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PATENT-RELATED FLEXIBILITIES IN THE MULTILATERAL LEGAL FRAMEWORK AND THEIR LEGISLATIVE IMPLEMENTATION AT THE NATIONAL AND REGIONAL LEVELS - PART II

Document prepared by the Secretariat

1. In the context of the discussions on Development Agenda recommendation 14, Member States, at the sixth session of the Committee on Development and Intellectual Property (CDIP) held from November 22 to 26, 2010, in Geneva, requested the International Bureau of the World Intellectual Property Organization (WIPO) to extend document CDIP/5/4 to cover five new flexibilities.

2. The present document addresses the requested five additional flexibilities.

3. The CDIP is invited to take note of the contents of this document and its Annexes.

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I. EXECUTIVE SUMMARY

4. The Committee on Development and Intellectual Property (CDIP), at its fifth session held from April 26 to 30, 2010, in Geneva, requested the Secretariat to revise document CDIP/5/4 on patent-related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional level. Document CDIP/5/4 Rev. was presented for consideration at the sixth session of the CDIP held from November 22 to 26, 2010.

5. At the sixth session of the Committee, the Secretariat submitted for the consideration of delegates document CDIP/6/10 on "Future work on flexibilities in the Intellectual Property System", which proposes in Part A, under the title "Work in the area of patents", a list of new issues for consideration.

6. Following the request of the CDIP, the Secretariat has prepared this preliminary study on these five other flexibilities, namely: transition periods, the patentability of substances existing in nature, disclosure-related flexibilities, aspects related to substantive examination and the ex-officio Intellectual Property (IP) Office control of anti-competitive clauses in patent licensing agreements. The approach followed is the same one adopted in the previous document on flexibilities, CDIP/5/4 Rev., which means that the document addresses a non-exhaustive number of flexibilities in the patent area, describing the conceptual development for each, and including annexes and tables reflecting corresponding legal provisions in a substantial number of countries.

7. This document is divided into five distinct parts:

Part I is focused on the transition periods available to the World Trade Organization Agreement (WTO) Members in order to implement the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement). In particular, it provides an illustration of the different periods for its implementation according, first, to the level of development of Members and, second, to product patent protection in sectors where patents are not available at the time of entry into force of the WTO Agreement;

Part II provides an illustration of the issues related to the patentability of substances existing in nature, and the position adopted by Members when it comes to the patentability of substances that, although existing in nature, are subject to a technical process for their isolation/purification/synthesis;

Part III refers to the role played by disclosure and to the features adopted in patent laws to ensure that this function is fulfilled. Therefore, the disclosure of an invention is not in itself a flexibility, but, on the contrary, is a requirement imposed upon the applicant as a condition for the grant of the patent. Nevertheless, related aspects left open by the multilateral treaties are able to be implemented in a flexible way, such as the best mode requirement, the deposit of a microorganism as a mechanism to describe an invention that consists thereof of, or derives therefrom, and, finally, the manner in which some countries have implemented transparency measures for the indication of the origin of genetic resources;

Part IV provides information about patent examination, with a brief presentation of the most common systems. In addition, a number of comments are made about ways and means of cooperation available among countries that wish to undertake search and

substantive examination, in order to overcome the difficulties that such a task implies, as well as some comments about the way in which these options have been implemented in some Members States; and

Part V deals with the description of some Patent Laws that provide for ex-officio IP Office control on clauses of licensing contracts which are deemed to be anti-competitive.

8. Annexes I and II are appended to this document. Annex I contains relevant provisions of the national and regional laws. Annex II categorizes a number of specific elements of the above-mentioned flexibilities which have been considered as the starting point for this work. Although the identified laws represent the current situation worldwide, not all laws could be included. Future work may allow the Secretariat to include such information, if desired by Member States.

9. The present document is submitted, as the previous one, in the framework of Recommendation 14 of the WIPO Development Agenda, according to which WIPO shall make available advice to developing countries, especially LDCs, on the implementation, understanding and use of flexibilities contained in the TRIPS Agreement.

II. TRANSITION PERIODS

A. Introduction

10. Members of the WTO are obliged to implement the provisions contained in the TRIPS Agreement within a deadline set in the treaty and determined as of the day of entry into force of the WTO Agreement[1]. Bearing in mind the difficulties that Members may face in relation to the implementation of these provisions, two sets of transition periods have been provided: a first, general transition period based on the recognition of different levels of development of Members and a second, particular one, which exclusively applies to the patent field.

B. Multilateral legal framework

11. According to Article 65, paragraph 1 of the TRIPS Agreement, "[s]ubject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement". This means that, given that the WTO Agreement entered into force on 1 January 1995, the period for implementing TRIPS provision expired on 1 January 1996.

12. However, subsection 2 of this article specifies that "a developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1". Hence, with regard to developing countries, the period for implementing the TRIPS Agreement was extended to 1 January 2000: this additional period is the first, general transitional period. A second, specific transition period in favor of developing country Members consists in delaying the granting of "product patent protection" for areas of technology that were not so protectable in their territory at the time of the application of the TRIPS Agreement, for an additional period of five years (and hence in that case the period for implementing the TRIPS provision in that area expired on 1 January 2005)[2]. When the exclusion of patentability covers pharmaceutical and agrochemical products, the flexibility provided by the transition period in order to delay the grant of "product patents" in these fields is accompanied by the obligation to put in place a system[3] for the filing of applications for patents on pharmaceutical and agricultural chemical products during this period and thus preserve the dates of filing and priority of those applications; hence, the criteria for patentability may be applied as of those dates. This system is called the Mailbox System[4]. The Mailbox shall be complemented by a parallel system of exclusive marketing rights (EMR)[5].

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1 Therefore, for newcomers, the date of entry into force of the WTO Agreement shall also apply.

2 This provision applies only to "product patents", leaving out any patents related to processes or uses, and applicable to any exclusion from patentability that existed at the time of entry into force of the TRIPS Agreement (not the WTO Agreement). Professor Joseph Strauss mentioned that the pre-TRIPS situation on exclusions from patentability showed that out of 92 Members States of the Paris Convention: 49 excluded pharmaceutical products, 35 food products, 22 chemical products and 9 microorganisms, "Flexibilities in the Patent System", WIPO Colloquium, Geneva, 2007.

3 Decision of the WTO Appellate Body (1997), in the case of India-Patent protection for pharmaceutical and agriculture chemical products. WTO Panel Report WT/DS50/R and Report of the WTO Appellate Body WT/DS50/AB/R.

4 Article 70.8 of the TRIPS Agreement stipulates that those Members that enjoy the transitional period (2005 for product patent protection for Pharmaceutical and Agricultural Chemical Products

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13. In relation to least-developed countries, Article 66, subsection 1, of the TRIPS Agreement establishes that "in view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement other than article 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65." This provision means that the initial deadline for the least developed countries to implement the TRIPS Agreement provisions expired on 1 January 2006. This period was extended until July 1, 2013, making use of the faculty reserved to the Council for TRIPS by Article 66, subsection 1 of the TRIPS Agreement, according to which it shall grant an extension of this period "upon duly motivated request by a least-developed country Member".

14. Least developed countries were also the object of two additional measures in the pharmaceutical field that provide more time for the implementation of sections 5 and 7 of the TRIPS Agreement. The first consists in a decision of the Council for TRIPS of June 2002, based on Art. 66.1, according to which "least developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply sections 5 and 7 of part II of the TRIPS Agreement or to enforce rights provided for under these sections until 2016". The reason for that decision is to implement paragraph 7 of the Ministerial Declaration on the TRIPS Agreement and Public Health, adopted in Doha in 2001, to address concerns expressed by those Members regarding public health problems. The second measure, contained in the Decision of the General Council of TRIPS on July 8, 2002[6], consists in a waiver on the obligation of least developed countries (LDCs) under paragraph 9 of Article 70; thus, for LDCs, there is no obligation of granting marketing rights until the same date of the previous measure (January 1, 2016). According to the interpretation of several authors, the obligation of establishing a mailbox system should not be included in that second waiver[7], and therefore a mailbox

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in Developing Countries and 2016 for pharmaceuticals in LDCs) shall: (a) notwithstanding the provisions of part VI, provide, as from the date of entry into force of the WTO Agreement, means by which applications for patents for such inventions can be filed; (b) apply to these applications the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or the priority date of the application; and (c) grant patent protection in accordance with this Agreement for the remainder of the patent term, counted from the filing date in accordance with article 33. The system established in this provision is usually called the "Mailbox System", given that reference is made to a metaphorical "mailbox" created to receive and store the applications for patents in pharmaceutical and agrochemical fields, assigning filing date, which will be considered when substantive examination takes place after the expiration of the transition period.

5 When a patent is the object of an application under the Mailbox System, the applicant shall receive, for that product, exclusive marketing rights "for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member" (Article 70, subsection 9 of the TRIPS Agreement).

6 WT/L/478.

7 See for example UNCTAD-ICTSD, "Resource Book on TRIPS and Development", Cambridge University Press, 2005, page 720.

system also has to be established if the country makes use of the flexibility of the transitional period in relation to the patent protection of pharmaceuticals.

C. Legislative Implementation at the national level

15. In the case of developed and developing countries, given that all transitional periods in their favor have expired, there seems to be no need for further development for the purpose of this work. The focus can thus be placed on LCDs.

16. Out of the 48 LDCs on the United Nations list, 33 are members of the WTO[8] and a significant number of these countries have already notified their laws on IP according to the process of notification provided in Article 63.2 of the TRIPS Agreement in order to assist the Council for TRIPS in its review of the operation of this Agreement[9]. On the issue of transition periods, LDCs could be grouped as follows: (i) Members of the WTO that had adopted legal provisions on patent and related matters, which are TRIPS compatible, before the deadline of the general transition period; (ii) Members of the WTO that enjoyed the general transition period; and (iii) Members that benefitted from transition period in pharmaceuticals (including the waiver on EMR).

17. Regarding the first group, there is the view that, upon the 2006 deadline, "virtually all of the LDC WTO Members had provided intellectual property protection regimes"[10], therefore renouncing the general transition period. In particular, the African countries members of African Intellectual Property Organization (OAPI) implicitly renounced the use of the general transition period, given that they were already part of a regional system providing IP protection according to standards comparable with those of the TRIPS Agreement. About the second group, it is noteworthy that some LDCs which joined the WTO after its entry into force, in their report of accession to the WTO in general, and to the TRIPS in particular, expressed explicitly their will to use such flexibility[11].

18. Regarding the third group, when the Decision of the Council for TRIPS extending for LDCs the transitional period for patent protection of pharmaceuticals (June 27, 2002) was adopted, many of the 25 African LDCs Members already provided such protection[12], as described in a report prepared by Mr.Thorpe for the Commission for Intellectual Property Rights (CIPR)[13]. But, for the few LDCs that are WTO Members and enjoy the transition period for pharmaceuticals, it is hard to identify those which implement expressly in the patent law the transitory provisions: one of those few cases is Cambodia[14], while few

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8 Angola, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African Republic, Chad, Congo (Democratic Republic of), Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda and Zambia.

9 See WTO document IP/C/W/543.

10 Musungu and Oh, "The Use of Flexibilities in TRIPS by Developing Countries", CIPIH, August 2005, page 8.

11 Such as Cambodia, Cape Verde, Nepal and Tonga: see respectively documents WT/ACC/KH/21, WT/ACC/CPV/30, WT/ACC/NPL/16 and WT/ACC/TON/17.

12 Carolyn Deere, "The Implementation Game", Oxford, 2009, page 71.

13 Phil Thorpe, "Study on the implementation of the TRIPS Agreement by Developing Countries", CIPR, 2001.

14 Art. 137 of the patent law of Cambodia provides: "The Pharmaceutical products mentioned in Article 4 of this law shall be excluded from patent protection until January 01, 2016, according to the

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other LDCs have explicitly stated in their report of accession to the WTO that they do not intend to provide patent protection to pharmaceuticals up to 2016[15]. Nevertheless, this kind of rule concerning the transitory exclusion of product patent protection, i.e., for pharmaceuticals, is nowadays frequently included in draft laws that are under consideration by LDCs, either already WTO members or in the negotiation process for joining the WTO.

19. Concerning developing countries, almost all WTO developing country Members have already notified their IP laws under Article 62.3 of the TRIPS Agreement[16]. Taking into account the fact that the transition period for developing countries expired on January 1, 2000, their legislation was reviewed in 2000 and 2001, while the legislation of newly acceded Members is reviewed at a single review meeting[17]. In this connection, some of the new developing countries Member have explicitly stated in their accession reports their intention of not using any kind of transition period, while they had the right to do so at the time of joining[18].

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declaration of the Ministerial conference in Doha on the TRIPS Agreement and Public Health dated November 14, 2001".

15 Cape Verde, Nepal and Tonga.

16 See document IP/C/W/543.

17 See document IP/C/W/543.

18 Armenia, Croatia, Estonia, Former Republic of Macedonia, Georgia, Jordan, Kyrgyz Republic, Latvia, Moldova, Oman, Saudi Arabia, Chinese Taipei, Ukraine, Viet Nam. See respectively the reports, relating thereto, of the working Party on the accession to the WTO: WT/ACC/ARM/23. WT/ACC/HRV/59, WT/ACC/EST/28, WT/ACC/807/27, WT/ACC/GEO/31, WT/ACC/JOR/33, WT/ACC/KGZ/26, WT/ACC/LVA/32, WT/ACC/MOL/37, WT/ACC/OMN/26, WT/ACC/SAU/61, WT/ACC/TPKM/18, WT/ACC/UKR/152, WT/ACC/VNM/48.

III. PATENTABILITY OF SUBSTANCES EXISTING IN NATURE

A. Introduction

20. It is widely accepted that "products of nature" cannot be considered as patentable subject matter, given that they constitute nothing more than a mere "work of nature" which takes place without any human contribution. For this reason, through case law[19] or statutory provisions[20], it has been established that the fact that a substance already exists in nature is a limit to its patentability. Therefore, a new mineral discovered in the earth is not patentable, and neither is a new property of a known material nor a substance that exists in nature (many organic chemicals are produced by naturally occurring biological processes). The same reasoning is generally applied when the matter under consideration is a living material, such as a microorganism or a new plant discovered in a wild region. It has been noticed that in order to apply the products of nature doctrine, there is no need to distinguish between inanimate or living material, but rather between naturally occurring and human-made subject matter: needless to say, in that regard, that only the latter deserves patent protection[21]. The recourse to patent protection in relation to processes using living organisms[22] is also widely accepted, provided the requirements of patentability are fulfilled[23]; in particular, there is general agreement about the patentability of a process of isolation of a substance existing in nature[24]. In the light of the above-mentioned introduction, the focus of the following comment will be about the protection of the substance rather than of the process.

21. The border-line between what should be considered as patentable subject matter and what, to the contrary, should fall under the exclusion of patentability, is of particular interest when considering how to protect new inventions in the area of biotechnology. Biotechnology is a fast-moving field, where new products and services are developed as the outcome of complex and cumulative sets of technologies such as microbiology, biochemistry, genetics, engineering and, more recently, bioinformatics. There is a

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19 In the United States of America (USA), the product of nature doctrine had been propounded by the Supreme Court in the case of Funk Bros. Seed Co. v. Kalo Inoculant Co.,333 U.S. 127 (1948). In the same line, the Australian High Court decision in the case of National Research Development Corporation v. Commissioner of Patents (1959) 102 CLR 252.

20 In relation to this, it would be convenient to mention the laws of Argentina, Brazil, Chile, Dominican Republic, Nicaragua, Uruguay, and the countries of the Andean Community.

21 Sidney A. Diamond, Commissioner of Patent and Trademark v. Ananda M. Chakrabarty et al. No. 79-136. 447 U.S. 303 (1980).

22 L. Bently and B. Sherman, "Intellectual Property Law", Third Ed., Oxford, 2009, page 422.

23 D. Chisum and M. Jacobs, "Understanding Intellectual Property Law", Matthew Bender, 1992, pages 2-23.

24 In the case relating to a patent on the "molecular cloning and characterization of a further gene sequence coding for human relaxin" (Decision T 272/95 of 23 October 2002), the European Patent Office (EPO) Board of Appeal had the opportunity to interpret Rule 23 (e) (2) EPC which establishes that "an element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene may constitute a patentable invention, even if the structure of that element is identical to that of a natural element". The appellant's argument was that a gene sequence has to be considered a discovery, and so excluded from patentability according to Article 53 (a) EPC. However, the Board specified that the above mentioned rule allows the patentability of biological material, and in particular of an element isolated from the human body, such as a gene sequence.

common understanding that the biological revolution in the use and the creation of novel living organisms has nowadays the same level of impact on society that the industrial revolution had two centuries ago, when it changed the way inanimate products were manufactured.

22. The influence of biotechnology in diverse sectors such as agriculture, pharmaceuticals, biochemicals, environment, food and beverages industry and so on is very well documented, not only since recent years,[25] but since the 1980s[26]. However, we will not linger over the role played by the patent system in promoting innovation in this sector[27] because it would go beyond the object of the present work.

23. Concerning the definition of biotechnology, it is important to make a distinction between, on the one hand, "classical biotechnology", defined loosely as "the production of useful products by living micro-organisms" – this kind of technology originated with the discovery of a fermentation process producing this interesting product commonly known as grape juice[28], a process already known by Sumerians and Babylonians around 4,000 years BC – and, on the other hand, "modern biotechnology" "which began in the 1970s with the development of two basic techniques: recombinant DNA technology and hybridoma technology" [29] which consist in introducing changes into the DNA molecules of a living organism. As a result of these modern biotechnologies, new drugs have been developed; among others, human insulin, interferon, vaccines and treatments for diabetes, cancer and for many other human diseases.

24. The term "biotechnology" includes[30] three types of subject matter: (i) the "biomatter itself" which includes: "non-living biomatter" such as amino acids, peptides, proteins, fats and nucleic acids, better known as antibodies, hormones, enzymes, antibiotic, steroids, cholesterol and DNA molecules (chemical compounds which differ from chemical compounds as understood from the chemist perspective due to the fact that they are part of living entities) and "living biomatter", that comprises: cells (the smallest reproducible unit of life), microorganisms (consisting in one cell or cluster of cells, which include the ability to exist by themselves in nature or just under laboratory conditions or as part of multicellular organics, such plants or animals); (ii) methods and processes of making products of biotechnology, such as processes for producing plants and animals which are the product of human ingenuity, having a distinctive name, character and use, including processes for the creation products from cells, such as hormones, enzymes and the like. Therefore, understanding how to transfer genetic information from one organism to another and (iii) methods of use or uses in respect of (i) and (ii) above.

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25 See, e.g., Biotechnology Industry Organization, Industry Facts, available at *http://www.bio.org* and OECD on Biotechnology, Policy and statistics: *http://www.oecd.org/countrylist/0,3349,en_2649_34537_36428358_1_1_1_37437,00.html*.

26 Biotechnology international trends and perspectives, OECD, 1982, pages 19 and 64.

27 J. Cubert, "US Patent Policy and Biotechnology: Growing Pains on the cutting Edge" (1995) *JPTOS*, pages 77 - 174.

28 Philipp W. Grubb, "Patents in Biotechnology", Swiss Biotech. V 4 page 12.

29 Philipp W. Grubb, "Patents for Chemicals, Pharmaceuticals and Biotechnology", 4th edition, Oxford, 2007, page 246.

30 See John R. Rudolph, "A study of issues relating to the patentability of biotechnological subject matter", 1996, prepared for the Intellectual Property Policy Directorate Industry, Canada, page 7.

25. The patentability of living material has certainly been identified as one of the main reasons behind the impressive development of the biotech sector, particularly[31] after the landmark decision of the United States (US) Supreme Court in the Chakrabarty[32] case (1980) that has allowed the patentability of a living organism (previous to that decision, they were considered products of nature). In particular, from an economic development point of view, in some countries this sector is the source of a billion dollar industry that stimulated innovation and has been responsible for an extraordinary rise in new businesses[33]; however, the views on the best way to get benefit from biotechnology vary from country to country, and thus an important number of developed[34] and developing[35]

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31 The impact of the Chakrabarty Decision is recognized well beyond the United States; in that regard see, for instance, the opinion of the Advocate General to the Court of Justice of European Communities in the Netherlands (supported by Italy and Norway) v European Parliament and Council of the European Union (supported by the European Commission), [2002] A ll ER (EC) 97(ECJ, Case C-377/98), Para 36.

32 Sidney A. Diamond, Commissioner of Patent and Trademark v. Ananda M. Chakrabarty et al. No. 79-136. 447 U.S. 303 (1980).

33 E.g. Jasemine Benjamin, "Patent Eligibility of Biotechnological Inventions in the United States, Europe and Japan: How much Patent Policy is Patent Policy", 34 *Geo. Wash. Int. L. Rev*., pages 223, 224 (202).

34 The Canadian government has been supporting biotechnology for about two decades. In 1983, the federal government launched the National Biotechnology Strategy (NBS), which focused on R&D and human resources development. The National Biotechnology Advisory Committee was formed to advise the Minister of Industry on issues related to industry growth and competitiveness. In the 1990s, as the number of biotechnology applications entering the marketplace increased, attention turned to consumer, social, ethical and other public interest issues. Among others, in particular the following two documents show the way in which development issues have been approached: "National Biotechnology Business Strategy: Capturing Competitive Advantage for Canada" (fifth report 1991) and "The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process".

35 Such as Brazil, Cuba, India and Korea. In *India***,** a technical group of experts, chaired by Dr. RA Mashelar, at the request of the Ministry of Commerce and Industry, submitted a report on a number of patent law issues (2006) which addressed the issue of the patentability of microorganisms. In this report, it is mentioned that "India is one of the bio-diversity rich countries, it would, thus, be prudent for us to protect biotechnological inventions as that would help Indian biotechnology research compete globally attracting collaboration, FDI, contract R&D, etc to the best advantage of the Indian R&D and biotech industry". *South Africa*, through its National Biotechnology Strategy (June 2001), while admitting that the country has derived important benefits in traditional biotechnology areas (one of the largest brewing companies, competitive companies in dairy products as cheese, yogurt and maas) did not do enough in the modern biotechnology; hence, the Strategy was designated to make up for lost ground and to stimulate the growth in sectors of national priority, such as human health, food security and environmental sustainability. In Cuba, since 1981 the Frente Biológico (Biological Front) has been created to coordinate and hierachize the activities in the area of biotechnology. The aim of this program was clearly that of developing and applying biotechnology in the country, so, several institutions have been created since then, such as the CIB (Centro de Investigaciones Biológicas), CIGB (Centro de Ingeniería Genética y Biotecnología), CIE (Centro de Immunoensayo), CNIC (Centro Nacional de investigaciones Científicas), IPK (Instituto de Medicina Tropical Pedro Kouri) and INOR (Instituto Nacional de Ontología y Radiobiología). The case of *Brazil* is worth mentioning: in this country, the perception of the competitive advantage of biotechnology also arose in the 80s when the Brazilian Government began financing scientific, technological and capacity building projects. Nowadays, Brazil has a developed legislative legal framework (Innovation Law no. 10.973/2004; Goods Law No. 11.196/2005; Bio safety Law no. 11.105/2005; Policy on Biotechnology Development, Decree no.

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countries have implemented various policies to stimulate that sector. On the same line, patent policy has also evolved, from the technical point of view, because the patent system was originally designed for the purpose of inanimate inventions, while the subject matter in the biotechnology field comprises living organisms, which also have the property of self-replication.

26. The flexibility under examination focuses on the way the products of nature doctrine has been implemented in the patent law of Member States, either as an express exclusion from patentability or through recourse to the invention-discovery dichotomy as the boundary on patentability or, finally, through the adoption of any other provision that regulates the patentability of living materials, from the patentable subject matter point of view. Therefore, in this study, there will be no reference to the novelty, inventive step (non-obvious) or industrial applicability (utility) requirements as applied to "products of nature".

B. The International Legal Framework

27. The international legal framework on the issue under examination is constituted mainly by the TRIPS Agreement (Art. 27) and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of the Patent Procedure.

28. Article 27 of the TRIPS Agreement[36] does not contain, in the list of allowed exclusions from patentability, either "products of nature" or "discoveries", although their inclusion had been considered during the discussions as shown by section 5 1.4.2 of the Anell Draft[37], which was highly inspired by the previous work on the topic carried out within WIPO[38]. In some authors' view, there is no need to specify that products of nature cannot be patentable, in so far as article 27.1 of the TRIPS Agreement establishes that the subject of the patent protection is an "invention", it can be interpreted as excluding both discoveries and products of nature[39]. Moreover, the TRIPS Agreement does not adopt a specific notion of invention and does not explicitly bind Members to protect, or to forbid the patentability of substances existing in nature.

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6.041/2007; Policy on Productive Development of 12/05/2008). For more information see http://www.mct.gov.br/index.php/content/view/3546.html

Field Code Changed

The *Korean Government* began promoting biotechnology in the 1980s and in 1994 it established a basic plan for the promotion of biotechnology. Recently, in 2006, the Second Framework Plan for Biotechnology Promotion was adopted, while the government expenditure on biotechnology R&D is one of the highest among OECD countries.

36 Article 27.3 b) is the object of a revision process which started four years after the entry into force of the TRIPS Agreement: it seems speculative at this point in time to identify the outcome of this process. Thus, any reference to the flexibility under analysis is based in the text in force.

37 Document MTN.GNG/NG11/W/76.

38 Alternative A of Article 10 (1) (iii) of the draft treaty presented to the Diplomatic Conference for the provision of a Treaty supplementing the Paris Convention as far as patents are concerned, held in The Hague in 1991, contains as an exception to patentability "discoveries and material or substances already existing in nature".

39 See N. Pires de Carvalho, "The TRIPS Regime of Patents Rights", Kluwer Law International, NY, 2002, page 143 and Shamnad Basheer, "Limiting the Patentability of Pharmaceutical Inventions and Microorganisms: A TRIPS compatibility review", *IP Institute*, November 2005, page 24.

29. It is commonly understood that a mere discovery cannot be patentable *per se*, while an invention can be, provided that other conditions (patentability requirements) are fulfilled and subject to the provision of paragraphs 2 and 3 (facultative exclusion from patentability). Despite the simplicity of the previous statement it is difficult to apply it in practice, mainly because of the difficulties in defining the concept. WTO Panel decisions have often relied on dictionary definitions, but it has been noted that a dictionary definition is only of limited use in our context, since the term "invention" has a special meaning in patent law[40]. Indeed, an important number of countries provide an express definition of invention[41], while others countries in order to avoid adopting a definition of invention, have chosen a "negative" approach, providing a list of what cannot be considered as an invention[42].

30. The products of nature doctrine applies to inanimate and to living subject matter. Regarding the latter, provisions on the patentability of living material are of particular interest, such as article 27 2. and 3. a) and b) of the TRIPS Agreement. Nevertheless, it is proposed that the facultative exclusions related to *ordre public* and morality (Article 27.2) as well as on plant and animal varieties, and essentially biological processes for the production thereof (27 3.a)), be left aside for a separate piece of work. Thus, the present document concentrates on the relationship between the obligation under the TRIPS Agreement to provide protection to "microorganisms" and the doctrine of "products of nature" which allows the exclusion from patentability of nature's work.

31. Several authors have stressed the fact that the TRIPS Agreement provides for an important degree of flexibility in order to allow countries to define their own policy in relation to the issue of products of nature. In deed, it has been observed that there is no definition of invention within the TRIPS Agreement, and therefore Members may set the threshold that separates discoveries from inventions based on different criteria, such as the modification of the substance to the extent that the new one differs from the one preexisting in nature[43], the technical means employed in the identification of the substance and the identification of its utility the level of purity of the non-naturally occurring product compared to the naturally occurring one, or whether the quantities produced in nature are not sufficient to cover the needs for commercial use. According to the TRIPS Agreement, there is also room to define what a microorganism is, for instance, by adopting a narrow concept of microorganism, some subject matters such as

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40 Shamnad Basheer, "Limiting the patentability of Pharmaceutical Inventions and Micro-organisms: a TRIPS Compatibility Review*", IP Institute,* November 2005, page 19.

41 Among others, Australia (Annex 1), Canada (Art. 2), U.S.A (Art. 101), Japan (Art. 2.1), Argentina (Art. 4 literal a)), Chile (Art. 31), El Salvador (Art. 106), Guatemala (Art. 1), Honduras (Art. 4.1), Mexico (Art. 15) y Panama (Art. 11). Also in the WIPO Model Provisions for Developing Countries on Inventions Nº 840(S), OMPI, Geneva, 1979, Art.112.(1).

42 Among others, Germany (Art. 1(2), Austria (Art. 1), Belgium (Art. 3.1), Denmark (Art. 1.2), Spain (Art. 4.2), France (Art.L.611-10.2), Hungary (Art. 1.2), Italy (Art. 12), Netherlands(Art. 2.1), United Kingdom (Art. 1(2)), Sweden (Art. 1), the European Patent Convention (Art. 52.2), Argentina (Art. 6), Brazil (Art. 10), Chile (Art. 37), Costa Rica (Art. 1.3), Cuba (Art. 38), El Salvador (Art. 107 literals a) and b)), Guatemala (Art. 2), Honduras (Art. 5), Mexico (Art. 19), Panama (Art. 14), Peru (Art. 27), and in the Decision no.486 of the Andean Community (Art. 15) which binds Bolivia, Colombia, Ecuador and Peru).

43 K. Bozicevic "Distinguishing products of nature from products derived from nature", (1997) 69 *JPTOS,* page 415.

human, animal and plants cells and genes[44] could be left out of the area of patent protection; while by adopting a wide definition of microorganism, it would be possible to include any biological matters, including those mentioned before, and even viruses, which in principle and based on a scientific definition, are not automatically included, because viruses depend on cells to multiply[45].

32. There is no single term to define a microorganism, although it is widely accepted that the defining property is its microscopic size: in other words, it is something not visible to the naked eye[46]. Important differences exist in relation to what is comprehended within the term, both from the scientific point of view[47] and in existing patent case law[48]. Adopting different definitions[49], in some authors' view, does not prevent addressing the TRIPS Agreement obligations[50], except when the definition adopted by a given country has the effect of denying the protection provided for in the TRIPS Agreement, as expressly stated in the CIPR Report[51] and supported by the United Kingdom (UK) Government[52]. Some authors[53] also suggest that making a distinction between genetically modified microorganisms and naturally occurring ones, in order to set

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44 L. Westerlund, "Biotech Patents: Equivalents and exclusions under European and US Patent Law", Kluwer Law International, 2002.

45 "Somewhere between non-living and living matter are viruses. A virus is a tiny infective particle composed of protein and nucleic acids…outside of a living entity do no demonstrate any of the qualities of living things, however once in living organisms, viruses are able to move and invade cells, and take over the genetic manufacturing aspect of a cell and reproduce themselves". See John R. Rudolph, "A study of issues relating to the patentability of biotechnological subject matter", 1996, prepared for the Intellectual Property Policy Directorate Industry Canada, page 10.

46 Decision of the Enlarged Board of Appeals, European Patent Office EPO, T 356/93 (OJ 1995, 545).

47 From the definitions provided by Mike Adcock and Margaret Llewelyn, "Micro-organisms, definitions and Options under TRIPS", Occasional Paper 2, Quaker United Nations Office-Geneva, page 16, it is clear that a wide range of differences exist: i.e., while the Institute of Science, UK, states that " Multicellular organisms are normally not included, nor fungi, apart from yeast", another definition provided by Brock, Biology of Microorganisms includes "cells and cell clusters" and another definition, by Evans and Killington, includes "fungi".

48 EPO case law (T 356/93) has established that micro-organisms comprise "bacteria and yeasts, but also fungi, algae, protozoa and human, animal and plants cells…including plasmids and viruses".

49 For a wide range of definitions see for example Mike Adcock and Margaret Llewelyn, "Micro-organisms, definitions and options under TRIPS", Occasional Paper 2, Quaker United Nations Office-Geneva, pages 4-7.

50 See for example, Mike Adcock and Margaret Llewelyn, "Micro-organisms, definitions and Options under TRIPS", Occasional Paper 2, Quaker United Nations Office-Geneva, page 10; Shamnad Basheer, "Limiting the patentability of Pharmaceutical Inventions and Micro-organisms: a TRIPS Compatibility Review", *IP Institute*, November 2005, page 54 and Correa Carlos, "Patenting Human DNA: what flexibilities does the TRIPs Agreement allow?", *Journal of World Intellectual Property*, Vol. 10, Issue 6, Nov. 2007, page 426.

51 See page 66 of the Report where it is stated: "in the Absence of a universally recognized definition of what constitute a "microorganism" developing countries remain free to adopt a credible definition that limits the range of material covered".

52 The UK Government Response to the Report of the CIPR (13 of August 2005).

53 See for example Carlos M. Correa, "A Guide to Pharmaceutical Patents", Vol II, Chapter 6, page 15, South Centre, July 2008.

boundaries between what is patentable and what is not, is compatible with the TRIPS Agreement. However, this may raise a number of considerations according to another author's view[54], due to the fact that this distinction is not incorporated in the TRIPS Agreement.

33. The second Treaty that constitutes an important part of the multilateral legal framework in this area is the Budapest Treaty[55]. It has proven to be extremely useful in complementing/replacing the written description[56] of living organisms in patent applications, through the deposit thereof with an International Depositary Authority[57]. The Treaty gives important latitude to Contracting States, first of all because there is no indication of what should be considered as patentable subject matter and, more importantly, because it does not include a definition of the term microorganism, leaving this decision to Contracting States' consideration[58].

C. Legislative implementation of the flexibilities previously mentioned

34. Two kinds of national legal approaches for implementing flexibilities can be identified: countries that provide an express general exclusion from patentability of substances existing in nature and/or the discovery exception; and countries which provide specific provisions allowing or excluding the patentability of subject matter that consists of, or which is derived from, naturally occurring products, under certain circumstances.

Countries that provide an express general exclusion from patentability of substances existing in nature and/or the discovery exception

35. A certain number of countries have adopted statutory provisions excluding "products of nature"[59], while another group of countries arrived to a similar solution by applying the exclusion from patentability of "discoveries"[60]. In both cases the application of principles

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54 Shamnad Basheer, "Limiting the patentability of Pharmaceutical Inventions and Micro-organisms: a TRIPS Compatibility Review", *IP Institute,* November 2005, page 57.

55 The main feature of the Treaty is that a Contracting State which allows or requires the deposit of microorganisms for the purposes of patent procedure must recognize, for such purposes, the deposit of a microorganism with any "International Depositary Authority", irrespective of whether such authority is on or outside the territory of the said State.

56 An invention is disclosed by means of a written description. Where an invention involves a microorganism or the use of a microorganism, disclosure is not always possible in writing, but can only be effectuated by the deposit, with a specialized institution, of a sample of the microorganism.

57 On March 1, 2010, there were 38 such authorities: seven in the United Kingdom, three in the Russian Federation and in the Republic of Korea, two each in Australia, China, Italy, Japan, Poland, Spain and the United States of America, and one each in Belgium, Bulgaria, Canada, the Czech Republic, France, Germany, Hungary, Latvia, India, the Netherlands and Slovakia.

58 In practice, the term "microorganism" is interpreted in a broad sense, covering biological material the deposit of which is necessary for the purposes of disclosure, in particular regarding inventions relating to the food and pharmaceutical fields.

59 Article 3 C of the Indian Patent Law includes the following text "…or discovery of any living thing or non-living substances occurring in nature".

60 The Court of Appeal of Singapore, in the *Case Merk & Inc v Pharmaforte Singapore Pte Ltd*, [2000] 3 slr 717 at 734. In UK two main cases, *Genetech v. Wellcome*, [1989] RPC 147, 262 (Mustill Lj) and *Biogen v. Medeva*, [1987] RPC 1, 131 (Lord Mustill). In Australia the High Court in *National Research Development Corporation v. Commissioner of Patents (NRCD),* [1959] 102 CLR 252.

of the patent system will determine whether the fact that the matter for which protection is sought, because already existing in nature, is a product of nature or a discovery. The patent law or the case law may set requirements or principles under which the human intervention brings this to the category of invention[61], in which a case, it will deserve a patent if, and only if, the patentability requirements are fulfilled.

36. For instance, in the USA court precedents, applying general principles of the patent law, have indicated that patentability as defined in Section 101 excludes "the law of nature, physical phenomena, and abstracts ideas"[62]. Regarding the non-patentability of products of nature, in the case *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[63], the Supreme Court, in a patent infringement suit where the validity of certain patent claims was at stake[64], expressed the following:

> "…Bond (the inventor) does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are, of course, not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end…Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature, and hence is not patentable…"

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61 R. Merges, "Patent Law and Policy", The Michie Company, 1992, page 124.

62 Le Roy v. Tatham, 14 How. 156,175,14 L.Ed.367 (1853).

63 *Funk Brothers Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127 (1948).

64 This is the background of the case taken from the Court decision: "Through some mysterious process, leguminous plants are able to take nitrogen from the air and fix it in the plant for conversion to organic nitrogenous compounds. The ability of these plants to fix nitrogen from the air depends on the presence of bacteria of the genus Rhizobium which infect the roots of the plant and form nodules on them. These root nodule bacteria of the genus Rhizobium fall into at least six species. No one species will infect the roots of all species of leguminous plants. But each will infect well defined groups of those plants…It was the general practice, prior to the Bond patent, to manufacture and sell inoculants containing only one species of root nodule bacteria. The inoculant could therefore be used successfully only in plants of the particular cross-inoculation group corresponding to this species. Thus, if a farmer had crops of clover, alfalfa, and soybeans, he would have to use three separate inoculants. There had been a few mixed cultures for field legumes. But they had proved generally unsatisfactory because the different species of the Rhizobia bacteria produced an inhibitory effect on each other when mixed in a common base, with the result that their efficiency was reduced. Hence, it has been assumed that the different species were mutually inhibitive. Bond discovered that there are strains of each species of root nodule bacteria which do not exert a mutually inhibitive effect on each other."

37. In contrast with the *Funk* case, the Supreme Court, in Diamond v.Chakrabarty[65], stated that a genetically altered living organism is patentable:

> "respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter - a product of human ingenuity "having a distinctive name, character [and] [447 U.S. 303, 310] use." Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887).
>
> Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under 101".

38. Elaborating along the same line of thought, a US District Court has recently invalidated 15 claims contained in 7 patents related to the BRCA 1 and 2 breast and ovarian cancer susceptibility genes. The opinion states that patentable subject matter must be markedly different from a product of nature and concludes that the existence of DNA in an isolated form alters neither its fundamental quality of embodying biological information, as it exists in the body, nor the information it encodes[66]. However, attention has to be drawn to the fact that an appeal of that decision is currently pending before the United States Court of Appeals for the Federal Circuit[67].

39. An Indian judicial case, *Dimminaco A.G. v. Controller of Patents*[68], shed some light on the patentability of inventions that use living material. A patent concerning a process of preparation of infectious Bursitis Vaccine was denied by the Controller of Patents, on the ground that a process for producing a vaccine containing living organisms does not constitute either a process of manufacture or a substance produced by manufacture, given that the recourse to living organisms is not comprised in the term "manufacture" utilized in the definition of invention. On appeal, the High Court of Calcutta observed[69] that the office made a mistake in denying a patent just because the final product of the process contained a living organism; the Court observed that the invention fulfilled the patentability requirements through reading Section 2 (i) (j) with Section 5 (1) (a) of the Patent Act[70].

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65 Case 447 U.S. 303 No. 79-136 of 16 June 1980.

66 *Association for Molecular Pathology, et al., v. United States Patent and Trademark Office, et at*., 702 F. Supp.2d 181 (S.D.N.Y. 2010), page 121.

67 Appeal No. 2010-1406.

68 *Dimminaco A.G. v. Controller of Patents*, High Court of Calcutta, case No. 268/2002, January 15, 2002.

69 It is important to highlight that the decision of the High Court of Calcutta was adopted before the reforms of the Indian Patent Act of June 2002 and April 2005.

70 According to Section 2 (i) (j) with Section 5 (1) (a) of the Patent Act, "in the case of inventions claiming substances intended for use, or capable of being used, as food or as medicine or drug no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable." In the light of this rule of law, a process aimed to obtain a vaccine shall be patentable; in order to verify if such a process shall be considered a "process of manufacture" according to the Patent Law, it has been observed by the Court that one can have recourse to the so called "vendibility test". According to the latter if the invention results in the production of some vendible item or it improves or restores former

[Footnote continued on next page]

Countries which provide specific provisions allowing or excluding the patentability of subject matter that consists of, or which is derived from, naturally occurring products.

40. Some countries expressly provide that the previous existence of a naturally occurring material is not an impediment for patent protection of the biological material that is isolated from its natural environment, produced by means of a technical process[71], or in purified or altered form[72]. Some countries also extend this protection to elements isolated from the human body or otherwise produced by means of a technical process, which might include the sequence or partial sequence of a gene[73]. This is the case, for instance, of the Member States of the European Union, where a Directive has been adopted on the legal protection of biotechnological inventions in 1998 (Articles 3 (2) and 5 (2) and recitals 13,16, 17, 20 and 21).

41. The Biotechnology Directive (98/44/EC) expressly states that biological material may be the subject of a patent (Art. 3.1), if the invention thereof fulfills the patentability requirements. The Directive adds that a biological material "isolated from its natural environment" or "produced by means of a technical process", even if it previously occurred in nature, may be an invention. In this respect, the following text of the EPO Examiners Guidelines may shed some light:

> " (Chapter IV 2.3.1) To find a previously unrecognised substance occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect. In addition, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as one aspect of the invention."
>
> " (Chapter IV 3.2) Biotechnological inventions are also patentable if they concern an item on the following non-exhaustive list: (i) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature. Hence, biological material may be considered patentable even if it already occurs in nature (see also IV, 2.3.1)".

42. The Biotechnology Directive (98/44/EC) applies the same criteria to the patentability of genetic inventions. In fact, on the one hand it excludes from patentability the "human body… and the simple discovery of one of its elements, including the sequence of partial sequence of a gene", but on the other hand, it establishes that "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene" shall be patentable, and further specifies "even

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[Footnote continued from previous page]

conditions of a vendible item or its effect is the preservation and prevention from deterioration of some vendible products we are dealing with a process of manufacture; in other words, a vendible product means something which can be the object of a purchase or sale. And a vaccine produced through the process that is the subject of the patent application shall be defined as such.

71 L. Bently and B. Sherman, "Intellectual Property Law", Third Ed., Oxford, 2009, page 422.

72 D. Chisum and M. Jacobs, "Understanding Intellectual Property Law", Matthew Bender, 1992, pages 2-23.

73 Merk J. Devison and others, "The Australian IP Law", Cambridge, 2008, page 417.

if the structure of that element is identical to that of a natural element". Needless to say, the patentability requirements also apply to the inventions occurring in these fields; moreover, stringent requisites have been set regarding the requirement of industrial applicability[74]. In fact, the industrial application of a gene sequence or a partial sequence has to be disclosed in the patent application[75], and hence a mere DNA sequence without indication of a function does not contain any technical information and therefore is not a patentable invention[76].

43. The general comments previously made on the patentability of biological material at the EPO coincide with the practice of the USPTO and JPO, offices that have been cooperating through informal agreements[77] that go beyond the cooperation provided for in multilateral treaties. In the area of biotechnology, intensive work towards harmonization of practices has been carried out, based on several studies on this field[78].

44. It is important to highlight that the focus given to the flexibility under study does not cover exclusion on the grounds of *ordre public* or morality, which might be the object of a further study. However, but for the sake of clarity, it is important to mention that, even in Europe, where the patentability of an isolated element of the human body or otherwise produced by technical process (including the sequences or partial sequences of genes) is allowed under the EU Directive 98/44, the Enlarged Board of Appeal of the European Patent Office has denied a patent on an invention claiming compositions (cultures) of human embryonic stem cells (hES cells)[79], on the basis of Article 53 (a) of the European Patent Convention (EPC). According to the latter provision, "European patents shall not be granted in respect of: (a) invention the exploitation of which would be contrary to "*ordre public*" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the contracting States".

45. A second group of countries have adopted a legislative provision which excludes from patentability subject matters that coincide with naturally occurring products; among others, Argentina, Brazil, Chile, the Dominican Republic, Nicaragua, the Andean Countries, and Uruguay. There are important differences among these legislative provisions, but they share the idea that when a product already exists in nature, human intervention aimed to isolate, purify or produce synthetically the product does not suffice to make the outcome of the human development patentable[80]. The construction of

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74 Directive 98/44/EC, recital 24 "in order to comply with the industrial application criterion it is necessary, in cases where a sequence or partial sequence of a gene is used to produce a protein or part of a protein, to specify which protein or part of a protein is produced or what function it performs".

75 In this sense see WIPO document (SCP/5/5), which stated: "…an invention concerning gene sequence that produce a protein, not only which protein is produced, but also the function or utility of the protein should be disclosed in order to meet the requirement of industrial applicability".

76 Matthias Herdegen, "Patents on Parts of the Human Body, Salient Issues under EC and WTO Law", *Journal of World IP*, 2002, Vol. 5, issue 2, page 148.

77 In the early 1980s, the Trilateral Offices started to propose a co-operative approach to solving common challenges.

78 Among others, Trilateral Project 24.1 on "Biotechnology Patent Practices Comparative Study" and Trilateral Project B3b on "Patentablity of DNA fragments".

79 EBA Decision of 25 November 2008.

80 Article 7 b) of the Patent Law of Argentina (Law no. 24.481 modified by law 25.859); in this sense the Examination Guidelines paragraph 2.1.7.1 (Part C, Chapter IV of Resolution 243/03) states:

[Footnote continued on next page]

several laws to exclude some of the previous subject matter is built upon specific concepts, e.g., what is a microorganism[81] or an express indication that fit the threshold of inventions above isolation/purification human contribution on a product of nature.

46. In some authors' view, the adoption of more stringent criteria of what is an invention, in particular excluding isolation or purifications as a relevant contribution to make the subject matter patentable, is compatible with article 27 of the TRIPS Agreement[82]. But clearly, in the absence of a panel ruling on the issue, doubts expressed by some remain on the table for consideration[83].

[Footnote continued from previous page]

"living matter and substances preexisting in nature even if purified and isolated and/or characterized, are considered discoveries and in consequence will not be patentable"; Article 10 IX of the Brazilian Patent Law and Article 15 b) of the Andean Community Decision 486.

81 The Brazilian law allows the patentability of transgenic microorganisms (Art. 18 III), which are defined as "organisms…that express, by means of direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions".

82 Shamnad Basheer, "Limiting the patentability of Pharmaceutical Inventions and Micro-organisms: a TRIPS Compatibility Review*", IP Institute,* November 2005, page 58 and Correa Carlos, "Patenting Human DNA: what flexibilities does the TRIPs Agreement allow?", *Journal of World Intellectual Property*, Vol. 10, Issue 6, Nov. 2007, page 424.

83 See Strauss (1998), pages 109-110 cited by J, Watal, "Intellectual Property in the WTO and Developing Countries", Kluwer, 2001, page 133. Matthias Herdegen, "Patents on Parts of the Human Body- Salient Issues under EC and WTO Law", *Journal of World Intellectual Property*, 2002, Vol. 5, issue 2, page 149. For an "open", negative, definition of invention and more power to national judges in order to circumscribe this definition according to the values of the society see also W.Cornish & D. Llewelyn, "Intellectual Property, Patents, Copyright & allied rights", 6th edition, Sweet & Maxwell, London, 2007, page 215.

IV. DISCLOSURE-RELATED FLEXIBILITIES

A. Introduction

47. The introduction of the disclosure requirement within the patent system[84] has marked an important shift in the economic role of the patent system, which moved from being a mechanism that promoted the introduction of finished products into the national streams of commerce, to a system primarily focused on the knowledge that is behind the invention and the contribution of that knowledge to the technical arts[85].

48. Through the disclosure the inventor describes the invention, sharing with society the content of his invention and thus making the knowledge contained in his patent application available to everybody in order to stimulate future innovation[86]: this means that third parties are able to use the invention when the patent expires, but, more importantly, they have the opportunity to improve upon, be inspired by, or test and understand how the invention works[87], already during the patent term.

49. The disclosure function has been considered one of the reasons which justify the existence of patent system[88] or, one of the principal purposes of the patent system[89]. However, some authors[90] consider that the role played by the disclosure is more a sub-product of the patent system whose primary justification is to offer incentives to create, develop, and commercialize new technologies and innovation. In the view of several authors[91] and government bodies[92], the disclosure function is a cornerstone of the patent policy, but some actions are needed to reinvigorate its key role.

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84 As highlighted by D. Chisum, the statutory requirement of an enabling disclosure is long-standing; it was stated in the first United States Patent Act of 1790, Chisum, *Comment: Anticipation, Obviousness, Enablement: An Eternal Golden Braid,* 15 Am. Intell. Prop. L. Ass´n Q.J. 57 (1987). In the same vein, in the 18 Century, by a British judicial creation, the requirement that patent applicants clearly and fully describe their inventions in a specification was grafted in law (Liardet v. Johnson, (1778) 481 N.B. 173 (K.B.)).

85 Robert Patrick Merges, "Patent Law and Policy", The Michie Company, 1992, page 513.

86 Jeanne C. Fromer, "Patent disclosure", *Iowa Law Review*, 2009, page 545. See also Carolyn Abbot and David Booton, "Using Patent Law's Teaching Function to Introduce an Environmental Ethic into the Process of Technical Innovation", page 23, available at: http://works.bepress.com/cgi/viewcontent.cgi?article=1000&context=david_booton.

87 The safe harbor that constitutes the research exception varies considerably from one country to another: to verify the scope of this exception in a certain number of countries see CDIP/5/4 Rev.

88 SCP/12/3 Rev.

89 National Research Council of the National Academies, "A Patent System for the 21st Century", 2004, page 6.

90 Timothy Holbrook, "The Disclosure function of the Patent System (or lack Thereof)", *Harvard Law Review*, Vol. 118, 2007, page 2027.

91 See Jeanne C Fromer, *supra* note 86, who pointed out the following reasons: i) the way patents documents are structured doesn't allow the readers to "glean truly useful information from it"; ii) the rule of willful infringement creates a disincentive to read patent documents due to the worries of "treble damages" in patent infringement cases and iii) weak enforcement by patent offices of adequate standards of disclosure.

92 National Research Council of the National Academies, "A Patent System for the 21st Century", 2004.

50. Courts in different jurisdictions have openly embraced the vision according to which the disclosure function is the centerpiece of patent policy[93]. The US Supreme Court in a unanimous decision declared that: "the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure"[94]; the same is true for the Federal Circuit[95].

51. The disclosure function is implemented through a condition imposed to the inventor to disclose the invention in his/her application, in return for the patent grant. Therefore, patent laws worldwide set up certain legal requirements that need to be fulfilled by the patentee in order to properly disclose the invention. The nature of these requirements has been studied by legal experts and scholars[96], by courts[97], as well as within multilateral discussions[98].

52. The disclosure requirement coincides to a certain degree worldwide, but certain specificities remain left to the choice of the national legislators, so national patent laws of Member States may present some differences in relation to certain aspects of the disclosure[99]. The main elements of the disclosure requirement could be enunciated as follows: (i) the inventor shall describe his invention clearly enough to allow an expert in the field/skilled in the art to understand it and make and use it without undue experimentation: this is the so called "enablement" standard; and (ii) the inventor has to set the boundaries of what he/she is claiming to be protected through a patent by the description of the invention, therefore, his/her claims shall be "supported by" or "based on" the description (this corresponds to Art. 84 European Patent Convention); this relationship between claims and description corresponds to the "written description" in US practice. On the other hand, the obligation to include in the specification the best mode known by the applicant for practicing the claimed invention is limited to only a few jurisdictions, including the U.S.

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93 See for example *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 63 (1998) cited by Timothy Holbrook, see *supra* footnote 76.

94 See for example *Bonito Boats, Inc. v. Thunder Craft Boats, Inc*., 489 U.S. 141 (1989).

95 "Linchpin" and "quid pro quo" are the kind of expressions used by the Federal Circuit to define the role played by disclosure within the patent system, *E.g*. W.L. Gore, v. Garlock, Inc., 721 F.2d 1540, 1550 (Fed. Cir.1983) and Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F. 3d 956, 970 (Fed. Cir. 2002).

96 See for example, Irah H. Donner, "Patent Prosecution, Law, Practice and Procedure", BNA Books, Sixth Ed., Volume II, page 2171.

97 The United States Court of Appeals for the Federal Circuit in the case *University of Rochester, v. G.D. Searle & Co., Inc, Monsanto Company, Pharmacia Corporation and Pfizer inc*, 249 F.Supp.2d 216 (W.D.N.Y. 2003), declared "The United States Supreme Court also recently acknowledge written description as a statutory requirement distinct not only from the best mode requirement, but also from enablement". The Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co*., 535 U.S. 722, 736 (2002) declared " [A] number of statutory requirements must be satisfied before a patent can be issued. The claimed subject matter must be useful, novel, and not obvious. 35 U.S.C. 101-103 (1994 ed. And Supp. V). In addition, the patent application must describe, enable, and set forth the best mode for carrying out the invention".

98 Among others, the work undertaken by the Standing Committee on Patents (SCP), see WIPO document SCP/6/5.

99 Such as the condition of the indication of the best mode contemplated by the inventor and the measures to enforce the requisites of disclosure.

Enablement

53. In the opinion of some authors[100], the rules on enablement do not vary significantly from one country to another; for example, this conclusion was reached in a study that compares the law of the Europe, India and United States. In a similar line of thought other scholars have indicated the existence of slight differences, e.g. when comparing US patent law and the European Patent Convention (EPC)[101]. In particular, the EPC contains an Article, reported as follows, which is very close to that used in many other legislations:

"Article 83. Disclosure of the invention.

The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art".

54. Enablement relates to the concrete teaching that the inventor includes in the specification which allows a person of ordinary skill in the art to make and use the invention that is claimed. Thus, the enablement presents two components: "how to make" and "how to use"[102]. According to the first component a person skilled in the art, applying ordinary skill and knowledge, can reproduce the invention on the basis of the application, while according to the latter there must be utility for every claim made, and such utility must always be expressly stated and never inferred[103].

55. The description must be elaborated keeping in mind that the addressee of the information is a person with ordinary skill in the art, as has been pointed out by the Federal Circuit: "A patent is not a scientific treatise, but a document that presumes a readership skilled in the field of the invention"[104].

56. It is not required of the inventor to provide information about each and every detail of the invention or to produce a description completely free of errors, as it is the intention of the requirement that only an ordinary level of experimentation be required to work the invention[105]. Courts and offices normally establish whether there is undue experimentation by weighing several factors[106].

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100 See for example Aniruddha Sen, "Clear and Complete Disclosure in Biotechnology Patent Applications – A Comparison of the Laws in the USA; Europe and India", *International Law*, 2006, vol. 2, no. 1, page 93.

101 Professor Merges said "the only truly distinctive feature of European Enablement doctrine is its insistence that an inventor explicitly identify the problem she has solved in her specifications", R. Merges, "Patent Law and Policy", The Michie Company, 1992, page 553.

102 Aniruddha Sen, see *supra* footnote 100.

103 Aniruddha Sen, "Clear and Complete Disclosure in Biotechnology Patent Applications – A Comparison of the Laws in the USA; Europe and India", *International Law*, 2006, vol. 2, no. 1, page 94.

104 *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co*., 228 F.3d 1338, 56 USPQ2d 1332, 1336 (Fed. Circ. 2000).

105 In this sense see Decision of the Technical Board of Appeals EPO (T 931/91).

106 See Ira H. Donner, *supra* footnote 96, who identifies several factors: 1) the quantity of experimentation necessary; 2) the amount of direction or guidance presented in the application; 3) the presence or absence of working examples; 4) the nature of the invention; 5) the state of the

[Footnote continued on next page]

Written description

57. The written description requirement ensures that the invention described in the specification will be accessible to the public at the time the application is filed. As pointed out by different authors, this requirement stems from two issues: the priority of the applications[107] and the question of new matter as a limit to disclosure modifications[108].

58. In a decision of the US Supreme Court[109] it has been established that the specification has two purposes: the first is to enable artisans to make and use the invention (enablement as described under (a) above), and the second is to put the public in possession of what the party claims as his own invention (written disclosure), as follows:

> "The specification, then, has two objects -- one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artisans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. It is not pretended that the plaintiff's patent is not in this respect sufficiently exact and minute in the description. But whether it be so or not is not material to the present inquiry. The other object of the specification is to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented. It is therefore for the purpose of warning an innocent purchaser or other person using a machine of his infringement of the patent, and at the same time of taking from the inventor the means of practicing upon the credulity or the fears of other persons by pretending that his invention is more than what it really is or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification. Nothing can be more direct than the very words of the act. The specification must describe the invention "in such full, clear, and distinct terms as to distinguish the same from all other things before known."

59. The written description is mandatory for the subject matter that is the object of the patent application, so there is a need that claims be supported by the specification. The specification may be a constraint when it does not provide support to the claims, i.e. when the specification indicates a range not mentioned in the claims[110] but could also be a way to defend certain uses of embodiments that were not included in the claims[111].

[Footnote continued from previous page]

prior art; 6) the relative skills of those in the art, 7) the predictability of the art; and 8) the breath of the claimed invention.

107 *In re* Smith, 481 F. 2d 910 (C.C.P.A. 1973).

108 *In Re* Smythe, 480. F2d 1376 (C.C.P.A. 1962).

109 *Evans v. Eaton*, 20 U.S. (7 Wheat.) 356 (1822).

110 *In re* Fisher, 427 F.2d 883 (C.C.P.A. 1970), the CCPA affirmed a decision of the examiner which considered that a claim which recited a potency of an hormone of 1 activity per milligram with no upper limit was not supported by a description that recited the potency of the hormone between 1.11 and 2.30 activity per milligram. The hormone was extracted from the glands of certain animals and use by injection in humans serves to treat certain form of arthritis.

111 *In re Intelpro Corp. v. Environ Products Inc.*, Civ. App. No. 99-1059 (Fed. Circ., Sept. 15, 1999), *cert. denied*, 529 U.S. 1108 (2000).

60. The USPTO Guidelines[112] on written description are focused on "possession", in the sense that an appropriate written description is the tool to convey sufficient details to one skilled in the art to reasonably conclude that the inventor has possession of the claimed invention[113].

Best mode

61. Disclosure of the best mode is required in a certain number of countries, such as the Andean countries, Argentina, Australia, Brazil, Costa Rica, Egypt, India, Jordan, Malaysia, Mexico, New Zealand, Thailand and the USA, while it has been excluded from the national patent law of other countries[114] or it has been simply not included, as is the case for many other patent laws[115].

62. The rationale of such a provision is to oblige the inventor to share with society a part of the knowledge that could remain hidden, even if the invention has been disclosed. As stated by the Federal Circuit, the "sole" purpose of the best mode requirement is "to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived"[116]. It has been pointed out that there is no statutory requirement for the disclosure of specific examples[117]; what is required is that the specification includes the best mode contemplated by the applicant[118]. It is not required to update the best mode in the context of a foreign priority application[119] or in continuing applications claiming the benefit of an earlier filing date[120].

63. The best mode requirement involves two main aspects: the first is subjective and consists in establishing whether the inventor, at the time of the application, had in mind a best mode of practicing what is claimed as the invention. The second, more objective, consists in establishing whether the specification adequately discloses what was the best mode contemplated by the inventor[121]. It is important to clarify that determining compliance with the best mode requirement is a very difficult task for patent offices[122],

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112 Revised Interim Guidelines (Dec. 21 of 1999).

113 This emphasis en possession has being highlighted by the Federal Circuit, see *LizardTech, Inc, v. Earth Resource Mapping, Inc.* 424 F.3d 1336, 1345 (Fed Cir. 2005) and *University of Rochester, v. G.D. Searle & Co., Inc, Monsanto Company, Pharmacia Corporation and Pfizer inc.,* 249 F.Supp.2d 216 (W.D.N.Y. 2003).

114 The UK Patent Act of 1949, s. 32 (1) (h) requires "best mode", but it is not included under the Act of 1977. In that sense see Terel "It should be noted that it is not necessary to describe the best method known to the applicant", "The Law of Patents", Sweet & Maxwell, 1994, page 78 and W. Cornish "Now all that is called for is the disclosure be clear and complete", in W. Cornish & D. Llewelyn, "Intellectual Property, Patents, Copyright & allied rights", 6th edition, Sweet & Maxwell, London, 2007, page 237.

115 Out of 115 national laws analyzed, 84 do not include best mode requirement.

116 *Chemcast Corp. V. Arco Indus. Corp*., 913 F.2d 923, 926, 16 USPQ2d 1033, 1035 (Fed Cir. 1990)

117 *In re* Gay, 309 F. 2d 768 (CCPA 1962).

118 *Ernsthausen v. Nakayama*, 1 USPQ2d 1539 (Bd. Pat. App. & Inter. 1985).

119 *Standard Oil Co. V. Montedison, S.p.a*., 494 F. Supp. 370 (D.Del. 1980).

120 Transco Products, Inc. v. Performance Contracting Inc., 38 F. 3d 551 (Fed. Cir. 1994).

121 Aniruddha Sen*, supra* footnote 102.

122 In relation to the criteria, the examiner has to follow in order to determine whether the inventor knew that one mode was better than another, and if so, whether the disclosure is adequate to enable one of ordinary skill in the art to practice the best mode, see for instance the USPTO website:

[Footnote continued on next page]

and therefore, many patent laws leave that determination to courts in the framework of validity or enforcement procedures.

64. The best mode requirement is considered a tool to promote competition, not just after the patent expires, but even within the patent term; for that reason, it has been frequently mentioned as in line with the interest of developing countries[123]. Nevertheless, the subjectivity that is necessarily involved in the determination of the inventor's state of mind at the time of the application makes this requirement a source of litigation; therefore, suggestion have been made to abolish it in the United States[124], and pending patent law reform legislation would end the requirement[125].

B. The International legal framework

65. The content of Article 29 of the TRIPS Agreement built significantly on the discussion that was undertaken within WIPO[126] and that ended in a "Diplomatic Conference for the

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http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2165_03.htm#sect2165.03 where it is indicated that: "According to the approach used by the court in Chemcast Corp. v. Arco Industries, 913 F.2d 923 has two components: (A) Determine whether, at the time the application was filed, the inventor knew of a mode of practicing the claimed invention that the inventor considered to be better than any other. The first component is a subjective inquiry because it focuses on the inventor's state of mind at the time the application was filed. Unless the examiner has evidence that the inventors had information in their possession: (1) at the time the application was filed (2) that a mode was considered to be better than any others by the inventors, there is no reason to address the second component and there is no proper basis for a best mode rejection. If the facts satisfy the first component, then, and only then, is the following second component analyzed. (B) Compare what was known in (A) with what was disclosed - is the disclosure adequate to enable one skilled in the art to practice the best mode? Assessing the adequacy of the disclosure in this regard is largely an objective inquiry that depends on the level of skill in the art. Is the information contained in the specification disclosure sufficient to enable a person skilled in the relevant art to make and use the best mode? A best mode rejection is proper only when the first inquiry can be answered in the affirmative, and the second inquiry answered in the negative with reasons to support the conclusion that the specification is non-enabling with respect to the best mode."

123 See Report of the Commission on Intellectual Property Rights, London 2002, page 117 and WIPO Model Law for Developing Countries on Inventions, Geneva 1979, Section 123 (3) "The description shall…in particular, indicate the best mode known to the applicant for carrying out the invention".

124 National Research Council of the National Academies (NRCNA), "A Patent System for the 21st Century", Washington 2004.

125 The U.S. Senate voted 95-5 March 8, 2011 to approve a patent reform bill, S.23, which includes a provision eliminating best mode as a ground for "canceled or held invalid or otherwise unenforceable" of the patent or any claim. On the other hand, in the House of Representatives another bill (H.R. 2795 109th Congress 2005-2006) that never became law, proposed the elimination of the best mode from U.S. CODE TITLE 35-PATENTS Section 112.

126 The Assembly of the Paris Union in 1983 decided the creation of a "committee of experts on the Grace Period for Public Disclosure of an Invention before filing application", which started working as its name suggest in the so called grace period in 1984. The Agenda was widened with the progress of the group and in 1987 (fourth meeting), among the 4 new issues that the committee took up 4 was the requirement of disclosure (Article 3).

Conclusion of a Treaty Supplementing the Paris Convention as far as Patents are Concerned"[127]; however, no consensus was reached.

66. Article 29 of the TRIPS Agreement incorporates as a "condition on patent applicants" the disclosure of the invention for which protection is sought in a "clear and complete" manner, to allow a person skilled in the art to carry out the invention. Therefore, the disclosure of the invention is mandatory for the applicant; however, the content and form of that disclosure is not specified (nor is the relationship between the disclosure and the claims), nor is the sanction for non compliance.

67. Thus, WTO Members are obliged to provide in their national legislations the disclosure requirement, to ensure that the patent system plays its role of disseminating knowledge.

68. Article 29 contains two flexibilities in the form of "may" provisions: firstly, Members may require the applicant to indicate the best mode for carrying out the invention known to the inventor and secondly, they may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants. Regarding the first, advantages and disadvantages have already been mentioned above. On the second, it would be useful for Members which undertake substantive examination of patent applications, particularly, developing and least-developed countries, because of the utility of that information in the examination process.

C. The requirement of information concerning the applicant's corresponding foreign applications and grant

69. As previously mentioned, the TRIPS Agreement incorporates the option for Members to require applicants to disclose information concerning the applicant's corresponding foreign application and grant. Certainly the adoption of such a provision at a national level would help the examination of the patent application in terms of speed and quality. In any case, if this option is implemented in the national law, it would not affect the basic principle of independence of patent applications[128].

70. The information under examination may be furnished by the applicant, if required by the patent law, or upon request of the patent office, where it is left to the discretion of the registrar to make that request. If the information concerning the applicant's corresponding foreign applications and grant is not filed in due course[129], the application may be rejected. As the TRIPS Agreement does not adopt a specific solution on this issue, a certain *margin of manœuvre* is left to Members.

D. Two other matters related to disclosure not covered by the TRIPS Agreement

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127 Records of the diplomatic conference shows how article 3 and rule 2 on disclosure was a matter were diverse views were expressed, particularly the best mode requirement divide the position of Europe lead by the German delegation and US.

128 UNCTAD-ICTSD, "Resource Book on TRIPS and Development", Cambridge University Press, 2005, page 452.

129 The difference comes from the wording of the patent law. It could be established the applicant shall accompany the application with the information regarding the corresponding foreign application (grant or rejection) or it could be provided that the Register may request the applicant to do so. The latter is the wording provided by the WIPO Model Law for Developing Countries on Inventions, in Section 128 "The applicant shall, at the request of the Patent Office…".

71. Other issues related to disclosure were not included in the text of Article 29 of the TRIPS Agreement, such as the disclosure of micro-organisms through their deposit with a depository authority[130], and the indication of the origin of biological material, which in the view of some Members of the WTO fits into the disclosure content[131].

The deposit of microorganisms to disclose the invention

72. Certainly the disclosure of micro-organisms and biological material could present a difficult task. In order to solve that problem, a number of national patent laws have accepted the deposit of biological material as an equivalent or a complement to the description made in the specification. Therefore, for a "clear and complete description" of an invention that consists of, or is derived from, a microorganism or cultured cells, reference could be made to a deposit at a depositary institution.

73. The Budapest Treaty permits the deposit of the micro-organism through a Depositary Authority (internationally recognized, in accordance with the procedures of the Treaty and its Regulations)[132].

Indication of the origin of biological material

74. The review process of Art 27.3 (b) of the TRIPS Agreement has covered the issue of disclosure of the origin of genetic resources within the broader subject of the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD)[133] and, in particular within the objective of the latter to realize a system on prior informed consent and benefit sharing in relation to the access and exploitation of biological resources [134]. In that regard, some Members have expressed their concern that patents might be granted to inventions that use biological material without respecting the provisions of the CBD.

75. On that topic WTO Members have tabled different proposals, among which are the following: Switzerland advocated a revision of the legal framework under WIPO administered treaties (PCT and PLT)[135]; a group of "mega-diverse" Countries[136] proposed that the TRIPS Agreement be amended to require patent applicants to indicate the "source and the country of origin of resources" and provide evidence of "prior informed consent and fair and equitable benefit sharing"; the African Group proposed to add a new paragraph 3 to Article 29 on the disclosure requirement[137]; and the EU and its

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130 Article 3 and rule 2 of the Draft Treaty presented to the Diplomatic Conference (see note 112) contain specific provision on the deposit of "biologically reproducible material".

131 The so called "TRIPS disclosure proposal", see document IP/C/W/368/Rev.1, page 28 for more details.

132 See paragraph 33, above.

133 The Doha Declaration of November 2001 instructed the Council for TRIPS to analyze the relationship between TRIPS and CBD in the framework of its work to review art. 27.3.(b).

134 For an in depth analysis see WTO document IP/C/W/368/Rev.1.

135 The Swiss proposal was first submitted for consideration at the fourth session of the Working Group on PCT Reform held in May 2003. The proposal was described as an enabling clause because it would allow Member States to implement the requirement if they wished.

136 Namely: Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, India, Peru, Thailand, and Venezuela.

137 The text proposed is "3. Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the

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Member States expressed willingness to discuss within the TRIPS Council the introduction of a multilateral system for disclosure, which would not affect the validity of patents[138].

76. One author[139] has classified national laws into three groups: "weak disclosure measures"[140], "medium disclosure measures"[141] and "strong disclosure"[142] measures. Nevertheless, the consistency of some of those provisions with the TRIPS Agreement has been questioned, particularly those that propose rejection of the patent application or invalidation of the granted patent as a sanction for noncompliance.

77. For some authors[143], requirements to indicate the origin of a biological material, or evidence related to Prior Informed Consent/Benefit Sharing (PIC/BS), are not considered patent substantive requirements, but related to the "content or form" of the application, using the same terminology as the PCT. Therefore, it has been proposed that inclusion of such requirements in the multilateral system be explored through a revision of Rule 51 *bis* 1 (a) (i) to (v) of the PCT, entitled "Certain National Requirements Allowed Under Article 27".

78. Some authors argue that the requirement of the indication of the origin of biological material is a component of the disclosure requirement, and that any revision of the multilateral legal framework consequentially implies a revision of Article 29 of the TRIPS Agreement[144].

79. Some have suggested invoking existing doctrines promoting the fair behavior of the applicant during the prosecution of the patent. Thus, the USA jurisprudence has pointed out that a patent applicant "has a duty of candor and good faith in dealing with the patent office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability"[145]. A breach of this duty constitutes inequitable conduct, which subjects any resulting patent to nullification[146].

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invention and to provide confirmation of compliance with all access regulation in the country of origin".

138 Therefore the requirement should not act "*de facto o de jure*" as an additional formal or substantial patentability criterion and sanctions should fall out side of the patent law.

139 Michael Blakeney, "Proposals for the Disclosure of Origin of genetic Resources in patent Applications", WIPO/IP/GR/05/01.

140 Adopted for instance by Egypt, the EU, and Sweden.

141 Adopted for instance by Denmark, New Zealand, Norway and Switzerland.

142 Adopted for instance by Andean Community, Brazil, Costa Rica and India.

143 See Martin Girsberger, " *The Journal of World IP*", 2004, Vol 7, issue 4, page 462.

144 See Carlos M. Correa, "The politics and practicalities of the disclosure of Origin Obligation", Occasional Paper 16, 2005, page 5, at *http://www.quno.org.*

145 *McKesson Info. Solutions, Inc. v. Bridge Medical, Inc.,* 487 F.3d 897, 913 (Fed. Cir. 2007). Inequitable conduct requires two elements: materiality and intent, and those two elements have been circumscribed on a case by case basis by the U.S. jurisprudence. It has been pointed out that information is material "when a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent" (Symantec Corp. v. Computer Assocs. Int'l, Inc., 522 F. 3d 1279, 1297 (Fed. Cir. 2008)), while in relation to the issue of intent to deceive the examiner, courts look at all the facts surrounding an applicant's overall conduct to infer culpability

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80. Attention should be drawn to the work of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, which continues to consider the following options on genetic resources: (i) mandatory disclosure; (ii) further examination of this issue; (iii) development of guidelines or recommendations and iv) alternative mechanisms, such as the creation of an international information system on disclosed genetic resources and prior art[147]. During the Third Intersessional Working Group, held in Geneva, from February 28 to March 4, 2011, proposals coming from Member States were circulated for discussion[148].

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because "intent rarely can be, and need not be, proven by direct evidence" (*Cargill, Inc. v. Canbra Foods, ltd.*, 476 F.3d 1359, 1364 (Fed. Cir. 2007)).

146 Some authors have proposed that failure of the duty of candor by the patent applicant on matters that are essential for the substantive decision of the Office be sanctioned by the non-enforceability of the patent, which will be restore when the patentee clean his hands: in this sense see e.g., N. Pires de Carvalho, "Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solutions", *Washington University Journal of Law*, 2000, page 371.

147 For an in depth analysis, see Technical on Disclosure Requirements in Patents Systems related to Genetic Sources and Traditional Knowledge (WIPO/GRTKF/IWG/3/14).

148 See documents (WIPO/GRTKF/IWG/3/2) and (WIPO/GRTKF/IWG/3/4).

V. SUBSTANTIVE EXAMINATION

A. Introduction

81. WIPO Member States' or regional IP offices conduct a prior art search and substantive examination in order to check compliance with conditions of patentability prescribed by the applicable patent law[149]. Search and examination thus ensure that granted patents meet the prescribed legal requirements.

82. The quality of search and examination, therefore, is very important for the legal certainty of the patent system as well as for the confidence in the patent system by society at large. On the other hand, it is expensive to maintain a system of full substantive examination. Further, in order to search the maintenance of up-to-date prior art documentation is essential, which also requires considerable financial and human resources.

83. Conducting search and substantive examination for all applications may thus not be the best approach for all patent offices. Complex tasks and costs associated with the administration of search and examination are well recognized, and finding the best way to allocate limited resources is a challenge. Therefore, different options should be considered, such as conducting only formal examination, or conducting formal examination and search, or conducting also substantive examination, but relying on work carry out by others via cooperation arrangements.

84. For search and substantive examination, IP offices can consider entering into cooperation agreements with other offices having the skills and resources to perform these tasks. This kind of collaboration may take the most diverse forms. For instance, a given office may "rely" on the work undertaken by another office by means of informal cooperation agreements or may be bound by the work undertaken by others, by means of, for example, more formal agreements.

Different options for examination

85. Some countries have chosen to adopt a system where just the formalities of the patent applications are checked and, once the formality requirements are met, the patent is granted. When a patent is enforced at a later stage, its validity may be challenged by the alleged infringer. From the point of view of the patent office, the system of formal examination leads to a considerable cost saving in terms of staff expenditure, allowing

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149 The examination process among countries that conduct search and examination varies significantly. For example, at the UKIPO applicants request the search; in the case where the request is not made on time, applications are considered withdrawn. Then, after the publication of the application, applicants shall request that substantive examination be undertaken. At the EPO, a search request is implied by filing the patent application and takes place before publication, but applicants, after publication of the applications, have to request the substantive examination. At the JPO as well no request for search is needed and search is undertaken at the time of substantive examination, which needs by the way to be requested by applicants after the publication of their patent application. In front of the USPTO, no request for search or examination is needed; both are implied by filing an application and take place after publication of the application.

the country to allocate its resources to other areas of priority. However, the costs for examining the validity of questionable patents are transferred to the post-grant phase, in particular to courts as well as to patent owners and third parties.

86. Another option is a system where the patent office, once an application is filed and the formalities are checked, conducts a prior art search and establishes a search report. According to this kind of procedure the patent will be granted without examination as to patentability, and the search report is published together with the granted patent, allowing third parties to better assess its validity. Such a system can rely on an Officer's or on examiners, or may outsource the work to another office.

87. Arrangements for outsourcing search and examination are made by a number of countries. Indeed, this type of arrangement is fundamental to the establishment of "international-type" search reports by an International Authority under the PCT, which can be used by national Offices. Another possibility for countries with limited resources is to re-register[150] patents already granted in another country, instead of providing formality checks and substantive examinations. In general, an application for re-registration has to be filed with the office within a certain time limit after the grant of the foreign patent. Thus, the validity of patents is secured to a certain extent, since they have been subjected to substantive examination in another country. This system may only work satisfactorily if administrative arrangements have been established between the granting country and the re-registering country.

Cooperation for search and examination

88. Keeping in mind that patent application filings have risen steadily[151] and the increasing complexity of patent documents, cooperation is an interesting solution for IP offices not only in developing and least developed countries, but also for developed countries looking for solutions to their backlog in patent examination.

89. According to a study prepared by London Economics[152], the backlog that main IP Offices such as the United States Patent and Trademark Office (USPTO), the European Patent Office (EPO) and the Japanese Patent Office (JPO) are facing is estimated to grow by 13 months over the next 5 years. The same study considers that one year of pendency time at these offices is estimated to impose costs of £7.6 billion per annum on the global economy.

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150 For example the Hong Kong Patent Office re-register patents that have been granted by State Intellectual Property Office of the People's Republic of China (SIPO), United Kingdom Patent Office (UKPO) or EPO (when UK has been designated). Brunei is also another example of a country having adopted a re-registration system.

151 According to WIPO, World Intellectual Indicators of 2010, approximately 1.91 million patent applications were filed across the globe in 2008. The long term trend in the data provided by this Report shows that the number of applications filed worldwide has had a sustained upward trend since 1995, except for a small drop in 2002. In relation to PCT applications, the PCT Yearly Review of 2009 shows that international applications through PCT has increased constantly, since less than 5000 on 1978 to almost 175.000 in 2008 (a decrease of 4.5% in the total number of filings was witnessed in 2009).

152 "Economic Study on Patent Backlogs and a System of Mutual Recognition", London Economics, January 2010.

90. Therefore, considerations of practices to improve patenting process have been high on the agenda[153], including accelerated examination[154] and work sharing initiatives[155].

91. Work sharing initiatives among IP offices are built upon the recognition that the use of resources by multiple offices regarding the same invention is wasteful. The PCT has been considered by many as the most cost effective system for the rationalization of resources in the international context. Under the PCT, the international application is subject to an international search[156], and the results (International Search Report) with a written opinion on the patentability of the invention are sent to the applicant[157]. After publication, the applicant may opt for a "preliminary examination", which is the object of an "international preliminary examination report"[158]. These reports (international Search Report, Written Opinion and International Preliminary Examination Report), together with

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153 See for example, the speech of the Prime Minister Junichiro Koizumi in 2003 to the 156th session of the Japanese Diet (www.kantei.go.jp/foreing/koizumispeech/2003/01/31sisei_e.htlm) and the speech of David Cameron announcing a fast track for patent application at Leeds (release of the UK Intellectual Property Office of the28th of March 2010).

154 Within certain patent offices, such as the Canadian Intellectual Property Office (CIPO), Germany Patent and Trademark Office (DMPA), Japan Patent Office (JPO), European Patent Office (EPO), IP Australia, Korean Intellectual Property Office (KIPO), States Intellectual Property Office of the People's Republic of China (SIPO), United Kingdom Patent Office (UKPO) and United States Patent and Trademark Office (USPTO), it is possible to ask for an accelerated examination of the patent application. Usually this procedure is contained in internal notices/rules, but certain countries patent law contains provision on this matter, for instance, Article 61 of the Korean Patent Law. The grounds and conditions which allow the recourse to such accelerated procedure may vary from country to country. For instance, at the USPTO it is possible "to make applications special" because of the applicant's age or health or if the application" provided other requirements are fulfilled (see Guidelines for Applicants under the New Accelerated Examination Procedure AESD). At the Japanese Patent Office (JPO), four kinds of patent application shall have access to an accelerated examination: (1) working invention-related applications; (2) internationally-filed applications; (3) academic institutes-related applications and (4) SME-related applications. Accelerated examination can also be requested when a patent has already been granted in another country, for instance, at the Australian Patent Office where it is possible to ask for a "modified examination" if: (1) the patent application is for a standard patent; (2) a patent has been granted in at least one country among USA, Canada, New Zealand or a country that is signatory of the European Patent Convention; (3) the foreign patent is in English; (4) the foreign patent is for the same invention and (5) a certified copy of the granted foreign patent has been filed on request of the Commissioner. It has to be mentioned that in some cases accelerated examination is possible also in case of patent application related to certain kinds of technologies, such as green technologies (UKPO) or technologies in the area of the defense industry, or related to the promotion of certain objectives of the state, such as the promotion of exports, venture business or the development of new technology or quality certification (Article 9 of the Enforcement Decree of the Patent Act of the Republic of Korea).

155 Peter Drahos describes the advantage as follows: "mutual exploitation allows an office to utilize the work of another office without obliging it to do so", "The Global Governance of Knowledge", Cambridge University Press, 2010, page 191.

156 This international search is carried out by one of the 14 International Searching Authorities (The Offices of Egypt, India and Israel, which have been appointed, have not yet notified the date on which they will start functioning as an ISA).

157 Rule 44 of PCT.

158 This is limited to residents or nationals of a Contracting State bound by Chapter II (Art. 31 (2) (a) of PCT).

a copy of the published application are sent to the national offices where the applicant is seeking protection, for their own decision on patentability. The advantages that this process brings to Contracting States in terms of work sharing are evident, while at the same leaving the final decision regarding patentability in the hands of each IP office[159].

92. In the framework of programs for accelerated patent examination, some IP offices[160] have concluded bilateral agreements for mutual recognition of work carried out by another office, such as the so called "Patent Prosecution Highway" (PPH)[161]. At the time of requesting accelerated examination in the Office of Second Filing (OSF), the applicant provides the search and examination reports from the Office of First Filing (FFO); therefore the second office benefits from the work previously carried out. Other ways of cooperation have also been developed, such as the "utilization pilot project"[162], JP FIRST[163], new route[164] and a few others[165]. While an important number of common features are shared among these projects[166], they are nevertheless all unique in view of the differences existing among them.

93. The constraints faced by IP offices of developing countries and LDCs that conduct search and substantive examination, are different than those faced by bigger IP Offices. However, experience shows that cost effective alternatives are relevant to all of them, for example:

- to utilize, in various ways, search and examination reports prepared by other offices. Some offices, for example those of Australia, Malaysia and Singapore, require a

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159 In 2008, PCT national phase entries accounted for 52% of patent applications filed abroad (The PCT Yearly Review 2009).

160 The PPH involves either USPTO or JPO bilateral agreements, among them (USPTO-JPO) and with other offices, namely, USPTO with EPO, UK, Canadian, Korean, Australian, Danish and Singaporean Patent offices; and also JPO agreements with KIPO, UKPO, DPMA and Danish PO. There are also several PPH PCT Agreements; for more information see: *http://www.wipo.int/pct/en/filing/pct_pph.html*

161 A pilot project initiated in July 2006 between USPTO and JPO.

162 This initiative aims to encourage cooperation between EPO and national IP Offices. The work carried out by national IP offices is used by EPO examiners.

163 The JPO Fast Information Release Strategy aims to encourage sharing of information, when the first filing takes place at the JPO. The application receives examination priority at the JPO, so when it receives first action at the other offices (via the traditional system of the Paris Convention), reports prepared by the JPO are already received by these offices (in about 80% of cases).

164 It consist in a pilot project that explores the idea of giving one single filing day for both, first and second office filing.

165 For example, SHARE, that consists in the commitment of each office to give priority to examining applications for which it is the first filing office (FFO).

166 These projects in general include at least some of the following features: (i)the office where the application is first filed accelerates the processing in order to ensure that the results of search or examination are available rapidly for use by other participating offices; (ii) offices where the subsequent applications are filed delay processing pending the search or examination report becoming available from the office where the application was filed first; (iii) offices may make arrangements for direct access to search and examination reports by the other office(s), to provide a more efficient process for the second office and reduce the burden of applicants; the first office may also be able to access the results of the later search and examination reports by other offices; and (iv) an accelerated examination procedure may be available if the application is reported as being in order for grant by the other participating office(s).

search and examination to be carried out before grant, but allow the systematic replacement of a part or all of the national search and examination process by evidence that equivalent work has already been done before by another (recognized) office. This might be in the form of an applicant supplying a search report, a search and examination report, or the specification of a patent actually granted on an equivalent application.

- to require the applicant to submit information concerning searches, grants or refusals of equivalent applications in other countries in order to provide additional information, which can then be used by the examiner to assist or improve the search and examination process (see comments on disclosure made on paragraphs 68 and 69).

- where no corresponding applications can be found in other countries, to entrust the prior art search and examination to other patent offices, in general against payment.[167]

- to rely on PCT international search reports and international preliminary reports on patentability. These tools provide a high quality search and an opinion on novelty, inventive step and industrial applicability which, while not stating whether the invention is patentable according to any individual national law, will usually give a good idea of whether the most important aspects of patent laws are likely to have been complied with. The international route also assists in identifying equivalent applications in the national phase so that further search and examination reports can be viewed when they are published by individual offices. Family matching of applications is generally more reliable for PCT applications than for families constructed using Paris Convention priority details. It is important to highlight that 41 national and three regional patent offices provide details of their national phase entries through the PATENTSCOPE® Search Service[168], in some cases providing links directly to national websites with details of the national phase application.

- to use the service of WIPO under the ICE (International Cooperation for Examination of Inventions), which is part of a wider program call WPIS (WIPO's Patent Information Service). This program is intended to assist the offices of developing countries and LDC's in examining pending applications in areas where they lack expertise or in relation to complex subject matter. Within the ICE, WIPO acts as agent between the requesting IP Office in the developing countries and the donor offices which provide a search and examination report and/or opinions.

94. In sum, based on a cost and benefit analysis, Member States have many options in designing the search and examination mechanism that best fits their national/regional patent systems.

95. The shared challenge of all patent offices is how to maximize the quality of granted patents with often limited resources. Although various forms of international cooperation have been developed already, more effective mechanisms to tackle this challenge are being sought by a number of patent offices.

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167 In the patent law of certain countries, such as Argentina, it is provided that the national IP Office may seek expert opinions from researchers working in universities or science and technology institutes in the country (Law No. 24.481 of 1995, Art.27).

168 *http://www.wipo.int/patentscope/search/en/search.jsf.*

B. The international legal framework

96. The international legal framework for patent prosecution does not specify any particular model of examination. The TRIPS Agreement leaves a large *room for manœuvre* to Members. However attention has to be drawn to two limits: the first one is contained in Article 62 (1) which states the principle of reasonableness of procedures and formalities for the acquisition and maintenance of IPRs. Secondly, Article 62 (2) obliges WTO Members to ensure that, provided the substantive conditions for acquisition of the right are given, the granting or the registration of the right will take place within a reasonable period of time, so as to avoid unwarranted shortening of the period of protection. Particular attention has to be paid to the latter, keeping in mind that the 20 years term of protection that patent provides, begins from the date of filing the application.

VI. EX-OFFICIO IP OFFICE CONTROL OF ANTI-COMPETITIVE CLAUSES IN PATENT LICENCING AGREEMENTS

97. Patent policies and competition policies are in some tension, since the first promotes innovation by granting an exclusive right, while the second seeks to avoid market barriers[169]. However it has been observed that the two systems have a common goal, i.e. enhancing consumer welfare[170]. The interface between the intellectual property system and competition policies is the subject of a specific thematic project at the CDIP "Project on Intellectual Property and Competition Policy" (see document CDIP/4/4 Rev).

98. Patent licenses may contain a number of restrictive provisions, such as price restrictions, quantity restrictions, territory restrictions, and field of use restrictions. While several of those clauses are considered in line with the nature of the IP system, others might be challenged under competition policies.

99. Some examples of clauses which, under certain circumstances, might be considered anti-competitive, are the so-called "grantback" clauses. According to an author's view, "grantback" is a term generally applied to the requirement by the licensor that the licensee provides rights under related patents (present or future)[171]. And through "cross-licensing", a reciprocal license to use a specific technology, two companies could produce the effect of competing less harshly[172].

100. Anti-competitive practices in licensing agreements can be present in different forms, and identifying them is not always easy. The EU Commission, for instance, has provided a detailed list of "hardcore" restrictions in technology transfer agreements in Articles 4 and 5 of the Regulation (EC) no 772/2004. Another interesting approach is that of the Japanese Fair Trade Commission (FTC) Guidelines on licensing agreements. In this document the Japanese FTC stated that restrictions would be deemed reasonable or not based on two elements, first, market share and second, effect on competition, thus reducing the list of clauses regarded as unlawful per se[173].

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169 Carlos M. Correa, "Intellectual Property and Competition Law", ICTSD, paper no. 21, October 2007, page 1.

170 See Carlos M. Correa, *supra* footnote 169, or Tu Than Nguyen, "Competition Law, Technology Transfer and the TRIPS Agreement", *EE* ; 2010, page 36. The apparent conflict between patent law and competition law is illusory, as it is generally agreed that, in the long run, securing some form of protection or reward for the inventor results in higher R&D spending, more innovation, and, in effect, better and cheaper products for consumers. This common goal of the two systems of IP and competition has been explicitly stated, for instance, in the US Antitrust Guidelines for the Licensing of Intellectual Property in 1995, as well as in the European Commission Guidelines on the application of Article 81 EC to technology transfer agreements in 2004, in the Guidelines for the Use of Intellectual Property under the Anti-monopoly Act promulgated in 2007 by the Fair Trade Commission of Japan, and in the Guidelines on the treatment of IPRs under Competition Law adopted by the Competition Commission of Singapore in 2007.

171 Brian G.Bruinsvald, Dennis P. O'Reilly, D. Brian Kacedon, "Drafting Patent License Agreements", *BNA Books*, 2008, page 48.

172 Pierre Régibeau and Katharine Rockett, "The Relationship Between Intellectual Property Law and Competition Law: An Economic Approach", University of Essex and CEPR, 2004, page 36.

173 Christopher Heath, "Competition Law and IP in Japan, in "The Interface between IPRs and Competition Policy", edited by Steven D. Anderman, Cambridge, 2008, pages 261-263.

101. In order to avoid unwarranted effects from patent licensing, it is important for a country to provide preventive tools and remedies. In this context, it has been noted that a specific legislative regulation, like in Europe, or the elaboration of guidelines, like in the USA and Japan, on IP licensing and anti-competitive practices may be a positive approach. This may allow authorities to determine a number of contractual clauses that are felt to be indispensable to the contract, as well as to indicate those clauses that are non desirable because of their anticompetitive effect [174].

102. There are three categories of legislations addressing actions taken by the IP offices in respect of patent licensing contracts that seem to contain anticompetitive clauses; first, some patent laws provide an ex-ante control by the IP office of voluntary license agreements[175], while in other cases, the IP offices transfer the file to the competition authority after identifying a clause that appears to be anticompetitive. It seems that in the first case, the decision on whether or not to register the contract is taken by the IP office, while in the second case, such decision is taken by the competition authorities after an evaluation of the anticompetitive effects of the clause in question. Finally, the third type of patent laws provides that certain clauses, when contained in technology transfer agreements, are null and void, without affecting the registry of the contract as such.

A. International legal framework

103. A general rule about IPR-related anti-competitive practices is contained in Article 8.2 of the TRIPS Agreement, which text is as follows: "Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology". This rule is very general, leaving a wide room for maneuver for implementation. In this regard, as a general rule, Article 8.2 may apply only to IPR-related abuses or practices, but not to practices where IP has only and incidental effect[176].

104. A more detailed regulation of the matter is contained in Article 40 (2) of the TRIPS Agreement, which gives Members the competence to regulate in their national law a set of rules addressing anticompetitive "practices or conditions" in licensing contracts that may "in particular cases" constitute and abuse of IPRs. Members of WTO have flexibility to adopt "appropriate measures" to prevent or control" those practices, provided these measures are consistent with other provisions of the TRIPS Agreement.

105. The TRIPS Agreement does not specify which kind of practices could be considered anti-competitive; it just provides a non-exhaustive list of conditions deemed to affect competition, namely: " exclusive grant back conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations

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174 Pierre Régibeau and Katharine Rockett, "The Relationship Between Intellectual Property Law and Competition Law: An Economic Approach", University of Essex and CEPR, 2004. page33.

175 For example, Section 41 of the Patent Law No.3054 of 1992 of Ghana and Section 68 (4) (b) of the Industrial Property Act No. 3 of 2001 of Kenya.

176 Thus, merger controls (in particular, the sale and acquisition of enterprises) may involve ancillary licensing transactions, and authorization of a merger may be made conditional on certain licensing concessions by the merging firms either inter se or as regards third-party access to the technology in question. The provisions of Article 8.2 do not apply to merger controls merely because of these IPR implications. The same holds true for merger controls over the establishment of joint ventures.

of that Member". As highlighted by one author, the fact that these examples of anti-competitive practices may be "deemed" a priori to be abusive and anti-competitive, does not change the fact that measures taken still need to be determined on a case by case basis"[177].

106. It is a common practice to register contracts related to licenses with IP offices [178]. In these cases, some offices screen the clauses of the license contracts, including those related to anticompetitive practices. On the other hand, Article 28.2 of the TRIPS Agreement does not establish specific conditions regarding substantive or formal requirements in respect of patent licence agreements, which allow Members to determine such conditions. However, the tendency in developing countries seems to be to progressively abandon technology screening along with investment screening practices[179], although this trend may not cover anticompetitive clauses.

107. Nevertheless, while Members of WTO enjoy an important degree of flexibility in establishing which contractual clauses could be deemed anti-competitive, there is a common idea that designating a clause or an entire agreement as anticompetitive, should not be done in a general and abstract manner, but rather "in reasonably detailed circumstantial form and by reference to its actual impact on the conditions of competition existing in the markets concerned"[180].

B. National legal framework

108. Provisions dealing with IPRs and technology transfer are often incorporated into the competition law regimes of developed countries, where competition law is well established[181]. Thus, in general, these countries have not adopted a system of control by the IP office on anti-competitive practices, mainly because the antitrust authority or the judicial authority is charged with enforcing competition law.

109. Nevertheless, patent laws of developed countries frequently provide that anti-competitive clauses contained in patent licences shall be deemed null and void; this is the case, for instance, of Australia. Section 144 of the Australian Patents Act lists a series of conditions[182] that cause the nullity of certain clauses, however, the remedy is not the absence of the contract's registration, but the one provided for by the Civil Code in case of void conditions.

110. The situation in developing countries and LDCs is very different. In general, competition policy is often a new instrument and there is not always a body able to address questions related to anti-competitive practices. However, many of these countries have made recourse to the flexibility provided by Articles 28.2 and 40.2 of the TRIPS Agreement and

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177 Daniel Gervais, "The TRIPS Agreement Drafting History and Analysis", Third Ed., Sweet and Maxwell, 2008, page 434.

178 TRIPS Agreement, Article 28 provides an important degree of flexibility in terms of requirements related to assignments or licensing contracts.

179 On this trend see Joel Davidow,"Liberalization of Antitrust Rules for IP Licensing", *The Journal of World IP*, 2004, Vol 7, issue 4, page 491-500.

180 UNCTAD-ICTSD, "Resource Book on TRIPS and Development*",* Cambridge University Press, 2005, page 559.

181 Tu Than Nguyen, "Competition Law, Technology Transfer and the TRIPS Agreement", *EE* ; 2010, page 166.

182 Another example is Ireland.

adopted IP laws where anti-competitive licensing clauses, which impede the registry of the licence agreement, have been listed[183] or a general clause specifying that license contracts containing clauses able to restrict competition will not be registered[184].

111. The use of ex-officio IP office control on anti-competitive clauses on patent licences agreements has been adopted in the patent laws of countries from different regions, i.e. Africa[185], Asia[186] and Latin-America[187].

[Annexes in English follow]

183 For instance, Patent Law of Ghana.

184 For instance, Article 33 (4) of the Industrial Property Law of the Dominican Republic it is established that “licensing contracts must not contain restrictive commercial clauses affecting production, marketing of technological development of the licensee and restricting competition”. Then the article follows providing a couple of example of clauses in the sense of the previous provision.

185 Ghana, Kenya, South Africa, Uganda, United Republic of Tanzania, Zambia and Zimbabwe.

186 Indonesia, Philippines, Saudi Arabia, Singapore, Sri Lanka and United Arab Emirates.

187 See for example Guatemala, Nicaragua, Paraguay and Uruguay.