

## MULTILATERAL AGREEMENTS AND POLICY OPPORTUNITIES

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### Introduction

This chapter analyzes the opportunities for local production and technological learning allowed by the use of some of the “flexibilities” contained in the TRIPS Agreement. The chapter is structured as follows. First, it presents the concept of TRIPS ‘flexibilities’ and the main areas where they apply. This section will briefly examine the interpretive value of the Doha Declaration on TRIPS and Public Health which confirmed some of those flexibilities. Second, the chapter will explore the extent to which some of the flexibilities in the area of patent and test data protection may create a favourable policy space to promote domestic production in developing countries. Finally, the chapter will provide recommendations for developing countries in terms of both domestic and international policies.

### TRIPS flexibilities generally

The term ‘flexibilities’ has become a common way of designating various legal doctrines and mechanisms that help to mitigate the effects deriving from the exclusive rights conferred by IPRs. The degree to which such flexibilities are incorporated into national laws determine the room available to adopt measures to protect legitimate competition and consumers’ welfare. As examined below, some of these measures may be specifically used, within certain limits, to allow for the domestic production of IPRs-protected products.

The ‘flexibilities’ allowed by the TRIPS Agreement have been extensively explored in academic analyses<sup>1</sup> and authoritative reports<sup>2</sup>. There is broad consensus that the TRIPS Agreement does not establish a set of uniform rules and that, despite some detailed provisions and the incorporation of the obligations under pre-existing IPRs conventions, it does not cover all aspects of IPRs. Moreover, there are ambiguities in the text that allow for different modalities of implementation whereas, in some cases notably in the area of enforcement, the treaty provisions indicate the objectives to be met rather than the specific ways in which they may be achieved.

The TRIPS flexibilities may be useful for different objectives, ranging from local production to the importation of protected products at the lowest possible price.

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<sup>1</sup> See, e.g. J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT’L L. & POL. 11 (1997). S. Musungu and C. Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, South Centre and WHO, Geneva: 2006; C Correa, *Trade Related Aspects of Intellectual Property Rights (Volume VI of Commentaries on the GATT/WTO Agreements)*, Oxford University Press, 2007.

<sup>2</sup> See the *Report of the Commission on Intellectual Property Rights (CIPR)* established by the government of United Kingdom, 2002 ([www.iprcommission.org](http://www.iprcommission.org), (last visited 25 October, 2007), and the *Report of the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH)*, 2006, available at [www.who.int](http://www.who.int) (last visited 25 October, 2007).

Examples of possible objectives for the application of such flexibilities are given in Table 1.

**Table 1. TRIPS flexibilities: for what purposes?**

Purpose	Flexibilities	Relevant TRIPS provisions
Prevent the appropriation of subject matter existing in nature	Definition of invention	Article 27.1
Avoid patents on minor developments, undue limitations to legitimate competition	Determination of level of patentability requirements	Article 27.1
Access to products at lower prices	Parallel imports; compulsory licenses	Article 6, article 31
Remedy anti-competitive practices	Compulsory licenses	Article 31 (k)
Permit the local exploitation of patented inventions	Compulsory licenses	Article 31
Allow follow-on innovation	Research exception	Article 30
Speed up competition after patent expiry	'Bolar exception'	Article 30

The existence of a number of flexibilities in the TRIPS Agreement has been confirmed by the WTO Ministerial Conference, the highest WTO body, through the Declaration on the TRIPS Agreement and Public Health, adopted in Doha in November 2001<sup>3</sup>. The Declaration is the first WTO instrument to specifically use the concept of 'flexibility' with regard to the TRIPS Agreement (see Box 1). Although the Doha Declaration focused on IPRs related to public health, it is relevant to IPRs in any field of technology<sup>4</sup>.

**Box 1. Doha Declaration on TRIPS and Public Health- Paragraph 4**

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

<sup>3</sup> WT/MIN(01)/DEC/W/2, 14 November 2001, Hereinafter "the Doha Declaration".

<sup>4</sup> A declaration is not, under WTO law an 'authoritative interpretation' in terms of Article IX.2 of the Marrakesh Agreement Establishing the WTO. However, in practice it may have equivalent effects. Members have provided in paragraph 5 of the Doha Declaration an agreed interpretation on certain aspects of the TRIPS Agreement that future panels and the Appellate Body cannot ignore.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

Paragraph 5 of the Doha Declaration specifies some of the flexibilities available to facilitate access to pharmaceutical products. The wording of the *chapeau* of this paragraph makes it clear that it only enumerates some of the possible flexibilities. Sub-paragraphs (a) and (b) (see Box 2) are particularly relevant to the implementation of measures intended to expand domestic production with the use of protected technologies.

**Box 2. Doha Declaration on TRIPS and Public Health- Paragraph 5 (a) and (b)**

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

- a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Sub-paragraph (a) of paragraph 5 of Doha Declaration confirms the relevance of article 7 of the TRIPS Agreement for the interpretation of its provisions<sup>5</sup>. This article provides that the protection and enforcement of intellectual property rights ‘should contribute to the promotion of technological innovation and to the transfer and dissemination of technology’, thereby suggesting that the TRIPS Agreement must be interpreted in a manner that favors access by third parties to technology necessary to further innovation and domestic production. The Agreement should not be regarded as a charter of absolute rights to control the exploitation of protected technologies, but rather as an instrument that requires the use of such technologies ‘to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare’ (article 7).

The confirmation of the Members’ leeway to determine the grounds for the granting of compulsory licenses in sub-paragraph (b) opens the possibility of providing for such

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<sup>5</sup> It is worth noting that before the adoption of the Doha Declaration, in *Canada-Patent protection of pharmaceutical products*, a WTO panel argued, in connection with TRIPS Article 30, that “the goals and the limitations stated in Articles 7 and 8 ” as well as those of “other provisions of the TRIPS Agreement which indicate its object and purposes ...must obviously be borne in mind” (WT/DS114/R, 17 March 2000, para. 7.26).

licenses in cases of lack of industrial exploitation of a patent, as further discussed below.

Although limited to Least Developed Countries (LDCs), paragraph 7 of the Doha Declaration confirms<sup>6</sup> that transfer of technology in order to create manufacturing capacity is consistent with the objectives of the TRIPS Agreement.

### **Preserving the freedom to operate**

Patenting in developing countries is overwhelmingly of foreign origin. Globally, there was an increase in non-resident patenting of 7.6% from 2004 to 2005, while resident patent filings increased by 6.6%; the most notable increases can be seen at patent offices of ‘emerging States’, particularly China<sup>7</sup>. However, patent statistic may be misleading. In the case of China, for instance, there are three categories of patents: utility models, design patents, and invention patents. The first two categories of patents (which are granted without prior examination) accounted for 64.1% of the total number of patent applications in 2005, and the growth rate in industrial design was higher than that of invention patents<sup>8</sup>. In Brazil, similarly, statistics show a high participation of residents in total patenting, but Brazilian patent figures include both patents and utility models. The great majority of the latter are filed by domestic applicants and account for about 50% of all domestic applications and grants<sup>9</sup>.

Given the control that foreigners may exert through the patent system over technologies necessary to undertake local production, a key policy issue is what concepts and criteria are applied to determine the patentability of inventions. Although the TRIPS Agreement specifies the standards to be used (novelty, inventive step or non-obviousness, industrial applicability or utility), governments enjoy considerable room to determine several important aspects of this as well as of other important components of their patent policy (see Table 2).

**Table 2**

### **Flexibilities regarding patentability criteria and claims’ coverage**

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<sup>6</sup> Paragraph 7: ‘We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2...’.

<sup>7</sup> WIPO, *2007 WIPO Patent Report* (WIPO, Geneva, 2007), available at [http://www.wipo.int/ipstats/en/statistics/patents/patent\\_report\\_2007.html#P143\\_10808](http://www.wipo.int/ipstats/en/statistics/patents/patent_report_2007.html#P143_10808) (last visited 19 November 2007).

<sup>8</sup> X Li, ‘Demystifying explosion in patenting growth rate’, *South Bulletin*, Issue 1, October 2007, available at <http://www.southcentre.org> (last visited 19 November 2007).

<sup>9</sup> See <http://www.rieyt.org/interior/interior.asp?Nivel1=1&Nivel2=3&Idioma> (last visited 19 November 2007).

Flexibility	Possible use	Relevant TRIPS provisions
Definition of invention	Determining the admissibility or not of patents on natural substances, including genes	Article 27.1
Patentability criteria	Establish the level of the inventive step requirement; avoid 'evergreening' patents	Article 27.1
Disclosure	Information sufficient to execute the invention	Article 29
Scope of claims	Protection limited to actually obtained embodiments of an invention	None
Doctrine of equivalents	Literal infringement or infringement by equivalence	None

Defining the concept of invention raises several issues of interest for a policy aiming at promoting local production. One of such issues is whether 'invention' should be broadly understood, as in many developed countries, so as to encompass claims on genes and other substances found in nature, even if merely isolated or purified. It may be argued that countries rich in genetic resources have a lot to gain if patents of that kind were allowed, as they may encourage investment in developing and commercializing new products. However, most of those countries lack the technological capacity and, above all, the capital required to initiate and sustain viable activities in this field. The window of opportunity to file patents on natural substances may be exploited more effectively by foreign companies. Local patenting, in the absence of a robust domestic industry and a supportive scientific and technological infrastructure, may be small or null. In addition, allowing patents for natural substances, genes may generate high social costs, for instance, if the realization of diagnostic tests is subject to the control of the patent owner<sup>10</sup>.

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<sup>10</sup> As illustrated by the affordability problems created by Myriad Genetic's patents over *BRCA1* and *BRCA2* breast cancer genes cancer. See 'BC sidesteps patent claim, transfers BRCA gene testing to Ontario', *CMAJ*, 21 January, 2003; 168 (2), available at <http://www.cmaj.ca/cgi/reprint/168/2/211.pdf> (last visited 22 November, 2007).

Deciding where to set the bar of inventiveness is one of the critical aspects in patent policy. Patents may be conferred on the basis of a more or less strict scrutiny of inventive step. A low requirement leads to the proliferation of patents –sometimes called ‘low quality’ patents<sup>11</sup>- that may be used to keep competitors out of the market, especially if they are unable or unwilling to bear the costs of challenging the validity of wrongly granted patents.

A strict inventive step reduces the number of patents granted; as result, the space for competition is broader. However, in this case the possibility of acquiring patents is essentially limited to large companies or entities with significant technological capacity. In addition to the hurdles of complying with a rigorous standard of inventive step, the cost of patenting and litigation may be too high for small and medium companies, particularly in developing countries.

Despite its importance for some public policies, such as public health, competition and industrial development, governments commonly pay little attention to the determination of the optimum level of inventive step to be applied. Rather than a deliberate State policy, as noted by Drahos, ‘[I]t is the daily patent office routines of a country that determine the build-up of patents in an economy...’<sup>12</sup>. Patent offices tend to establish the criteria for patentability on the basis of their own choices, often with the assumption that the more patents granted the better. Some patent offices, such as those from the US, Japan, Australia and the European Patent Office (EPO) have significantly influenced, through technical assistance (provided directly or through WIPO) the way in which developing country patent offices operate. Broad interpretations of the patentability standards and of the scope of claims have led many of such offices to ordinarily grant patents on minor developments, as illustrated by the proliferation of ‘evergreening’ patents in the pharmaceutical sector<sup>13</sup>. In fact, developing country patent offices ‘have been integrated into a system of international patent administration in which the grant of low-quality patents by major patent offices is a daily occurrence’<sup>14</sup>. Another illustration is provided by the acceptance by some patent offices<sup>15</sup>, under the influence of the EPO,

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<sup>11</sup> For the US case, see generally A Jaffe and J Lerner, Innovation and Its Discontents : How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It, Princeton University Press, Princeton, 2004.

<sup>12</sup> P Drahos, ‘Trust me’: *patent offices in developing countries*, Centre for Governance of Knowledge and Development available at [www.cgkd.anu.edu.au](http://www.cgkd.anu.edu.au) (last visited 19 November 2007).

<sup>13</sup> In *AstraZeneca Canada Inc. v. Canada (Minister of Health)* (2006 SCC 49), for instance, the Supreme Court of Canada referred to “commercial strategy of the innovative drug companies to evergreen their products by adding bells and whistles to a pioneering product even after the original patent for that pioneering product has expired even if the generic manufacturer (and thus the public) does not thereby derive any benefit from the subsequently listed patents’.

<sup>14</sup> P Drahos, *op. cit.*

<sup>15</sup> This is the case, for instance, of China and Viet Nam. See on the latter N Dzung, Vietnam patent law. Substantive law provisions and existing uncertainties, *Chicago-Kent Journal of Intellectual Property* (2007, No. 6, p. 138-156).

of patents on the ‘second indication’ of known pharmaceuticals, even where the respective national laws exclude the patentability of methods of medical treatment and other subject matter without industrial applicability.

It has been argued that the application of lax patentability standards in developing countries could have beneficial effects, as it would allow small and medium companies to apply for and obtain patents that would not be viable if stricter standards were applied. This is a questionable argument, though. First, there is no justification to detract knowledge from the public domain to favour some local companies over others, when all may utilize the same set of technologies in a competitive environment. Second, marginal changes to the state of the art are generally low-risk and require small investment. The argument of recovering high costs in R&D does not apply in these cases. Third, other titles, such as utility models, or new schemes based on liability rules<sup>16</sup>, could be more appropriate than patents to promote minor innovations in a manner that optimizes social benefits. Fourth, foreign applicants are generally much better equipped than local companies to take advantage from lax patentability standards. The World Bank has been right in recommending developing countries to apply more flexible IPRs standards than do their developed counterparts, and particularly, that they “could set high standards for the inventive step, thereby preventing routine discoveries from being patented. Regarding patent scope, it is sensible to exercise strict claims and discourage multiple claims in patent applications.”<sup>17</sup>.

Patent laws generally establish the extent to which an invention needs to be disclosed in order to obtain a valid patent. The general standard is that disclosure should be ‘sufficiently clear and complete for the invention to be carried out by a person skilled in the art’ (article 29, TRIPS Agreement). Some laws, such as in the US, also require the applicant to indicate the *best mode* for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

The general rule about disclosure, however, is differently applied by patent offices. Many follow a very flexible approach and allow, for instance, the so-called ‘Markush claims’ which cover a large number of possible embodiments of an invention, even if never empirically obtained and tested for the claimed application of the invention. In the chemical field such claims permit to protect a chemical structure with multiple functionally equivalent chemical entities allowed in one or more parts of the compound, thereby sometimes covering millions of possible compounds. After a patent containing Markush claims has been granted, it is common for the patent owner to select a number of the embodiments and obtain, in some jurisdictions, a new patent on the selection for an additional period.

Another relevant issue is the level of detail that patent specifications should include in order to adequately disclose the invention. Patent agents tend to draft patent applications in a way that do not disclose all the relevant information that potential competitor may need to put the invention into practice. Although the concept of ‘person skilled in the art’ is generally considered as a notion of universal applicability, the information contained in the specifications may need to be more comprehensive in applications filed

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<sup>16</sup> See J Reichman, Of Green Tulips and Legal Kudzu: Repackaging Rights in Subpatentable Innovation. (2000; *Vanderbilt Law Review* 53:pp. 1743-1798).

<sup>17</sup> WORLD BANK, *GLOBAL ECONOMIC PROSPECTS AND THE DEVELOPING COUNTRIES 2002* 129 (2001: Washington D.C)p. 143.

in countries with low local scientific and technological capacity than in those with a pool of people that may understand complex technical.

It is important to note that the TRIPS Agreement does not prevent a Member country from adopting a strict concept of ‘a person skilled in the art’ for assessing the patentability (for instance, a person with university degree or large experience in a technological field) while resorting to a less qualified ‘person skilled in the art’ to consider the extent of disclosure of an invention. In fact, the disclosure requirement could be set in developing countries in accordance with the average knowledge of a skilled person in such countries<sup>18</sup>.

Despite the room left to WTO Members to determine the modes of disclosure, recent FTAs entered into between the US and a number of countries contain a limitation to the disclosure obligation. For instance, according to article 15.9 of RD-CAFTA, ‘each Party shall provide’ that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing date’. This provision, limits the disclosure obligation to what is necessary to *execute* the invention, although this may be insufficient to *understand* how it works, thereby reducing the value of patent documents for domestic specifications and researchers as a source for follow on innovation or research in new fields. Another implication of this provision is that it may be read as preventing the incorporation of a best mode requirement (that is, information about the best way known to the applicant to implement the invention)<sup>19</sup>.

The scope of claims may have important implications for establishing the ‘freedom to operate’ with regard to production and follow-on innovation. Broad claims may be rarely justified, such as in the cases of ‘pioneer’ inventions. They distort competition and discourage production and innovation, particularly when systematically allowed for merely incremental innovations<sup>20</sup>.

One modality of broad claims is that based on *functional* terms, that is, claims that describe what an invention does, not what the invention structurally is. Functional claims cover all possible ways of obtaining a given result. One example is US patent 4.627.192 granted over sunflower seeds that produce certain levels of oleic acid. It discloses a sunflower seed having an oleic acid content of 80% and a low linoleic acid content. Any sunflower variety producing these levels would be covered under the patent, and not only that identified by the ‘inventor’<sup>21</sup>.

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<sup>18</sup> See, e.g. UNCTAD, *The TRIPS Agreement and Developing Countries* (Geneva and New York, 1996), p. 33.

<sup>19</sup> A coalition of patent lawyers and corporations has lobbied for the derogation by the US Congress of the best mode requirement. See [http://www.aipla.org/Template.cfm?Section=By\\_Topic&template=/ContentManagement/ContentDisplay.cfm&ContentID=9895](http://www.aipla.org/Template.cfm?Section=By_Topic&template=/ContentManagement/ContentDisplay.cfm&ContentID=9895) (last visited 30 November, 2007). The Advisory Commission on Patent Law Reform had also recommended its elimination in 1992.

<sup>20</sup> See, e.g., R Mazzoleni and R Nelson, The benefits and costs of strong patent protection: a contribution to the current debate, *Research Policy* (1998, No. 27, p. 273-284).

<sup>21</sup> This was the ‘Pervenets’ variety only.

An interesting example of a legislation that applies a strict approach to patent scope is provided by Pakistan's Patents Ordinance, as revised in 2002. Section 13(3) requires that '[E]ach application shall relate to one invention only'. As a result, separate applications need to be filed for intermediates and the final product and eventually for processes of manufacture. Moreover the new sub-sections 15(2A)<sup>22</sup> and (8)<sup>23</sup> require the structural definition of chemical products and separate applications for an active ingredient and their derivatives and salts. Hence, patent applications generally claiming the 'pharmaceutically acceptable salts, prodrugs, etc.' without disclosing its physical, chemical, pharmacological and pharmaceutical properties would not be acceptable.

The post-war Japanese patent policy provides an interesting example of a system deliberately designed to increasing the room for local companies to produce and innovate around foreign patented technologies. In accordance with Section 1 of the Japanese patent law the purpose of the patent system was "to encourage inventions by promoting their protection and utilization *so as to contribute to the development of industry*" (emphasis added). One of the key elements of that policy was to allow patents with narrowly defined claims. The system was effective in enhancing the negotiating capacity of domestic companies to obtain technology transfer from or to establish other agreements with foreign patent owners. The alleged pro-industrial bias of the Japanese patent law raised considerable criticism in US circles. The U.S. General Accounting Office (GAO) undertook a survey of U.S. firms with experience in patenting in Japan, which identified a number of practices that favoured the dissemination of technology amongst domestic companies and the development of their own patent packages<sup>24</sup>. Such practices included:

-laying open patent applications for public examination during the examination process, combined with long delays prior to the actual commencement of (deferred) examination (on average, approximately three years);

-allowing for pre-grant opposition;

-allowing compulsory cross-licensing in the event of an improvement patent;

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<sup>22</sup> Section 15 (2A) For a chemical product intended for use in medicine or agriculture, the specification shall be specific to one chemical product only describing the physical, chemical, pharmacological and pharmaceutical properties or, as the case may be, the properties related to its use in agriculture and its impact on environment.

<sup>23</sup> Section 15(8): 'Claim or claims in respect of a complete specification of a chemical product intended for use in agriculture or medicine shall be structurally defined and shall relate to a single chemical product only, excluding its derivatives and salts, each of which, with a material or a novel improvement in its claim from the main product, shall be filed as a separate invention or where applicable as a divisional application. Where structural description is not possible, as in the case of biological products, the "product by process" claim shall be made and protection shall be limited to the product obtained with the claimed process only: Provided that a claim which is based on a mere admixture resulting only in aggregation of the properties of the component substances thereof, or a processing of producing such substance, shall not be allowed'.

<sup>24</sup> United States General Accounting Office, *Intellectual Property Rights: U.S. Companies' Patent Experiences in Japan* (GAO/GGD-93-126) (1993: Washington, DC: GAO), quoted in Girouard, R Girouard, *U.S. Trade Policy and the Japanese Patent System* (1996: BRIE Working Paper 89, available at <http://brie.berkeley.edu/publications/WP%2089.pdf>, last visited 29 November 2007).

-patent flooding, that is, surrounding a patent with a number of patents on improvements in order to force the owner of the first patent to enter into negotiations or grant a license to the owner of the subsequent patents. For instance, ‘a U.S. firm reported to GAO that a Japanese competitor had surrounded its patents for a “breakthrough synthetic fiber” with 150 patents on incremental improvements to the U.S. company’s invention, and that the Japanese firm subsequently tried to pressure the U.S. firm into cross-licensing its “core” technology’<sup>25</sup>.

In accordance with GAO’s 1993 report, the Japanese patent law was biased in favour of industrial development, and against the individual inventor: “patent experts contend that the Japanese patent system seeks to promote technology development by disseminating technology, rather than rewarding inventors with exclusive rights”.<sup>26</sup>

The worst combination for a patent policy aiming at promoting both industrial development and innovation is a low inventive step standard coupled with broad patent claims. Such combination is ‘not in the interest of developing nations (nor, in the judgment of many, of the developed nations either)’<sup>27</sup>.

Finally, the methods used for interpretation of patent claims and, particularly, when an infringement may be established or not, may greatly affect the space left for local production and innovation. One of the main methods applied for claim interpretation is the ‘doctrine of equivalents’. This doctrine has attracted large interest of scholars and professionals in developed countries, but its applicability and implications have been scarcely explored in developing countries. Commonly, this doctrine is not spelled out in the statutes, but results from case law. Thus, this important body of policy is determined by judges rather than by the agencies responsible for industrial and technological development. An expansive doctrine of equivalents may have negative effects on innovation<sup>28</sup>, as it allows the patent owner to block follow-on innovations based on the original invention.

The basic issue addressed by the doctrine of equivalents<sup>29</sup> is whether non-literal infringement may be prevented by the patent owner. The way in which issues such as how an ‘equivalent’ is defined and at what date its existence is judged are key to determine how much space competitors have to work around a patented invention. Thus, if a monohydrate variant of a pharmaceutical product is deemed equivalent to a

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<sup>25</sup> Girouard, op. cit., p. 5.

<sup>26</sup> GAO Report, quoted in Girouard, op. cit., p. 17

<sup>27</sup> J Barton, “Integrating IPR policies in development strategies. Background paper for Bellagio meeting, 30 October – 2 November 2002, available at [www.ictsd.org](http://www.ictsd.org) (ipronline) (last visited 20 December 2007).

<sup>28</sup> See, e.g., R Merges, *Patent law and policy. Cases and materials* (1992: Boston; Contemporary Legal Educational Series) p. 705.

<sup>29</sup>T Adam, Patent scope and doctrine of equivalence: critical aspects, in Chamas, C., Nogueira, M. and Scholze, S. (coordinators), *Intellectual property for the academy*, Fundacao Oswaldo Cruz, Ministerio da Ciencia e Tecnologia, Fundacao Konrad Adenauer, Brasil, 2000.

patented trihydrate variant, the production and sale of a competitive product, not strictly claimed in the patent, may be banned by the patent owner.

Countries have many options to deal with the doctrine of equivalents, ranging from requiring literal infringement to considering that infringement exists when a substantially similar means is used to perform a substantially similar function, independently of the inventive step exhibited by the variant used. Judging the equivalence at the date of infringement (as currently done, for instance, under US and Japanese law) rather than at the date of the patent application, expands the control of the patent owner on innovations around its patent.

### Exceptions to patentability

There are a few cases in which the TRIPS Agreement permits not to grant patents based on the type or certain characteristics of the subject matter (see Table 3).

Table 3

#### Flexibilities about patentable subject matter

Flexibility	Possible use	Relevant TRIPS provisions
Non patentability of inventions contrary to <i>ordre public</i> or morality in deciding public health	Harmful or morally unacceptable products	Article 27.2
Non patentability of diagnostic, therapeutic and surgical methods	Allows, e.g. the exclusion of patents on second uses of known products	Article 27.3 (a)
Plants and animals	Permits the exclusion e.g. of genetically modified plants or animals	Article 27.3 (b)

According to article 27.2 of the TRIPS Agreement, Members “may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law”.

Non-patentability may only be established under article 27.2 if the commercial exploitation of the invention is prevented in the respective country and such prevention is necessary to protect the interests referred to above. This exclusion would not allow to determine, for instance, the non-patentability of an HIV/AIDS vaccine, even if that were necessary to protect public health, since a condition for the TRIPS-consistency of the exclusion would be the ban to circulate the invention in the territory of the country.

Of immediate relevance to public health policy is Article 27.3 (a) of the Agreement, which permits Members to exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals”. Most countries in the world do not grant patents over such methods due to ethical or public health reasons, or simply because they do not meet the industrial applicable requirement imposed by most patent laws.

The exclusion of therapeutic methods may constitute one of the grounds for denying patents covering ‘second indications’ of pharmaceutical products, as patents regarding such indications are essentially equivalent to patents on methods to treat a disease. This may be particularly important in countries with manufacturing capacity in pharmaceuticals, where second indication patents may be used to block the introduction of generics. In fact, Argentina, Brazil<sup>30</sup> and India do not grant patents on second indications. They have rejected the rather elusive argument that second indication patents may benefit local producers as they may be able to find new applications for existing drugs without incurring the costs of developing them. Marketing a known product for a new indication requires new clinical studies that demonstrate the efficacy and safety of the product. The cost of such studies is too high for most domestic pharmaceutical companies and poses a high barrier for the hypothetical use of second indication patents as a window of opportunity to expand their business.

### **Research and ‘early working’ exceptions**

Can experimentation, including for commercial purposes, be legitimately conducted by third parties on patented inventions? Or is the patent owner entitled to block it? Can the producer of generic pharmaceutical or agrochemical products undertake tests to carry out the procedures for marketing approval before the expiry of the relevant patent? The reply to these questions depends on national laws. The TRIPS Agreement, in article 30, permits Members to provide for limited exceptions to the exclusive rights conferred by a patent, subject to a three-step test<sup>31</sup>.

The patent holder’s legitimate interests do not include the faculty to control further experimentation or research on a patented invention<sup>32</sup>. It is vital for society to ensure a sustained scientific and technological progress based on past innovations. The patent owner cannot be given the power to prevent new generations of innovators to rely on an

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<sup>30</sup> Divergences arose in Brazil between the Instituto Nacional de Propriedade Industrial, which favored second indication patents, and ANVISA (the national health authority) which aimed at excluding such patents. See, e.g., M Basso, *Intervention of Health Authorities in Patent Examination. The Brazilian Practice of the Prior Consent*, *International Journal of Intellectual Property Management*, vol. 1, No. 1, 2006.

<sup>31</sup> See, e.g. C Correa, *Trade Related Aspects of Intellectual Property Rights (Volume VI of Commentaries on the GATT/WTO Agreements)*, Oxford University Press, 2007.

<sup>32</sup> See, e.g. H Holzapfel and J Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, August 5, 2007 Draft, available at [http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=joshua\\_sarnoff](http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=joshua_sarnoff).

invention that, in turn, was derived from the pool of knowledge available to the inventor. Innovators ought to have the possibility of using their predecessors' work to develop their own creative and inventive capacities: '[T]he ability to experiment free from the threat of patent infringement or from the tax of patent licenses is critical to scientists and to competitors seeking to develop non-infringing or blocking improvements. A broad experimental use exception is therefore essential to furthering scientific knowledge and technological development to benefit humanity'<sup>33</sup>.

Allowing for the experimentation on patented inventions may be important to initiate or expand industrial activities in various situations (see Table 4).

**Table 4**

**Flexibilities regarding research and product approvals**

Flexibility	Possible use	Relevant TRIPS provisions
Experimentation or research on patented invention	<ul style="list-style-type: none"> <li>-challenge the validity of a patent;</li> <li>-request a voluntary or compulsory license;</li> <li>-invent around a patented product or process;</li> <li>-improve a patented invention.</li> </ul>	Article 30
Early working ('Bolar') exception	Approval of pharmaceutical products before the expiry of relevant patents	Article 30

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<sup>33</sup> J. Sarnoff, BRIEF OF *AMICI CURIAE* CONSUMER PROJECT ON TECHNOLOGY, ELECTRONIC FRONTIER FOUNDATION AND PUBLIC KNOWLEDGE IN SUPPORT OF PETITIONER, MERCK KGaA, v. INTEGRA LIFESCIENCES I, LTD. and THE BURNHAM INSTITUTE, On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit, February 22, 2005.

A research or experimentation exception would seem to be clearly validated under the first and second steps of article 30 ('limited exceptions' that 'do not unreasonably conflict with a normal exploitation of the patent') of the TRIPS Agreement. If patent protection is conceived as a 'means to induce inventors to disclose their invention to the public in order to facilitate the dissemination and advancement of technical knowledge, it appears illegitimate to prevent experimental use during the term of the patent'<sup>34</sup>.

Such an exception may foster 'inventing around' patented inventions and follow-on innovations. It may also facilitate challenges to the validity of wrongly granted patents or the request of a compulsory license. Such an exception may also legitimize the undertaking of the tests necessary to obtain the marketing approval of a pharmaceutical product when an 'early working' exception (discussed below) is not formally provided for.

In order to ensure a sufficient freedom to experiment or carry out research on a patented invention, the exception should desirably meet the following requirements<sup>35</sup>:

- the exception may be invoked by any party, including commercial entities<sup>36</sup>, and not only when experimentation or research is done privately or in an academic environment<sup>37</sup>;
- the exception should cover acts done with or without gainful intent;
- the exception should cover any acts done for experimental purposes, including production, importation and use of samples of the patented product or implementation of the patented process for testing and research;
- the exception should be applicable to acts conducted for scientific or technological purposes<sup>38</sup>; it should not be limited to academic activities<sup>39</sup>.

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<sup>34</sup>M Senfteben, *Copyright limitations and the three-step test. An analysis of the three-step test in international and EC copyright law*, Kluwer Law International, The Hague, 2004, p. 229.

<sup>35</sup> For an analysis of comparative law on the subject see C Correa, International Dimension of the Research Exception, SIPPI Project, AAAS, Washington D. C., available at <http://sippi.aaas.org/intlexemptionpaper.shtml>, 2005 (last visited 30 November, 2007).

<sup>36</sup> For instance, in Panama (Law No. 35, 1996, article 19.2) there is no patent infringement when "an industry or enterprise... engages in acts of manufacture or use of the invention for experimental purposes relating to the subject matter there or for purposes of scientific or education research."

<sup>37</sup> See, however, the Mexican and Argentine laws according to which the exception applies to a third party who performs research "privately or in an academic environment" (article 22(1) and 36(a) respectively).

The formulation of the research or experimentation exception, if intended to promote follow-on innovation and industrial development, should clearly distance itself from the very narrow interpretation given by the US courts<sup>40</sup>.

A well crafted experimentation or research exception serves both the interests of public policies in reducing prices of drugs via generic competition, and industrial policies aimed at expanding local production. A comparative review of current legislation<sup>41</sup>, however, reveals that policy makers in developing countries have not paid significant attention to the problems associated to experimentation or research on patented inventions and many countries, including some with significant scientific and technological potential have not fully utilized the room left by the TRIPS Agreement to provide for such exception<sup>42</sup>.

Some countries have also incorporated the so-called ‘early working’ or “Bolar exception”, which allows a generic pharmaceutical company to conduct the acts necessary to carry out tests and obtain marketing approval of a generic product before the expiry of the patent, for commercialization thereof after its expiry<sup>43</sup>. As mentioned, a Bolar-type exception results from the application of an experimental exception<sup>44</sup>.

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<sup>38</sup> Provisions that exempt both experimentation and scientific activities are contained, for example, in the patent laws of Costa Rica [article 16(2)(b)and (c)], Cyprus [article 27 (3) (iii)], Guatemala [article 130(c)], Kazakhstan. (article 12), Kyrgyzstan [article 13(ii)], Mauritius [article 21(4)(d)], Mongolia [article 18(2)(2)], Nicaragua [article 46(a) and (b)], and Paraguay [article 34 (a) and (b)]. The Brazilian Industrial Property Code, 1996, refers to “acts practiced by non-authorized third parties, with an experimental purpose, related to scientific or technological studies or research”. In the Bangui Agreement (revised in 1999), the exception alludes to “acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research” (article 8(1)(c)).

<sup>39</sup> Many patent laws refer, however, to scientific research only (e.g., patent law of Algeria [article 12(1)], Barbados [article 6(1)], Cuba [article 54(3)], Egypt [article 101(1) (1)], Guinea-Bissau [article 4(c)], Kenya [article 58(1)], Lebanon (article 42) Malaysia [article 37(1)], Saudi Arabia (article 24) and Uganda [article 29(a)].

<sup>40</sup> See *Madey v. Duke University*, 307 F.3d 1351 (Fed. Cir. 2002).

<sup>41</sup> See C Correa, 2005, ob. cit.

<sup>42</sup> Ibidem

<sup>43</sup> For instance, the Thai Patent Act B.E 2522 (1979), as amended by B.E 2535 (1992), provides that the patentee's exclusive rights shall not apply to ‘any act in respect of applications for drug registration, the applicant intending to produce, sell or import the patented pharmaceutical when the patent expires’ (article 36.5).

<sup>44</sup> For instance, the patent law of Croatia (1999) exempts ‘acts done for the purposes of the research and development of the subject matter of the protected invention, in particular: making, using, offering for sale, importation, or exportation of the protected product, where such acts are reasonably connected with the experiments and tests necessary for the registration of the human and veterinary medicines, medical and veterinary products or preparations for the protection of plants’ (article 5.2).

The TRIPS consistency of the ‘Bolar exception’ was confirmed by the WTO Dispute Settlement Body in *Canada--Patent Protection for Pharmaceutical Products*<sup>45</sup>. It may be important to encourage the development of a domestic pharmaceutical industry, as it allows an early entry into the market with generic versions of off-patent products. In order to maximize such effect, the exception should be framed in a manner that

-does not require an extension of the patent term in exchange for the availability of the exception. Although such extension has been provided for under the US law and the law of a few other countries (e.g. Australia), it is not a condition for the TRIPS-consistency of the exception and would unnecessarily delay the market entry of generic products.

-allows for acts required to obtain marketing approval domestically and abroad, thus allowing the generic companies to export and exploit economies of scale<sup>46</sup>.

However, the US FTAs entered into with a number of countries since year 2000 limit the permission to export protected subject matter for ‘purposes of meeting marketing approval requirements’ in the exporting country, as allowed under Canadian and other laws. This would prevent generic producers from FTAs’ Parties from exporting samples of a patented product in order to obtain marketing approval in another country during the life of the patent in such Parties, even if the patent had expired or did not exist in the foreign country where market authorization were sought.

*Data exclusivity*

The protection of undisclosed test data necessary for the marketing approval of pharmaceutical and agrochemical products was first introduced in an international instrument by the TRIPS Agreement in article 39.3. This has been one of the most controversial provisions in the implementation of said Agreement. Under a literal interpretation of the TRIPS obligation, in accordance with the Vienna Convention on the Law of the Treaties, such data must be protected under unfair competition rules (article 10bis of the Paris Convention for the Protection of Industrial Property), which does not require the grant of exclusive rights.

The application of unfair competition rules has a clear pro-competitive and pro-development effect, as it allows domestic companies to enter the market as long as patent protection does not exist, without the need of unnecessarily duplicating trials to obtain test data that are already available (see Table 5).

**Table 5**

**Protection of test data**

Flexibility	Possible use	Relevant TRIPS provisions
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<sup>45</sup> See Report of the WTO Panel, *Canada - Patent Protection for Pharmaceutical Products*, WT/DS114/R (2000).

<sup>46</sup> See, for instance, Section 55(2)(2) of the Patent Act of Canada, which has become a model for other national laws.

Protection of test data against unfair competition	Approval of generic products may rely on existing test data or prior approval of the originator's product in the country or abroad.	Article 39.3
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However, the US, the European Union and other developed countries have adopted *sui generis* regimes that provide for a term of exclusivity for the use of test data by the originator company, even in the absence of patent protection. Many developing countries have been coerced to accept a similar solution, through unilateral pressures or in the context of their accession to the WTO<sup>47</sup> or the negotiation of FTAs. Notably, the US FTAs drastically depart from the TRIPS standard with regard to data protection. They oblige Parties to grant exclusive rights for at least five years for pharmaceuticals and ten years for agrochemicals counted from the date of approval of the product in their territory, irrespective of whether the data are undisclosed or not. Such exclusivity would also apply irrespective of whether the national health authority requires or not the submission of the data, that is, even in cases where the authority relies on the approval made in a foreign country. 'Data exclusivity' covers chemical entities that are not 'new', as they may have been previously approved in other countries or in the same country (in the case of new indications).

An extreme version of data exclusivity was incorporated into the CAFTA-Dominican Republic FTA, where a waiting period of five years was provided for. According to article 15.10.1 (b), a Party may require that the person providing the information in another territory seek approval in the Party within 5 years after obtaining marketing approval in the other territory. Thus, in accordance with one interpretation, the originator of the test data would enjoy a full ten years period of exclusivity during which no other party would be able to use, without his consent, directly or indirectly, the relevant test data<sup>48</sup>.

In recognizing the negative effects of data exclusivity on access to medicines in developing countries, a bipartisan agreement reached in June 2007 between the Republican and Democratic parties at the US Congress made concrete suggestions to mitigate the data exclusivity requirements in the FTAs, albeit only limited to those agreements signed by the US government with Peru and Panama. It introduced the concept of 'concurrent' protection, that is, the term of data exclusivity protection is to be counted from the date of marketing approval in the United States and not in the Party

<sup>47</sup> See F. Abbott and C. Correa, *Intellectual Property Issues in WTO Accession Negotiations*, QUNO, Geneva, 2007, available at <http://www.quno.org/geneva/pdf/economic/Issues/WTO-IP-English.pdf> (last visited 24 November 2007).

<sup>48</sup> However, the five year term may be interpreted as allowing a Party to establish the obligation to seek approval in its territory within a shorter term (e.g. one year) in order to secure data protection. See C Correa, *Implementación de la protección de datos de prueba de productos farmacéuticos y agroquímicos en DR-CAFTA -Ley Modelo*, ICTSD, Geneva, available at [www.ictsd.org](http://www.ictsd.org) (last visited 24 November 2007).

where protection is sought. In addition, data exclusivity is mandated for a period that 'shall normally mean five years from the data on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them.'" This means that the period of exclusivity could be less than 5 years, that a country may require disclosure of information about the cost of producing the data and establish the period of exclusivity on a case-by-case-basis.

The EU currently pursues trade negotiations with a number of countries including the Andean Community, MERCOSUR, CARIFORUM (Caribbean), and ACP countries<sup>49</sup>. A negotiating paper submitted by the EU to the CARIFORUM countries in the context of the negotiation of Economic Partnership Agreements (EPAs) includes a number of TRIPS-plus provisions with regard to copyright, data bases, trademarks, industrial designs and geographical indications, as well as with regard to enforcement, but does not contain additional substantive standards on health-related issues<sup>50</sup>. This approach would be limited, nevertheless, in accordance with the EU Commissioner, to those countries considered sufficiently 'poor' by the EU to receive such special treatment. More advanced developing countries may be subject to demands of TRIPS-plus standards, particularly with regard to test data<sup>51</sup>.

### **Compulsory Licenses**

Compulsory licenses, including non-commercial government use, are important TRIPS flexibilities that may be used, *inter alia*, to allow or encourage local production of protected products. Such licenses may be used both for local production as well as for importation of patented products. When these are inputs for the production of other products, importation under such licenses may be a requisite to permit local production on viable economic conditions.

Prior to the TRIPS Agreement, it was well accepted that under the Paris Convention for the Protection of Industrial Property (the Paris Convention), countries could issue compulsory licenses to address situations of 'lack of working' of a patent<sup>52</sup>. The paradigm that underpinned this Convention included the transfer of technology and the development of industrial capacities through compulsory licenses. The lack of working was qualified as an 'abuse'<sup>53</sup>.

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<sup>49</sup> That is, the countries from Africa, the Caribbean and the Pacific signatories of the Lomé Convention (1975), succeeded by the Cotonou Agreement (2000).

<sup>50</sup> However, the proposed standards on enforcement (e.g. expanded border measures) may affect trade in medicines and active ingredients.

<sup>51</sup> An European Parliament resolution of 12 July 2007 on the TRIPS Agreement and access to medicines, called on the European Council 'to meet its commitments to the Doha Declaration and to restrict the Commission's mandate so as to prevent it from negotiating pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licences, within the framework of the EPA negotiations with the ACP countries and other future bilateral and regional agreements with developing countries'.

<sup>52</sup> See, e.g., M. Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licences at International Law* (1997; 35 OSGOODE HALL L.J. 243).

<sup>53</sup> See article 5A of the Paris Convention.

Compulsory licenses were extensively used in Canada since the 1960's in order to promote the development of a local pharmaceutical industry<sup>54</sup>. The policy was widely successful. When Canada was forced to change it, as a result of US pressures and the adoption of the North American Free Trade Agreement, a vibrant domestic pharmaceutical industry had already been established<sup>55</sup>. The US has also made a broad use of compulsory licenses. Although they were granted to remedy anti-competitive practices (particularly in the context of companies' mergers that may lead to a monopolistic market position) or for government use, their impact on local production was probably significant.<sup>56</sup>

During the Uruguay Round negotiations, developed countries made intense efforts to secure that the TRIPS Agreement would not allow the granting of compulsory licenses in cases of lack of local exploitation of a patent. This position obviously aimed at preserving the room for transnational enterprises to decide where to set up production facilities and where to exploit their IPRs merely through importation. Such efforts concluded with an ambiguous compromise contained in article 27.1 of the Agreement<sup>57</sup>. While the US and some commentators have read this article as the death sentence of any working obligations for patent owners, a proper interpretation of the provision does not support this view<sup>58</sup>.

The obligation to work a patent –understood as the local manufacture of the patented product or the industrial use of the patented process– was first established in the United Kingdom and incorporated into many national laws during the nineteenth and twentieth centuries. During the twentieth century, however, most industrialized countries relaxed or eliminated such an obligation in order to facilitate the transborder activities of transnational corporations in increasingly globalized markets.

Although the WTO bodies have not confirmed -or denied- the possibility of granting compulsory licenses in cases of lack of local exploitation of a patent, the Doha Declaration (paragraph 5) confirmed the right of WTO Members to determine the *grounds* for the grant of a compulsory license. In January 2001, the US brought a complaint against Brazil arguing that the Brazilian law's authorization to grant compulsory licenses when patents were not worked was TRIPS-inconsistent<sup>59</sup>. However, the US withdrew the complaint before a panel was established. It is unclear whether US fared losing the case and setting a negative precedent for the interests of

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<sup>54</sup> See, e.g. J Reichman and C. Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS and an Overview of the Practice in Canada and the United States of America*, Issues Paper No. 5, UNCTAD and ICTSD, Geneva, 2002.

<sup>55</sup> At the end of 2006, generic medicines accounted in Canada for 44 per cent of all prescriptions and 18 per cent of the \$17-billion market. It invested 15% of sales in R&D. See [http://www.canadiangenerics.ca/en/issues/economic\\_benefits.shtml](http://www.canadiangenerics.ca/en/issues/economic_benefits.shtml) (last visited 24 November 2007).

<sup>56</sup> See e.g. Reichman and C. Hasenzahl, *op. cit.*

<sup>57</sup> Article 27.1: "...patent rights shall be enjoyable without discrimination...whether the products are imported or locally produced".

<sup>58</sup> See e.g., C Correa, Can the TRIPS Agreement Foster Technology Transfer to Developing Countries? in *International public goods and transfer of technology under a globalized intellectual property regime*, Keith E. Maskus and Jerome H. Reichman (editors), Cambridge Press, Cambridge, 2005.

<sup>59</sup> See *Brazil – Measures Affecting Patent Protection*, Request for the Establishment of a Panel by the United States, January 9, 2001, WT/DS199/3.

the US companies or whether the agreement reached with the Brazilian authorities gave US enough comfort to withdraw the complaint<sup>60</sup>. The issue has been never raised again before the WTO, despite the fact that several national laws contain provisions allowing for compulsory licenses in cases of lack of working.

In some cases, ‘working’ is defined by national laws as encompassing local production or importation of the patent product<sup>61</sup>. This obviously dilutes the working obligation. In some cases, however, national laws include provisions that seem to allow the granting of compulsory licenses in the absence of domestic production<sup>62</sup>. Such provisions are, in some cases, subject to additional conditions, such as the supply of the domestic market through imports (see Box 1).

### **Box 3. Examples of compulsory licenses grounded on failure to work the patent**

**United Kingdom:** Patents Act 1977 Chapter 37 (as amended by the Copyright, Designs and Patents Act 1988)

Section 48(3): “The grounds [for the grant of compulsory licence] are:

- (a) where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;
- (b) where the patented invention is a product, that a demand for the product in the United Kingdom-
  - (i) is not being met on reasonable terms, or
  - (ii) is being met to a substantial extent by importation;
- (c) where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked-
  - (i) where the invention is a product, by the importation of the product
  - (ii) where the invention is a process, by the importation of the product obtained directly by means of the process or to which the process has been applied ...”

**Ireland:** Patents Act 1992 (of February 27, 1992)

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<sup>60</sup> Without prejudice to their respective positions, the United States and Brazil agreed to enter into bilateral discussions before Brazil makes use of Article 68 against a U.S. patent holder. *Brazil – Measures Affecting Patent Protection*, Notification of Mutually Agreed Solution, WT/DS199/4, G/L/454, IP/D/23/Add.1, July 19, 2001.

<sup>61</sup> See, e.g. Decision 486 of the Andean Community (article 60).

<sup>62</sup> It should be borne in mind that the grant of compulsory licenses due to failure to work is subject to the terms provided for by article 5A of the Paris Convention (three years from grant of the patent, four from the application date). Such terms do not apply to compulsory licenses granted on other grounds.

Section 70(2): “The grounds (for compulsory licence) referred to ...

- (a) that the invention which is the subject of the patent, being capable of being commercially worked in the State, is not being commercially worked therein or is not being so worked to the fullest extent that is reasonably practicable;
- (b) that a demand in the State for a product which is protected by the patent is not being met, or is not being met on reasonable terms, or is being met to a substantial extent by importation;
- (c) that the commercial working in the State of the invention which is the subject of the patent is being prevented or hindered by the importation of a product which is protected by the patent;

Although the FTAs and bilateral IPRs agreements signed by the US with some countries (e.g. Jordan, Sri Lanka) limited the grounds for the grant of compulsory licenses, in the FTAs signed after the Doha Declaration the US seems to have restrained itself from requesting a limitation of that kind, openly inconsistent with said Declaration.

As mentioned above, and although limited to LDCs, paragraph 7 of the Doha Declaration requires the transfer of manufacturing technology in pharmaceuticals. Moreover, the WTO Decision of 30 August 2003 sets out a mechanism to facilitate exports of pharmaceutical products to countries with insufficient manufacturing capacity in the field<sup>63</sup>. In adopting the WTO Decision and the amendment to the TRIPS Agreement, and in order to overcome the US opposition, the Chairman read a Statement indicating, inter alia, that ‘Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives’.

However, the statement may only serve as an auxiliary means of interpretation. It cannot add obligations or restrictions to those set out in the Decision/amendment. A member country can legitimately apply the Decision in order to expand exports from its domestic industry while contributing to the solution of health problems in other developing countries. A chair’s statement can not create obligations to which members have not consented to nor provide an authentic interpretation of WTO rules. Such statement shares the legal status of the minutes of an international agreement and can only be considered as ‘circumstances of conclusion’ in accordance with article 32 of the Vienna Convention on the law of the Treaties<sup>64</sup>.

Another option for undertaking local production is the use of ‘refusal to deal’ as a ground for the granting of compulsory licenses<sup>65</sup>. Given the freedom that WTO

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<sup>63</sup> The text of the Decision was incorporated into a new article (31bis) of the TRIPS Agreement, still pending of ratification in accordance with WTO rules.

<sup>64</sup> H. Ruse-Khan, The role of the Chairman’s Statements in the WTO, *Journal of World Trade* 41(3) 2007, p. 524.

<sup>65</sup> See generally C Correa, *Intellectual Property and Competition Law: Exploring Some Issues of Relevance to Developing Countries* (2007; Geneva, ICTSD), available at [http://www.iprsonline.org/resources/docs/corea\\_Oct07.pdf](http://www.iprsonline.org/resources/docs/corea_Oct07.pdf).

Members have to determine such grounds, ‘refusal to deal’ may be deemed an *autonomous* ground therefor<sup>66</sup>. Compulsory licenses for “refusal to deal” are specifically provided for in some cases in national laws (see examples in Box 4). However, even in the absence of such provisions, those licenses may be based on the application of competition laws. The ‘essential facilities’ doctrine<sup>67</sup> has been applied in some jurisdictions to deal with situations where access to a technology is essential to undertake production. For instance, the Italian Competition Authority (ICA) decided to grant a compulsory license for an alleged abuse of a dominant position through the refusal by Merck to grant Dobfar (a chemical pharmaceutical manufacturer) a license to produce an active ingredient (ceimipenem/cilastatina-IC) needed for the production of an antibiotic (carbapenems). The ICA considered that Merck’s refusal to license its product amounted to an abuse of dominant position “since it prevented Dobfar from producing the IC and enabled Merck to maintain its dominance over the relevant pharmaceutical markets, cutting out potential competitors. Namely, the IC was deemed to be an essential resource for the production of generics by Merck’s potential competitors, whereas Dobfar was considered an indispensable supplier for such competitors and in turn, Merck was seen as an indispensable supplier for Dobfar”<sup>68</sup>

#### **Box 4. Refusal to deal as a ground for compulsory licenses**

**China:** Patent Law of the People’s Republic of China (1992), Chapter VI, Compulsory Licence for Exploitation of the Patent

Section 51: “Where any entity which is qualified to exploit the invention or utility model has made requests for authorization from the patentee of an invention or utility model to exploit its or his patent on reasonable terms and such efforts have not been successful within a reasonable period of time, the Patent Office may, upon the application of that entity, grant a compulsory licence to exploit the patent for invention or utility model.”

**Germany:** Patent Law (Text of December 16, 1980, as last amended by the Laws of July 16 and August 6, 1996)

Section 24-(1): “A non-exclusive authorization to commercially exploit an invention shall be granted by the Patent Court in individual cases in accordance with the following provisions (compulsory licence) if

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<sup>66</sup> This is not prevented by the fact that article 31(b) of the TRIPS Agreement only refers to the refusal of a voluntary license as a pre-condition for granting compulsory licenses, except in the cases where this requirement is waived.

<sup>67</sup> See C Correa, ICTSD, 2007, op. cit.

<sup>68</sup> R Coco and P Nebbia, P. Compulsory Licensing and Interim Measures in *Merck: A Case for Italy or for Antitrust Law?*, *Journal of Intellectual Property Law & Practice* (2007, 2(7), p. 452). See also for other cases C Correa, ICTSD, 2007, op. cit.

1. the applicant for a licence has unsuccessfully endeavoured during a reasonable period of time to obtain from the patentee consent to exploit the invention under reasonable conditions usual in trade ...”

**Ireland:** Section 70(2): “The grounds (for compulsory licence) referred to ...

(d) that by reason of the refusal of the proprietor to grant a licence or licences on reasonable terms-

(i) a market for the export of a product which is protected by the patent and is manufactured in the State is not being supplied;

(ii) the working or efficient working in the State of any other invention which is the subject of a patent and which makes a substantial contribution to the art is prevented or hindered; or

(iii) the establishment or development of commercial or industrial activities in the State is unfairly prejudiced ...”

Despite the importance of compulsory licenses as a means for opening the door to local production, it must be borne in mind that such a license does not entail *per se* access to the know-how required for actual production, which is not normally contained in the patent specifications. Hence, the recipient of the license should possess the required technological capacity or obtain external support to effectively execute the invention at reasonable cost.

## Conclusions

The multilateral rules on IPRs set out by the TRIPS Agreement limit the WTO members’ room to use foreign protected technologies for local production. However, governments retain certain policy space under said Agreement to promote local production, although it is much narrower than in the pre-TRIPS era,

The so-called ‘flexibilities’ in the TRIPS Agreement may be used for a multiplicity of purposes. In some cases, the intended policy objectives may be achieved through the importation of the required products. This may be the case, for instance, when an emergency occurs and immediate supplies are necessary. In other cases, the flexibilities of the Agreement may be used to facilitate domestic production and thereby foster technological learning and advance in the development process.

As examined in this chapter, there are various flexibilities that well informed governments may exploit if they desire to expand the ‘freedom to operate’ in relation to local production. First and foremost, they may adopt exceptions to the patentability, as allowed by the TRIPS Agreement, and define such critical aspects as the concept of ‘invention’ and the bar with which the requirement of inventive step is to be assessed. These constitute core flexibilities regarding patent protection. If strict patentability

criteria are applied to refuse low inventive patents, there would be no need later to confer a compulsory license to allow for domestic production (or other purposes). Developing countries are more exposed to pressures by foreign governments and companies when a compulsory license is issued -what is seen as a 'political' decision affecting acquired 'property rights'- than in cases where a patent is refused for 'technical' arguments relating to the lack of inventive step.

There are a variety of measures that countries may apply to mitigate the monopolistic effects of granted patents. Some of them may be instrumental, directly or indirectly, to policies that encourage domestic production. For example, the experimentation exception may facilitate 'inventing around', the acquisition of voluntary or compulsory licenses, or legal challenges against invalid patents. The 'Bolar exception' and protection of test data under unfair competition law (without exclusivity) may widen the room for the operation of the local pharmaceutical industry. Compulsory licenses for failure to work a patent or for 'refusal to deal' may open the necessary space for local production in various industries.

The extended use by developing countries of the TRIPS flexibilities will serve the purposes of the individual countries and contribute to set precedents that other countries may benefit from. However, such countries should avoid accepting in the WTO accession process or in entering into trade agreements requirements that erode such flexibilities. Understandably, the offers of WTO or bilateral preferential access to large markets with quantifiable benefits are in some cases too attractive to be turned down, and governments are ready to make concessions in the area of IPRs, where costs and benefits are more difficult to quantify. But market access may bring ephemeral gains in the face of growing competition from other countries equally entitled to preferential treatments, while the limitations imposed on local production and innovation by TRIPS-plus standards may have enduring effects on the development prospects of the countries that, for whatever reason, accept them.

In sum, there is room for developing countries to use TRIPS flexibilities to open space for local production. They face, however, the multiple challenges of preserving such space in bilateral and multilateral negotiations, effectively implementing the permitted flexibilities in national laws, and applying them when IPRs may emerge as a stumbling block against domestic production or other legitimate States' objectives.