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STUDY ON THE ROLE OF PATENT SYSTEMS IN PROMOTING INNOVATIVE MEDICINES, AND IN FOSTERING THE TECHNOLOGY TRANSFER NECESSARY TO MAKE GENERIC AND PATENTED MEDICINES AVAILABLE IN DEVELOPING COUNTRIES AND LEAST DEVELOPED COUNTRIES

Document prepared by the Secretariat

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INTRODUCTION

1. Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its twentieth session held in Geneva from January 27 to 31, 2014, the present document is submitted by the Secretariat as a study on the role of patent systems in promoting innovative medicines, and in fostering the technology transfer necessary to make generic and patented medicines available in developing countries and least developed countries (LDCs).

2. In line with the decision taken at the twentieth session of the SCP, the study is confined to fact-finding. The study has been drawn up based on the thorough review of various relevant literatures on the above topic. Due to the complexity and multifaceted nature of the topic, the study may not exhaust all relevant issues, which could be subject to further research.

3. Section one of the study explains issues implicated in empirically measuring the relationship between patent systems and innovation or technology transfer in the pharmaceutical sector. Section two proceeds to review empirical studies, and other literature, examining the role of the patent system as a whole in promoting innovative medicines. In addition, this section describes how certain elements of patent systems affect or may potentially affect pharmaceutical innovation. The third section reviews empirical studies on the role of patent system in the dissemination or transfer of pharmaceutical technologies. Further, it describes how certain elements of patent systems affect or may potentially affect pharmaceutical technology transfer.

MEASURING THE RELATIONSHIP BETWEEN PATENT SYSTEMS AND INNOVATION AND TECHNOLOGY TRANSFER IN THE PHARMACEUTICAL SECTOR

4. It is important to empirically account for the effects of patent protection on pharmaceutical innovation and technology transfer to assess its impact on welfare. In order to account for such effects, indicators are required. This section introduces indicators commonly used to assess the relationship between a patent system and innovation or technology transfer in the pharmaceutical sector, and explains various issues arising from the use of such indicators. The section then explains challenges shared across numerous studies on measuring the relationship between patent systems and pharmaceutical R&D or technology transfer.

Indicators of Innovation and Technology Transfer in the Pharmaceutical Sector

5. The level of pharmaceutical R&D expenditures has been used as a proxy or indication of innovation.[1] Private returns to pharmaceutical R&D using the market value of the firm's stock, debts and assets of a firm have also been used to assess the effect of a change in the patent system on innovative activity.[2] Additionally, the composition of pharmaceutical R&D expenditures[3] may be used as a proxy or indication of innovation.

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1 See, for example, Antara Dutta, Siddharth Sharma, *Intellectual Property Rights and Innovation in Developing Countries: Evidence from India* (Georgetown University, 2008); Bohumir Pazderka, *Patent Protection and Pharmaceutical R&D Spending in Canada* (Canadian Public Policy – Analyse de Politiques, Vol. XXV, No. 1, 1999); Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012); Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection* (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007).

2 See, for example, Ashish Arora, Lee Branstetter, Chirantan Chatterjee, *Strong Medicine: Patent Reform and the Emergence of a Research-Driven Pharmaceutical Industry in India* (Conference Draft for NBER Conference on Location of Biopharmaceutical Activity March 6-8, 2008), p. 15.

3 The composition of R&D expenditures may refer to the form the R&D expenditures take. For example, in Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012), the authors examined R&D in the form of clinical trials to examine the impact of patent protection on pharmaceutical innovation.

6. However, the use of R&D data as indicator of innovation and technology transfer may not always be possible. In particular, it has been reported that lack of reliable data may restrict research on and analysis of the influence of IPRs on pharmaceutical R&D and technology transfer.[4] Obtaining reliable data on R&D expenditures, receipt of payment for contract R&D, venture capital investments and other forms of R&D expenditures may be challenging.[5] Cockburn (2009) pointed out that even where such data was available, its utility might be limited if, for example, a country's definition of what constituted R&D had changed over a period of time.[6]

7. Another indicator or proxy for pharmaceutical innovation or R&D activity is patent grants and patenting activity.[7] Patent counts have been referred to as "one of the few direct quantitative glimpses into the innovation process available".[8] As stated by Zvi Griliches in a text on R&D and patents, "to a first approximation, one can use patent data as indicators of technological activity in parallel with or in lieu of R&D data".[9] Both cross-sectional studies, i.e., studies involving data collection from a particular point in time over a short period, and studies over a longer period of time measuring innovation show a strong relationship between R&D data and patenting activity data.[10] Furthermore, studies have found that patent applications are also a useful indicator of innovative activity in the pharmaceutical sector[11] in light of the reported tendency of the industry to patent promptly in the discovery phase of research due to the novelty requirement and competition in the sector. [12]

8. However, the use of patenting activity to measure innovation may pose challenges as well. The value of a pharmaceutical innovation may not be captured by merely counting the patent or patent application.[13] As the patentability criteria primarily relate to technical advancement from the existing state of the art, mere grant of a patent does not necessarily reflect the economic value of an invention or the therapeutic value of pharmaceuticals. Additionally, in assessing whether the adoption of a patent system resulted in increased innovative activity in the area of neglected diseases, one study noted that it was difficult to identify a relevant disease from the

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4 For example, Cockburn explained that a lack of detailed and dependable data has restricted research and analysis on the influence of IPRs on pharmaceutical R&D and technology transfer. See Iain M. Cockburn, *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research* in The Economics of Intellectual Property – Suggestions for Further Research in Developing Countries and Countries with Economies in Transition (WIPO, 2009), pp. 160-166.

5 Iain M. Cockburn, *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research* in The Economics of Intellectual Property – Suggestions for Further Research in Developing Countries and Countries with Economies in Transition (WIPO, 2009), p. 161.

6 Id. at pp. 161-62. Further, the author noted such challenges potentially give rise to the need to resort to original data sources (e.g., company financial reports) to conduct an analysis of the impact of patents on pharmaceutical R&D.

7 Antara Dutta, Siddharth Sharma, *Intellectual Property Rights and Innovation in Developing Countries: Evidence from India* (Georgetown University, 2008), p. 3-4; Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001), p. 267; Jean O. Lanjouw, Margaret MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries* (WHO CIPIH Studies, 2005), p. 14; Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection* (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007), p. 439.

8 Zvi Griliches, *R&D, Patents and Productivity* (National Bureau of Economic Research Project Report, 1987), p. 14.

9 Id.

10 Id.

11 Jean O. Lanjouw, Margaret MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries* (WHO CIPIH Studies, 2005), p. 14.

12 Id.

13 Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection* (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007), p. 439. Qian (2007) sought to overcome this problem by using citation weights in order to examine the role of the patent system in innovative medicines.

description of the patent application alone.[14] The same study remarked that using patent data from one particular country or region might also present difficulties because it did not take into account pharmaceutical innovations not patented in that particular country or region.

9. Further, a number of studies on the role of patent systems in pharmaceutical innovation have used survey data (generally surveying pharmaceutical industry participants) to assess the importance of patent protection in the R&D and commercialization of pharmaceuticals.[15] Such surveys, in some cases, have been used to complement statistical data. For instance, a 2001 study discovered that while surveys provided insight on the type of market toward which pharmaceutical R&D was directed, such finding was indiscernible through the use of their statistical data sources alone.[16] However it has been remarked that assessing the impact of patents on pharmaceutical R&D through surveys may be problematic in situations in which R&D capabilities have yet to develop.[17] For example, surveys may be more indicative of the effect of patent systems on pharmaceutical R&D in countries in which there is a well-established pharmaceutical industry, such as India, and thus there are industry representatives to survey.[18] In countries in which domestic R&D capabilities are underdeveloped, surveys of domestic pharmaceutical industry participants may not be an informative indicator of innovation.[19]

10. In relation to indicators measuring technology transfer, some studies used, *inter alia*, patent citations.[20] In addition, studies have used market outcome data to assess the relationship between patent protection and the diffusion of pharmaceuticals or pharmaceutical technology, such as drug launch data, including the date and location of a drug's first retail sales, price and quantity sold.[21] In addition, trade data has also been used as an indicator of the transfer or dissemination of pharmaceutical technology[22], which may include licensing payments[23] and the

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14 Jean O. Lanjouw, Margaret MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries* (WHO CIPIH Studies, 2005), p. 14.

15 See, for example, Antara Dutta, Siddharth Sharma, *Intellectual Property Rights and Innovation in Developing Countries: Evidence from India* (Georgetown University, 2008), p. 23; Edwin Mansfield, *Patents and Innovation: An Empirical Study* (Management Science, Vol. 32, No. 2, 1986, pp. 173-181), p. 173; Edwin Mansfield, Mark Schwartz, Samuel Wagner, *Imitation Costs and Patents: An Empirical Study* (The Economic Journal, Vol. 91, No. 364, 1981), pp. 907-918, p. 915; Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001), p. 267; Jean O. Lanjouw, Margaret MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries* (WHO CIPIH Studies, 2005), p. 17.

16 Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001), p. 281. The authors discovered, solely through the use of answers to questionnaires issued to Indian pharmaceutical firms, that nearly half of pharmaceutical research in India was directed towards products tailored to suit developing countries or LDC markets for diseases found globally (i.e., not for tropical diseases).

17 Iain M. Cockburn, *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research* in The Economics of Intellectual Property – Suggestions for Further Research in Developing Countries and Countries with Economies in Transition (WIPO, 2009), pp. 160-161.

18 Id.

19 Id.

20 See, for example, Adam B. Jaffe, Manuel Trajtenberg, *Patents, Citations, and Innovations: A Window on the Knowledge Economy* (MIT Press, 2002); Wolfgang Keller, *Trade and the Transmission of Technology* (Journal of Economic Growth, Vol. 7, No.1, 2002); Giovanni Peri, *Determinants of Knowledge Flows and Their Effect on Innovation* (Review of Economics and Statistics, Vol. 87, No.2, pp. 308-322, 2005).

21 See, for example, Margaret Kyle, Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS* (WIPO Meeting Doc. WIPO/IP/ECON/GE/3/13/REF/KYLE, 2013); Jean O. Lanjouw, *Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry* (U.C. Berkeley, 2005).

22 See, for example, Mercedes Delgado, Margaret Kyle, Anita M. McGahan, *The Influence of TRIPS on Global Trade in Pharmaceuticals, 1995-2006* (NBER Conference on Location of Biopharmaceuticals, 2010)

23 Iain M. Cockburn, *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research* in The Economics of Intellectual Property – Suggestions for Further Research in Developing Countries and Countries with Economies in Transition (WIPO, 2009), pp. 165-166. See also, L Branstetter, R. Fisman, C. Foley, *Do Stronger Intellectual Property Rights Increase International Technology Transfer? Empirical Evidence from U.S. Firm-Level Panel Data* (Quarterly Journal of Economics, Vol. 121, No. 1, pp. 321-349, 2006), which used licensing payments tracked in trade statistics (pursuant to an obligation

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value of imports and exports.[24] However, unless publicly disclosed, information concerning licensing agreements may be difficult to obtain.[25]

Challenges in Measuring the Effect of Patent System on Innovation and Technology Transfer in the Pharmaceutical Sector

Patent reform as an endogenous policy choice

11. At least two concerns on measuring the effect of patent protection on innovation and technology transfer appear to be shared across many of the studies. The first is that the patent law reform, or IPR reform more generally, was often an endogenous policy choice.[26] In other words, a country's adoption or enhancement of patent protection was a response to the needs of domestic innovators. For example, enhanced patent protection may be considered an appropriate policy choice, reflecting the increased innovation capacity of domestic inventors or responding to technological advancement. In such a case, innovation precedes to the patent law reform, thereby making it difficult to attribute the cause of increased pharmaceutical innovative activities to strengthened patent protection.

12. However, numerous studies have claimed that developing countries and LDCs had to introduce IPR reforms and adopt a higher level of IP protection as a result of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement).[27] Accordingly,

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on behalf of multinationals to report the value of royalties paid by affiliate companies for the sale or use of intangible property) in order to show how licensing payments received by United States of America multinational companies from their foreign affiliates changed subsequent to patent law reform.

24 The value of imports and exports refers to the value in dollar amount of pharmaceutical products imported to, or exported from, a country in a particular year. See, for example, Mercedes Delgado, Margaret Kyle, Anita M. McGahan, *The Influence of TRIPS on Global Trade in Pharmaceuticals, 1995-2006* (NBER Conference on Location of Biopharmaceuticals, 2010). The authors used the UN Comtrade Database (http://comtrade.un.org/), which provides records (including the value in dollar amount of imports and exports) on merchandise trade from over 200 reporting countries or areas covering 48 years of data and over 6000 different products.

25 In particular, it has been noted that non-priced licensing transactions (e.g., cross-licenses) are generally not publicly disclosed (Iain M. Cockburn, *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research* in The Economics of Intellectual Property – Suggestions for Further Research in Developing Countries and Countries with Economies in Transition (WIPO, 2009), pp. 165-166).

26 Joan-Ramon Borrell, *Patents and the faster introduction of new drugs in developing countries* (Applied Economics Letters, Vol. 12, No. 6, pp. 379-382, 2006), p. 380; Iain M. Cockburn, *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research* in The Economics of Intellectual Property – Suggestions for Further Research in Developing Countries and Countries with Economies in Transition (WIPO, 2009), p. 164; Antara Dutta, Siddharth Sharma, *Intellectual Property Rights and Innovation in Developing Countries: Evidence from India* (Georgetown University, 2008; Margaret Kyle, Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS* (WIPO Meeting Doc. WIPO/IP/ECON/GE/3/13/REF/KYLE, 2013), pp. 2-11; Jean O. Lanjouw, *Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry* (U.C. Berkeley, 2005), pp. 10-11; Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001), p. 266; Jean O. Lanjouw, Margaret MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries* (WHO CIPIH Studies, 2005), p. 2; Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012), p. 1162; Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection* (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007), p. 438.

27 Intan M. Hamdan-Libramento, *How compliant are developing countries with their TRIPS obligations?* (CEMI-WORKINGPAPER-2009-001, École polytechnique fédérale de Lausanne, 2009), pp. 2-3; Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012), p. 1162; Margaret Kyle, Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS* (WIPO Meeting Doc. WIPO/IP/ECON/GE/3/13/REF/KYLE, 2013), p. 2; Jean O. Lanjouw, Iain Cockburn, New Pills for Poor People? Empirical Evidence after GATT (World Development Vol. 29, No. 2, pp. 265-289, 2001), p. 266; Yi Qian, *Do National Patent Laws Stimulate*

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many of the studies that address this issue converge on the view that, in general, a developing country's reform of its patent laws subsequent to the TRIPS Agreement may be regarded as having an external cause or origin (i.e., patent law reform may be regarded as exogenous to the analysis). Therefore, changes to patent laws to comply with the TRIPS Agreement can be used, in certain cases, as "a natural experiment to understand how IPR influences economic activities and behaviors", including the effect of IP protection on innovative activities.[28]

Confounding factors

13. Although the TRIPS Agreement may provide a "natural experiment", numerous studies issue a caveat similar to that in a Lanjouw et al. (2005) study on pharmaceutical research on medicines for developing countries: "reforms to the global patent regime centered on the TRIPS Agreement can no longer be viewed as a clean experiment for examining firm responses to strengthening patent protection".[29] A second concern shared across numerous studies on this issue is the influence of non-patent based initiatives or policies on innovation or the market for technology.[30] These "confounding factors" can affect observed trends in data on the effect of patent systems on pharmaceutical innovation or technology transfer.[31] To account for any potential influence in the analysis, empirical studies tried to control these factors in various ways depending on the data and methodology used.

14. Studies have identified economic freedom[32], trade liberalization[33], pharmaceutical industry characteristics[34], the origin of legal system of the country under analysis[35], an increase in country income or public concern[36], technological advances[37], characteristics of latent innovative potential (e.g., GDP, GDP per capita, educational attainment, etc.)[38], enhanced effectiveness of

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Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007), p. 438.

28 Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012), p. 1162, quoting Intan M. Hamdan-Libramento, *How compliant are developing countries with their TRIPS obligations?* (CEMI-WORKINGPAPER-2009-001, École polytechnique fédérale de Lausanne, 2009), p. 30.

29 Jean O. Lanjouw, Margaret MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries* (WHO CIPIH Studies, 2005), p. 2.

30 Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001), p. 282; Jean O. Lanjouw, Margaret MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries* (WHO CIPIH Studies, 2005), p. 2; Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection* (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007), pp. 439-440.

31 Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001), p. 282.

32 Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection* (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007), p. 440.

33 Antara Dutta, Siddharth Sharma, *Intellectual Property Rights and Innovation in Developing Countries: Evidence from India* (Georgetown University, 2008), pp. 19-20.

34 Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection* (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007), p. 440.

35 Id.

36 Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001), pp. 282-283.

37 Id. at p. 283.

38 Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection* (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007), p. 440.

alternate appropriation mechanisms (such as first-mover advantage)[39], the size of the market for the pharmaceutical product[40], R&D tax credits[41], among others, as determinants of innovation that might influence an assessment of patent protection on pharmaceutical innovation.

15. Similarly, studies that assess the role of the patent system in fostering access to, or technology transfer of, pharmaceuticals have identified the following factors, among others, as potentially affecting analyses of the effectiveness of the patent system for facilitating the transfer and dissemination of technology: (i) economic development or income level[42]; (ii) a lack of private and social insurance and other risk-sharing mechanisms[43]; (iii) a lack of infrastructure (e.g., licensing legislation, manufacturing facilities, clinics, monitoring mechanisms for regulatory compliance, and transport, storage, dispensing, billing and accounting facilities)[44]; (iv) the perceived significance of international reference pricing[45]; (v) price controls[46]; (vi) the presence of a competitive local pharmaceutical industry[47]; (vii) tariffs[48]; (viii) pharmaceutical regulatory policies[49]; and (ix) drug heterogeneity (and the heterogeneity of potential alternative drug treatments)[50]. Additionally, it has also been noted that discriminatory and non-transparent regulatory regimes, procurement inefficiencies and the proliferation of falsified and substandard medicines may affect the availability of pharmaceuticals.[51]

THE ROLE OF PATENT SYSTEMS IN PROMOTING INNOVATIVE MEDICINES

16. The following section first reviews empirical literature on the role of patent systems as a whole in pharmaceutical innovation. It then proceeds to review literature considering the role of relevant elements of the patent system in pharmaceutical innovation.

Empirical Studies

17. The review of empirical literature on the role of patent systems as a whole in pharmaceutical innovation demonstrates that there is no single effect of patent protection on pharmaceutical innovation across all countries. Numerous studies surveying pharmaceutical industry participants on the importance of patent protection in incentivizing pharmaceutical R&D have indicated that patent protection is critical for pharmaceutical innovation. Survey studies of pharmaceutical industry participants in developed countries have shown that patents are crucial for R&D in the pharmaceutical sector. One of the main arguments put forward by industry with

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39 Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001), pp. 284-285.

40 Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012), p. 1160.

41 Bohumir Pazderka, *Patent Protection and Pharmaceutical R&D Spending in Canada* (Canadian Public Policy – Analyse de Politiques, Vol. XXV, No. 1, 1999), p. 31.

42 Margaret Kyle, Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS* (WIPO Meeting Doc. WIPO/IP/ECON/GE/3/13/REF/KYLE, 2013), p. 14.

43 Mercedes Delgado, Margaret Kyle, Anita M. McGahan, *The Influence of TRIPS on Global Trade in Pharmaceuticals, 1995-2006* (NBER Conference on Location of Biopharmaceuticals, 2010), p. 7.

44 Id.

45 Id.

46 Iain M. Cockburn, *Intellectual Property Rights and Pharmaceuticals: Challenges and Opportunities for Economic Research* in The Economics of Intellectual Property – Suggestions for Further Research in Developing Countries and Countries with Economies in Transition (WIPO, 2009), p. 160.

47 Jean O. Lanjouw, Patents, *Price Controls and Access to New Drugs: How Policy Affects Global Market Entry* (U.C. Berkeley, 2005), p. 11.

48 Id.

49 Id. at pp. 11-12.

50 Joan-Ramon Borrell, *Patents and the faster introduction of new drugs in developing countries* Applied Economics Letters, Vol. 12, No. 6, pp. 379-382, 2006), p. 381.

51 *Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade (WTO, WIPO, WHO 2012) (hereinafter the "Trilateral Study"),* p.42 and 53.

respect to the need for strict protection of IPRs is the high cost of R&D for new medical products. Statistical studies, however, have revealed mixed effects, in particular with regard to the effects of strengthened patent protection in developing countries, or with regard to pharmaceuticals to treat diseases predominantly incident in developing countries or LDCs.

18. On the basis of a systematic overview of publications on the cost of developing pharmaceuticals, *Promoting Access to Medical Technologies and Innovation – Intersections between public health, intellectual property and trade* (2012) by the WTO, WIPO, WHO (the Trilateral Study) noted that estimations of R&D costs varied more than nine fold – from $92 million US dollars ($161 million US dollars capitalized) to $883.6 million US dollars ($1.8 billion US dollars capitalized).[52] The study, however, notes the difficulty of verifying the data due to confidential nature of such information and that all those estimations are based on many variables.[53] In addition, it has been asserted that there is no concordance of views on the appropriate methodology to measure the cost/investment required to develop pharmaceuticals.[54] Notwithstanding this debate, some commentators have claimed that three attributes of pharmaceutical development are indisputable: (i) that the fixed costs of pharmaceutical development are extremely large in relation to the marginal costs of production; (ii) the development project failure rate is high; and (iii) imitation costs are small in relation to development costs.[55]

19. As stated above, various survey-based studies of pharmaceutical industries in developed countries conclude that patents are instrumental in incentivizing pharmaceutical R&D and that, in the absence of patent protection, many of the pharmaceutical inventions would not have been developed or commercially introduced.[56] The findings in Pazderka (1999) conform to conclusions drawn in survey studies that at least with respect to developed countries, patents are instrumental in incentivizing pharmaceutical R&D.[57] In particular, in a study of the impact of 1987 Canadian legislation strengthening patent protection, Pazderka discovered an increase in the growth of pharmaceutical R&D spending in Canada beginning around 1987. The study

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52 The Trilateral Study, pp 107-108.

53 Id. The Trilateral Study lists the following variables: the estimated average length of development, the average size and costs of clinical trials, and the probability of success that products will finally make it to market.

54 See, for example, Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012).

55 Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012). See also, Henry Grabowski, Patents and New Product Development in the Pharmaceutical and Biotechnology Industries (Federal Reserve Bank of Dallas, 2002). Grabowski explained that in relation to imitation costs, the inventor's cost was extremely high due to the failure of most new pharmaceutical candidates to survive testing and obtain market approval. The study found the sales peak of the median pharmaceutical (of a sample of 118 compounds) was not enough to cover the R&D costs of the average compound. As a result, Grabowski indicated that "blockbuster" pharmaceuticals were integral to economic success.

56 For example, in a survey of various British industries, including the pharmaceutical industry, Taylor et al. (1973) estimated that as much as two-thirds of pharmaceutical R&D would have been "lost" in the absence of patent protection (Christopher Thomas Taylor, Aubrey Silberston, Z. A. Silberston, *The Economic Impact of the Patent System: A Study of the British Experience* (Cambridge University Press, 1973)). See also a study of Mansfield (1986) surveying pharmaceutical firms, among others, in the United States of America which concluded that 65% of the commercially introduced pharmaceutical inventions of firms included in the sample would not have been commercially introduced in the absence of patent protection; and that 60% of the pharmaceutical inventions of firms in the sample would not have been developed in the absence of patent protection (Edwin Mansfield, *Patents and Innovation: An Empirical Study* (Management Science, Vol. 32, No. 2, pp. 173-181, Feb. 1986)). Similarly, on the basis of a 1994 survey of R&D managers from firms located in the United States of America from various manufacturing industries, Cohen et al. (2000) arrived at findings similar to those in previous survey studies and concluded that patents were effective for protecting returns to innovation in the pharmaceutical industry (Wesley M. Cohen, Richard R. Nelson, John P. Walsh, *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)* (NBER Working Paper Series, Working Paper No. 7552, 2000)).

57 Bohumir Pazderka, *Patent Protection and Pharmaceutical R&D Spending in Canada* (Canadian Public Policy – Analyse de Politiques, Vol. XXV, No. 1, 1999).

cautioned, however, that such increase was not exclusively attributable to strengthened patent protection. Similarly, Qian (2007) also found that increased pharmaceutical R&D was not exclusively attributable to strengthened patent protection, but that the potential benefits of pharmaceutical patent protection depended on development level, economic freedom, education and other macroeconomic factors.[58] In particular, the study found that patents had a positive effect on more developed countries with higher levels of education. The study also found that, conditional on the level of development, pharmaceutical patent protection was positively correlated with domestic pharmaceutical R&D expenditures and domestically originated pharmaceuticals that were patented in the United States of America. Similarly, Kyle et al. (2012) found that market characteristics and the income level in the country for which a pharmaceutical was intended influenced the impact of pharmaceutical patent protection on pharmaceutical R&D.[59] Thus, with respect to diseases that affect high-income countries, the study concluded that patent protection in those countries was associated with greater R&D efforts.

20. In contrast to the above empirical evidence on the impact of patents in pharmaceutical innovation in developed countries, the evidence on the effect of patent protection in developing countries or on R&D for pharmaceuticals to treat diseases found predominantly in developing countries or LDCs does not indicate a consistent trend. In a study of Lanjouw et al. (2001), an increase in the inventive activity on at least some pharmaceuticals directed at LDC markets was reported as a result of the TRIPS Agreement and free trade agreements with IP provisions.[60] In parallel with the findings in Qian and Kyle et al. (2012), Lanjouw et al. also found that market characteristics influenced investments in pharmaceutical R&D. In particular, the research community showed less apparent interest in diseases for which good and low-cost therapy exists than diseases for which it was lacking.[61] Ultimately, Lanjouw et al. remarked that at the time of the study, it was too early to determine whether the TRIPS Agreement had incentivized pharmaceutical R&D for diseases predominantly affecting developing countries and LDCs.

21. In another study, Lanjouw et al. (2005) concluded that there was a steady rise in pharmaceutical inventive activities in at least certain areas of particular interest to developing countries and LDCs.[62] Relative to pharmaceutical research overall, Lanjouw et al. explained that the level of innovative activities regarding diseases predominantly affecting developing countries or LDCs was low. Although notably, the study reported an apparent steep increase in the early 2000s of patenting activity and bibliometric citations relating to diseases for which there was still a need of a good, low-cost treatment. Lanjouw et al. remarked, however, that it could be too early to determine whether such increase would continue.

22. Kyle et al. (2012) found a significant difference between evidence on the association of IP with R&D efforts for global diseases, and evidence on the association of IP with R&D efforts for

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58 Yi Qian, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment? A Cross-Country Analysis of Pharmaceutical Patent Protection* (The Review of Economics and Statistics, Vol. 89, No. 3, pp. 436–453, 2007).

59 Using a data set on pharmaceutical clinical trials that spanned 17 years (from 1990 to 2006), Kyle et al. found that generally, pharmaceutical R&D was positively related with the size of the market in which patent protection existed. The authors further discovered that the strength of the relationship between patent protection and R&D efforts varied according to the income level of the country. Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012).

60 Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001).

61 The authors cautioned of the difficulty of interpreting the study's data, however, and listed a number of factors that might bias trends observed in the data, such as an increase in public concern, an increase in LDC income, new opportunities in technology influencing the ease of scientific research, and an increase in the efficacy of alternative appropriation mechanisms.

62 Jean O. Lanjouw, Margaret MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries* (WHO CIPIH Studies, 2005).

neglected diseases.[63] On the basis of this significant difference, the authors concluded that patent protection in high income countries was related to greater R&D investments in diseases that affected high income countries, but that patent protection in developing countries and LDCs did not stimulate greater R&D efforts in treatments for neglected diseases.

23. Numerous studies have focused on the impact of pharmaceutical patent protection on pharmaceutical innovation in India.[64] Maskus (2012) noted that the larger and more technologically advanced firms were able to take advantage of new patent law to increase patent filings and R&D expenditures, also in India.[65] Dutta et al. (2008), which used data on Indian firms of various industries from 1989 to 2005 to test whether IPR reform increased innovation in various industries, found trends of increased pharmaceutical R&D in India.[66] Arora et al. (2008) reached a similar conclusion using data from 315 Indian pharmaceutical firms from 1990 to 2005.[67] In particular, that study found that in anticipation of the implementation of pharmaceutical patent protection, large Indian pharmaceutical firms had increased their innovative activity and had shifted to R&D-intensive business models. However, at least one recent study found that the notion that product-patent regimes incentivize innovation was unsupported by patent data from India's pharmaceutical industry.[68] In particular, that study found that the growth of pharmaceutical innovation in India had declined in its product-patent regime.

24. Regarding the type of diseases toward which Indian pharmaceutical firms directed their R&D, the survey studies showed that Indian firms dedicated a not insignificant share of R&D budgets to products for LDC markets and tropical diseases. In particular, the study in Lanjouw et al. (2001) reported that approximately 16% of the aggregate R&D expenditure for respondents to the survey was aimed at tropical diseases or targets at LDC markets. In their subsequent research, Lanjouw et al. (2005) reported that 10% of the aggregate R&D expenditure for respondents to the study was aimed at such diseases.

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63 Margaret Kyle, Anita M. McGahan, *Investments in Pharmaceuticals Before and After TRIPS* (The Review of Economics and Statistics, Vol. 94, No. 4, pp. 1157-1172, 2012). The list of neglected diseases included in the study's sample was the neglected tropical diseases identified by the WHO, in addition to those considered in the Lanjouw et al. (2001) study.

64 See, for example, George T. Haley, Usha C.V. Haley, *The effects of patent-law changes on innovation: The case of India's pharmaceutical industry* (Technological Forecasting & Social Change 79, pp. 607–619, 2012); Jean O. Lanjouw, Iain Cockburn, *New Pills for Poor People? Empirical Evidence after GATT* (World Development Vol. 29, No. 2, pp. 265-289, 2001); Jean O. Lanjouw, Margaret MacLeod, *Statistical Trends in Pharmaceutical Research for Poor Countries* (WHO CIPIH Studies, 2005). See also Shubham Chadhuri, Pinelopi K. Goldberg, Panle Jia, *Estimating the Effects of Global Patent Protection in Pharmaceuticals: A Case Study of Quinolones in India* (The American Economic Review, Vol. 96, No. 5, 2006) for a study empirically investigating the welfare effects (i.e., the effects on the Indian pharmaceutical industry and on Indian consumers) of the TRIPS Agreement in India.

65 Keith E. Maskus, *Private Rights and Public Problems - The Global Economics of Intellectual Property in the 21st Century* (Peterson Institute for International Economics, 2012). In his section on India pharmaceutical patents, Maskus referred to India's Patents (Amendment) Act of 2005, which included, among other changes, product patent protection in the area of pharmaceutical and other chemical inventions. The India Controller General of Patents Designs and Trademarks website provides information on the history of the India Patent System (http://ipindia.nic.in/ipr/patent/patents.htm).

66 Antara Dutta, Siddharth Sharma, *Intellectual Property Rights and Innovation in Developing Countries: Evidence from India* (Georgetown University, 2008).

67 Ashish Arora, Lee Branstetter, Chirantan Chatterjee, *Strong Medicine: Patent Reform and the Emergence of a Research-Driven Pharmaceutical Industry in India* (Conference Draft for NBER Conference on Location of Biopharmaceutical Activity March 6-8, 2008).

68 Haley et al. tested for changes in patenting activity by major Indian pharmaceutical companies, contrasting data from 2001 to 2004 on patenting activity under India's process-patent regime with preliminary data from 2005 to 2008 on patenting activity under India's Patents (Amendment) Act of 2005 which introduced, among other changes, product patent protection in the area of pharmaceutical and other chemical inventions.
George T. Haley, Usha C.V. Haley, *The effects of patent-law changes on innovation: The case of India's pharmaceutical industry* (Technological Forecasting & Social Change 79, pp. 607–619, 2012).

Elements of patent systems and their role in promoting innovative medicines

25. In addition to survey or statistical studies examining the role of patent systems in pharmaceutical innovation, various literatures exist on the influence or significance of particular elements of the patent system, which may differ from one country or region to another, in promoting pharmaceutical innovation. While the international legal framework, e.g., Article 27 of the TRIPS Agreement, requires pharmaceutical products and processes to be patentable subject matter, the legal framework at the national or regional level primarily influences innovation and dissemination of technology in the pharmaceutical sector. The architecture of the patent system may differ among national and regional systems in order to suit national or regional needs or policy objectives. To examine the role of the patent system in promoting innovative medicines, the following paragraphs draw on literature on the role of patent systems to describe how certain elements of the patent system affect, or may potentially affect, innovation in the pharmaceutical sector.

Patentability of biotechnological inventions

26. One of the elements relevant to pharmaceutical innovation are questions of patentability, especially the patentability of biotechnological inventions. As noted in an OECD case study, "the traditional chemical paradigm of drug discovery and development [in the pharmaceutical industry] is being replaced by a new biotechnological paradigm"[69], and biotechnology is playing an increasing role in pharmaceutical R&D and production.[70]

27. As patent protection of biotechnological inventions has raised some specific issues which may not exist in the same way in other areas of technology, some countries have adopted specific biotechnology patent laws or guides which regulate the application of patent law to inventions in this field.[71] One of the issues over which the national laws diverge is the patentability of natural substances or synthesized or extracted chemical compounds. While some jurisdictions consider such isolated or purified matter as patentable subject matter[72], some argue that such naturally occurring substances should be generally excluded from patentability as they are not inventions but discoveries.[73] Moreover, to deal with ethical considerations, some countries exclude through express legislative provisions certain categories of biotechnological inventions from patent protection, in particular, for reasons of public order and morality.[74]

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69 OECD, *Innovation in Pharmaceutical Biotechnology: Comparing national innovation systems at the sectoral level* (OECD, 2006), p. 9.

70 Trilateral Study (WTO, WIPO, WHO 2012), p. 125.

71 See, for example, the European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions and the March 2014 United States Patent and Trademark Office (USPTO) guidance memorandum *Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products*.

72 For example, Article 3 of the European Parliament and Council Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions states "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature".

73 A recent United States of America Supreme Court case, *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc.*, 569 U.S. __ (2013) held isolated DNA is not patentable. The Court found a natural occurring DNA segment is not patentable subject matter because it is a product of nature. However, the Court did find that complementary DNA (cDNA), synthetically create exons-only strands of nucleotides, is eligible for patent protection because it is not a "product of nature". For issues related to patentability of biotechnological inventions, see Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights (Document SCP/13/3, 2011), and External Experts' Study Regarding Exclusions, Exceptions and Limitations for the Standing Committee on the Law of Patents (Document SCP/14/INF/2).

74 For example, Article 6(2) of the EU Directive on the Legal Protection of Biotechnological Inventions of July 6, 1998 provides a non-exhaustive list of inventions which should not be considered patentable because their commercial exploitation is considered contrary to on the basis of public order and morality. This list includes are processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes and processes for modifying the

[Footnote continued on next page]

28. While the national laws may diverge on the issue of patentability of biotechnological inventions[75], the determination of what is patentable and what is not under the relevant law may be an important indication for directing the R&D for creation of inventions in this field.[76]

The patentability of first and second medical indications

29. The patentability of first and second medical indications, which varies across national or regional patent law, is also one of the elements relevant to the innovation dimension in the pharmaceutical sector.[77] The Trilateral Study reports the view of opponents of first and second medical use patents that such patents reward uninventive activities, needlessly extend patent protection for a medical substance and inhibit access.[78] One publication noted that patent protection might be unnecessary due to the fact that new chemical entities were not involved and therefore there were no significant R&D investments that must be recouped.[79] Further, it has been suggested that the patenting of a new use of a known product, in particular a second medical indication, is inconsistent with the novelty requirement[80] because the product as such or its method of manufacture are not new,[81]. In addition, it has been argued that second medical indication patents are substantially equivalent to patent protection over a method of therapeutic treatment, which is generally excluded in many countries.[82]

30. The Trilaterla Study, however, reports proponents' view that additional medical use in itself can be inventive and that the development and clinical testing of a second use is no less in need of incentives than the first use, and in some cases may be more therapeutically valuable than the first use.[83] It has also been stated that the possibility of patenting secondary uses might incentivize R&D on treatments for neglected diseases through the external or collaborative access to company-owned chemical compound libraries.[84]

The application of novelty, inventive step/non-obvious and capable of industrial application/useful requirements

31. The patentability requirements of novelty may play a role in the pharmaceutical innovation cycle. Since one of the features of the patent system is to make new information available to the public in exchange of the exclusive rights, an invention which has already been put in the public domain (and thus the public does not gain any new information through its disclosure) should be, by definition, excluded from patent protection. However, the application of the novelty

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[Footnote continued from previous page]

genetic identity of animals which are likely to cause them suffering, without any substantial medical benefit to man or animal, and also animals resulting from such processes.

75 Part VI of *The Role of Intellectual Property Rights in Biotechnology Innovation* (Edward Elgar Publishing, David Castle, ed., 2009) provides national, international and historical comparisons of the role and patentability of intellectual property rights in biotechnology innovation.

76 In general, a number of survey-based studies state that patent system is an important incentive for investment in R&D in the field of biotechnology. See, for example, *Research and Patenting in Biotechnology: A Survey in Switzerland*, Publication 1 (12.03).

77 Trilateral Study (WTO, WIPO, WHO 2012), p. 128. A "first medical indication" (also called "secondary use", "new use" or "second medical indication" if the first or an earlier use is medical in nature) patent refers to a patent for the medical use of a known product.

78 Id at p. 130.

79 UNCTAD, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide* (UNCTAD, 2011), p. 50.

80 This is because the product as such or its method of manufacture are not new, rather, what is new is an identified effect on the body. See Carlos Correa, Guidelines for the examination of pharmaceutical patents: Developing a Public Health Perspective (ICTSD – UNCTAD 2007), p. 21.

81 Id at p. 21.

82 Id.

83 Trilateral Study (WTO, WIPO, WHO 2012), p. 130.

84 WIPO, *Follow-On Innovation and Intellectual Property* (WIPO), p. 4.

requirement has been described as a potential impediment to pharmaceutical innovation[85] and a factor contributing to the sub-optimality of the patent system as a means to protect pharmaceutical investments.[86] According to this view, because the novelty requirement may bar the patenting of a known molecule, the patent system does not account for extensive development and commercialization costs required to develop a known, and therefore unpatentable, molecule into a market-approved pharmaceutical product to which the public has access.[87]

32. The inventive step/non-obviousness criterion impacts incremental innovation, which can play a critical role in the development of improved products that meet public health needs.[88] It has been stated that incremental innovation, which relies on small successive improvements, is the basis for real therapeutic advances in the pharmaceutical industry.[89] As discussed in the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), many of the modifications required to adjust existing treatments to more closely meet the needs of poorer populations are likely to be incremental innovations.[90,] In a paper to demonstrate the role of patents in incremental innovation, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) described five cases where a patented compound required further biology/chemical advances to overcome substantial and manufacturing challenges in order to deliver a medicine to patients.[91] According to the paper, the incremental innovation in each of these cases, which had required significant R&D efforts, resulted in significant advances such as a reduction in the amount of dosages while maintaining efficacy, improved formulation, raised efficacy, among others.[92]

33. In that respect, the CIPIH Report, *Public health, innovation and intellectual property rights* (WHO, 2006) emphasized the importance of demarcating the line between incremental innovations with real improvements, and those that offered no therapeutic benefits.[93] Though discerning the difference may be challenging in practice, the CIPIH further noted that the concept of "evergreening"[94] was importantly distinct from incremental innovation. The Trilateral Study reported some concerns about evergreening that it could be used to prolong patent protection in an inappropriate manner, thus creating a negative effect on further innovation as well as on access to medicines.[95] In the context of the patent system and to the extent that the evergreening debate concerns the grant of patents, the Trilateral Study stated that evergreening might generally be considered from two perspectives: (i) the patentability criteria defined by

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85 Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability* (Texas Law Review Vol. 87 No. 3, Feb. 2009).

86 Shamnad Basheer, *The Invention of an Investment Incentive for Pharmaceutical Innovation* (The Journal of World Intellectual Property, Vol. 15, No. 5–6, pp. 305–364, 2012), pp. 312-313.

87 Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability* (Texas Law Review Vol. 87 No. 3, Feb. 2009), pp. 517-531. The author states that the problem the novelty requirement poses to pharmaceutical innovation extends to both university research and pharmaceutical company research. The pressure on academic researchers to publish research results is high and thus it is not uncommon for university researchers to disclose the invention to the public more than one year prior to the filing of a patent application.

88 WHO Commission on Intellectual Property Rights, Innovation and Public Health Report, *Public health, innovation and intellectual property rights* (WHO, 2006) (hereinafter the "CIPIH"), pp. 130-140; Trilateral Study (WTO, WIPO, WHO 2012), pp. 125-130.

89 CIPIH (WHO, 2006), pp. 130-131.

90 Id.

91 IFPMA, *Incremental Innovation: Adapting to Patient Needs* (IFPMA, 2013). The IFPMA has described incremental innovation as the process of expanding therapeutic classes, available dosing options, determining new physiological interactions of known medicines and improving existing medicines.

92 IFPMA, *Adaptive Innovation, Intellectual Property and the Public Interest: How Patent Extension Leads to More, Better and Safer Medicines* (IFPMA, 2006).

93 CIPIH (WHO, 2006), pp. 133-134.

94 The CIPIH describes evergreening as occurring when, "in the absence of any apparent additional therapeutic benefits, patent-holders use various strategies to extend the length of their exclusivity beyond the 20-year patent term".

95 Trilateral Study (WTO, WIPO, WHO 2012), p. 131.

national law and interpreted by case law and practice; and (ii) the manner in which examiners apply the patentability criteria and whether it is in line with the established definition and interpretation.[96] In practice, some patent offices have adopted search and examination guidelines in order to support patent examiners' work in applying the patentability criteria in accordance with its applicable national/regional law.[97]

34. With regards to the requirement of industrial application/utility, it has been noted that the requirement may prevent the patenting of pharmaceutical compounds in a situation in which the inventor synthesizes compounds without knowing how they can be applied to reach a result.[98] In addition, it has been stated that the application of the utility requirement had important implications for pharmaceutical innovation relating to research tools, specifically with regard to patenting genes.[99]

Claim construction

35. An UNCTAD study noted that, a doctrine of literal infringement[100] or a narrow scope of the doctrine of equivalent[101] could, on the one hand, potentially promote improvement of patented invention by third parties, because it allowed them to work around existing pharmaceutical patents, but on the other hand, potentially provided disincentives to creation of a new invention.[102]

Term of protection

36. The term of patent protection, and patent term extensions, may also influence pharmaceutical product development. It has been stated that the uniform 20-year term of patent protection and patent term extensions, which effectively endorse the uniform 20-year term of protection, contribute to the sub-optimality of the patent system as a means to incentivize pharmaceutical innovation.[103] This uniformity, it is argued, does not account for inventive merit, social value or substantial investments.[104] A 2014 study tested whether, under a fixed patent term, R&D investments were distorted away from technologies with substantial time lags between invention and commercialization (such as pharmaceuticals). It found that cancer

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96 Id.

97 Such guidelines provide guidance for patent examiners in determining the inventive step/non-obviousness criterion with respect to common types of pharmaceutical patent claims such as formulations and compositions, combinations, dosage, salts, ethers and esters, polymorphs, selection patents, analogy processes etc.

98 Wendy H. Schacht, John R. Thomas, *Patent Law and Its Application to the Pharmaceutical Industry: An Examination of the Drug Price Competition* (Congressional Research Service Report, 2005), p. 63.

99 UNCTAD, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide* (UNCTAD, 2011), pp. 73-74. Issues of contention across numerous jurisdictions concerning the application of the utility requirement to genes involve the level of utility or specific application that should be disclosed in a patent application, and whether the claims should be restricted to the disclosed functions or they should extend to the gene's subsequently determined functions (See, for example, *Patent issues related to influenza viruses and their genes* (WIPO Life Sciences Program Working Paper, 2007).

100 According to the doctrine of literal infringement, patent infringement exists when the allegedly infringing product or process includes each element as recited in the patent holder's claims (See, for example, WIPO, *Claiming what Counts in Business: Drafting Patent Claims with a Clear Business Purpose* (http://www.wipo.int/sme/en/documents/drafting_patent_claims_fulltext.html#cons)).

101 According to the doctrine of equivalents, patent infringement exists where, although the allegedly infringing product or process presents insubstantial differences from the claimed invention, it is "equivalent" to the claimed invention. (See, for example, WIPO, Claiming what Counts in Business: Drafting Patent Claims with a Clear Business Purpose (http://www.wipo.int/sme/en/documents/drafting_patent_claims_fulltext.html#cons)).

102 UNCTAD, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide* (UNCTAD, 2011), pp. 95-97.

103 Shamnad Basheer, *The Invention of an Investment Incentive for Pharmaceutical Innovation* (The Journal of World Intellectual Property (2012) Vol. 15, No. 5–6, pp. 305–364), pp. 313-314.

104 Id.

medicines with longer time lags between their invention and commercialization tended to have lower levels of R&D investment.[105]

37. Different views have been expressed about the impact of patent term extensions on public health.[106] One view on the impact of patent term extensions on public health holds that patent term extensions incentivize pharmaceutical research activity and ultimately result in more innovative products.[107] In a report on the relationship between patent-term extensions and pharmaceutical innovation, it was stated that patent term extension is one consideration among many that factor into a private entity's decision whether to increase pharmaceutical R&D activities.[108] However, some have stated that patent term extensions may encourage companies to seek patent protection for products that are the most profitable, which may not necessarily be the products that best serve the society's needs.[109] Further, *Médecins Sans Frontières* considered that, from the viewpoint of access to medicines, patent term extensions delayed generic entry to the market.[110]

Exceptions and limitations to the rights

38. According to the discussions in the CIPIH, the scope of the experimental use and/or scientific research exception shapes the extent to which follow-on research may be conducted.[111] In some countries, the exception is limited to acts carried out without commercial or gainful intent, whereas in other countries, activities carried out with commercial intent are also included within the scope of the exception.[112] For local pharmaceutical producers among others, the commercialization is of primary importance and therefore, the issue is the extent to which this exception authorizes them to use patented substances for the development of new products.[113] Generally, this exception applies to research *on* a patented invention; many countries do not apply the exception to research made *with* the patented invention, which for example is what downstream researchers do when they conduct genetic research with patented research tools.[114]

39. Studies on the relationship between compulsory licensing or patent exhaustion regimes and changes in pharmaceutical R&D demonstrate that these limitations to the rights impact inventive activity in the pharmaceutical sector. One study based on a theoretical two-country model on the role of compulsory licensing in pharmaceutical innovation found that, if broadly used, compulsory licensing undermined incentives for innovation; however, the study clarified

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105 Eric Budish, Benjamin N. Roin, Heidi Williams, *Do firms underinvest in long-term research? Evidence from cancer clinical trials* (MIT Department of Economics, 2014). The study empirically tested a theoretical model devised by its authors using the Surveillance, Epidemiology, and End Results (SEER) data, compiled by the National Cancer Institute (NCI), data from the US National Cancer Institute (NCI)'s Physician Data Query Cancer Clinical Trials Registry and a data set of the 71 FDA approved oncology drugs. The authors cautioned that other factors, such as a higher demand for treatments or lower R&D costs, may also influence the negative correlation between R&D investments and the length of clinical trials.

106 Trilateral Study (WTO, WIPO, WHO 2012), p. 183.

107 Office of Technology Assessment, Congress of the United States, *Patent-Term Extension and the Pharmaceutical Industry* (U.S. Government Printing Office, August 1981), pp. 3-5.

108 Further, the study claimed whether firms would actually increase R&D expenditures on the basis of anticipated returns was largely speculative, though it was likely that firms would increase pharmaceutical R&D activities due to the increased incentive that a longer effective patent term provides. Id. at p. 39-40.

109 Govin Permanand, *EU Pharmaceutical Regulation: The Politics of Policy-Making* (Manchester University Press, 2006), p. 110.

110 Médecins Sans Frontières, *Briefing Note: Trading Away Health: The Trans-Pacific Partnership Agreement (TPP),* (MSF, 2013).

111 CIPIH (WHO, 2006), pp. 53-54.

112 See document SCP/20/4 and the Trilateral Study (WTO, WIPO, WHO 2012), p. 134.

113 UNCTAD, *Using Intellectual Property Rights to Stimulate Pharmaceutical Production in Developing Countries: A Reference Guide* (UNCTAD, 2011), p. 103.

114 See document SCP/20/4 and the Trilateral Study (WTO, WIPO, WHO 2012), p. 134.

that this finding did not necessarily entailed a decrease in welfare.[115] The study showed that there were circumstances in which welfare effects increased globally when compulsory licensing was used, even in light of its effect on innovation.[116] In another study that assessed whether a decrease in patenting activity followed six compulsory licenses issued by the United States of America in the 1980s and 1990s, the results indicated that, in five out of six cases, patenting activities had continued at the same or at an even higher pace than prior to the issuance of the compulsory licenses.[117] With respect to one case in which the patenting activities declined, the author concluded that the result of that case supported the theory that predictable or anticipated compulsory licenses in significant markets were likely to decrease innovative efforts. Further, a 2014 study examined the impact of compulsory licenses issued on the US patents held by German patent holders pursuant to the 1918 United States of America Trading-with-the Enemy Act. It found that innovation in chemical and pharmaceutical technologies in Germany was encouraged, rather than discouraged, by the US compulsory licenses.[118]

40. In relation to the effect of parallel importation on pharmaceutical innovation, Ganslandt et al. explained that the value of a pharmaceutical patent lied in part on the scope for price differentiation, which depended on barriers to arbitrage.[119] As a consequence, the author explained that one might expect that countries with national exhaustion policies, which had a narrow area of exhaustion (i.e., a barrier to arbitrage) and therefore a greater scope for price differentiation, offered stronger incentives to innovate at the expense of higher consumer costs.[120] A similar argument regarding the impact of parallel importation[121] on pharmaceutical R&D investment is that price differentials allow pharmaceutical companies to undertake more R&D in the long run.[122] In other words, the incentive to innovate would be less if they had to set a common price in all of their markets.[123]

41. One study using a "North-South model" investigated the interaction between government price regulation policies and parallel trade with a focus on the pharmaceutical sector, and

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115 Charitini Stavropoulou, Tommaso Valletti, *Compulsory licensing and access to drugs* (European Journal of Health Economics, 2014). The "welfare" is defined as the sum of consumer surplus and the firm's profit.

116 This study employed a two-country model to examine the interaction between a "North" country in which a company held patents on a medicine and a "South" country which purchases that medicine from the company in the "North". The study's global welfare analysis demonstrated that global welfare increased under compulsory licensing of what the study referred to as "lower quality drugs" (drugs for which consumers are less willing to pay and with reduced market coverage) even when the "South" country is relatively large and therefore negatively influences global pharmaceutical R&D.

117 Colleen Chien, *Cheap Drugs at What Price to Innovation – Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?* (Berkley Technology Law Journal, Vol. 18, 2003). The author reported that out of the six companies subjected to compulsory licenses in the study's sample, only one (Merieux with respect to a United States of America Federal Trade Commission order to lease a rabies vaccine) showed a decline in patenting subsequent to the license.

118 Joerg Baten Tubingen, Nicola Bianchi, Petra Moser, *Compulsory Licensing – Did Licensing During WWI Discourage German Invention* (2014).

119 Mattias Ganslandt, Keith E. Maskus, *Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union* (Journal of Health Economics, Vol. 23, pp. 1035-1057, 2004) p. 1035-1036.

120 Id.

121 "Parallel importation" refers to "the import of goods outside the distribution channels contractually negotiated by the manufacturer. Because the manufacturer/IP owner has no contractual connection with a parallel importer, the imported goods are sometimes referred to as grey market goods, which in fact is somewhat misleading, as the goods as such are original, only the distribution channels are not controlled by the manufacturer/IP owner. Based upon the right of importation that an IP right confers upon the IP owner, the latter may try to oppose such importation in order to separate markets. If, however, marketing of the product abroad by the IP owner or with his consent leads to the exhaustion of the domestic IP right, also the right of importation is exhausted and can thus no longer be invoked against such parallel importation". (WIPO, *International Exhaustion and Parallel Importation*, http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm).

122 Tommaso M. Valletti, *Differential pricing, parallel trade, and the incentive to invest* (Journal of International Economics, Vol. 70, pp. 314-324, 2006), p. 315.

123 Id.

showed the circumstances under parallel trade in which R&D investment rises.[124] For example, R&D investment increases under parallel trade when the "South" accounts for R&D expenditures and the cost to firms of supplying the "South", and does not have price regulation. Another study used a three-country model to examine the consequences of an international exhaustion system in an emerging economy.[125] The authors found, for example, that in an emerging economy with technologically heterogeneous firms (i.e., firms at varying levels of technological advancement), parallel importation resulted in increased pharmaceutical R&D by the more technologically advanced firms.[126] Another finding of the study was that in an emerging economy where trade costs were low, allowing parallel imports of pharmaceuticals would result in less pharmaceutical R&D by both technologically more advanced firms and technologically less advanced firms.

Research tools

42. Patentable biotechnological inventions are not necessarily end products such as new drugs, but can be "upstream" research tools[127] that are essential for the development of "downstream" pharmaceutical products.[128] For instance, it has been explained that broad patenting of upstream research tool may impede R&D of downstream technologies and prevent improvements in pharmaceuticals, whereas narrower claims may facilitate downstream use.[129] One study using interview and archival data on the effects of upstream research tool patents and licensing on biomedical innovation found that although the patenting of such research tools had further complicated the patent landscape, the increase in patents on research tools had not substantially impeded drug discovery.[130] Additionally, the study found little evidence that concerns regarding patents on upstream research tools had impeded university research.[131] The study did, however,

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124 Anna Rita Bennato, Tommaso Valletti, *Pharmaceutical innovation and parallel trade* (International Journal of Industrial Organization, Vol. 33, pp. 83–92, 2014). The study used a two-country model ("North" and "South") to examine the interaction between price regulation policies and parallel imports, with a focus on the pharmaceutical sector. In the Study's model, the pharmaceutical products were supplied by "North"; "North" has a system for distributing, selling, and administering drugs, but "South" does not; and "North" did not regulate pharmaceutical production or consumption. In the model, parallel trade could only flow from "South" to "North"; "North" could decide on its applicable exhaustion regime; and "South" could choose its drug pricing scheme.

125 Andrea Mantovaniy, Alireza Naghaviz, *Parallel Imports and Innovation in an Emerging Economy: The Case of Indian Pharmaceuticals* (Health Economics, Vol. 21, No. 11, pp. 1286–1299, November 2012). The authors found, for example, that in an emerging economy with technologically heterogeneous firms (i.e., firms at varying levels of technological advancement), parallel importation results in increased pharmaceutical R&D by the more technologically advanced firms. The study explained this is because the costs of trade shift parallel importation-related market share losses from the more to the less technologically advanced firm, which encourages the more technologically advanced firm to increase R&D. Additionally, the study also found that in an emerging economy where trade costs are low, allowing parallel imports of pharmaceuticals will result in less pharmaceutical R&D by both technologically more advanced firms and technologically less advanced firms.

126 The authors explained this was because the costs of trade shift parallel importation-related market share losses from the more to the less technologically advanced firm, which encourages the more technologically advanced firm to increase R&D.

127 WHO, *Genetics, genomics and the patenting of DNA Human Genetics Programme Chronic Diseases and Health Promotion World Health Organization 2005 - Review of potential implications for health in developing countries* (WHO, 2005), p. 39 broadly defines research tools as "any tangible or informational input into the process of discovering a drug or any other medical therapy or method of diagnosing diseases".

128 Trilateral Study (WTO, WIPO, WHO 2012), p. 134.

129 Id.

130 Walsh, J., A. Arora, W. Cohen, *Research Tool Patenting and Licensing and Biomedical Innovation* in Patents in the Knowledge-Based Economy (National Academies Press, 2004). Data comprised 70 interviews with IP attorneys, business managers and scientists from 10 pharmaceutical firms and 15 biotechnology firms in addition to university researchers and technology transfer officers from 6 universities, patent lawyers, government employees and trade association personnel. The interview questions focused on changes in patenting, licensing activity, the relationship between pharmaceuticals, biotechnology firms, universities and the impact of patent policy on firms' decisions.

131. "Working solutions", undertaken by university and industry researchers, had permitted research in biomedical innovation to continue largely unimpeded. The study identified inventing around patented inventions, obtaining

[Footnote continued on next page]

discover evidence of delays associated with negotiating licenses to upstream research tools in addition to evidence of the redirection of research to areas less encumbered by IPRs.[132] Another study similarly noted that patents on research tools were rarely enforced and it was rare for research projects to be halted due to patent issues. However that study found that the situation was different for reach-through claims where, based on a patent on an upstream research tool, a patentee claims royalty on products developed by a third party using that research tool.[133]

43. In addition, with regards to university research involving genetic diagnostics, Walsh et al. found evidence that patented gene-based research tools interfered with university research.[134] A study by the United States of America National Academy of Sciences on trends in the patenting and licensing of genomic and protein inventions and their impact on biomedical research also found that gene patents apparently had an inhibiting impact on research and clinical practice involving gene-based diagnostic tests.[135]

Patent trolls and patent thickets

44. Some studies have found that certain business strategies, such as "patent trolls"[136] and the phenomena of "patent thickets"[137], also influence pharmaceutical innovation. Patent trolls have been considered to contribute to increases in transaction costs.[138] Recent survey studies on the effect of patent demands or patent trolls on venture-backed startup companies indicated that patent trolling was beginning to impact the life sciences/pharmaceutical industry.[139] In an article examining whether university patent holdings in the biopharmaceutical sector are a target for patent monetizers, the authors concluded that conventional wisdom[140], which held that the

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[Footnote continued from previous page]

licenses, using the technology without a license, court challenges, going offshore and the development and use of public databases and research tools as "working solutions."

132 In addition, citing earlier studies, the authors recalled that the incentive function of patents benefited biomedical innovation, and that the productivity of biomedical research had enhanced because of research tools. See Walsh, J., A. Arora, W. Cohen, *Research Tool Patenting and Licensing and Biomedical Innovation* in Patents in the Knowledge-Based Economy (National Academies Press, 2004).

133 Straus, 2002 and Cohen et al., 2002 cited in *A Survey in Switzerland: Research and Patenting in Biotechnology*, publication No. 1 (12.03).

134 Walsh, J., A. Arora, W. Cohen, *Research Tool Patenting and Licensing and Biomedical Innovation* in Patents in the Knowledge-Based Economy (National Academies Press, 2004).

135 National Research Council, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (The National Academies Press, 2006). Data used in the study included literature and testimony from scholars, government officials and stakeholders; patent information; a survey of university licensing of selected categories of patents; and a survey of biomedical research scientists.

136 There is no generally agreed definition of "patent troll". However, the term is generally associated with a patent holder that does not engage in the manufacturing of the patented product and rather uses its patent rights to extract rents from alleged infringers. (See, for example, Robert P. Mergers, *The Trouble with Trolls: Innovation, Rent-Seeking, and Patent Law Reform* (Berkeley Technology Law Journal, Vol. 24, pp. 1583-1614, 2010).

137 There is no generally agreed definition of "patent thicket". However, in general, it refers to a situation in which a product involves a web of patents owned by a number of different patentees, requiring a company that wants to commercialize the product to "clear" all the patents involved. (See, for example, *Report on the International Patent System* (WIPO, Document SCP/12/3/Rev 2, 2009)).

138 *Report on the International Patent* System (WIPO, Document SCP/12/3/Rev 2, 2009), pp. 74-76.

139 In a study by Robin Feldman, survey results from a sample of over 200 venture capitalists and portfolio companies revealed that 30% of venture capitalists in the study's sample that received patent demands had received them in the life sciences sector (See Robin Feldman, *Patent Demands & Startup Companies: The View From the Venture Capital Community* (UC Hastings Research Paper No. 75, 2013), p. 36). Another survey study conducted in 2013, which surveyed approximately 300 venture capitalists and venture-backed startups, found 13% of bio/pharma or medical device venture capitalists reported having received patent demands (See Colleen Chien, *Patent Assertion and Startup Innovation* (Santa Clara University School of Law Legal Studies Research Papers Series Accepted Paper No. 26-13, 2013), p. 11).

140 The article explained that conventional wisdom held that because of the high costs of drug development, fewer patents were granted in the industry relative to other industries (due to the difficulty of entering the bio/pharmaceutical product market) and the scope of patents was less broad , thus patent monetization was not a problem for biotechnology or pharmaceuticals.

biopharmaceutical sector was largely insulated from patent trolls, suffered from weaknesses and therefore was a susceptible target for patent monetizers.[141]

45. The Trilateral Study discussed potential issues related to patent thickets and their influence on pharmaceutical development and dissemination: excessive transaction costs in connection with licensing agreements, impediments to R&D and difficulties in inventing around the patented invention.[142] Studies conducted on the effect of patent thickets on pharmaceutical innovation have produced varying results. In a survey of 843 members of the American Association for the Advancement of Science assessing the effects of patenting on research across a range of fields, 40% of respondents (especially in biosciences) reported that their research had been affected by difficulties in obtaining patented technology. The consequences of such difficulties were delayed research (58%), changing research (50%) and abandoning research (50%).[143] However, another study on the effects of patents on biomedical research found an apparent lack of substantial evidence for a patent thicket problem in biomedical research, which was associated with a general lack of awareness on behalf of researchers regarding intellectual property status.[144] However, a European Commission Report on the pharmaceutical sector reported that patent thickets were common practice, and that generic pharmaceutical companies increasingly perceived patent thickets as an obstacle to market entry.[145]

THE ROLE OF PATENT SYSTEMS IN FOSTERING TECHNOLOGY TRANSFER NECESSARY TO MAKE GENERIC AND PATENTED MEDICINES AVAILABLE IN DEVELOPING COUNTRIES AND LDCs

46. The patent system aims to improve the efficiency of the flow of knowledge and to facilitate the transfer of technology by setting up a legal framework that allows technology holders to disclose their inventions, license their patents or sell their patents without fear of free-riding. The role of patents systems in fostering transfer of technology in general has been extensively addressed elsewhere, and therefore, those discussions are not included in this study.[146] This section first reviews empirical studies examining the relationship between patent systems and the transfer or dissemination of pharmaceutical technology. It then proceeds to review literature considering the role of selected elements of the patent system in pharmaceutical technology transfer.

Empirical Studies

47. Technology transfer, which may occur through various channels, in the pharmaceutical sector identified by the IFPMA include the transfer of physical objects (e.g., laboratory or production equipment for the manufacture of pharmaceuticals, packaging and active pharmaceutical ingredients), skills (e.g., training courses for researchers or general practitioners), techniques related to knowledge, technology and information, and knowledge required to operate technology related to a compound.[147] Moreover, technology transfer in the pharmaceutical sector

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141 Robin Feldman & W. Nicholson Price II, *Patent Trolling – Why Biopharmaceuticals are at Risk*, University of California Hastings College of Law Legal Studies Research Paper Series, No. 93, 2014), pp. 13-19.

142 Trilateral Study (WTO, WIPO, WHO 2012), pp. 135-136.

143 Stephen Hansen, Amanda Brewster, Jana Asher, Michael Kisielewski, *The Effects of Patenting in the AAAS Scientific Community* (American Association for the Advancement of Science, 2006).

144 National Academy of Sciences, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* (National Academy of Sciences, 2006), p. 132.

145 European Commission Competition DG, *Pharmaceutical Sector Inquiry: Final Report* (European Commission, 2009), pp. 187-200.

146 In the context of the SCP, see, for example, document SCP/14/4 Rev.2 and related discussions under the agenda item “Transfer of Technology”.

147 IFPMA, *Technology Transfer: a Collaborative Approach to Improve Global Health: The Research-Based Pharmaceutical Industry Experience* (IFPMA, 2011).

may occur at each stage of the innovation cycle: from drug discovery to full-scale commercialization.[148] In general, technology transfer has been identified as a key aspect of the pharmaceutical industry's business model.[149]

48. In general, some studies have acknowledged that intellectual property protection and effective enforcement is a requisite condition for pharmaceutical technology transfer for research-based pharmaceutical companies.[150] At the same time, case studies on pharmaceutical technology transfer and local production have assessed a country's IP regime as just one component of the framework for local production and technology transfer.[151] Therefore, they make evident that the patent system is limited in the extent to which it can facilitate the transfer of technology: components that influence the transfer of pharmaceutical technology include the pharmaceutical regulatory environment, investment policy, industrial policy, science and innovation policy, governance, education, skill level of the workforce, absorption capacity and political stability, among others.[152]

49. Within the context of technology transfer for purposes of local pharmaceutical production, a WHO review of pharmaceutical technology transfer initiatives for local production in developing countries showed that patents had a variable impact on local production; the extent of the impact depended on the therapeutic area, country and technical capacity of the local pharmaceutical industry.[153] For vaccines, one WHO report noted that know-how rather than patents and other types of IP had been the main barrier to technology transfer for local production in developing countries.[154] The evidence that local production increases access to pharmaceuticals, however, is inconclusive.[155]

50. Empirical studies examining the relationship between patent systems and technology transfer to make medicines available in developing countries and LDCs are very scarce. Instead, numerous empirical studies have examined the relationship between patent protection and pharmaceutical product launch in developing countries, between patent systems and the pharmaceutical trade value, or between patent protection and general availability of medicines in developing countries and LDCs. Although they do not explain the role of patent systems in fostering transfer of technology in the pharmaceutical sector, since technology transfer may occur through various channels, some of the studies are introduced below:

- A study by Kyle et al. examining the results of increased patent protection on the speed of drug launch, quantity sold and price found that, on average, access to new pharmaceuticals increased with the adoption of the TRIPS Agreement.[156] The study used data in 59 countries (including high, middle and low income) from 2001 to 2011, and found that the price premium for patented products was lower subsequent to the implementation of the TRIPS Agreement, potentially reflecting an increase in the use of price controls, governments' bargaining power or the threat of compulsory licensing. The study also found

148 See, for example, Ali Sajid, Pandit Vinay, Shekhar Chander, *Technology Transfer in Pharmaceuticals* (International Research Journal of Pharmacy, Vol. 3, No. 6, 2012).

149 IFPMA, *The Changing Landscape on Access to Medicines* (IFPMA, 2012), p. 53.

150 See, for example, IFPMA, *Technology Transfer: a Collaborative Approach to Improve Global Health: The Research-Based Pharmaceutical Industry Experience* (IFPMA, 2011).

151 See, for example, United Nations Conference on Trade and Development (UNCTAD), *Local Production of Pharmaceuticals and Related Technology Transfer: A series of case studies by the UNCTAD Secretariat* (UNCTAD, 2011); WHO, *Pharmaceutical Production and Related Technology Transfer* (WHO, 2011).

152 Id.

153 WHO, *Pharmaceutical Production and Related Technology Transfer* (WHO, 2011).

154 WHO, *Access to Vaccines Through Technology Transfer and Local Production* (WHO, 2011).

155 WHO, *Local Production for Access to Medical Products: Developing a Framework to Improve Public Health* (WHO, 2011). See also Trilateral Study (WTO, WIPO, WHO 2012), pp. 163-165.

156 Margaret Kyle, Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS* (WIPO Meeting Doc. WIPO/IP/ECON/GE/3/13/REF/KYLE, 2013).

that the probability of a new product launch increased, in addition to quantities sold, conditional on price.

- Studies have also found the effects of patent protection on the launch of pharmaceuticals differ based on the distribution of income within a country or country income level.[157] For example, Borrell found the distribution of income within an economy influences the effect of patent systems on the launch of pharmaceuticals.[158] He tested the hypothesis that patent holders are more likely to launch new products in markets in which their patents are protected than in markets in which their patents are not protected due to the expectation that patent protection entails higher prices and larger profits. According to the study's estimates and evidence, the patent regime has had a strong positive influence on the availability of HIV/AIDS therapies in developing countries with relatively equally distributed incomes. The study found that developing countries with relatively large income inequalities, however, did not support the price premiums that incentivize the early launch of patented pharmaceuticals.

- The study of Lanjouw found that with respect to high income countries, enhanced patent protection tended to stimulate market entry.[159] The evidence that enhanced patent protection increased access to new pharmaceuticals was mixed, however, for low and middle income countries that were encouraged to adopt stronger patent regimes. The study found evidence that high levels of patent protection tended to encourage more frequent entry in the short term, specifically with regard to countries with less local production capacity. Conversely, the study found that in the longer term, this may not be the case: countries with local production capacity and extensive patent protection may have fewer new pharmaceutical products enter the market in the longer term. Lanjouw concluded that patent regimes which provide short-term protection for products, or long term protection for manufacturing processes only, promote more or faster launches in developing countries.

- In a study evaluating multilateral and bilateral trade subsequent to the implementation of the TRIPS Agreement for evidence on whether the TRIPS Agreement met the stated objective of the "transfer and dissemination of technology" with respect to *inter alia* biopharmaceutical products, Delgado et al. found mixed results for developing countries in biopharmaceutical trade post-TRIPS implementation.[160] Relative to a control group of non-IP products, there was an increase in pharmaceutical exports from developing countries but no significant increase in imports to those countries. The study concluded that the TRIPS Agreement had yet to spur significant changes in the level of biopharmaceutical trade to developing countries and LDCs.

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157 See, for example, Jean O. Lanjouw, *Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry* (U.C. Berkeley, 2005) and Joan-Ramon Borrell, *Patents and the faster introduction of new drugs in developing countries* (Applied Economics Letters, Vol. 12, No. 6, pp. 379-382, 2006).

158 Joan-Ramon Borrell, *Patents and the faster introduction of new drugs in developing countries* (Applied Economics Letters, Vol. 12, No. 6, pp. 379-382, 2006).

159 Jean O. Lanjouw, *Patents, Price Controls and Access to New Drugs: How Policy Affects Global Market Entry* (U.C. Berkeley, 2005).

160 Mercedes Delgado, Margaret Kyle, Anita M. McGahan, *The Influence of TRIPS on Global Trade in Pharmaceuticals*, 1995-2006 (NBER Conference on Location of Biopharmaceuticals, 2010).

Elements of patent systems and their role in pharmaceutical technology transfer

51. In general, it has been acknowledged that a linkage between the patent system and the dissemination of technologies lacks conclusive evidence.[161] Nevertheless, certain elements in the patent system could have implications for the transfer of technology in the pharmaceutical sector. Those elements are described below in a non-exhaustive manner.[162]

Inventive step/non-obvious criteria

52. The inventive step/non-obvious criteria, in addition to its impact on innovation discussed above, may affect pharmaceutical technology transfer. The Trilateral Study reported a concern that evergreening strategies might impede the development of generic versions of the patented product, therefore implicating technology transfer in the pharmaceutical sector.[163] In a European Commission report on the pharmaceutical sector, the Commission found that companies reportedly filed a significant number of patents on variations of the same product, especially for blockbuster medicines late in the life cycle of a medicine when the main patent was about to expire.[164] This practice reportedly made it difficult for generic competitors to develop a generic version without infringing one of the patents filed around a medicine, and increased the likelihood of litigation between generic and originator companies.[165]

Disclosure

53. As a trade-off to the exclusive patent rights, all patent law requires applicants to disclose the invention to the public. In many countries, such disclosure has to be made in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.[166] This enabling disclosure requirement aims at the effective dissemination of technological knowledge by allowing others to learn about the technology published in patent applications and patents. It is generally explained that the disclosure function of the patent system contributes not only to the tacit transfer of technology but also to the transfer of technology through licensing agreements and transfer of rights. For example, one study noted that the disclosure requirement had particular importance in the pharmaceutical sector to enable reproduction of pharmaceutical inventions during its patent term (e.g., pursuant to a compulsory license) or subsequent to the expiration of the patent.[167]

54. Since a patent application is not a recipe for manufacturing a commercially viable product, as indicated in the Trilateral Study, one of the fundamental questions raised with respect to the role of the disclosure requirement is to what extent a patentee must disclose his invention within the patent system in order to contribute to the transfer of technology and further innovation.[168] For example, according to some, broad Markush claims may cover a vast number of compounds which had not been assessed by an applicant and supported by the disclosure in the specification, and thus should not be allowed.[169]

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161 See document SCP/14/4 Rev.2.

162 For discussions on elements in the patent system which could have implications for the transfer of technology in general, see document SCP/14/4 Rev.2

163 Trilateral Study (WTO, WIPO, WHO 2012), p. 131. For the discussion on evergreening and its effect on innovation see paragraphs 32-33 of this document.

164 European Commission Competition DG, *Pharmaceutical Sector Inquiry: Final Report* (European Commission, 2009).

165 Id.

166 This requirement is found in Article 29.1 of the TRIPS Agreement.

167 Carlos Correa, *Guidelines for the examination of pharmaceutical patents: Developing a Public Health Perspective* (ICTSD – UNCTAD 2007), p. 4.

168 Trilateral Study (WTO, WIPO, WHO 2012), p.59.

169 Carlos Correa, *Guidelines for the examination of pharmaceutical patents: Developing a Public Health Perspective* (ICTSD – UNCTAD 2007), pp. 12-14.

Patent status and legal status

55. In addition to technical details of inventions, published patents and applications also disclose the scope of protection (boundary of the right), the owners of the right, information concerning any associated rights (e.g., licenses) and other information relating to the legal status of the patents and patent applications. Determining the legal status[170], *inter alia*, is a key aspect in freedom to operate (FTO) assessments, which may be undertaken at each stage of the pharmaceutical innovation cycle and technology transfer, and used to make decisions on R&D, product launch, commercialization and negotiating licenses.[171] In addition, identifying the patent status, i.e., all patents related to a specific pharmaceutical product, is important for technology transfer purposes, including FTO assessments and procurement processes.[172] However, a WHO publication reported that the identification of the patent status of the particular pharmaceutical might prove difficult for a number of reasons: multiplicity of patents covering a pharmaceutical product; lack of a reference to the international nonproprietary name (INN) in a patent application; and the technical language of the specification, among other reasons.[173] As a result, specific expertise may be required to assess the patent status of medicines.[174]

Exceptions and limitations to the rights

56. Some studies noted that allowing parallel importation of pharmaceuticals could potentially enable firms to reverse engineer such imports available on the market.[175] On the other hand, as suggested by some study, wide availability of parallel import products may discourage foreign right holders from investing in the domestic market, depending on the characteristics of such market.[176]

57. As regards compulsory licensing, a survey study in Switzerland found that survey participants, in particular research based institutes, welcomed a compulsory licensing regulation in those cases where abusive monopoly positions were apparent.[177] The Trilateral Study reported that compulsory licensing had been issued to local producers in a number of countries to increase access to pharmaceuticals, including India, Thailand, Brazil, Ecuador and Indonesia, among others.[178] The effectiveness of compulsory licenses as a tool for the transfer of technology has been widely debated. Some noted that, since the transfer of know-how not disclosed in a patent application could only be made by concluding voluntary licenses or through reverse engineering, compulsory licenses might be most effective when the technology was already known and only access to it was required.[179]

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170 "Legal status" may refer to various legal and administrative events that occur during the life cycle of a single patent.

171 Id. at p. 62 and pp. 136-137.

172 Id.

173 WHO, *How to conduct patent searches for medicines* (WHO, 2010), p. 2.

174 Trilateral Study (WTO, WIPO, WHO 2012), p. 62.

175 See, for example, Keith E. Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries* (Final Report to WIPO, 2001), p. 41.

176 Some studies suggested that the impact of parallel imports on innovation and investment depend on the relevance of IPRs to the market power, size of the domestic market, the risk of re-export of parallel imported goods and the reasons for different pricing. See, for example, Rod Falvey and Neil Foster, *The role of intellectual property rights in technology transfer and economic growth: theory and evidence*, UNIDO Working Paper, 2006.

177 *A Survey in Switzerland: Research and Patenting in Biotechnology*, publication No. 1 (12.03).

178 Trilateral Study (WTO, WIPO, WHO 2012), pp. 174-177.

179 See, for example, Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* (Oxford University Press, 2001).

Licensing of technology

58. Patent licensing is one of the channels for promoting technology transfer to, and the further development of technology by, licensees. Voluntary licensing agreements have been used to transfer pharmaceutical technology to generic producers in developing countries.[180] One WHO study that looked at trends in initiatives supporting local production and technology transfer of pharmaceuticals to developing countries found that, in general, voluntary licenses incorporating a technology transfer component (i.e., supporting a producer's capacity to produce in addition to licensing the legal right to use the patented invention) had increased since the mid-1990s.[181] Further, a patent pool[182] is seen as an additional tool to transfer technology in the pharmaceutical sector.[183]

59. Some countries have adopted policies that encourage universities and research institutions to seek patent protection for inventions arising out of government-funded research.[184] Such policies were first embodied in the 1980 United States of America Bayh-Dole Act and subsequently adopted by a number of developing countries.[185] In the case of pharmaceuticals, the CIPIH stated that a Bayh-Dole-type policy might facilitate the exclusive licensing of a compound from a university, which did not have the skill or resources to engage in clinical trials and mass production, to a pharmaceutical company.[186] It noted that the exclusive licensing of upstream technologies might have the effect of restricting dissemination and use of such technologies, and thus resulted in higher prices for the final product.[187] Numerous articles have questioned whether Bayh-Dole-type legislation in developing countries, if not tailored to suit the specific context of the R&D environment, would result in the intended economic benefits.[188] For example, Sampat explained that if the main objective of Bayh-Dole legislation was to generate licensing revenues, a Bayh-Dole-type of legislation might not produce that intended effect in developing countries where public universities had a limited research base.

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180 See, for example, Trilateral Study (WTO, WIPO, WHO 2012), pp. 180-181.

181 WHO*, Pharmaceutical Production and Related Technology Transfer* (WHO, 2011).

182 A patent pool is an agreement between two or more rights holders to group and license their rights relating to a specific technology to each other and to third parties, subject to certain conditions such a payment of royalties. By reducing transaction costs for licensees, patent pools provide easy access to all patented technologies in the pool needed to produce standardized products.

183 Trilateral Study (WTO, WIPO, WHO 2012), p. 118.

184 One motivation for this policy is to promote technology transfer: to encourage universities or other research institutions that may lack the resources to launch a product commercially to license or assign technologies to institutions that have the resources to commercialize an invention. See Bhaven N. Sampat, *The Bayh-Dole Model in Developing Countries: Reflections on the Indian Bill on Publicly Funded Intellectual Property* (ICTSD, 2009) for a discussion on the purpose of legislation modeled on the Bayh-Dole in India and other developing countries.

185 CIPIH (WHO, 2006), pp. 55-57.

186 Id.

187 Id.

188 See, for example, Evita Paraskevopoulou, *The Adoption of Bayh-Dole Type Policies in Developing Countries* (The Innovation Policy Platform, Policy Brief, 2013); David C. Mowry, Bhaven N. Sampat, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?* (Journal of Technology Transfer, Vol 30, No. 1/2, pp. 115-127, 2005); Bhaven N. Sampat, *The Bayh-Dole Model in Developing Countries: Reflections on the Indian Bill on Publicly Funded Intellectual Property* (ICTSD, Policy Brief No. 5, 2009); Anthony D. So, Bhaven N. Sampat, Arti K. Rai, Robert Cook-Deegan, Jerome H. Reichman, Robert Weissman, Amy Kapczynski, *Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience* (PLoS Biology, Vol. 6, No. 10, 2008).