nonpatentable, because it fails to satisfy various traditional patent requirements: it is a “discovery,” it does not meet the requirement of industrial applicability, or it is equivalent to a method of therapeutic treatment (when such methods are deemed nonpatentable).<sup>59</sup> The Swiss formula suffers from “the logical objection that it lacks novelty, since it claims the use of the compound

---

54. See ROBERT P. MERGES, PATENT LAW AND POLICY: CASES AND MATERIALS 489 (Michie 1992).

55. This was the case, for instance, of nimodipine, a known cardiovascular agent for which an application to cerebral disorders was found.

56. See GRUBB, *supra* note 44, at 208.

57. See HANSEN & HIRSCH, *supra* note 51, at 120.

58. The Swiss formula is the “use of X for the manufacture of a medicine to treat Y.”

59. See *infra* Part II.D.

for preparation of a medicament, and normally the medicament itself will be the same as that already used for the first pharmaceutical indication.”<sup>60</sup> Many patent laws recently adopted in developing countries make no specific reference to the availability of patents for uses, leaving unclear whether their protection for processes covers “uses” and “methods of use.”

In the case of first indication, nothing in TRIPs obliges countries to introduce additional protection for the second indication. While TRIPs requires member states to protect *products* and *processes*,<sup>61</sup> it does not specifically refer to the protection of new uses, thus leaving member countries free to choose whether or not to protect them. In principle, a country that broadly excludes methods of medical treatment could also broadly exclude new therapeutic uses for old products. There are, however, limits to this approach. Consistency is required in defining excludable therapeutic methods. The impact of any such exclusions on local needs and industry should also be taken into account.

#### D. *Methods for Treatment and Diagnostics*

Developing countries could consider the exclusion from patentability of diagnostic, therapeutic and surgical methods for the treatment of humans or animals.<sup>62</sup> Most countries do not grant patents on such methods, due to ethical reasons or to difficulties with actually enforcing those patents. In addition, a method that is applied to the human body is not considered industrially applicable and so does not comply with one of the key patentability requirements of most patent laws. However, in the United States, patent practice increasingly favors the patenting of medical methods if they satisfy the definition of process and the other conditions of eligibility.<sup>63</sup>

Article 27.3(a) of TRIPs explicitly allows members to refuse patents for methods of therapeutic and surgical treatment and for diagnostics, including its application to animals.<sup>64</sup>

---

60. GRUBB, *supra* note 44, at 221.

61. See TRIPs Agreement, *supra* note 1, art. 27.1, 28.

62. For instance, U.S. Patent No. 4,188,395 (Feb. 12, 1980) claimed a method combating circulatory diseases in warm blooded animals in need of such treatment orally or parenterally which comprises administering to the animals an amount effective for combating circulatory diseases relating to heart action and blood pressure an active compound according to claim 1 either alone or in admixture with a diluent or in the form of a medicament.

63. A bill enacted in 1996, which amended 35 U.S.C. § 287(c), determined, however, that the use of patented surgical procedures is protected from infringement suits. See GRUBB, *supra* note 44, at 220.

64. See TRIPs Agreement, *supra* note 1, art. 27.3.



It should be noted that, even in the absence of specific provisions excluding the patentability of the referred methods, methods may not be eligible for protection due to the lack of industrial applicability, which is one of the essential requirements for patentability.<sup>65</sup>

If the patentability of such methods were, however, admitted by national laws, its implications on the supply of health services should be assessed. Diagnostic, therapeutic and surgical patents, even if rarely granted, may negatively affect low-income patients' access to required treatments, particularly in new areas such as gene-therapy.<sup>66</sup>

In any case, the nonpatentability of methods would not affect the patentability of equipments and substances necessary to execute them.<sup>67</sup>

#### E. Traditional Medicines

Traditional medicine—medicine based on the use of natural products and the knowledge held in indigenous and local communities—is of great importance in the health-care systems of many developing countries. It has been estimated that around 7500 plant species are utilized in indigenous medicine, many of which, such as indigo, have multiple uses.<sup>68</sup> There are two major obstacles to affording patent protection to traditional medicine. First, the novelty requirement will generally impede the patentability of such products. Second, policy choices made to increase access to medicines, including a limitative approach towards the patentability of natural occurring products and uses of existing products, as well as strict patentability requirements, may lead to the exclusion of protection for most traditional medicinal products.<sup>69</sup>

Moreover, national patent protection of traditional medicine does not address biopiracy concerns. Since the granting of patents is dependent on each *national* law, the nonpatentability in one country

---

65. See *infra* Part IV.C.

66. Although the gene therapy methods may not be patentable if the suggested exclusion is provided for, the vectors and constructs that may be used could be patentable, as well as *ex vivo* process steps not involving the administration of the transformed cells to the patient. See GRUBB, *supra* note 44, at 244.

67. In cases where the protection of such equipment or substances could lead to a de facto monopolization of the nonpatented method, governments may have recourse to compulsory licenses. See *infra* Part X.

68. See Darshan Shankar, *Tribal and Rural Farmen-Conservers*, in 14 AGROBIO-DIVERSITY AND FARMERS' RIGHTS 170 (M.S. Swaminathan ed., Konark Publishers PVT LTD 1996).

69. See Ong Chui Koon, *Intellectual Property Protection of Traditional Medicine and Treatments in Malaysia*, in PERSPECTIVES ON INTELLECTUAL PROPERTY: INTELLECTUAL PROPERTY ASPECTS OF ETHNOBIOLOGY 6 (Michael Blakeney ed., Sweet & Maxwell 1999).

does not mean that traditional knowledge could not be patented in another country without the authorization of the communities that developed or possessed that knowledge. In these cases it may be necessary to request the nullification of the patent, if wrongly granted, in the foreign country.<sup>70</sup>

Many proposals have been made to protect traditional knowledge through a *sui generis* regime. This is the case, for instance, of proposals relating to “tribal,” “communal,” or “community intellectual rights,”<sup>71</sup> and “traditional resource rights.”<sup>72</sup> The establishment of such a regime would not conflict with TRIPs, to the extent that the scope of intellectual property protection would be enlarged rather than restricted. Moreover, if a *sui generis* regime were established, it would be outside the scope of TRIPs, which only applies to the categories of intellectual property rights specified in its article 2.

Other approaches, outside of the intellectual property sphere, may also serve to *promote* the use of traditional knowledge for preventive and curative health care, or to block unauthorized appropriation by foreign countries. Act No. 8423 (1997) of the Philippines, for example, aims “to accelerate the development of traditional and alternative health care” by improving the manufacture, quality control and marketing of traditional health care materials.<sup>73</sup> Peru passed a law in July 1999, which bans the non-value-added export of some botanical species with known healing properties, which had become the target of massive extraction by foreign laboratories. The law covers the two best-known medicinal plants in Peru’s indigenous pharmacopoeia: “cat’s claw” and “maca”; and legislators are considering expanding the norm to cover “yacun” and “para-para.”

### III. SCOPE OF CLAIMS

Patent claims define the rights of the inventor. The scope of patent claims determines the extent of the inventor’s monopoly

---

70. One example of this was the action initiated by the government of India in relation to a patent on *turmeric* granted in the United States, which was finally revoked.

71. See Tewolde Egziabher Berhan, *A Case of Community Rights, in THE MOVEMENT FOR COLLECTIVE INTELLECTUAL RIGHTS*, The Institute for Sustainable Foundation/The Gaia Foundation, Addis Ababa 38 (S. Tilahun & E. Sue eds., 1996).

72. See DARRELL POSEY & GRAHAM DUTFIELD, *BEYOND INTELLECTUAL PROPERTY: TOWARD TRADITIONAL RESOURCE RIGHTS FOR INDIGENOUS PEOPLES AND LOCAL COMMUNITIES* (International Development Research Centre 1996).

73. There is no intention to discuss here the different suggestions for the protection of traditional knowledge, nor to propose the adoption of any of them. The purpose here is only to indicate the need to consider this issue at the national level. See *infra* Part III.D.

protection, and is thus an important issue to be considered when designing and applying national patent laws. This issue is particularly relevant to health-related inventions, due to the prevailing practices of patenting in this area. Recently, scholars have warned that overly broad patents in the field of biotechnology could remove important research tools from the public domain and block whole areas for further research.<sup>74</sup> The broad protection sometimes conferred in the case of inventions related to pharmaceuticals has also been questioned.<sup>75</sup>

Patent claims essentially consist of a one-sentence definition of the invention where the technical contribution made by the inventor should be unambiguously spelled out. The scope of patent protection and, therefore, the room left for independent research and third party competition, is determined by the wording used in claims. Issues such as *how* a product is described and the *coverage* of the patent are of particular importance. The following discussion illustrates some of the possible forms and coverage of *product* patent claims.

A chemical product can generally be described in *structural* terms, by specifying, for instance, its chemical composition. This type of description offers the safest way of delineating the scope of protection.

Some countries accept, under certain conditions, *functional* claims whereby the invention is described in terms of what it *does* rather than what it *is*. Such claims can allow extremely broad coverage, since they confer exclusive rights on any means that is appropriate to achieve the claimed functions, i.e., all ways of solving a problem are protected.

Another form of claims are the so called *product-by-process* claim,<sup>76</sup> where a product is characterized by the process by which it is obtained and not by its elements and structure. These claims are in particular relevant for biological products that cannot be described in terms of their structure or composition, for instance, where a macromolecule is secreted by a micro-organism. These are accepted

---

74. See Alan White, *Problems of Patent for Research Tools*, BSLR (Mar. 1998).

75. See Zaveri, *supra* note 50; B. Keayla, *TRIPs—Impact on Health and Pharmaceuticals, Regional Consultation on WTO Multilateral Trade Agreements and Their Implications on Health—TRIPs* (Bangkok, Aug. 16-18, 1999).

76. These claims may read, for instance, “compounds X when prepared by a process as Y.” In the United States, the concept of “means-plus-function” claims is used to describe claims in which the invention is expressed as a means or step for performing a specified function without the recital of structure, material or acts in support thereof.

by the EPO only if the products themselves are new and inventive, and therefore, patentable.<sup>77</sup>

*Use-bound* claims protect the use rather than the product. An infringement of a use-bound claim can only occur when a product is prepared or sold for the specific use claimed in the patent.

In terms of coverage, claims can be more or less precise and focused. A claim may refer to a well-defined compound of therapeutic value. Often, however, in the chemical and pharmaceutical field, patent claims are drafted in a manner that cover hundreds if not thousands of compounds. This is the result, for instance, of describing a family of chemical compounds by showing the common structural nucleus of all members with a variable substituent.<sup>78</sup>

National laws, including those of developed countries, deal with these issues in very different ways. Functional claims have generally been admitted in the United States, though broad functional language that may impede further research, and development has been condemned.<sup>79</sup> The EPO on the other hand, accepts functional claims only when there is no other means to describe the invention in a more precise manner. "Product-by-process" claims are generally admitted by the EPO and some European countries only if it is impossible to define a product by its structural features,<sup>80</sup> and if the obtainable product is new and inventive. Under "product-by-process" claims, protection is generally only extended to a product *obtained* with the claimed process; hence, the same product if obtained by another process would not infringe on an existing claim.<sup>81</sup>

Acceptance of nonstructural and broad coverage claims expands the domain under the control of patent owners. Broad claims may have a negative impact on research and could unduly block competition. They are also likely to lead to a great number of legal conflicts, ultimately increasing the costs for companies and consumers. Narrowing the scope of patents through strict claim description and coverage requirements creates more room for

---

77. See TREVOR COOK, CATHERINE DOYLE & DAVID JABBARI, *PHARMACEUTICALS BIOTECHNOLOGY & THE LAW* 73, 76 (Stockton Press 1991).

78. In the case of process patents, many possible variants may result from broad numeric parameters describing a reaction temperature.

79. See Mary Helen Sears & Thomas Hahn, *Drafting and Interpreting Means (or Step) Plus Function Patent Claims*, PAT. Y.B. 70 (1999).

80. See the decision of the Board of Appeals of the European Patent Office T0150/82 (Feb. 7, 1984).

81. This limitation in the scope of protection may be overcome if it is interpreted that any product *obtainable* with the process is protected, a solution that, however, has been refused by many patent offices. See GRUBB, *supra* note 44, at 203.

innovation and competition. From a health policy perspective, an appropriate balance needs to be struck.

The TRIPs Agreement is absolutely silent on these matters. Nothing in TRIPs obliges members to admit functional or other types of claims as described above. Provided that there is no discrimination based on the field of technology, TRIPs provides members full freedom to determine the form and limits of allowable claims. Any WTO member may require that, wherever possible, a product invention be precisely defined in terms of its specific composition or structure,<sup>82</sup> particularly in the field of chemical substances, in order to avoid excessively broad claims and ensure the practicability of the invention. This requirement may be particularly useful in fostering the role of patent documents as a source of information and to facilitate the negotiation of contractual licenses and the actual use of patented inventions.

Implementing regulations of the patent law may also contain specific instructions for claims corresponding to different fields of technology, such as chemicals, digital and mechanical inventions in order to take into account the characteristics of each field. Policy makers should recognize that, while health-related inventions may require special attention, the rules adopted will apply to all fields of technology, and that patent office personnel should be well trained in order to adequately apply the provisions on this matter.

#### IV. PATENTABILITY REQUIREMENTS

To qualify for a patent, an inventor must show that his or her invention is novel, manifests an “inventive step,” i.e., that the invention was nonobvious, and is industrially applicable. The manner in which these criteria are defined and applied is crucial to determine the pool of knowledge that is subtracted from the public domain. This issue is acutely important for pharmaceuticals. The registration of a large number of patents on pharmaceutical compositions, therapeutic uses, polymorphs, processes, and forms of administration relating to an active ingredient often permit companies to create a high barrier against competition. If aggressively enforced through “strategic,”<sup>83</sup> or even “sham,” litigation practices,<sup>84</sup> companies can discourage

---

82. This was, for instance, the practice followed by Japan until the revision of its patent law in 1994.

83. See John Barton, *Adapting the Intellectual Property System to New Technologies*, 10 INT'L J. TECH. MAG. (1995).

84. The doctrine on “sham” litigation applies when a lawsuit is baseless and there is an intent to use it as a tool for monopolization. See FEDERAL TRADE COMMISSION STAFF, 1

competition by local companies. Additionally, secondary patents may extend the market power conferred by the original patent.<sup>85</sup> Such abuses may be particularly severe in developing countries where there is a lack or limited tradition in controlling such practices under antitrust regulations.

It is hard to undo overly broad patents and secondary patents. Once a patent has been granted, it is presumed valid. Challenging parties bear the burden of proving that the patent was wrongly issued. Consumers, especially in developing countries, rarely have the resources to challenge overly broad patents, though they bear the cost in higher product prices, and decreased access to patented goods.

Strong inter-firm competition in the pharmaceutical industry has led to numerous challenges of pharmaceutical patents by affected competitors.<sup>86</sup> However, small generic firms in developing countries often do not have the resources to undertake such costly litigation. Moreover, the wave of mergers and acquisitions that has taken place in the 1990s has dramatically reduced the number of major players and accentuated the oligopolistic structure of the pharmaceutical industry. This trend increases the importance of administering a patent system to protect competitors and the public from restrictions derived from patents granted on the basis of insufficiently precise patentability criteria.

The flexibility, or lack thereof, in the application of the patentability criteria may vary from country to country and over time. The correct interpretation and application of the patentability criteria are crucial for balancing public and private interests, and also to help avoid excesses that undermine the credibility of a patent system.

The eligibility standards for novelty and inventive step determine the extent to which free competition prevails.<sup>87</sup> Technologically advanced countries that invest a substantial portion of their Gross National Product (GNP) in research and development may understandably favor permissive novelty standards and low standards

---

ANTICIPATING THE 21ST CENTURY: COMPETITION POLICY IN THE NEW HIGH-TECH, GLOBAL MARKETPLACE (1996).

85. See *Walker Process Equipment Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), and subsequent case law on antitrust liability when there is an attempt to enforce invalid patents. See also Arun Chandra, *Antitrust Liability for Enforcing a Fraudulent Patent in the United States*, PAT. WORLD (Apr. 1999).

86. For an analysis of the vast litigation involving pharmaceutical patents, see COOK, DOYLE & JABBARI, *supra* note 77; HAROLD WEGNER, *PATENT LAW IN BIOTECHNOLOGY, CHEMICALS & PHARMACEUTICALS* (Stockton Press 1994); HANSEN & HIRSH, *supra* note 51; and GRUBB, *supra* note 44.

87. See Reichman, *Legal Hybrids*, *supra* note 18, at 2448-53.

of inventive step. However, even those policies are increasingly controversial given the importance of incremental innovation in some sectors and the growing number of patents that protect trivial developments.<sup>88</sup> On this issue, it has been shown that a higher innovative step requirement can increase the value of patents, because patents issued under this rule are stronger and less vulnerable to challenge by competitors. In some industries, this effect outweighs any effect of having less patents.<sup>89</sup>

Less technologically advanced countries may prefer to set higher standards of novelty and inventive step in order to preserve and enhance competition without violating minimum international standards. In so doing, they would simply follow in the footsteps of many of today's advanced countries, which adopted similar policies when they were themselves developing countries.

Policy makers should recognize that there may be subtle relationships between novelty and inventive step. For example, in traditional U.S. patent law, especially before the creation of the Federal Circuit Court of Appeals in 1982, the nonobviousness standard was so high that courts took a relatively liberal attitude toward novelty. Today, when the nonobviousness bar is set very low, this permissive tradition may be anticompetitive and harmful to patenting around the invention by not filtering out patent requests that do not sufficiently depart from prior art.

Developing countries should also note that high standards of novelty and inventive step can work against local innovators who cannot meet these standards. One way to address this problem is to adopt a *sui generis* law that deals with "minor" inventions that fail to meet the patent standard of novelty or inventive step. Examples from the European tradition include *sui generis* industrial design laws that protect appearance designs, and utility model laws that protect "minor" inventions generally. However, recent studies also propose that developing countries should adopt laws to protect unpatentable

---

88. See Scherer, *supra* note 13, at 112 (recommending more rigorous eligibility standards in order to avoid the protection of trivial developments). For examples of trivial patents granted in the United States, see RICK FEINBERG, PECULIAR PATENTS: A COLLECTION ON UNUSUAL AND INTERESTING INVENTIONS FROM THE FILES OF THE U.S. PATENT OFFICE (Carol Publ'g Group 1994). See also PATNEWS (Dec. 14, 1999) (software and "business" patents, such as an application filed on August 26, 1996, on a method for trading securities between individuals; an application filed in September 1997 (granted in November 1999) on a method of automatically accessing Web page information).

89. See Robert M. Hunt, *Nonobviousness and the Incentive to Innovate: An Economic Analysis of Intellectual Property Reform*, Federal Reserve Bank of Philadelphia, Working Paper No. 99-3 (1999).

know-how on the basis of nonexclusive rights. These laws could stimulate follow-on innovation in exchange for compensation without any strong exclusionary right.<sup>90</sup>

#### A. Novelty

The patent system was conceived to reward the inventor for contributions to the pool of existing knowledge. The criteria used to define what is new are key determinants of the scope of possible limitations to the free access and use of technical knowledge and products in the public domain. The stricter the novelty and other requirements, the smaller the number of applications that will receive a patent. The test of novelty considers how much distance separates one claimed invention from prior art. It applies before the existence of inventive step is considered.<sup>91</sup>

The novelty requirement in modern patent laws is based on an assessment of the prior art on a *universal* basis, that is, the prior art anywhere in the world. Generally, novelty is destroyed by previous written publication, prior use, or any other form of public communication of the invention.

Within this framework, the legal definition and application of the novelty requirement significantly differs among countries. In some jurisdictions a flexible standard is applied, thus permitting the granting of a great number of patents. For instance, in the United States, disclosure that has taken place outside the United States is only destructive of novelty when made in written form.<sup>92</sup>

National legislation and practice differs on numerous other important questions. The United States, for example, requires complete disclosure in a *single* publication to destroy novelty, despite the fact that a skilled person may have been able to derive the invention without effort from a combination of publications. In some cases, disclosure may not have been made *expressis verbis* in a prior writing, but may be implicit therein. If a “photographic” approach to novelty, i.e. only based on explicitly disclosed information, is applied, then equivalents to an invention implicitly disclosed in the prior art may not be sufficient to deny patentability. The result can be the

---

90. See Reichman, *Legal Hybrids*, *supra* note 18, at 2504-58; Reichman, *From Free Riders to Fair Followers*, *supra* note 18, at 58-75.

91. See *infra* Part IV.B.

92. This may permit the patenting in that country of knowledge, including indigenous communities, used but not published in written form outside the United States. See Carlos Correa, *Access to Plant Genetic Resources and Intellectual Property Rights*, Commission on Genetic Resources for Food and Agriculture, FAO, Background Study Paper No.8 (1999).



patenting of pieces of existing knowledge that are already contained in the prior art. This result can be avoided by following the EPO's practice of considering implicit teachings to be disclosed and part of the prior art.<sup>93</sup>

Another aspect left to national legislation is to establish whether novelty would only be destroyed when the anticipation *enabled* the execution of the invention, or whether a mere disclosure of the prior art would be sufficient; for instance, where a compound was made and tested even if a clear description of its properties or a method of production were not available.<sup>94</sup>

### B. *Inventive Step*

An invention, even if novel, is not patentable if its technical teaching would or could have been discovered in due course by a person with average skills in the respective field. In U.S. practice, for example, courts applying the nonobviousness standard, the U.S. equivalent to inventive step, undertake a three-step factual inquiry, examining: (1) the scope and content of the prior art to which the invention pertains; (2) the differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art. Courts then make a final determination of nonobviousness by deciding whether a person of ordinary skill could bridge the differences between the prior art and the claims at issue given the relevant prior art.<sup>95</sup>

Though sometimes difficult to apply, the inventive step or nonobviousness requirement is critical to prevent the granting of patents on trivial developments.

The inventive step is often evaluated by considering the "unexpected" or "surprising" effect of the claimed invention. U.S. courts, however, currently reject this approach and stress that patentable inventions may result from either painstaking research, slow trial and error, or serendipity.<sup>96</sup>

Many countries' case law holds that there is no inventive step if it would be obvious—for a person with average skills to test new matter with a significant likelihood of success. In the United States, the existence of an inventive step in relation to chemical compounds

---

93. See HANSEN & HIRSCH, *supra* note 51, at 96.

94. This was the approach adopted by the U.K. Patent law of 1977. See COOK, DOYLE & JABBARI, *supra* note 77, at 79.

95. See JAY DRATLER JR., INTELLECTUAL PROPERTY LAW, COMMERCIAL, CREATIVE, AND INDUSTRIAL PROPERTY § 2.03[3] (Law Journal Press 1999) (1991).

96. See *id.*

has been judged by taking into account the structural similarity between the claimed and the prior art compounds, the prior art suggestion or motivation to make the new compound, and the obviousness of the method of making the claimed compound.<sup>97</sup>

Similar to novelty, national laws may be more or less stringent in evaluating inventive step or “non-obviousness.” Moreover, in any domestic legal system, courts may elevate or relax the inventive step standard at different intervals in response to either prevailing attitudes towards competition, the perception of a need to protect new technologies, such as computer programs and biotechnological inventions, or the availability (or lack thereof) of alternative forms of protection in unfair competition laws, or utility model laws.

In establishing the existence of inventive step, it is necessary to consider not only the knowledge derived from a single prior document, but also the combined knowledge of existing literature, patent documents, and other prior art. However, current U.S. practice disfavors such an approach and holds that “the subject matter of a claim is not rendered obvious by prior art unless there is some specific suggestion or teaching in the prior art that points the way to it.”<sup>98</sup>

In the chemical and pharmaceutical field, there is often a close structural relationship between a compound which is claimed as new and inventive, and known compounds, such as salts of acids, bases, isomers, and homologues. In these cases it may often be deemed *obvious to try* the new compound, thus leading to its nonpatentability. The EPO, for example, has taken the view that the fact that certain advantages were predictable made it obvious to prepare a new compound.<sup>99</sup> In the United States, by contrast, the presence of a predictable advantage is not deemed sufficient to exclude patentability.<sup>100</sup>

The TRIPs Agreement is not specific with respect to the issue of inventive step. Article 27.1 of TRIPs establishes that patents shall be granted to protect inventions, which “involve an inventive step” and in a footnote, it allows member countries to interpret “inventive step” as synonymous to “non-obvious.”<sup>101</sup>

---

97. However, as mentioned before, in *In re Deuel*, these criteria were relaxed. The patenting of gene sequences has been allowed despite that gene sequencing has become a standard technique.

98. DRATLER, *supra* note 95.

99. See European Patent Office Technical Board of Appeal, T 154/82, IPD 7031.

100. See GRUBB, *supra* note 44, at 195-96.

101. See TRIPs Agreement, *supra* note 1, art. 27.1 n.5.

There is no agreement to harmonize the standard of inventive step/nonobviousness in practice. This suggests that developing countries may be well advised to consult and coordinate on this issue, possibly through their regional organizations.

A possible option for developing countries is to define and apply strict criteria for inventive step, in order to avoid the granting of patents that may unduly block competition in health-related products and processes. Such strict criteria may prevent the protection of locally developed “minor” innovations. But these innovations may be covered by utility models, or other forms of *sui generis* protection for expertise to provide compensatory rewards without exclusive property rights, rather than by diluting the inventive step requirement.

However, inventive step criteria cannot be so strict as to undermine the duty to grant patents in all fields of technology under article 27.1 of TRIPs.<sup>102</sup> Coordination among developing countries’ patent offices could help establish sound state practices and to avoid disputes.

### *C. Industrial Applicability*

The third criterion for patentability relates to the industrial applicability of the invention. Patent law around the world aims to protect technical solutions to a given problem, not abstract knowledge. The application of this criterion to health-related inventions is particularly important vis-à-vis inventions consisting of *uses* of a product since uses of health-related inventions may be considered as methods of treatment of the human body, not industrially applicable, and therefore not patentable.

Countries differ in their treatment of industrial applicability. Under U.S. law, certain developments that do not lead to an industrial product may be patented: an invention only needs to be useful.<sup>103</sup> This usefulness concept is broader than the “industrial applicability” concept required in Europe and other countries. The U.S. rule permits the patentability of purely experimental inventions that cannot be made or used in an industry, or that do not produce a

---

102. The application of a too restrictive criteria may give rise to “non-violations” claims under article 64 of TRIPs. See Oliver Cattaneo, *The Interpretation of TRIPs Agreement: Considerations for the WTO Panels and Appellate Body*, 3 J. WORLD INTELL. PROP. 660-63 (2000).

103. See 35 U.S.C. § 101 (1982).

technical effect,<sup>104</sup> as illustrated by the large number of patents granted in the United States on “methods of doing business.”<sup>105</sup>

The application of the industrial applicability requirement is often complex in the chemical, pharmaceutical, and biotechnology industries, where there are particular problems relating to the acceptable degree of speculative information. Thus, in the USA, mere speculation about chemical homologues would be insufficient, while *in vitro* testing in animal tumor models of products intended for human use may be deemed sufficient.<sup>106</sup> TRIPs does not define the concept of industrial applicability and, therefore, leaves countries with considerable flexibility.<sup>107</sup>

## V. SPECIAL CASES IN PHARMACEUTICALS

Several issues relating to the application of patentability requirements may be specific to health-related inventions. WTO member countries retain a considerable degree of flexibility in addressing most of them. These issues may be appropriately treated in implementing regulations and guidelines for the patent office, rather than in the law itself.

Developing countries, particularly those implementing for the first time the patenting of pharmaceutical inventions, should carefully craft policy in these areas to ensure that patents are granted to real contributions to the prior art and to avoid granting trivial invention patents that impede competition. Poor drafting or administration of patent laws may also permit abusive practices that illegitimately extend patent protection beyond the TRIPs mandated twenty-year term.

### A. Selection Patents

A “selection patent” is a patent under which a single element or a small segment within a large known group is “selected” and independently claimed based on a particular feature not mentioned in the large group.<sup>108</sup> If the large group of elements is already

---

104. See DAVID BAINBRIDGE, *INTELLECTUAL PROPERTY* 270-72 (Pitman Publ'g 1992).

105. See *The Growing Flood of 'Wall Street' Patents*, PATNEWS (Sept. 29, 1994).

106. See DRATLER, *supra* note 95, § 2.03[2].

107. It allows a member country to consider “capable of industrial application” as synonymous with the term “useful.”

108. A “selection invention” may take place, for example, when a range of products characterized as having N carbon atoms have been patented, and later on a patent on a specific range (e.g., C1-C4) is claimed. Substantial differences exist in the treatment of these patents, including between the EPO and some national offices in Europe.

patented,<sup>109</sup> the patent owner may use the selection patent to extend the term of protection beyond the expiration of the original patent, at least for the selected subset. While accepted in some jurisdictions when the selected elements possess a surprising advantage, selection patents have been denied when the supposed advantage is a property shared by all or nearly all of the large group. Germany has refused selection inventions by holding that disclosure of even a large group of elements is fully equivalent for the purposes of inventive step to the disclosure of each compound within the group.<sup>110</sup>

An important policy issue is, therefore, to decide if and under which conditions selection patents should be admitted. TRIPs leaves broad discretion to national laws and practices in this area.

### *B. Prior Public Availability*

Where a product has already been available to the public, the composition or inner structure of the product can be deemed to belong in the public domain even if not published, since the product could have been analyzed and reproduced by a skilled person.<sup>111</sup> This approach is also compatible with TRIPs.

### *C. Polymorphism*

Some therapeutically active ingredients present polymorphic forms, that is, they may crystallize in diverse forms, which may have different properties that are more or less significant in terms of their therapeutic use. Independent patent applications on such forms have become frequent.<sup>112</sup> Such forms can be deemed within the prior art, and therefore, nonpatentable if they were inevitably obtained following the process of the basic patent on the active ingredient or were covered by a previous product patent.

Some companies use patentability of polymorphs as a means to extend the monopoly protection of a known active ingredient. For example, GlaxoSmithKline applied for a patent on a polymorph of cimetidine approximately five years after the original patent was granted. That patent, however, was nullified in the United Kingdom and other countries on the grounds that the polymorph was inevitably

---

109. Often broad (generic) patent claims are admitted, covering a large number (sometimes thousands) of possible compounds.

110. See GRUBB, *supra* note 44, at 197-99.

111. See, for instance, the decision of the EPO in G 1/92, O.J. 1993 277.

112. For instance, "Form II olanzapine polymorph having a typical x-ray powder diffraction pattern as represented by the following interplanar spacings . . ." Patent Application, WO 96/30375.

obtained by applying the process already claimed in the original patent.<sup>113</sup> Another example is the case of ranetidine. The patentee obtained a patent in the United States for a polymorph expiring in 2002 as opposed to 1995 for the main patent.<sup>114</sup>

TRIPs leaves ample freedom to member countries to deal with this issue in their patent office administration. Patent offices should be aware of the possible unjustified extension of the term of protection arising from the successive patenting of the active ingredient and its polymorphs.

#### D. *Analogy Processes*

Some countries have permitted patenting of non-novel processes, sometimes called *analogy processes*, if the resulting chemical is novel and displays unexpected properties. The United States has held “analogy process” claims to be unpatentable unless they are inventive in themselves,<sup>115</sup> but it has carved out an exception for biotechnology. The products and processes of biotechnology have posed hard problems for applying the inventive step standard, since many biotechnology “inventions” repeat previously invented processes in slightly different contexts. This problem led to a statutory amendment of U.S. law in 1995, which lowered the nonobviousness standard by deeming a biotech process claim nonobvious if it involves new and nonobvious starting materials or produces a new and nonobvious result.<sup>116</sup> While this solution, targeted at biotechnology, may be deemed discriminatory, and hence inconsistent with article 27.1 of TRIPs, it has been extended by case law to other fields of technology.<sup>117</sup>

While the protection of “analogy processes” has been accepted in many jurisdictions as a logical means of protecting new developments, no country is obliged under TRIPs to follow this approach of expanding the realm of patentable subject matter.

#### E. *Compositions*

Claims are sometimes directed to a pharmaceutical composition, that is, to a formulated product containing an active ingredient and

---

113. See COOK, DOYLE & JABBARI, *supra* note 77, at 89; HANSEN & HIRSCH, *supra* note 51, at 113.

114. See COOK, DOYLE & JABBARI, *supra* note 77, at 90; GRUBB, *supra* note 44, at 205.

115. See GRUBB, *supra* note 44, at 206.

116. See DRATLER, *supra* note 95.

117. See GRUBB, *supra* note 44, at 207.

appropriate additives.<sup>118</sup> For instance, patents have been granted separately with regard to the injectable and oral forms of ofloxacin, a drug used to treat HIV patients. There is also a separate patent for the topical eye use of ofloxacin.<sup>119</sup> Another example is a patent on a formulation form of “ddl,” another drug used to combat HIV, granted in Thailand, which may deter the entry of a generic version of the product in that country.

Compositions may refer to combinations of previously known products. For example, patents on the combination of the following formulations were granted in the United States: Aspirin 325 mg. + Carisoprodol 200 mg. + Codeine Phosphate 16 mg., with the expiration date August 13, 2002.<sup>120</sup>

If composition claims are accepted subsequent to a patent on the relevant active ingredient, the patent owner may be able to artificially extend the term of protection granted under the basic patent.<sup>121</sup> Unless the composition, which often consists of the simple mixture of components, includes additives that generate a truly new and inventive product, a pharmaceutical composition should generally be deemed anticipated by the effective ingredient that it contains, and not patentable.

Another means to address the problem is to limit the scope of composition claims so that composition claim holders cannot prevent commercialization of other compositions containing the same active ingredient, or of the active ingredient in bulk, after the basic patent has expired.

#### *F. Optical Isomers*

A special case takes place when a compound is an optically active enantiomer<sup>122</sup> of a compound previously known only in racemic

---

118. For instance, U.S. Patent No. 4,188,395 (Feb. 12, 1980) contains the following claims on compositions:

A pharmaceutical composition containing as an active ingredient an effective amount for combating circulatory diseases relating to heart action and blood pressure of a compound according to claim 1 in admixture with a solid or liquefied gaseous diluent or in admixture with a liquid diluent other than a solvent of a molecular weight less than 200 except in the presence of a surface-active agent.

119. See PIERRE CHIRAC, *WORKING COMPULSORY ACCORDING TO TRIPS: THE ESSENTIAL DRUG CANDIDATES* 24 (Médicins Sans Frontières 1999).

120. See Keayla, *supra* note 75, at 18.

121. See COOK, BOYLE & JABBARI, *supra* note 77, at 91.

122. Enantiomers are chemical compounds which behave in relation to one another as an image does to its mirror image. In organic chemistry, enantiomers occur for example in compounds which comprise a carbon atom with four different substituents. See HANSEN &

form. While some patent offices, such as the EPO, have ruled that such enantiomers may be deemed novel, the existence of inventive step has been denied, since it is obvious that in such types of molecules optically active forms can exist. It is routine to test whether one, or the other enantiomers in isolation, is more active than the mixture of both (racemic mixture). Today, it is generally accepted that one optical isomer will typically have much higher activity than the other, so that superior activity for at least one of the isomers as compared to the racemate is to be expected.<sup>123</sup>

#### G. Active Metabolites

In some cases, patents may be accumulated on a compound and on the active metabolite that produces the desired effect in the body. For instance, in the case of terfenadine, which had been sold for many years in the United Kingdom as an antihistamine, the patent holder obtained a further patent on the active metabolite and attempted to block competition in the market of terfenadine, after the patent for the latter had expired. This was deemed to be an unacceptable attempt to extend patent protection.<sup>124</sup>

#### H. Prodrugs

When metabolized in the body, inactive compounds can produce a therapeutically active ingredient, called "prodrug." Countries must determine whether the patent on the compound covers the prodrug, and the extent to which claims relating to certain compounds should also be allowed to include their prodrugs.<sup>125</sup>

### VI. DISCLOSURE

Patents grant temporary monopolies to inventors in exchange for public disclosure of the invention. The full disclosure of the invention is a basic principle of patent law. Access to the information on the invention is one of the traditional justifications for granting temporary exclusivity to the inventor. Though relevant to health-related

---

HIRSCH, *supra* note 51, at 113. It is estimated that over a quarter of known pharmaceuticals present that property. See also COOK, DOYLE & JABBARI, *supra* note 77, at 84.

123. See GRUBB, *supra* note 44, at 199-200; HANSEN & HIRSCH, *supra* note 51, at 113-18.

124. See GRUBB, *supra* note 44, at 212-13.

125. In the United Kingdom, for instance, it was held that sales of hetacillin, an acetone adduct of ampicillin which was immediately hydrolyzed in the body to ampicillin, infringed the ampicillin patent, because it was "ampicillin in disguise." See GRUBB, *supra* note 44, at 211.



inventions, the problem of assuring adequate disclosure is of a general nature.

In order to perform its informative function, invention disclosures should at minimum be such that the invention can be understood and executed by an expert with average skills in the discipline concerned. This test should be applied at the national level, i.e., the description should be sufficient to teach the invention to a local expert.<sup>126</sup>

The law should require that the disclosure be sufficient so that a person of ordinary skill could reproduce the invention. A strict rule would require patent applicants to provide sufficient information to enable the reproduction of each embodiment of the invention for which they seek patent protection. If several embodiments are claimed, an enablement requirement would mandate disclosure of each embodiment.<sup>127</sup> This approach would prevent excessively broad claims covering embodiments of the invention that have not been described by the applicant in a form that allows their reproduction by a third party.

Another possible approach, applied by some patent offices, is to permit more generalized claims for those inventions constituting a substantial *technical contribution*. Thus, pioneer inventions—those that open a whole new technical field—may be entitled more generality in their claims than mere “follow-up” inventions. Follow-up inventions are those that only constitute improvements or “minor” innovations.

Article 29 of TRIPs covers disclosure obligations. According to this article, members may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing or at the priority date of the application. This standard only requires the applicant to submit the best mode known at the date of the application or priority. This information rarely includes the actual expertise for the execution of the invention, since production has seldom started at that date.

One important issue not addressed by TRIPs relates to the disclosure of inventions relating to microorganisms. Access to the relevant knowledge concerning microorganisms is only possible through access to the biological material itself. Such access may be made available to third parties with the publication of the patent

---

126. See UNCTAD, *supra* note 1, at 33.

127. However, some patent offices, such as the EPO, accept that, in order to be valid, the disclosure need not include specific instructions as to how all possible variants within the claim definition can be obtained. See COOK, DOYLE & JABBARI, *supra* note 77, at 80.

application.<sup>128</sup> However, in order to protect the legitimate interests of the applicant, this access is for experimental purposes only.<sup>129</sup>

It is important to ensure that the scope of protection for biological material patents corresponds to the material actually deposited. If there is no correspondence between the description and the deposited material, then the patent, or individual claim, may be deemed void.

Finally, national laws may require that biological material patent applicants inform the country of origin of the biological material, and to demonstrate that they have complied with the relevant rules with regard to access to the material. This requirement<sup>130</sup> will help to ensure compliance with the provisions of the Convention on Biological Diversity (CBD) and of related national legislation.

## VII. EXCEPTIONS TO EXCLUSIVE RIGHTS

All national patent laws contain exceptions to the exclusive rights granted by a patent. The content and scope of these exceptions vary widely. Some exceptions are particularly relevant to the health area. All of the exceptions considered below are recognized in some fashion in many developed countries. Outright exceptions to the exclusive rights of a patent, which operate without the need of a specific authorization by a court or administrator, and in favor of any third party, may be extremely important in fostering innovation, promoting the diffusion of technologies, or facilitating access at the lowest possible prices to health-related goods.

Article 30 of TRIPs treats the exceptions issue only in general terms and leaves WTO member states with considerable freedom to define the nature and extent of exceptions to the exclusive rights of patent owners.<sup>131</sup> Comparative law reveals different types of

---

128. In the case of the United States, access to a deposited sample is possible after granting of the patent.

129. The Budapest Treaty (1977) has created a system for the international recognition of the deposit of microorganisms that facilitates the tasks of patent offices and provides adequate guarantees to the applicants and patent holders.

130. An obligation of this type was incorporated in the draft of the European Union Directive relating to patents on biotechnology, as recommended by the European Parliament in July 1997. Although it was removed from the final approved text, Recital 27 of this Directive mentions an obligation to provide information as to geographical origin of biological material where this is known, without prejudice to patent validity.

131. See TRIPs Agreement, *supra* note 1, art. 30. Exceptions to exclusive patent rights must meet three conditions: (1) they should be limited, (2) they should not unreasonably conflict with the normal exploitation of the patent, and (3) they should not unreasonably prejudice the legitimate interests of the patent owner. These conditions are to be applied taking into account the legitimate interests of third parties.

exceptions that may be provided for within the scope of article 30.<sup>132</sup> However, national practice is not a blank check, and any particular exception may be challenged before WTO tribunals.

Conversely, the boundaries of article 30 may be affected by new state practices, which may result from the wholesale adoption of certain practices by many developing countries or their regional organizations. Such a strategy would not save any given practice that constituted a clear violation of TRIPs, but it might produce a differential approach in any judicial review where the violation was not clear.

#### A. *Experimental Use*

A basic objective of the patent law is to promote innovation. However, overly broad patent rights may harm innovation.<sup>133</sup> One mechanism to address this problem is through a patent exception relating to research and experimentation permitting the use of the invention without compensation to the owner for such purposes. An experimental use exception may foster technological progress based on “inventing around” or improving a protected invention, as well as permit evaluation of an invention in order to request a license, or for other legitimate purposes, such as to test whether the patent is valid.<sup>134</sup>

While the experimentation exception is rather narrow in the United States,<sup>135</sup> many countries, notably in Europe, explicitly authorize experimentation on an invention without the consent of the patent owner, for scientific as well as commercial purposes.<sup>136</sup>

An experimental use exception, including one for certain commercial purposes, seems to clearly fall within the category of admissible exceptions under article 30 of TRIPs.<sup>137</sup> However, actual application of such an exception that leads to rival products not significantly different from the patented product may be deemed an infringement under the “doctrine of equivalents” in some countries’ national case law.<sup>138</sup>

---

132. See CORREA, *supra* note 1, at 75-89.

133. See Roberto Mazzoleni & Richard Nelson, *The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate*, 27 RES. POL’Y 275 (1998).

134. See Rebecca Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); DAVID GILAT, 11C STUDIES, EXPERIMENTAL USE AND PATENTS 16 (VCH 1995).

135. See WEGNER, *supra* note 86, at 267.

136. See William R. Cornish, *Experimental Use of Patented Inventions in European Community States*, 29 INT’L REV. INDUS. PROP. & COPYRIGHT L. 735, 736 (1998).

137. See CORREA, *supra* note 1, at 76.

138. See *infra* Part VIII.

A provision on this matter may be drafted in more or less broad terms, depending on the general policy adopted and on the expected implications of such exception on foreign investment, transfers of advanced technology, and local research and development.

*B. Early Working*

Another exception specifically applicable to pharmaceutical patents<sup>139</sup> relates to using an invention without the patentee's authorization for the purpose of obtaining approval of a generic product before the patent expiration date. This procedure may permit the marketing of generic version promptly after the patent expires. Since generic competition generally lowers prices,<sup>140</sup> this exception—known in the United States as the “Bolar exception”<sup>141</sup>—promotes the affordability of off-patent medicines.

The availability of generics either under a brand name (branded generics) or a generic name (commodity generics) would lead to increased competition in the pharmaceutical market, and to correspondingly lower prices for the consumers and improved affordability of drugs.<sup>142</sup>

Some countries (e.g., the United States and Israel) have adopted the “early working” exception while simultaneously extending pharmaceutical patent terms, but other national laws need not include this linkage. Given that commercialization of the generic product does not take place until after the expiration of the patent, the early working exception can be regarded as fully compatible with article 30 of TRIPs.

In the case of Canada, the law established a Bolar-type exception that not only allowed tests with the invention, but also production and stockpiling of the product for release immediately after the expiration of the patent.<sup>143</sup> The European Union requested a panel against Canada under the WTO dispute settlement mechanism in connection with this exception. The panel decision confirmed that an early

---

139. It may also apply to agrochemical products and other products the commercialization of which is subject to prior administrative approval.

140. See WORLD HEALTH ORGANIZATION, *supra* note 20, at 31.

141. It is named “Bolar” after the U.S. case *Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, *cert. denied*, 469 U.S. 856 (1984). The Bolar (early working) exception was first introduced in the United States by the U.S. Drug Price Competition and Patent Term Restoration Act (1984), and has been explicitly adopted by Canada, Australia, Israel, Argentina, and Thailand. In many European countries it has been recognized by case law based on the experimental use exception.

142. See WORLD HEALTH ORGANIZATION, *supra* note 20, at 31.

143. See Canada Patent Act § 55(2)(2) (1993).

working exception is *consistent* with TRIPs, even in the absence of an extended period of protection for the patent. However, the panel considered that the right to manufacture and stockpile before the expiration of the patent was not consistent with TRIPs.<sup>144</sup>

The WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) have supported the establishment of an “early working” exception in national laws “for the rapid production of generic products in order to promote competition and contain drug expenditure.”<sup>145</sup>

The “early working” exception, as noted above, may in some cases be considered as part of the experimental use exception. However, given the importance of this issue, and the uncertainty surrounding judicial interpretation, it seems advisable to include a specific provision on the matter.

### C. *Parallel Imports*

Parallel imports involve the import and resale in a country, without the consent of the patent holder, of a patented product, which was put on the market of the exporting country by the title holder or in another legitimate manner. For example, a company may buy a patented machine sold in Germany and then resell it in Canada, where the same patent is in force, without the patent holder’s permission.

The underlying concept for allowing parallel imports is that since the inventor has been rewarded through the first sale or distribution of the product, they have no right to control the use or resale of goods put on the market with their consent. In other words, the inventor’s rights have been “exhausted.”<sup>146</sup>

Parallel imports, where allowed, cover legitimate products, not counterfeited products.<sup>147</sup> In some instances, however, parallel

---

144. See WT/DS114/R (Mar. 17, 2000) (Canada-Patent protection of pharmaceutical products).

145. WORLD HEALTH ORGANIZATION, REVISED DRUG STRATEGY: WHO’S WORK IN PHARMACEUTICALS AND ESSENTIAL DRUGS 2 (Geneva 1998); UNAIDS, *supra* note 22, at 2.

146. The doctrine of “exhaustion of rights” may be applied at the national level (rights are deemed exhausted domestically and the commercialization in foreign countries is not deemed to have exhausted the patentee’s rights), at the regional level, as in the case of the European Community (exhaustion is deemed to have occurred if commercialization took place in a country member of a regional agreement), or at the international level. The presentation made in the text refers to this latter case.

147. Abundant literature and considerable case law (particularly in the European Community) exists on the doctrine of exhaustion and parallel imports. See Frederick Abbott, *First Report (final) to the Committee on International Trade Law of the International Law Association on the Subject of Parallel Importation*, 1 J. INT’L ECON. L. (1998).

imports have been admitted on a regional scale, even when originating in a country where the product was not protected.<sup>148</sup>

In economic terms, the acceptance of parallel imports may prevent market segmentation and price discrimination by title-holders on a regional or international scale. In other words, parallel imports allow consumers effectively to shop on the world market for the lowest price for a patented good.<sup>149</sup> Parallel imports are particularly important in the health sector, where the pharmaceutical industry sets prices differently throughout the world for the same medicines. Importation of a patented medicine from a country where it is sold at a lower price will enable more patients in the importing country to gain access to the product, without preventing the patent owner from receiving the remuneration for the patented invention in the country where the product was first sold.

On the negative side, states must evaluate the argument that there is an economic risk that the doctrine of exhaustion may discourage price discrimination favoring the developing countries. It has been argued that if parallel imports were to be admitted generally, then companies would tend to charge a single price worldwide, leading to an increase in the supposedly lower price that may otherwise be charged in low-income countries.<sup>150</sup> The pharmaceutical industry is concerned with cross-market leaks that could reduce its profit margins and thereby its ability to recoup R&D investments. There are further questions concerning parallel importation from markets where pharmaceuticals prices are regulated. For these and other reasons, states need to carefully monitor the actual implementation of their exhaustion policy.

Parallel imports have been admitted in many developed and developing countries, on a regional or international scale, for all or some areas of IPRs. For instance, in the European Communities (EC) the European Court of Justice has applied the doctrine of *regional* exhaustion of rights to the entire EC and to different types of IPRs, in order to prevent market segmentation.<sup>151</sup> Once a patented product has

---

148. See Case 187/80, Merck v. Stephar, 1981 E.C.R. 2063; Case 267/95, Merck v. Primecrown, 1996 E.C.R. 6285; Case 187/80, Beecham v. Europharm, 1996 E.C.R. 6285.

149. In some countries, laws have established regulations providing for exclusive licensing agreements for the importation and distribution of goods. These kind of regulations restrict competition and practically impede parallel importation.

150. However, price levels are generally established in different countries according to the consumers' ability to pay. Hence, the setting of a single world price may be not be economically viable.

151. In the case of the United Kingdom, however, the principle of international exhaustion has been admitted in some cases. The European Court of Justice has accepted parallel imports

been sold in an EC country, it can be resold in any other member country without infringing on the IPR holder's rights.

Some countries recognized the international exhaustion of patent rights (and thus permit parallel imports) in case law,<sup>152</sup> while others expressly establish exhaustion principles in national patent law. The Andean Group "Common Regime on Industrial Property," as contained in Decision 344 of 1993, states that the patent owner cannot exercise exclusive rights in the case of "importation of the patented product that has been marketed in any country with the consent of the owner, a licensee or any other authorized person."<sup>153</sup>

In the case of South Africa, the Medicines' Act has authorized the Minister to prescribe "conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public." The Minister, "in particular may . . . determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent."<sup>154</sup>

Parallel imports are permitted under TRIPs. Parallel importing is one of the measures that member countries may take to protect public health under article 8.1 of TRIPs.<sup>155</sup> More specifically, article 6 of TRIPs establishes that each member country has the freedom to incorporate the principle of international exhaustion of rights, the underlying justification for parallel imports, in its national

even in cases where the product was not protected by a patent in the exporting country. See Case 267/95, *Merck & Co. v. Primecrown Ltd.* (Dec. 1996).

152. In Japan, for instance, the High Court of Tokyo held in *Jap Auto Prods. Kabushiki Kaisha & Anor v. BBS Kraftfahrzeug Technik A.G.* (1994) that the parallel imports of auto parts purchased in Germany did not violate patents granted to BBS in Japan.

153. See TRIPs Agreement, *supra* note 1, art. 34(1). Similarly, the Argentine Patent Law provides that the rights conferred by a patent shall have no effect against "any person who . . . imports or in any way deals in the product patented or obtained by the patented process once the said product has been lawfully placed on the market in any country; placing on the market shall be considered lawful if it conforms to Section 4 of Part III of the TRIPs Agreement." Argentine Patent Law, No. 24.481 (1995).

154. See Medicines, art. 15c(a). As indicated by this text, the parallel import exception in South Africa is not general as in other countries mentioned above, but limited to medicines, and it is subject to the prior decision of the Ministry of Health. Despite these limitations, the South African law was challenged on this point by forty-two pharmaceutical firms (which have recently suspended, however, their judicial action against the law) and it was included in the Special 301 "Watch list." However, USTR announced, on December 1, 1999, the removal of South Africa from that list. For more information on this case, see Patrick Bond, *Globalization, Pharmaceutical Pricing and South African Health Policy: Managing Confrontation with U.S. Firms and Politicians*, INT'L J. HEALTH SERVS. (Mar. 23, 1999).

155. See TRIPs Agreement, *supra* note 1, art. 8.1.

legislation.<sup>156</sup> If passed, parallel importing must be permitted for patented goods in all fields of technology, and not only for health-related inventions.

Because article 6 gives complete freedom on the matter to member countries, parallel importing rules cannot be challenged by the WTO as a violation of TRIPs, although the authority of a dispute settlement panel to adjudicate the indirect impact of exhaustion on other rights and obligations remains uncertain.

Although article 6 appears to give member countries very broad leeway to implement parallel importation policies, the doctrine of international exhaustion as applied to patents remains controversial with respect to both legal and economic aspects. Several influential authorities contend that overuse of the exhaustion doctrine would conflict with the exclusive right of importation conferred by article 28(a) of TRIPs and with the thrust of article 27(1) of TRIPs, which forbids discrimination “as to . . . whether products are imported or locally produced.”<sup>157</sup> It has also been argued that an international exhaustion of rights conflicts with the principle of territoriality and independence of patent rights established by the Paris Convention.<sup>158</sup>

Other authorities counter that article 28 is subject to article 6 and therefore cannot be subject to WTO dispute settlement procedures.<sup>159</sup> Footnote 6 to TRIPs article 28.1(a) states that “this right [of importation], like all other rights conferred under this Agreement in respect to the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.”<sup>160</sup> The footnote to article 51 (“there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder”) also supports this position.<sup>161</sup>

General GATT principles also seem to support the permissibility of parallel imports. Under GATT, member countries must treat

---

156. According to an UNCTAD study, “Member countries also have the option (under Article 6 of the TRIPs Agreement) to adopt a worldwide exhaustion doctrine that could build upon the experience of economic integration schemes of industrialized countries.” UNCTAD, *supra* note 1, at 34. Similarly, a document published by the WHO, after review by the WTO, includes among the possible TRIPs-compatible exceptions “parallel importation of the protected product.” See Velásquez & Boulet, *supra* note 1, at 33.

157. TRIPs Agreement, *supra* note 1, art. 27.1.

158. See Yoshiaki Tsuda & Shuichi Sakuma, *Research on Parallel Trade of Patented Products*, PATS. & LICENSING 10 (Dec. 1996).

159. See Marco Bronckers, *The Exhaustion of Patent Rights Under WTO Law*, 32 J. WORLD TRADE 137 (1998); S. Verma, *Exhaustion of Intellectual Property Rights and Free Trade: Article 6 of the TRIPs Agreement*, 29 INT’L REV. INDUS. PROP. & COPYRIGHT L. 534 (1998).

160. TRIPs Agreement, *supra* note 1, art. 28.1(a) n.6.

161. See *id.* art. 51.



imported products in a manner not less favorable than the like products of national origin, while members cannot impose restrictions “other than duties, taxes or other charges.”<sup>162</sup> Further, widespread resort to the doctrine of international exhaustion by developing countries could acquire some weight as state practice, helping to resolve any legal uncertainty in this area.

The WHO has explicitly supported the use of parallel imports to advance the principle of “preferential pricing in poor countries.” WHO has stated that “in cases where drug prices are higher in poor countries than in richer ones, recourse to parallel imports in low-income countries in order to reduce prices might be appropriate, while preventing parallel exports to industrialized countries.”<sup>163</sup>

Finally, it is important to emphasize that the issue of parallel imports is completely distinct from the issue of counterfeit pharmaceutical products. Parallel imports, by definition, relate to products which have been legitimately put on the market, not to imitations of original products. Parallel imports would be subject, in principle, to the same import and other regulations applicable to any other imported medicine.

#### *D. Individual Prescriptions*

Patent laws commonly exclude from the effects of patent rights, medicines prepared for an individual case in a pharmacy or by a medical professional.<sup>164</sup> This exclusion, though not specifically provided for, may be deemed permitted under article 30 of TRIPs.

---

162. See GATT art. xi(1). An interpretation of these provisions is that parallel imports are not only legitimate, but that GATT *requires* WTO members not to forbid such imports. See Verma, *supra* note 159. The possible application of article XX.d of GATT, which allows for exceptions when necessary to secure compliance, inter alia, with “the protection of patents, trademarks and copyrights”; needs also to be considered in this context.

163. See WTO, Trade and Public Health, Statement of the WHO at the Third WTO Ministerial Conference, Nov. 30 to Dec. 3, 1999, Seattle, at 2. It should be noted that the prevention of parallel trade is an issue that needs to be addressed by the importing and not the exporting country. Thus, the acceptance of parallel importation in a given developing country would not prevent any other country, including industrialized countries, from treating parallel imports differently, to the extent that such treatment is GATT-consistent.

164. From a public health perspective, however, the proliferation of individual prescriptions may be risky, to the extent that there are no quality assurance mechanisms to protect the consumers.

## VIII. CLAIMS INTERPRETATION

Establishing the boundaries of protected inventions determines the actual scope of the rights conferred by a patent,<sup>165</sup> and is particularly important for some health-related inventions. It is a matter of national legislation to define when products or processes that are not *literally* described in a claim may be deemed “equivalent” and therefore considered as infringing on patent rights.

There are different approaches to deal with this issue.<sup>166</sup> Under one approach, equivalence may be found if the allegedly infringing variant of a process or product performs substantially the same function in substantially the same way to obtain the same result. Another approach relies not on a functional analysis, but on an objective comparison of the elements that constitute the variant and the invention, and particularly on the extent to which the variant introduced by the potential infringer may be deemed obvious<sup>167</sup> by a skilled person in light of the claimed invention. This latter approach may permit an adequate protection of the inventor’s interests, while leaving more room for third parties’ innovations in the field covered by the patent.<sup>168</sup> There is no rule in TRIPs to determine how narrow

---

165. See TOSHIKO TAKENAKA, INTERPRETING PATENT CLAIMS: THE UNITED STATES, GERMANY, AND JAPAN (VCM 1995).

166. See Mario Franzosi, *Il Brevetto: Quale Tutela?*, 169 QUADERNI DI GIURISPRUDENZA COMMERCIALE (1996); Reinhardt Schuster, *Germany’s Doctrine of Equivalents*, MANAGING INTELL. PROP., Dec.-Jan. (1995/1996); Steven Anzalone, *Infringement Under the Doctrine of Equivalents: The Search for Certainty*, PAT. WORLD (Sept. 1996). An example of the application of the doctrine of equivalents is provided by a case decided by the Osaka High Court on May 9, 1996. Sumitomo (Japan) had argued that it had independently developed a different form of t-PA, which had been previously patented by Genentech (U.S.A.). Sumitomo’s t-PA differed from Genentech’s in relation to the 245th position of the amino acids sequence. This difference was regarded by the Court as insufficient to avoid infringement since, despite that difference, Sumitomo’s product was equivalent to Genentech’s t-PA.

167. The date at which the equivalence is considered may be the filing date of the application or the date of infringement.

168. The United Kingdom employs a three-part equivalence test, established by Hoffman J. in *Improver Corporation v. Remington Consumer Products Ltd.* [1990] FSR 181:

If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or acontextual meaning of a descriptive word or phrase in the claim (a variant) was nevertheless within the language as properly interpreted, the court should ask itself the following three questions:

1. Does the variant have a material effect upon the way the invention worked? If yes, the variant is outside the claim. If no-
2. Would this (i.e., that the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art? If no, the variant is outside the claim. If yes-
3. Would the reader skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with the primary

or broad the “doctrine of equivalence” should be. This issue is up to national legislators.

In general, less technologically advanced countries may be expected to favor a narrow doctrine of equivalents, which is more pro-competitive and stimulates applications by those who work around patented inventions. In developed countries, such as in the United States, there are open questions about the desired scope of that doctrine; many think that a narrow doctrine of equivalents is required to promote innovation.<sup>169</sup> Country preferences relating to the doctrine of equivalents may also depend on a country’s pharmaceutical, chemical, and biotechnology development and manufacturing capacity, as well as the availability of alternative forms of protection for local innovation.

#### IX. COMPULSORY LICENSING

Compulsory licensing enables a government to license the right to use a patent to a company, government agency or other party without the title holder’s consent. A compulsory license must be granted by a competent authority to a designated person, who should generally compensate the title-holder through payment of a remuneration. Compulsory licenses do not deny patent holders the right to act against nonlicensed parties.

##### *A. Grounds for Granting Compulsory Licenses*

The provision of compulsory licenses is a crucial element in a health-sensitive patent law. Such licenses may constitute an important tool to promote competition and increase the affordability of drugs, while ensuring that the patent owner obtains compensation for the use of the invention. The use of such licenses, however, has been generally opposed by the research-based pharmaceutical industry,<sup>170</sup> on the grounds that they discourage investment and R&D.<sup>171</sup>

---

meaning was an essential requirement of the invention? If yes, the variant is outside the claim.

*Id.*

169. See MERGES, *supra* note 54, at 705.

170. See Bond, *supra* note 154.

171. On the impact of compulsory licenses on R&D in the United States, see F.M. Scherer, Comment, *in* COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY 104 (Robert Anderson & Nancy Gallini eds., Univ. of Calgary Press 1998).

Most countries, including developed countries, make available some forms of compulsory licenses.<sup>172</sup> Such licenses are one of the mechanisms that states can use in order to promote competition and access to drugs. While it is advisable that national laws provide for a compulsory licensing system (as further elaborated below), it should be borne in mind that such a system is not intended to, and cannot fix problems arising from the defective granting of patents, such as when the novelty or inventive step requirements are not satisfied. It is of critical importance to ensure that the patentability criteria are rigorously defined and applied in the pre-grant process.<sup>173</sup>

Compulsory licenses are generally available for lack or insufficiency of working,<sup>174</sup> to remedy anticompetitive practices, for cases of emergency, governmental or “crown” use, and for other public interest grounds. Most developed countries provide for use of compulsory licenses. Many developing countries that have recently revised their patent laws have also defined a more or less comprehensive list of reasons for granting compulsory licenses.

The WHO has recommended the use of compulsory licenses where there is “abuse of patent rights or a national emergency” in order to ensure that drug prices are consistent with local purchasing power. UNAIDS has also recommended the use of such licenses, as provided under TRIPs, “such as in countries where HIV/AIDS constitutes a national emergency.”<sup>175</sup>

Although U.S. patent law does not provide for compulsory licenses, compulsory licenses are allowed under special legislation,<sup>176</sup> and under antitrust law. The United States has a wealth of experience, perhaps the most, in granting compulsory licenses to remedy anticompetitive practices and for governmental use, including national security. More than one hundred such licenses have been granted, both for present and future patents. Licensees have generally

---

172. See CARLOS CORREA & SALVADOR BERGEL, *PATENTES Y COMPETENCIA* (Rubinzal-Culzoni Ediciones 1996); Carlos Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* (South Centre, Geneva, Working Paper No. 5 1999).

173. See *supra* Parts IV-V.

174. “Working” of a patent was originally understood as the execution of the invention in the country of registration, see PENROSE, *supra* note 8. The current trend in some countries is to admit that working may take place through importation. Article 27.1 of TRIPs has been interpreted by some (notably the research-based pharmaceutical industry) as excluding the possibility of requiring the local execution of the invention. See, however, the Brazilian Patent Law (1996), which established that such obligation was incurred only if economically viable. See Brazilian Patent Law art. 68.1 (1986).

175. See UNAIDS, *supra* note 22, at 2.

176. See 42 U.S.C. § 7608 (2000) (U.S. Clean Air Act); *id.* § 2183 (Atomic Energy Act 1988).

been required to pay a reasonable royalty, determined on the basis of the “willing-buyer, willing-seller” formulation, but in some cases the compulsory licenses have been conferred royalty free. In some cases, moreover, the patentee was required to make the results of its research readily available to other industry members, or to transfer the expertise.

Despite the provisions for compulsory licenses in many national laws, relatively few compulsory licenses have actually been granted.<sup>177</sup> But commentators generally agree that the mere authority to grant compulsory licenses promotes some degree of competition in its own right, and that the impact of the compulsory licensing mechanism therefore cannot be measured on the basis of the number of licenses granted. “The practical value of the existence of compulsory license provisions in the Patent Law is that the threat of it usually induces the grant of contractual licenses on reasonable terms, and thus the objective of actually working the invention is accomplished.”<sup>178</sup>

TRIPs specifically allows member states to grant compulsory licenses on grounds to be determined by each member country.<sup>179</sup> TRIPs specifies some grounds for the granting of compulsory licenses but does not restrict the possible grounds to those cited. In contrast, TRIPs is quite specific with respect to the *conditions* to be met should a compulsory license be granted. These conditions include: (1) the requirement—in certain cases—that a license be voluntarily requested before granted on compulsory terms, (2) nonexclusivity, and (3) an adequate remuneration to the patent holder.

A health-sensitive patent law may specifically provide for several grounds for compulsory licenses, notably:

- Refusal to deal: *when the patent holder refuses to grant a voluntary license which was requested on reasonable commercial terms*<sup>180</sup> and, for instance, the availability of a product that is

---

177. The largest number of compulsory licenses in Canada have been issued under the 1969 amendment that authorized automatic licenses on pharmaceuticals. In the United States, most compulsory licenses have been issued under antitrust laws.

178. S. LADAS, PATENTS, TRADEMARKS AND RELATED RIGHTS-NATIONAL AND INTERNATIONAL PROTECTION 427 (Harv. Univ. Press 1975). Friedrich-Karl Beier has recently presented a similar view in a comprehensive study on the matter compulsory licenses “through their mere existence as well as through the apprehension of compulsory license proceedings are liable to increase the willingness of a patent owner to grant a voluntary license.” See Friedrich-Karl Beier, *Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law*, 30 INT’L REV. INDUS. PROP. & COPYRIGHT L. 251, 260 (1999).

179. See TRIPs Agreement, *supra* note 1, art. 3.1.

180. This is contemplated, for instance, in U.K. Patent Law, art. 48.3.d and in China Patent Law, art. 51.

*negatively affected, or the development of a commercial activity jeopardized;*

- *Emergency: such as when urgent public health needs exist as a result of a natural catastrophe, war or epidemics;*<sup>181</sup>
- *Anticompetitive Practices: for instance, to correct excessive prices and other abusive practices;*
- *Governmental Use:*<sup>182</sup> *such as to provide health care to the poor;*
- *Lack or Insufficiency of Working of an invention needed for health care or nutrition; and*
- *Public Interest: broadly defined to cover other situations where the public interest is involved.*

TRIPs provides special rules for compulsory licenses granted to government agencies or contractors. National legislations may eliminate a patent owner's right to seek an injunction to bar the government or a government contractor from using its patent, allowing the patent owner only the right to seek compensation.<sup>183</sup> This is the practice in the United States, where the government may use patents without a license, and the patent owner's sole remedy is to seek compensation under 28 U.S.C. § 1498.<sup>184</sup>

Some public health-concerned organizations have urged countries to grant compulsory licenses for the "essential drugs" listed by the WHO. Such a policy may be of limited importance, however. Although new important therapeutic developments may be patented, and on the essential drugs list, most of the drugs on the list are off patent. Moreover, high-priced drugs, such as those useful to treat AIDS, are currently excluded from the list, and these are the medicines for which compulsory licensing may be most valuable.

A national law provision subjecting "essential drugs" (either as listed by WHO or otherwise defined by a national government) to compulsory licenses would not contradict the obligation to consider

---

181. The situation of some African countries in relation to AIDS may be deemed, for instance, a public health emergency.

182. These types of licenses are grounded, in some jurisdictions, on the concept of the eminent domain vested in the state.

183. See TRIPs Agreement, *supra* note 1, art. 31(h).

184. See 28 U.S.C. § 1498 (1994) (U.S. Executive Order 12889 regarding the implementation of NAFTA). Section 6 formally waives the requirement in NAFTA 1709.10.b to seek advance authorization from the patent owner on "reasonable commercial terms and conditions," if use of a patent is by or for the government. The government or its contractors are required to notify patent owners of the use, if there are reasonable grounds to know an invention is covered by a valid patent, but the government can proceed with use directly without seeking a license.

each application for a compulsory license on its individual merits.<sup>185</sup> Such a provision would specify one of the grounds for granting such licenses, but they could remain subject to case-by-case evaluation. Compulsory licenses for essential drugs would not relate to a full “field of technology” but to a limited number of inventions which are of utmost importance for public health, and thus may be deemed as not violating TRIPs prohibition on discrimination among fields of technology.<sup>186</sup> Moreover, article 8.2 specifically authorizes measures necessary to protect public health.<sup>187</sup> Measures necessary to protect public health are also accorded an exception to GATT rules. Article XX(b) of GATT specifically permits members to adopt measures, necessary to protect public health, which violate their general obligations under GATT.

The process by which compulsory licenses are granted will influence the freedom enjoyed by WTO members to grant compulsory licenses for health-related products. Countries will be in the strongest position to issue compulsory licenses if they establish the existence of health emergencies through public hearings and undertake serious negotiations with industry companies before issuing compulsory licenses. Action by many developing countries, or by their regional groups, dealing with common emergencies could also reinforce the legitimacy of compulsory licenses. Such measures are *not* necessary, however.

Countries should examine the potential negative impact of compulsory licensing, as with other measures limiting patentees’ rights. The consequences include the possibility of discouraging foreign investment, transfer of technology, and research, including research into local diseases. Although it has been argued that there may be some risk that compulsory licensing will lead to the marketing of inferior products (since they will be manufactured without the patentee’s cooperation), the production and commercialization of medicines are, in all countries, subject to prior approval and government controls.

The conditions for the application of compulsory licenses are of particular importance. Overly burdensome procedures may effectively discourage the use of the system and deprive compulsory licensing of its potential value as a pro-competitive tool. Particularly important implementation issues are considered below.

---

185. See TRIPs Agreement, *supra* note 1, art. 51(a).

186. See *id.* art. 27.1.

187. See *id.* art. 8.2.

*B. Imports/Exports*

TRIPs does not restrict the possibility that a compulsory license may be executed by means of the importation of a patented product.<sup>188</sup> This may, in fact, be the only viable means to execute a compulsory license in cases where the size of the local market does not justify local manufacturing, or where there is a need to promptly address an emergency situation. In a post-TRIPs scenario, however, in which most countries in the world will grant patent protection for pharmaceuticals, it will become increasingly difficult for a compulsory licensee to get independent sources of supply for a patented pharmaceutical. The patent holder may, for instance, through contractual prohibitions to export imposed on his licensees and distributors, effectively block the possibility of obtaining such products through imports. This will, in practice, significantly diminish the effectiveness of compulsory licenses as a tool to facilitate access to drugs. Nevertheless, the market need for satisfactory economies of scale would vary by drug, so that for some drugs compulsory licenses would be effective even in medium sized companies.

The compulsory licensee may import from a compulsory licensee in another country. In this case, the imported product would have been legitimately commercialized in the exporting country. Such importation may be deemed as legal parallel importation, since patent owners would have obtained remuneration in the exporting country and exhausted their rights there.<sup>189</sup> If this interpretation were held, there would be in fact no need to get a compulsory license to import.

A further question, however, is whether a compulsory licensee would be authorized to export. TRIPs stipulates that a compulsory license must be “predominantly” for the supply of the domestic market.<sup>190</sup> Thus, exports are possible, though they should probably not constitute the main activity of the licensee with regard to the

---

188. The importation of the product was a key element in the Canadian compulsory system mentioned above, as revised in 1969. See COMPETITION POLICY AND INTELLECTUAL PROPERTY RIGHTS IN THE KNOWLEDGE-BASED ECONOMY 65 (Robert Anderson & Nancy Gallini eds., Univ. of Calgary Press 1998). If the compulsory licensee imported legitimate products (sold in a foreign country by the patent holder or with his consent), its acts could be covered under an exception for parallel imports.

189. The admissibility of this interpretation may, however, be challenged in the WTO on the basis that a compulsory license does not imply the “consent” of the patent owner, as required in some jurisdictions to consider that his rights have been exhausted.

190. See TRIPs Agreement, *supra* note 1, art. 31(f).



licensed product. The article 31(f) limitation,<sup>191</sup> however, may not apply when a compulsory license has been granted to remedy anticompetitive conduct.<sup>192</sup> This exception corresponds to the practice followed in the United States of granting compulsory licenses under antitrust legislation.<sup>193</sup>

Whatever the approach taken, it is clear that successful compulsory licensing requires that adequate alternative sources of supply be secured, either through local manufacturing, which may be unfeasible for small countries, or importation.

### C. Registration

The value of the compulsory licensing system may be undermined if a licensee faces obstacles to registering (gaining approval to market) the protected product. Such obstacles may originate from an expansive interpretation of article 39.3 of TRIPs, as reportedly promoted in developing countries by the U.S. government.<sup>194</sup>

Article 39.3 of TRIPs obliges countries to protect confidential data<sup>195</sup> submitted for the registration of *new chemical entities*, only if their generation involved a “considerable effort.” Article 39.3, however, does not create exclusive rights on such data.<sup>196</sup> The only protection arguably conferred under TRIPs is against “dishonest” commercial practices in the framework of unfair competition law.<sup>197</sup>

Some countries provide exclusive data protection, but these are not mandated by TRIPs. In Europe, the first applicant may obtain exclusivity for the use of test data for six or ten years from the date of

---

191. *See id.*

192. *See id.* art. 31(k).

193. *See* United States v. Western Elec. Co., No.17-49, 1956 Trade Cases (CCH) 168, 246, (D.N.J. 1956); United States v. Int'l Bus. Mach. Corp., No.72-344, 1956 Trade Cases (CCH) 68, 245, (S.D.N.Y. 1956); United States v. Imperial Chem. Indus. Ltd., 100 F. Supp. 504 (S.D.N.Y. 1952) (final judgment).

194. *See* TRIPs Agreement, *supra* note 1, art. 39.3; Cita Priapantja, *Trade Secrets: How Does This Apply to Drug Registration Data?*, Paper presented at the “Asean Workshop on the TRIPs Agreement and its impact on pharmaceuticals,” Indonesian Department of Health and World Health Organization, Jakarta, May 2-4, 2000.

195. *See* TRIPs Agreement, *supra* note 1, art. 39.3. These data generally consist of the results of tests made with a new product in order to prove its efficacy and lack of negative effects. They do not involve any inventive step, and are protected under TRIPs in recognition of the investment made for their production, rather than on their value as “intellectual” assets.

196. *See id.* art. 39.3; Francois Dessemontet, *Protection of Trade Secrets and Confidential Information*, in INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPs AGREEMENT (Carlos Correa & Yusuf Adulqawi eds., Kluwer Law Int'l 1998).

197. *See* Dessemontet, *supra* note 196, at 258.

authorization,<sup>198</sup> while under NAFTA, a minimum exclusivity period of five years is recognized.

It is important to note that article 39.3 of TRIPs does not apply to pharmaceutical products which are not new. It only protects test data relating to “chemical entities,” thus apparently excluding polymorphs, compositions, delivery systems or uses, even if new.<sup>199</sup> In addition, once data on a new drug has been submitted, national health authorities may approve subsequent applications of generic products on the basis of similarity,<sup>200</sup> since such authorities will not have to examine or rely on confidential information.<sup>201</sup>

Some developing countries have been under pressure to adopt standards of protection on confidential data beyond those required by TRIPs. The adoption of such standards may lead to a restriction of legitimate generic competition for products, which are already in the public domain, particularly if exclusive rights were recognized. This issue, therefore, requires careful examination in the context of a policy aimed at increasing access to medicines.

Compulsory licenses may legitimately be granted for the importation, as well as the manufacture, of a protected product. Importation will be crucial for developing countries with limited technological or financial capabilities to undertake manufacturing of the protected product and to address emergency or anticompetitive situations, in which rapid action is necessary.

The duration of a compulsory license is an important issue. If the term is too short, there may be no incentive for a third party to request or accept a license. The general practice is for compulsory licenses to be granted for the remaining term of the patent. This is the solution proposed above, except when justified by reasons of public interest.

Determination of the remuneration to be paid to the patent holder is a key issue. The respective royalty rates may be established on the basis of the rates generally applicable in the respective sector.<sup>202</sup> Another possibility is to define a “reasonable” royalty as that which a third party would pay for a voluntary license. This method,

---

198. Directive 65/65, as amended by Directive 87/21.

199. See TRIPs Agreement, *supra* note 1, art. 39.3.

200. On the concept of “similarity” under European law, see Case 386/96 E.C.R. (Dec. 3, 1998).

201. This reasoning has been applied by the Supreme Court of Canada in *Bayer Inc., The Attorney General of Canada and the Minister of Health, Apotex Inc. and Novopharm Ltd.*, of May 19, 1999, to admit the registration of a “similar” product even *before* the expiration of the five years exclusivity period in force in that country.

202. See Argentine Patent Law, art. 43 (1995).

introduced by U.S. law in 1922, has been extensively applied in U.S. case law relating to the infringement of patent rights.<sup>203</sup> In the case of compulsory licenses for U.S. governmental use, however, remuneration is based on what the owner has lost, not on what the licensee has gained.<sup>204</sup>

The practice in Canada (while a system of compulsory licenses was in force), was to require royalty rates of four percent of the sales price of medicines under license. In India, the applicable policy guidelines normally limit royalty payments to a maximum of four percent of net sales, while royalties of up to eight percent have also been reported.<sup>205</sup>

In order to determine compensation, authorities may require the patent holder to disclose product-specific R&D investments, revenues and other relevant economic data, while ensuring adequate protection of any confidential commercial data. They may also take into account the domestic market share in the total world market for the licensed product, in order to determine what proportion of actual R&D costs the country should pay. In commercial practice, royalty rates usually range from .5% to 10% of the net sales of the licensed product, depending on the market volume and turnover of the specific product,<sup>206</sup> and on the stage of the technology in the life cycle, among other factors.<sup>207</sup>

Finally, it should be noted that the review of a decision granting a compulsory license may be made by an administrative or judicial body, and that the patentee's rights to such review may be limited, in accordance with TRIPs, to the legal validity of the license and to the accorded remuneration.

---

203. See DONALD CHISUM, PATENTS ¶ 20.02.2 (Matthew Bender 1992). In the area of copyright, the U.S. Court of Appeals for the District of Columbia has recently held that "reasonable" royalty rates under § 801(b) of the Copyright Act does not mean "market rates," but a rate determined according to statutory criteria. See *Recording Indus. Ass'n of Am. v. Librarian Cong.*, D.C. Cir. No. 98-1263 (1999).

204. See the U.S. decision in *Leasona Corp. v. United States*, 599 F.2d 958, 969 (1979).

205. See David Graber, Foreign Countries' Licensing Practices (cited in USTR's Annual Trade Barriers Report), *World Licensing Law Report/BNA*, No. 4, at 3 (1999).

206. See Peter Niess, Technology Evaluation and Pricing, *TECH. MONITOR*, Nov.-Dec. 1999, at 16-17.

207. See Vinay Kumar & Jyotti Bhat, *Estimating Payments for Technology: A Framework for SMEs*, *TECH. MONITOR*, Nov.-Dec. (1999).

## X. FINAL REMARKS

This Article discusses possible elements to be considered in patent laws in order to develop a health-sensitive approach that facilitates access to drugs, especially for the poor.

The main premises considered in the preparation of this monograph have been the following:

- *The granting and exercise of patents rights should be consistent with basic goals and interests of the society, particularly promotion and protection of public health.*
- *There is no single patent system. While recognizing its international obligations, each country should shape its patent law according to its socio-economic needs and objectives, including in relation to public health.*
- *Although TRIPs imposes various constraints, it leaves considerable room for countries to design their national laws to address public health concerns.*
- *Developing patent rules to improve access to medicines, particularly for the poor, is an important public health objective.*
- *The improvement of access to medicines requires a pro-competitive approach in several aspects of patent legislation.*
- *Such an approach should aim, as a priority objective, to ensure that patents are granted on developments that constitute true technical contributions, and that patent rights are not unduly used to block innovation and legitimate competition by generic products. In other words, a pro-competitive, public health-sensitive patent law should be primarily based on a proper application of the patentability requirements, supplemented by a set of exceptional measures, such as exceptions to patentability and compulsory licenses.*
- *Patent laws should contain appropriate mechanisms to correct excesses in the exercise of patent rights.*
- *A health-sensitive legal regime should allow governments to act efficiently in cases of emergency, including epidemic crises.*

Implementing a public health approach to patent policy requires not only appropriate legislation, but personnel in parliaments, patent offices, public health ministries, private sector, and courts, equipped to handle patent legislation design and implementation.

While all the issues presented in this Article are important for the design of a public-health sensitive patent law, priority should be given to those relating to the patentable subject matter and the treatment of

the specific cases concerning pharmaceuticals,<sup>208</sup> to the crafting of exceptions to patents rights, especially for experimentation and early working,<sup>209</sup> and to the development of a sound compulsory licensing system.<sup>210</sup> A national law that dealt appropriately with these issues would constitute an important step forward.

Public health goals can be significantly advanced through North-South cooperation, involving both the public and private sectors, through official assistance, licensing of technology, joint ventures, and other modalities. The climate, scope and effectiveness of such cooperation, however, may be significantly enhanced if developed countries abandon the use of unilateral actions for obtaining the protection of commercial interests of their patent holders, in developing countries. International cooperation in this area should recognize the fundamental right of any person to get access to basic health care, and the corresponding obligation of governments to protect and promote public health.

---

208. *See infra* Parts II, IV-V.

209. *See infra* Part VII.

210. *See infra* Part X.