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# **INNOVATION AND THE GLOBAL EXPANSION OF INTELLECTUAL PROPERTY RIGHTS: UNFULFILLED PROMISES**

Carlos M. Correa





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## I. INTRODUCTION

International intellectual property law developed since the end of the 19th century as an independent normative area. Three international conventions were adopted at the end of that century,<sup>1</sup> two of which became the very foundation on an international system on industrial property and copyright law. Thereafter, it took a long time to develop additional international rules on the subject, as it was only in 1952 that a new convention on copyright was established.<sup>2</sup> The internationalization of intellectual property gained momentum in the 1960s and 1970s when various negotiations led to the conclusion of new treaties in this field.<sup>3</sup>

The governance of the emerging set of international conventions on intellectual property was ensured through specialized bodies established by the same conventions. The union of the governing bodies of the Paris Convention and the Berne Convention gave rise to the United International Bureaux for the Protection of Intellectual Property (BIRPI as per its French acronym), which eventually provided the grounds for the creation of the World Intellectual Property Organization (WIPO) in 1967 with the mission of encouraging creative activity and promoting “the protection of intellectual property throughout the world.”<sup>4</sup>

The system of rules created by these international instruments operated in isolation from the multilateral trade system established by the General Agreement on Tariffs and Trade (GATT) in 1947. The creation of a linkage between the two systems was the result of an initiative of a group of US-based industries that sought to establish a framework for intellectual property protection of broad geographic coverage and capable of ensuring not only the recognition of rights, but also their effective enforcement. The role that the CEOs of large US companies played in inducing the US government to bring intellectual property as a “trade-related” issue into the GATT is well documented.<sup>5</sup> It is also well known that developing countries strongly opposed to this strategy. The government of India, for instance, argued that it would not be appropriate to establish within the framework of the GATT “any new rules and disciplines on intellectual property rights.”<sup>6</sup> Brazil attempted to narrow down the scope of any negotiation to the examination of trade issues that involved, in some way,

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<sup>1</sup> The Paris Convention on the Protection of Industrial Property (1883), Berne Convention for the Protection of Literary and Artistic Works (1886) and Madrid Agreement for the Repression of False or Deceptive Indications of Source on Goods were also adopted at that time (1891).

<sup>2</sup> Universal Copyright Convention (UCC), adopted in Geneva, Switzerland, in 1952.

<sup>3</sup> See the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations (1961), the International Convention for the Protection of New Varieties of Plants (UPOV) (1961), the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration (1967), the Patent Cooperation Treaty (1970), the Geneva Convention for the Protection of Producers of Phonograms against Unauthorized Duplication of their Phonograms (1971), the Brussels Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite (1974) and the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977).

<sup>4</sup> Convention Establishing the World Intellectual Property Organization signed at Stockholm on 14 July 1967, Preamble, second paragraph.

<sup>5</sup> See, e.g., Deveraux, C., Lawrence, R. and Watkins, M. (2006), *Case Studies in US Trade Negotiation*, Volume 1: Making the Rules, Washington DC: Institute for International Economics. See also Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, Cambridge Studies in International Relations, 2003.

<sup>6</sup> See ‘Applicability of the Basic Principles of the GATT and of Relevant International Intellectual Property Agreements or Conventions – Communication from India’, 5 September 1989, GATT Doc. MTN.GNG/NG11/W/39, para. 2.

the protection of intellectual property based on GATT principles, “provided that such principles are restricted to the trade-related aspects of the matter.”<sup>7</sup>

Indeed, the opposition of developing countries to establish a comprehensive agreement on intellectual property in the context of GATT led them to refuse the developed countries’ interpretation of the ambiguous mandate approved at the GATT Ministerial Conference in Punta del Este (Uruguay) in 1986, and to avoid engaging into negotiations on the subject until 1989. The change in their position is attributable to many factors, but the primary one is likely to have been the developed countries’ confessed strategy to link concessions in the areas of agriculture and textiles – the main targets for developing country negotiators – in the Uruguay Round to the acceptance of a new set of binding international rules on multiple aspects of intellectual property that would reflect the patterns of protection generally available in developed countries.<sup>8</sup>

Of course, the proponents of such rules articulated a discourse around the advantages that new disciplines on intellectual property would bring about to **all** participants in the multilateral trading system, including developing countries. Increased innovation, growing flows of foreign direct investment and technology transfer to these countries, and better prospects for economic growth were central components in this rhetoric.<sup>9</sup>

While a number of econometric studies have been conducted correlating intellectual property (or the ‘strength’ thereof) with these and other variables,<sup>10</sup> none of them conclusively shows that the claimed benefits have actually emerged from the implementation of high intellectual property standards. For instance, a literature review concluded, in relation to patents, that “the sheer size and growth of the recent literature might lead one to assume that patents are an extremely important instrument of economic development and growth, which therefore attract a great deal of interest from researchers and policy makers. But this seems at odds with the weak evidence that patents serve as an incentive for innovation and the fact that relatively few firms find them an important means of securing returns to innovation”.<sup>11</sup> A study on the impact of the TRIPS Agreement in four developing countries concluded that:

[p]revious studies in this area have been quick to attribute the changes in these dependent variables (increased FDI, R&D, etc.) to a strengthening of the patent

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<sup>7</sup> Communication from Brazil, 11 December 1989, GATT Doc. MTN.GNG/NG11/W/57, para. 11(a).

<sup>8</sup> See Carlos Correa, ‘Globalisation and intellectual property rights. The struggle of developing countries to influence TRIPS’, in S. Alam, Natalie Klein and Juliette Overland (editors), *Globalisation and the Quest for Social and Environmental Justice: The Relevance of International Law in an Evolving World Order*, Routledge, London, 2011.

<sup>9</sup> See, e.g., Suggestion by the United States for Achieving the Negotiating Objective, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, 20 October 1987, GATT Doc., No. MTN.GNG/NG11/W/14, at p. 2; Trade-related Aspects of Intellectual Property Rights: Submission from the European Communities, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, 14 November 1989, GATT Doc., No. MTN.GNG/NG11/W/49, at p. 7.

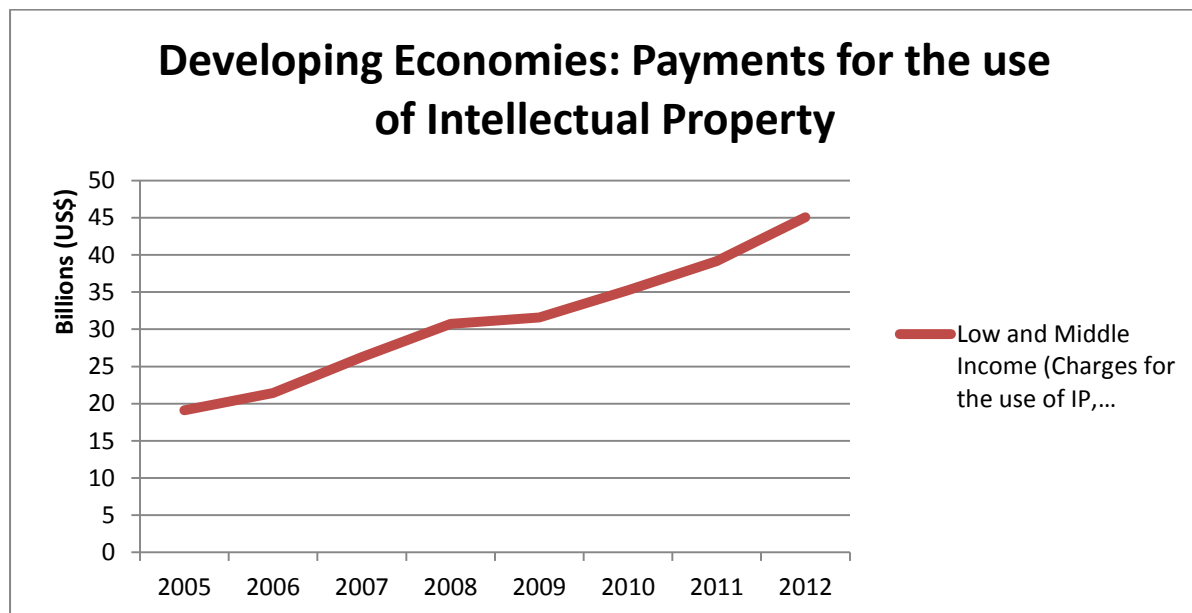
<sup>10</sup> See e.g., Keith E. MASKUS and Lei YANG, *The Impacts of Post-TRIPS Patent Reforms on the Structure of Exports*, The Research Institute of Economy, Trade and Industry, available at <http://www.rieti.go.jp/en/>.

<sup>11</sup> Bronwyn H. Hall, Christian Helmers, Mark Rogers, Vania Sena, *The Choice between Formal and Informal Intellectual Property: A Literature Review*, (2012) NBER Working Paper No. 17983, p. 35.

regime. However, based on the four country case studies, we found very little evidence for such optimism with respect to TRIPS compliance.<sup>12</sup>

One clear outcome of the increased levels of intellectual property protection seems to be the enormous increase in US receipts for the use of intellectual property abroad, which doubled between 1994 and 2014. Although most payments for the use of intellectual property are done by developed countries, those by developing countries have increased dramatically. As shown in figure 1, they have more than doubled since 2005, the year when the TRIPS Agreement became fully enforceable (except for Least Developed Countries).

Figure 1  
**Payments for the use of intellectual property in developing countries**



Source: Kithmina V. Hewage, ‘A Delicate Truth – Remittances and Royalty Payments in Financing Development’ (2014), South Centre, based on World Development Indicators, World Bank (2014).

## II. THE TRIPS AGREEMENT AND INNOVATION

One of the key arguments underpinning the grant of intellectual property rights and, in fact, the claimed benefits of implementing the standards of the TRIPS Agreement, is the positive role that such rights would play in promoting innovation. The global map of research and development (R&D), however, does not show a general improvement of R&D capabilities in developing countries in the last twenty years, with a few exceptions, notably in the case of China. In accordance with a study<sup>13</sup> the distribution of global R&D was as indicated in Box 1.

<sup>12</sup> Mani, S., & In Nelson, R. R. (2013), *TRIPS compliance, national patent regimes and innovation: Evidence and experience from developing countries*, Edward Elgar, p. 235.

<sup>13</sup> Jacques Gaillard, ‘Measuring Research and Development in Developing Countries: Main Characteristics and Implications for the Frascati Manual’, *Science, Technology & Society* 15:1 (2010).

Box 1  
**Global distribution of R&D expenditures**

OECD countries 78 %  
 Asia (excluding Japan) 19 % (China: 11.8 %)  
 Latin America 2.4 % (Brazil: 1.3%)  
 Near and Middle East 1.2 %  
 Africa 0.7 per cent

Although the participation in global R&D may have improved after 2010, the U.S., China, Japan and Europe together still account for about 78 per cent of the \$1.6 trillion total investment in R&D.<sup>14</sup> R&D investment has increased in India, Brazil and China in the last twenty years, but other developing countries, especially in Africa, perform low levels of R&D and there are no indications that there will be significant changes in the short term. The extent to which the increase in R&D investment in those three countries is related to or caused by the introduction of TRIPS-compatible rules on intellectual property is at least questionable. Significantly, none of these countries has entered into free trade or other agreements imposing TRIPS-plus standards. Hence, they would not qualify as granting “stronger” intellectual property rights protection, one of the variables considered in some studies to assess the impact of such rights.<sup>15</sup> The case of China deserves special consideration and, certainly, further research. China has sustained a high rate of R&D investment for nearly 20 years, and its total R&D investments are now more than 60 per cent those of the U.S. At the current growth rate, China’s total funding of R&D is expected to surpass that of the U.S. by 2022.<sup>16</sup> In fact, the growth of R&D budget in China largely accounts for the increased participation of developing countries in global R&D.

How much of the increment in R&D that has taken place in the last two decades may be attributed to intellectual property protection? It is not easy to respond to this question. However, if leading economists from the USA are right, it cannot be simply argued that innovation only or mainly occurs because such a protection is conferred. Moser, for instance, concluded a historical analysis indicating that ‘[o]verall, the weight of the existing historical evidence suggests that patent policies, which grant strong intellectual property rights to early generations of inventors, may discourage innovation’.<sup>17</sup> Bessen and Meurer noted that:

<sup>14</sup> See Batelle, 2014 *Global R&D Funding Forecast*, 2013, available at [http://www.battelle.org/docs/tpp/2014\\_global\\_rd\\_funding\\_forecast.pdf](http://www.battelle.org/docs/tpp/2014_global_rd_funding_forecast.pdf), p. 4.

<sup>15</sup> See, e.g., Falvey, Rod, Neil Foster and Olga Memedovic. *The Role of Intellectual Property Rights in Technology Transfer and Economic Growth: Theory and Evidence*, United Nations Industrial Development Organization (UNIDO), Vienna, 2006, available at: [http://www.unido.org/fileadmin/user\\_media/Publications/Pub\\_free/Role\\_of\\_intellectual\\_property\\_rights\\_in\\_technology\\_transfer\\_and\\_economic\\_growth](http://www.unido.org/fileadmin/user_media/Publications/Pub_free/Role_of_intellectual_property_rights_in_technology_transfer_and_economic_growth); Shapiro, Robert J. and Aparna Mathur, *How India Can Attract More Foreign Direct Investment, Create Jobs, and Increase GDP: The Benefits of Respecting the Intellectual Property Rights of Foreign Pharmaceutical Producers*, SONECON, January 2014, available at: <http://www.ipdelivers.com/resources/wp-content/uploads/2014/01/Report-on-FDI-IP-and-the-Pharmaceutical-Sector-in-India-Shapiro-Mathu-.pdf>.

<sup>16</sup> *Ibid.*, p. 3.

<sup>17</sup> Petra Moser, ‘Patents and Innovation: Evidence from Economic History’, *Journal of Economic Perspectives*, volume 27, number 1, Winter 2013, Pages 23-44.

...nations with patent systems were not more innovative than nations without patent systems. Similarly, nations with longer patent terms were no more innovative than nations with shorter patent terms.<sup>18</sup>

They also found that: “patents **do** provide profits for their owners, so it makes sense for firms to get them. But taking the effect of **other** owners’ patents into account, including the risk of litigation, the average public firm outside the chemical and pharmaceutical industries would be better off if patents did not exist.”<sup>19</sup> A survey by Lerner of patent laws in over sixty countries showed that strengthening of patent rights resulted in an increase in filings from foreign applicants, with no effect on filings by local inventors.<sup>20</sup>

Posner has argued that: “in most [industries], the cost of invention is low; or just being first confers a durable competitive advantage ... so there’s no point to a patent monopoly that will last 20 years... Most industries could get along fine without patent protection.”<sup>21</sup> In addressing the importance of non-intellectual property incentives for innovation, Shavell and Van Ypersele noted that “there is no necessity to marry the incentive to innovate to conferral of monopoly power in innovations”,<sup>22</sup> while Torrance and Tomlinson similarly concluded that “[a] growing body of empirical research appears to support the view that patent systems do not necessarily ‘promote the Progress of ... useful Arts’”.<sup>23</sup>

Other scholars have gone as far as suggesting the abolition of patents: “[I]n general, public policy should aim to decrease patent monopolies gradually but surely, and the ultimate goal should be the abolition of patents. After six decades of further study since Machlup’s testimony in 1958 failed to find evidence that patents promote the common good, it is surely time to reassess his conclusion that it would be irresponsible to abolish the patent system”.<sup>24</sup> The same scholars had noted earlier that: “historical evidence provides little or no support that innovative monopoly is an effective method of increasing innovation”.<sup>25</sup> They further stated that ‘in spite of the enormous increase in the number of patents and in the strength of their legal protection we have neither seen a dramatic acceleration in the rate of technological progress nor a major increase in the levels of R&D expenditure ... there is strong evidence, instead, that patents have many negative consequences. Both of these observations, the evidence in support of which has grown steadily over time, are consistent with theories of innovation that emphasize competition and first-mover advantage as the main drivers of innovation and directly contradict ‘Schumpeterian’ theories postulating that government granted monopolies are crucial in order to provide incentives for innovation.’<sup>26</sup>

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<sup>18</sup> J. Bessen and M. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* Princeton University Press, 2008, at p. 16.

<sup>19</sup> *Ibid.*, p. 16.

<sup>20</sup> Lerner J, ‘Patent Protection and Innovation Over 150 Years’ (2002) [http://www.epip.eu/papers/20030424/epip/papers/cd/papers\\_speakers/Lerner\\_Paper\\_EPIP\\_210403.pdf](http://www.epip.eu/papers/20030424/epip/papers/cd/papers_speakers/Lerner_Paper_EPIP_210403.pdf).

<sup>21</sup> R. Posner, ‘Why There Are Too Many Patents in America’, *The Atlantic* (12 July 2012), found at: <http://www.theatlantic.com/business/archive/2012/07/why-there-are-too-many-patents-in-america/259725/>.

<sup>22</sup> S. Shavell and T. van Ypersele, *Rewards Versus Intellectual Property Rights* (National Bureau of Economic Research, 1999), found at: <http://www.nber.org/papers/w6956>, at 32.

<sup>23</sup> A. Torrance and B. Tomlinson, ‘Patents and the Regress of Useful Arts’, 10 *Columbia Science and Technology Law Review* (2009), 130, at 164.

<sup>24</sup> The Case Against Patents, Michele Boldrin and David K. Levine, *Journal of Economic Perspectives*, vol. 27, no. 1, Winter 2013, Pages 3-22.

<sup>25</sup> M. Boldrin and D. Levine, *Against Intellectual Monopoly* (2007), found at: <http://levine.sscnet.ucla.edu/papers/ip.ch.8.m1004.pdf>, p. 2.

<sup>26</sup> M. Boldrin and D. Levine, *The Case Against Patents* (Federal Reserve Bank, Research Division, 2012), at 1.

A draft report prepared for the Australian government has also been critical of the way in which the patent system operates:

Despite the fact that patents are available for inventions in all technologies, it is arguable whether the patent system is of general benefit across the full range of technologies. Where a technology is relatively inexpensive to develop and can be quickly brought to market, innovators may be better served by simply entering the market quickly: recouping their costs through first mover advantage. Specific industries and the public may also benefit through fewer patents impeding their freedom to operate. In this respect patents are a blunt instrument, with generally the same duration and extent of rights being granted regardless of the development costs or market size of the invention.<sup>27</sup>

It is true that when the TRIPS Agreement was proposed and later adopted, there was much less interest in the academy on the impact of intellectual property rights, and the literature on the subject was not as abundant as it is today. However, there were many studies<sup>28</sup> (including the seminal contributions of Penrose<sup>29</sup> and Machlup<sup>30</sup>) which made it clear that the effects of such rights were strongly context-dependent, that is, it is not possible to expect the same outcomes when intellectual property is applied in countries with very different levels of technological capacity and industrial profile. It was also known that developed countries pursued imitative paths of development at the early stages of their industrialization process. In 1986, for instance, an office of the US Congress had concluded that [w]hen the United States was still a relatively young and developing country, it refused to respect international intellectual property rights on the grounds that it was freely entitled to foreign works to further its social and economic development.”<sup>31</sup>

The inappropriateness of a “one-size-fits-all” approach in the area of intellectual property has been highlighted in various reports<sup>32</sup> and in abundant academic work. Dosi and Stiglitz, for instance, have warned about the negative consequences of pretending that a system of intellectual property adapted to a developed country could work in the same way in a developing country:

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<sup>27</sup> Pharmaceutical Patents Review. Draft Report, April 2013, available at [http://www.ipaustralia.gov.au/pdfs/2013-05-27\\_PPR\\_Final\\_Report.pdf](http://www.ipaustralia.gov.au/pdfs/2013-05-27_PPR_Final_Report.pdf), p. 5.

<sup>28</sup>See, e.g. Wolfgang E. Siebeck, editor with Robert E. Evenson, William Lesser, and Carlos A. Primo Braga, *Strengthening Protection of Intellectual Property in Developing Countries A Survey of the Literature*, World Bank, 1990, available at [http://www-wds.worldbank.org/servlet/WDSContentServer/IW3P/IB/2000/01/06/000178830\\_98101903544215/Rendered/PDF/multi\\_page.pdf](http://www-wds.worldbank.org/servlet/WDSContentServer/IW3P/IB/2000/01/06/000178830_98101903544215/Rendered/PDF/multi_page.pdf).

<sup>29</sup> Penrose, E., 1951. *The Economics of the International Patent System*. Baltimore: Johns Hopkins University Press.

<sup>30</sup> Machlup, F. 1958. "An Economic Review of the Patent System." Subcommittee on Patents, Trademarks and Copyrights, Committee on the Judiciary, U.S. Senate, Study no. 15. Washington, D.C.: U.S. Government Printing Office.

<sup>31</sup> U.S. Congress, Office of Technology Assessment, *Intellectual Property Rights in an Age of Electronics and Information*, OTA-CIT-302, Washington, DC: U.S. Government Printing Office, April 1986. Moreover, historical studies have shown that the United States emerged as the world's industrial leader by illicitly appropriating mechanical and scientific innovations from Europe and that the leaders of the republic supported the piracy of European technology in order to promote the economic strength and political independence of the new nation (Doron Ben-Atar, *Trade Secrets. Intellectual Piracy and the Origins of American Industrial Power*, 2004, Yale University Press).

<sup>32</sup> See e.g., Commission on Intellectual Property, Final Report, London, 2002, available at [http://www.iprcommission.org/graphic/documents/final\\_report.htm](http://www.iprcommission.org/graphic/documents/final_report.htm).

As badly designed as the American IPR regime is for the United States, it is even worse suited for developing countries. But even if the American IPR regime were ideal for the United States, that does not mean that it would be ideal for others... In particular, the IPR regimes of the advanced developed countries are likely to be inappropriate for many developing countries, and this is likely to be especially so in areas like health and agriculture... Indeed, one-size-fits-all, policy prescriptions are rarely a good idea in any field, but this is one area where they may work particularly badly... There are, for instance, large distributional consequences of different IPR regimes, and developing countries may not have the resources to easily offset those effects.<sup>33</sup>

Swanson and Goeschl examined the impacts of enhanced property right regimes in agriculture in countries with different levels of development. They found that:

there are frictions within the system of technological dissemination that inhibit the flows of beneficial information, and that enhanced property right regimes will work most prominently against the interests of those states furthest from the frontier. Whenever this is the case, enhanced IPR regimes will have the impact of skewing the distribution of benefits towards those states on or near the technological frontier. In the case of those countries furthest from the frontier, it is probable that the impact of heightened IPR is likely to be negative over any reasonable time horizon.<sup>34</sup>

Significantly, the already mentioned report produced for the government of Australia not only seems to reach conclusions similar to those reflected in the referred to analyses, but it also highlights the lack of proportionality between the (limited) benefits that accrue to the developed countries that impose high standards of intellectual property on small economies, and the (large) ensuing costs that the latter need to bear:

A small country can have very little influence on the global economics of IP production by changing its own IP [intellectual property] protection policies. Given that Australia contributes less than 2 per cent of the world economy, extensions of Australian IP rights on their own are unlikely to influence a global firm's decisions as to whether or not to invest in IP...

As a system stretching back many centuries, there are numerous aspects of IP regimes that remain poorly designed. Yet international IP agreements have tended to be made without regard to such matters... As a result, intellectual agreements lock us into a number of inefficiencies which have clear costs to Australia and yet which confer benefits on other countries that are either small or negligible.<sup>35</sup>

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<sup>33</sup> Giovanni Dosi and Joseph E. Stiglitz, 'The Role of Intellectual Property Rights in the Development Process, with Some Lessons from Developed Countries: An Introduction', in Mario Cimoli, Giov Ann I Dosi, Keith E. Maskus, Ruth L. Okediji, Jerome H. Reichman, Joseph E. Stiglitz, *Intellectual Property Rights. Legal and Economic Challenges for Development*, Oxford University Press, 2014, p. 3-4.

<sup>34</sup> Timothy Swanson and Timo Goeschl, 'The Distributive Impact of Intellectual Property Regimes: A Report from the "Natural Experiment" of the Green Revolution', in Mario Cimoli, Giov Ann I Dosi, Keith E. Maskus, Ruth L. Okediji, Jerome H. Reichman, Joseph E. Stiglitz, *Intellectual Property Rights. Legal and Economic Challenges for Development*, Oxford University Press, 2014, p. 284.

<sup>35</sup> *Pharmaceutical Patents Review. Draft Report*, April 2013, pp. 22 and 32.

Similarly a report by the Australian Productivity Commission affirmed that an increase in intellectual property rights in a country which is a net importer of technology is “likely to benefit overseas rights holders disproportionately compared with domestic rights holders”.<sup>36</sup>

In summary, while the proponents of the TRIPS Agreement operated on the premise that minimum standards of protection would be equally beneficial for countries with diverse levels of socio-economic and technological development, the dominant view flowing from academic and other analyses seems to strongly reject that premise. As discussed in the following section, this is particularly the case of pharmaceuticals.

### III. DECLINING INNOVATION IN THE PHARMACEUTICAL INDUSTRY

The case of the pharmaceutical industry illustrates well the disconnection between innovation and the geographically broader and more extensive protection of intellectual property introduced by the TRIPS Agreement.

It is generally accepted that patents are not among the important means to appropriate returns to innovation in most sectors, with the notable exception of pharmaceuticals.<sup>37</sup> As noted by Harvard’s economist Scherer, “patents are unusually important in pharmaceuticals”.<sup>38</sup> The pharmaceutical industry played a major role in the development of the US strategy leading to the adoption of the TRIPS Agreement; this Agreement may never have existed in the absence of the effective lobbying made by that industry. The implementation of global rules ensuring the patenting of pharmaceutical products—which was denied in more than 50 countries at the beginning of the Uruguay Round<sup>39</sup>—and the protection of test data – for which there were no international rules before the TRIPS Agreement – was presented by that industry as an indispensable platform to sustain and increase investment in the development of new drugs.<sup>40</sup>

A study by Scherer published in 2004 predicted that the increase in the development of new drugs that would result from the implementation of the TRIPS rules in developing countries would be minimal, and that “global welfare is maximized by letting low-income nations free-ride on the patented inventions of first-world nations”.<sup>41</sup> In fact, the post-TRIPS Agreement period has been characterized by a continuous decline in pharmaceutical innovation, as measured by the number of new drugs approved for marketing. Figure 2 shows that the average number of new drugs<sup>42</sup> developed after 2000 (when the TRIPS Agreement

<sup>36</sup> Productivity Commission 2012, *Trade & Assistance Review 2010-11*, Annual Report Series, Canberra, p. 100.

<sup>37</sup> See Bronwyn H. Hall, Christian Helmers, Mark Rogers, Vania Sena, op. cit., p. 15.

<sup>38</sup> F. Scherer, p. 2.

<sup>39</sup> See, e.g., UNCTAD, *The TRIPS Agreement and Developing Countries*, Geneva, 1996, available at [http://unctad.org/en/Docs/ite1\\_en.pdf](http://unctad.org/en/Docs/ite1_en.pdf).

<sup>40</sup> See, e.g., Deveraux, C., Lawrence, R. and Watkins, M., op. cit.

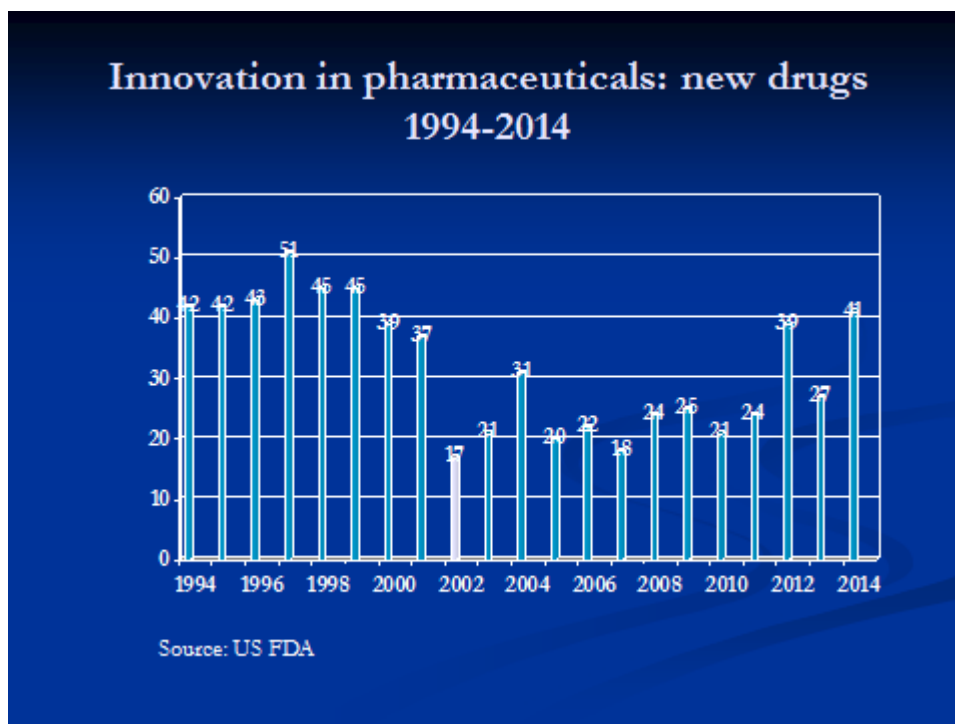
<sup>41</sup> F.M. Scherer, *A note on global welfare in pharmaceutical patenting*, WORKING PAPER NO. 03-11, Federal Reserve Bank of Philadelphia, available at <https://www.philadelphiafed.org/research-and-data/publications/working-papers/2003/wp03-11.pdf>, p. 10.

<sup>42</sup> The figure includes drugs that are classified as ‘new molecular entities’ (NMEs), which are characterized as ‘new’ for administrative purposes by the US Food and Drug Administration (FDA), but ‘nonetheless contain



became enforceable in developing countries)<sup>43</sup> was almost half of the average in the five previous years.

Figure 2



The extension to developing countries and the strengthening of patents and test data protection for pharmaceuticals have done nothing to prevent the plummeting efficiency of the pharmaceutical industry in developing new drugs.<sup>44</sup> Thus, the “number of new drugs approved per billion US dollars spent on RD has halved roughly every 9 years since 1950, falling around 80-fold in inflation-adjusted terms”<sup>45</sup>.

In addition, the extension of product patent and test data protection has not helped developing countries – the primary target of the whole TRIPS exercise – to address the diseases prevalent in those countries (often referred to as ‘neglected diseases’), since the lack of interest and, consequently, low investment in R&D by the pharmaceutical industry continues to be an outstanding feature of its business model. A report by the WHO Commission on Intellectual Property Innovation and Public Health (CIPHI) of April 2006 already noted that “[t]here is no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals on TYPE II and

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active moieties that are closely related to active moieties in products that have previously been approved by FDA (FDA, ‘New Drugs at FDA: CDER’s New Molecular Entities and New Therapeutic Biological Products’, available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm20025676.htm>.

<sup>43</sup> See article 65 of the TRIPS Agreement.

<sup>44</sup> See e.g., Dan Hurley, ‘A diabetes drug made the old-fashioned way’, *International New York Times*, November 15-16, 2014, p. 12.

<sup>45</sup> Scannell JW1, Blanckley A, Boldon H, Warrington B., Diagnosing the decline in pharmaceutical R&D efficiency, *Nat Rev Drug Discov.* 2012 Mar 1;11(3):191-200, summary available at <http://www.ncbi.nlm.nih.gov/pubmed/22378269>. As a result of the observed decline, the authors suggest that in the field of pharmaceuticals an inverse Moore’s Law (which predicated that the number of transistors in an integrated circuit would double every two years) applies (‘Eroom’s Law’).

particularly Type III diseases. Insufficient market incentives are the decisive factor”.<sup>46</sup> A more recent report confirmed that: “patents alone do not drive sufficient investment to counter diseases that predominantly affect poor people, because they do not offer a sufficiently profitable market; as a result, some diseases – or rather, some populations – are neglected”.<sup>47</sup>

While in 1975-1999, only 1.1 per cent of new therapeutic products had been developed for neglected diseases, between 1 January 2000 and 31 December 2011 only four new chemical entities were approved for neglected diseases (three for malaria and one for diarrhoeal disease), accounting for 1 per cent of the 336 new chemical entities approved during the this period.<sup>48</sup>

Most of the new R&D addressed to find treatments for the diseases prevalent in developing countries has not been driven by the expectation of profits sustained on the legal monopoly granted by intellectual property. A number of collaborative Product Development Partnerships (PDPs) have been set up to work on such diseases with the aim of developing affordable treatments.<sup>49</sup> Despite their limitations and financial vulnerability,<sup>50</sup> PDPs have become the only mechanism that may generate new drugs for diseases mainly affecting those countries.

The effects of an expanded protection of intellectual property have been particularly tangible in the case of treatments for HIV/AIDS. Prices of HIV treatments vary greatly between middle-income countries (MICs) depending, *inter alia*, on patent landscape, while the price of drugs for third-line treatments remains a major challenge as they are likely to be patented in key countries with manufacturing capacity.<sup>51</sup> In accordance with the Global Commission on HIV and the Law:

IP [intellectual property] protection is supposed to provide an incentive for innovation but experience has shown that the current laws are failing to promote innovation that serves the medical needs of the poor. The fallout from these regulations—in particular the TRIPS framework—has exposed the central role of

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<sup>46</sup> Commission on Intellectual Property Rights, Innovation and Public Health. Public health: innovation and intellectual property rights. WHO: Geneva; 2006. Available from <http://www.who.int/intellectualproperty/documents/thereport/CIPIH23032006.pdf>. Type II diseases are incident in both developed and developing countries, but with a substantial proportion of the cases in the latter. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries, such as malaria and Chagas.

<sup>47</sup> The Lancet – University of Oslo Commission on Global Governance for Health, *The political origins of health inequity: prospects for change*, 11 February 2014, available at [http://dx.doi.org/10.1016/S0140-6736\(13\)62407-1](http://dx.doi.org/10.1016/S0140-6736(13)62407-1), p. 12.

<sup>48</sup> Belen Pedrique, Nathalie Strub-Wourgaft, Claudette Some, Piero Olliaro, Patrice Trouiller, Nathan Ford, Bernard Pécoul, Jean-Hervé Bradol, “The drug and vaccine landscape for neglected diseases (2000-11): a systematic assessment”, *Lancet*, 24 October, 2013.

<sup>49</sup> See, e.g., V. Muñoz, F. Visentin, D. Foray and P. Gaulé, ‘Can medical products be developed on a non-profit basis? Exploring product development partnerships for neglected diseases’, *Science and Public Policy* (2014), available at <http://spp.oxfordjournals.org/content/early/2014/08/23/scipol.scu049.abstract>.

<sup>50</sup> Germán Velásquez, *Public-Private Partnerships in Global Health: Putting Business before Health?* Research Paper 49, South Centre, 2014, available at [http://www.southcentre.int/wp-content/uploads/2014/02/RP49\\_PPPs-and-PDPs-in-Health-rev\\_EN.pdf](http://www.southcentre.int/wp-content/uploads/2014/02/RP49_PPPs-and-PDPs-in-Health-rev_EN.pdf).

<sup>51</sup> See WHO, *Increasing Access to HIV Treatment in Middle-Income Countries: Key data on prices, regulatory status, tariffs and the intellectual property situation*, 2014, available at [http://www.who.int/phi/publications/WHO\\_Increasing\\_access\\_to\\_HIV\\_treatment.pdf?ua=1](http://www.who.int/phi/publications/WHO_Increasing_access_to_HIV_treatment.pdf?ua=1).

excessive IP protections in exacerbating the lack of access to HIV treatment and other essential medicines.<sup>52</sup>

In addition to the low number of new drugs developed after the TRIPS Agreement entered into force, innovation in pharmaceuticals presents other shortcomings. The great majority of the new drugs are ‘me-toos’, that is, drugs that do not perform better than previously existing treatments, but which are generally more expensive. For example, a specialized journal noticed that “a ‘new generation’ of antipsychotics was systematically prescribed by doctors, yet these drugs proved to be no more effective than the prior generation and were 10 times more expensive”.<sup>53</sup> More generally, it has been found that by the 1980s drugs were less than four times better than placebo; by the 1990s, twice as good, and by the 2000s just 36 per cent better than a placebo.<sup>54</sup>

Intellectual property is deemed to be necessary to drive private investment in drug research, which is believed to constitute the primary source of new treatments. The evidence suggests, however, that a large part of the new medicines with a genuine therapeutic impact emerge from public, not private, R&D laboratories: “...innovation depends on bold entrepreneurship. But the entity that takes the boldest risks and achieves the biggest breakthroughs is not the private sector; it is the much-maligned state.”<sup>55</sup>

A common argument for the justification for the minimum standards imposed by the TRIPS Agreement has been that it would effectively lead to more innovation in pharmaceuticals in developing countries, especially in those with a significant scientific and technological capacity such as India. While the TRIPS Agreement did not encourage the so-called ‘research-based’ pharmaceutical industry to improve drug innovation, has it promoted R&D in this field in developing countries? An analysis for pharmaceutical patents in 85 countries from 1978 to 1999 found that “national patent protection did not stimulate domestic innovation activities, except at higher development levels, and that above a certain level of patent protection, innovation activities are actually reduced”.<sup>56</sup>

There has been, in particular, great speculation about the boost that TRIPS rules could give to R&D on new drugs by Indian companies. The evidence so far available shows that this has not been the case. Local companies adapted in different ways to the post-TRIPS scenario, depending on their size and productive profile.<sup>57</sup> Some of the large local generic companies were taken over by pharmaceutical multinational companies,<sup>58</sup> thereby triggering

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<sup>52</sup> Global Commission on HIV and the Law, *HIV and the Law: Risks, Rights & Health*, available at <http://www.hivlawcommission.org/index.php/report>, p. 8.

<sup>53</sup> ‘Corporate influence over clinical research: considering the alternatives’, PRESCRIBER INTERNATIONAL, July 2012/Volume 21, no. 129, p. 192.

<sup>54</sup> Mark Olfson and Steven Marcus, ‘Decline in Placebo-Controlled Trial Results Suggests New Directions for Comparative Effectiveness Research’, 10.1377/hlthaff.2012.1353, *Health Affairs*, June 2013, vol. 32, no. 6, 1116-1125.

<sup>55</sup> Martin Wolf, ‘A much-maligned engine of innovation’. 4/8/13, <http://www.ft.com/cms/s/2/32ba9b92-efd4-11e2-a237-00144feabdc0.html>, comment on the book by Mariana Mazzucato ‘The Entrepreneurial State: Debunking Public vs Private Sector Myths’, Anthem Press, 2013.

<sup>56</sup> Bronwyn H. Hall, Christian Helmers, Mark Rogers, Vania Sena, op. cit., p. 15.

<sup>57</sup> See, e.g., Banji Oyelaran-Oyeyinka and Padmashree Gehl Sampath, *Latecomer Development: Innovation and Knowledge for Economic Growth*, Routledge, 2010, chapter 6.

<sup>58</sup> Ranbaxy, one of the firms taken over by a foreign (Japanese) company, was the local firm with the largest R&D budget in India. See, e.g., S Srinivasan, Narendra Gupta, Gopal Dabade, Anant Phadke, and Amit Sengupta, ‘Takeover of Indian Pharma Companies’, *Economic & Political Weekly*, Vol - XLV No. 43, October 23, 2010; D Sreedhar, MD Janodia, and VS Ligade, ‘Buyouts of Indian Pharmaceutical Companies by

the concern of the Indian government and civil society about the future of an industry that became the “pharmacy of the developing world”.<sup>59</sup>

A recent study on the TRIPS Agreement’s impact on the pharmaceutical industry in India concluded that TRIPS may have accelerated R&D related to improvement of existing medicines, but “in the absence of TRIPS, such activities would still have been undertaken. With larger domestic operations, Indian companies...would have had access to larger resources and would have been better placed to undertake such research”.<sup>60</sup> It has also been observed that there is an increase in patenting by large local and foreign companies, but an insignificant patent activity by small and medium local pharmaceutical companies.<sup>61</sup> While some Indian companies initiated R&D activities after the TRIPS Agreement came into effect, none of these companies has been “engaged in the entire process of drug development because they are not ready for a start-to-finish model in NCEs (new chemical entities) research and do not have the skills and funds required for development and marketing of a drug. The model adopted by Indian companies is to develop a new molecule up to a certain stage and then license it out to partners from developed countries, primarily to MNCs (multinational corporations)”.<sup>62</sup> Patenting by local companies focuses on “new or improved processes for products rather than products themselves. The product related applications are concerned with intermediates and formulations with maximum contribution in modified-release dosage forms”.<sup>63</sup>

While section 3(d) of the Indian Patent Act bans, in principle, the patentability of pharmaceutical formulations and other developments relating to existing drugs, the objection to patentability may be overcome if a significant increase in efficacy is found. In fact, many patents have been granted on such ‘incremental’ developments in India.<sup>64</sup> Table 1 shows examples of such patents, obtained by both local and foreign companies. In some cases, and despite the anti-evergreening purpose of section 3(d), a number of drugs received an extended patent protection through ‘secondary’ patents in India.<sup>65</sup>

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Multinational Pharmaceutical Companies: An Issue of Concern, *J Young Pharm.* 2011 Oct-Dec; 3(4): 343-344, Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3249749/>.

<sup>59</sup> See, e.g., Ellen t’Hoen and Carlos Passarelli, ‘The role of intellectual property rights in treatment Access: challenges and solutions’, *Current Opinion*, volume 8, No. 1, 2013, available at [www.co-hivandaids.com](http://www.co-hivandaids.com).

<sup>60</sup> Mani, S., & In Nelson, R. R. op. cit., p. 108.

<sup>61</sup> Neena Bedi, P M S Bedi and Balwinder S. Sooch, ‘Patenting and R&D in Indian pharmaceutical industry: post-trips Scenario’, *Journal of Intellectual Property Rights*, Vol 18, March 2013, p. 107.

<sup>62</sup> *Ibid.*, p. 109.

<sup>63</sup> *Ibid.*

<sup>64</sup> See in Sudip Chaudhuri, Chan Park and K. M. Gopakumar, *Five Years Into The Product Patent Regime: India’s Response*, UNDP, 2010, available at <http://apps.who.int/medicinedocs/documents/s17761en/s17761en.pdf>, p. 80.

<sup>65</sup> Gopakumar G Nair and Andreyra Fernandes, ‘Patent Policies and Provisions Relating to Pharmaceuticals in India’, *Journal of Intellectual Property Rights*, Vol 19, January 2014, p. 14.

**Table 1**  
**Pharmaceutical products that overcome the objection under section 3(d) of the Indian Patent Act**

Table 1—Patents which have overcome the objection under Section 3(d)		
Indian Patent No	Title of the invention	Patentee
223589	A crystalline polymorph of an Epothilone analog of Formula I	Bristol-Meyers Squibb Co
223767	Indolylakylamine derivatives	Wyeth
223849	8-Azabicyclo [3.2.1.] Octane-3-Methanamine derivatives compounds	Sanofi-Synthelabo
224394	Amorphous ammonium salt of Eprosartan	Smithkline Beecham Corporation
225283	Crystal of Diuridine Tetrphosphate or salt thereof and method for preparing the same, and method for producing said compound	Yamasa Corporation
239408	Novel Tyrosine derivatives	Orchid Research Laboratories Ltd
242111	Crystalline Clopidogrel Besylate and process for preparation thereof	Cadila Healthcare Limited
254576	Morpholine derivatives as Norepinephrine Reuptake inhibitors	Eli Lilly and Company Limited
254839	Polymorphic forms of Rifaximin, processes for their production and use thereof in medicinal preparations	Alfa Wassermann S P A
254845	Prodrugs containing novel bio-cleavable linkers	Piramal Enterprises Limited
254845	Prodrugs containing novel bio-cleavable linkers	Piramal Enterprises Limited
255388	Novel crystalline polymorphic form of a Camptothecin analogue	Cipla Limited

*Source:* Gopakumar G Nair and Andreyra Fernandes, ‘Patent Policies and Provisions Relating to Pharmaceuticals in India’, *Journal of Intellectual Property Rights*, vol. 19, January 2014, p. 13.

The TRIPS Agreement requires a minimum protection for patents of twenty years counting from the date of filing.<sup>66</sup> This is an arbitrary term, as there is no evidence suggesting that this is the optimum duration, particularly if applied to inventions of very different nature (both major or radical as well as incremental or minor) and the development of which require completely different levels of skill and investment. G. Becker, a Nobel Prize laureate has argued in relation to the twenty years term that “The current patent length of 20 years (longer for drug companies) from the date of filing for a patent can be cut in half without greatly discouraging innovation. One obvious advantage of cutting patent length in half is that the economic cost from the temporary monopoly power given to patent holders would be made much more temporary. In addition, a shorter patent length gives patent holders less of an effective head start in developing follow on patents that can greatly extend the effective length of an original patent. Even pharmaceutical and biotech companies... usually do not need more than about a decade of monopoly power to encourage their very large investments in new drugs”.<sup>67</sup>

A study on research in the area of cancer has called attention to the negative impact that the fixed term of patents may have on what type of research is conducted by the pharmaceutical industry. Eric Budish (Univ. of Chicago), Benjamin N. Roi (Harvard) and Heidi Williams (MIT) found that “...under a fixed patent term, research and development (R&D) investments may be distorted away from technologies with long time lags between invention and commercialization”. This means that companies focuses on research for drugs that may be commercialized and generate profits as soon as possible: “[s]ince society cares about an invention’s total useful life, but private firms care only about monopoly life, a distortion emerges not just in the level of R&D..., but also in the composition of R&D: society might value invention A more highly than invention B, but private industry may choose to develop B but not A”.<sup>68</sup>

<sup>66</sup> Article 33 of the TRIPS Agreement.

<sup>67</sup> <http://www.becker-posner-blog.com/2013/07/on-reforming-the-patent-system-becker.html>, 21-7-13.

<sup>68</sup> Eric Budish, Benjamin N. Roi and Heidi Williams, ‘Do firms underinvest in long-term research? Evidence from cancer clinical trials’, available at <http://economics.mit.edu/files/8651>.

The TRIPS Agreement, in summary, has done nothing to stop the decline in the innovation of the pharmaceutical industry in developed countries, or to induce R&D on new drugs in developing countries. Despite this, in many of these countries there has been a massive proliferation of patents in this area, based on “evergreening” strategies, that is, the practice of filing for patents, such as on derivatives, crystal forms, formulations or new uses of existing medicines, in order to block the market entry of generic producers.

A telling example of evergreening is offered by one of the patents revoked in Canada which gave rise to a complaint by the patent owner, the US company Eli Lilly, under the investment chapter of NAFTA.<sup>69</sup> The origin of the revoked patent can be traced to a broad patent filed in 1975, drafted on the basis of a ‘Markush claim’,<sup>70</sup> which covered 15 trillion compounds “useful in the treatment of mild anxiety states and certain kinds of psychotic conditions such as schizophrenia”.<sup>71</sup> Olanzapine was indicated as one of the “most preferred compounds”. In 1991, Eli Lilly obtained a new patent on olanzapine (as a ‘selection’ from the genus of compounds of the previous patent) and the use of olanzapine for the treatment of schizophrenia. Between 1995 and 1998, 16 separate additional patents were filed for the use of olanzapine in the treatment of health conditions as diverse as fungal dermatitis, bipolar disorder, sexual dysfunction, insomnia, anaesthetic agent, nicotine withdrawal, tic disorder, anorexia, depression, autism and mental retardation, pain, migraines, dyskinesia, addictive substance withdrawal, and Alzheimer’s disease.<sup>72</sup>

The proliferation of pharmaceutical patents – in many cases covering minor technical developments obvious for a person trained in the pharmaceutical field – does not reflect technological progress. As noted by Mercurio: “...there is no evidence that the increase in the volume of patents has had a positive or beneficial effect on innovation. This is problematic, and the lack of competition in certain sectors could potentially hamper innovation”.<sup>73</sup> The already mentioned draft report produced for the Australian government also reflects this concern:

Patents also have negative effects. They may increase prices – and so restrict supply – by more than the amount that would be required to provide the necessary incentives to innovate. This is important for pharmaceuticals because of their importance to human health. And though innovators seeking a patent must disclose considerable information about their inventions – thus providing a platform to others for further innovation – patents can also restrict follow-on innovators...

Countries that are major net exporters of intellectual property have tended to seek longer and stronger patents, not always to the global good.<sup>74</sup>

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<sup>69</sup> See, e.g., Carlos Correa, ‘*Investment Agreements: A New Threat to the TRIPS Flexibilities?*’, South Bulletin, Issue 72, 13 May 2013.

<sup>70</sup> A ‘Markush claim’ consists of the generic description of a chemical formula which includes a multiplicity of closely related compounds.

<sup>71</sup> Patent CA 1,075,687.

<sup>72</sup> See Government of Canada Counter Memorial of January 27, 2015 in Eli Lilly and Company and Government of Canada (Case No. UNCT/14/2), available at [www.italaw.com/sites/default/files/case-documents/italaw4131.pdf](http://www.italaw.com/sites/default/files/case-documents/italaw4131.pdf).

<sup>73</sup> Mercurio, Bryan. TRIPS, ‘Patents and Innovation: A Necessary Reappraisal?’, ICTSD and World Economic Forum, 2014, available at [www.e15initiative.org/](http://www.e15initiative.org/).

<sup>74</sup> *Pharmaceutical Patents Review. Draft Report* (April 2013), p. iv.

In fact, the patenting strategies of large pharmaceutical firms often aim not only at delaying the market entry of generic producers, but also at discouraging or blocking innovation. This “fencing” strategy is based on the acquisition of a series of patents, ordered in some way, to block certain lines or directions of R&D.<sup>75</sup>

#### **IV. ALTERNATIVE MODELS FOR R&D IN PHARMACEUTICALS**

“[A]re the incentives provided by the patent system appropriate...? Sadly, the answer is a resounding ‘no’.”<sup>76</sup> This statement by Nobel Prize Stiglitz encapsulates the growing scepticism in academic and other public circles about the role that intellectual property may play to effectively generate the new treatments needed in both developed and developing countries. An essential point is that innovation as such is not sufficient for a system of incentives to properly work. It must also ensure that the outcomes of the innovation process are accessible and affordable; an objective that becomes unachievable when patent owners can determine prices in exercising a monopolistic right.

High prices of pharmaceuticals, based on the exercise of patent rights,<sup>77</sup> severely affects developing countries where the States’ purchasing capacity is low and medicines often need to be paid by the patients themselves, if they can afford them at all. But high pharmaceutical prices are also shocking patients and creating financial problems to social security systems in developed countries. For instance, 11 of the new drugs approved for cancer in 2012 cost at least \$100,000 a year in the USA,<sup>78</sup> where a twelve weeks treatment with a patented drug for hepatitis C costs US\$ 84,000.<sup>79</sup>

The declining productivity in pharmaceutical innovation and the unaffordable costs of the patented outcomes of R&D have prompted analyses and proposals for new models of innovation in this field. Thus, a Consultative Expert Working Group on Research and Development: Financing and Coordination established by the World Health Assembly of the

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<sup>75</sup> Granstrand, O. (1999), *The Economics and Management of Intellectual Property*, Edward Elgar Publishing, Cheltenham, pp. 221-222.

<sup>76</sup> ‘Prizes, not patents’ (3.3.07), <http://www.project-syndicate.org/commentary/prizes--not-patents>.

<sup>77</sup> High prices may also be the result of data exclusivity regimes, i.e., those that prevent generic companies to use or rely on test on data for a certain period after the first approval of a drug to introduce a generic version thereof. For instance, a study found that ‘of all the current forms of intellectual property protection in Jordan, the provision for data protection has the most significant effect on the price of medicines’ (Ryan Abbott, ‘Access to Medicines and Intellectual Property in Jordan’, *Intellectual Property Watch*, 23/07/2012, available at <http://www.ip-watch.org/2012/07/23/access-to-medicines-and-intellectual-property-in-jordan/>. See also, for the case of Colombia, MEC Gamba, FR Buenaventura, and MDV Serrano, *Impacto de 10 Años de Protección de Datos en Medicamentos en Colombia*, IFARMA, Bogotá, March 2012, available at [http://web.ifarma.org/index.php?option=com\\_content&view=article&id=70:serie-buscando-remedio-qimpacto-de-10-anos-de-proteccion-de-datos-en-medicamentos-en-colombiaq&catid=22:buscando-remedio](http://web.ifarma.org/index.php?option=com_content&view=article&id=70:serie-buscando-remedio-qimpacto-de-10-anos-de-proteccion-de-datos-en-medicamentos-en-colombiaq&catid=22:buscando-remedio).

<sup>78</sup> See, e.g. The Economist, ‘The new drug war. Hard pills to swallow’, 1.4.2014, available at <http://www.economist.com/news/international/21592655-drug-firms-have-new-medicines-and-patients-are-desperate-them-arguments-over>.

<sup>79</sup> See, e.g., Drew Armstrong, ‘At \$84,000 Gilead Hepatitis C Drug Sets Off Payer Revolt’, 27.1.2014, available at <http://www.bloomberg.com/news/articles/2014-01-27/at-84-000-gilead-hepatitis-c-drug-sets-off-payer-revolt#q>.

World Health Organization in 2010, produced a set of recommendations<sup>80</sup> in view of the failure of the present incentive systems, in particular, intellectual property, to generate enough R&D in either the public or private sector in order to meet the health needs of developing countries.<sup>81</sup> Based on the evaluation of close to 100 proposals for mechanisms to promote better financing and coordination of research, the report concluded that an open approach to R&D should be promoted, with the results of R&D being treated as public goods not subject to the exclusive rights conferred by patents. It recommended new forms of shared financing, direct subventions, prizes and patent pools (to increase access to health products), including, in particular, a legally binding convention on R&D (see Box 2).

**Box 2**  
**Suggestions for an alternative model of R&D in pharmaceuticals<sup>82</sup>**

- 1) Open approach to R&D:
  - Use “open knowledge” innovation, such as precompetitive research and development platforms, open source and open access schemes, prizes, particularly milestone prizes
  - Increased sharing of outputs via equitable licensing and patent pools
- 2) Funding mechanisms:
  - All countries should commit to spend at least 0.01% of GDP on government-funded R&D for product development
  - Developing countries with a potential research capacity should aim to commit 0.05-0.1% of GDP to government-funded health research of all kinds.
  - Developed countries should aim to commit 0.15-0.2% of GDP to government-funded health research of all kinds
- 3) Pooling resources:
  - Make use of pooled funding mechanisms for increased efficiency and better coordination of financial resources
  - Portion of funds should be devoted to capacity-building in developing countries through measures such as direct grants to companies
  - 20% to 50% of funds raised for R&D should be channelled through a pooled mechanism
- 4) Strengthening research and development capacity and technology transfer:
  - Address the capacity needs of academic and public research organizations in developing countries
  - Give direct grants to companies in developing countries
- 5) Coordination:
  - Give WHO a central role in strengthening coordination in R&D for efficient use of resources
  - Establish a global health R&D observatory and relevant advisory mechanisms under the auspices of WHO

<sup>80</sup> WHO, *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination* (WHO, 2012), available at: [http://www.who.int/phi/CEWG\\_Report\\_5\\_April\\_2012.pdf](http://www.who.int/phi/CEWG_Report_5_April_2012.pdf).

<sup>81</sup> See also G Velazquez, *Rethinking the R&D Model for Pharmaceutical Products: A Binding Global Convention* (South Centre, April 2012).

<sup>82</sup> See WHO, *op. cit.*



6) New binding global instrument for R&D and innovation for health:

- Kick-start formal negotiations on an international treaty/convention on global health R&D.<sup>83</sup>

A starting point of these and other initiatives is that, as stressed by Dosi and Stiglitz: “[i]ntellectual property is only one way of incentivizing innovative research; it is only one part of what might be thought of as a country’s **innovation system**, the collection of institutions that promote innovation; there has been too much emphasis on IPR, to the exclusion of other ways of stimulating innovation and learning.... Moreover, much innovation occurs within and is supported by non-market systems”.<sup>84</sup>

The idea that innovation may flourish better in “open” systems rather than in those relying on the private appropriation of its results is growingly explored. It is not new, however, and it has been tested in some sectors. Mowery, Nelson and Martin, for instance, identified policies in the USA based on a knowledge base open and available to a wide range of firms and other users, which were successfully implemented in the area of semiconductors, the human genome and the development of new seeds. They concluded that “[i]n all of these areas, the support provided by public R&D programmes for the broad dissemination of fundamental knowledge neither discouraged industry R&D investment nor does it appear to have discouraged privately funded innovation”.<sup>85</sup>

In the field of drug discovery and development, an interesting example of “open research” is provided by the Open Source Drug Discovery, launched in 2008 by the Council of Scientific and Industrial Research of India, which made available a global platform for scientific collaboration to tackle the complex problems related to discovering novel therapies for neglected tropical diseases. With more than 4500 registered users from over 130 countries, it has become “the largest collaborative effort in drug discovery”.<sup>86</sup>

While this is not the place to consider this and other options (such as prizes and advanced purchasing commitments) in detail, the basic point to be made here is that the TRIPS Agreement has failed to increase innovation and generate benefits equitably distributed among all members of the WTO system. The same can be said with regard to the free trade agreements promoted by the USA and the European Union that entail a further expansion of intellectual property protection (“TRIPS-plus standards”), such as:

- extended term of patent protection (in the case of US FTAs);
- data exclusivity for pharmaceuticals and agrochemicals;

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<sup>83</sup> These negotiations have not started yet. A decision on the subject would have to be made in the WHO by 2016. See, e.g., ‘Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination’, Global Health Watch, available at <http://www.ghwatch.org/node/1932>.

<sup>84</sup> Giovanni Dosi and Joseph E. Stiglitz, ‘The Role of Intellectual Property Rights in the Development Process, with Some Lessons from Developed Countries: An Introduction’, in Mario Cimoli, Giov Ann I Dosi, Keith E. Maskus, Ruth L. Okediji, Jerome H. Reichman, Joseph E. Stiglitz, *Intellectual Property Rights. Legal and Economic Challenges for Development*, Oxford University Press, 2014, p. 4.

<sup>85</sup> David C. Mowery, Richard R. Nelson, Ben R. Martin, ‘Technology policy and global warming: Why new policy models are needed (or why putting new wine in old bottles won’t work), *Research Policy* 39 (2010) 1011-1023 p. 20.

<sup>86</sup> <http://www.osdd.net/about-us>.

- linkage between drug registration and patent protection (in the case of US FTAs);<sup>87</sup>
- strengthened enforcement measures.

There is abundant literature on the TRIPS-plus provisions in FTAs that highlights their likely negative impact on access to medicines, including reports by UN organizations and the UN Special Rapporteur on health issues.<sup>88</sup> The “Principles for Intellectual Property Provisions in Bilateral and Regional Agreements”,<sup>89</sup> developed under the auspices of the Max Planck Institute for Innovation and Competition, have noted the imbalances inherent to the intellectual property provisions in FTAs: “...these deals are driven by export interests and other objectives external to the IP system rather than the common goal to achieve a mutually advantageous, balanced regulation of IP among the parties. While these agreements may pursue an overall balance of concessions, they usually do not lead to international IP rules that address the interests of all countries affected”.

#### IV. CONCLUSIONS

The incorporation of intellectual property into trade agreements has not proven to bring about the promised benefits. The premises that have underpinned the global strengthening and expansion of intellectual property through such agreements – namely that the same standards of protection are suitable for countries with different levels of development and that innovation will be boosted – do not match the reality.

The effects of high standards of protection – as those mandated under the TRIPS Agreement and further extended under FTAs – have been critically examined in the developed countries themselves: “[i]ntellectual property is ... a social contrivance purportedly designed to increase welfare, by supposedly enhancing innovation (though... it may actually have exactly the opposite effect)”.<sup>90</sup> If intellectual property does not work in developed countries as generally described by their proponents, the situation can only be worse in developing countries with weak science and technological infrastructures, scarcity of risk capital and unsophisticated production profiles. These countries are currently paying the price of a system which primarily serves as a platform to extract rents (in the form of royalty payments and high prices) and which does little to promote local innovation and economic development.

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<sup>87</sup> See, e.g., Carlos Correa, ‘Expanding patent rights in pharmaceuticals: the linkage between patents and drug registration, in Neil Netanel (editor), *The Development Agenda: Global Intellectual Property and Developing Countries*, Oxford University Press, 2008.

<sup>88</sup> See, e.g. UNDP/UNAIDS, *The Potential Impact of Free Trade Agreements on Public Health*, Issue Brief, 2012, available at [http://www.unaids.org/sites/default/files/media\\_asset/JC2349\\_Issue\\_Brief\\_Free-Trade-Agreements\\_en\\_0.pdf](http://www.unaids.org/sites/default/files/media_asset/JC2349_Issue_Brief_Free-Trade-Agreements_en_0.pdf); Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, A/HRC/11/12, 31 March 2009, available at [http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12\\_en.pdf](http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf); Ayilyath, Manoranjan, ‘Free Trade Agreements and Access to Medicines: Need for Regulation’ (June 1, 2013). Available at SSRN: <http://ssrn.com/abstract=2273275>.

<sup>89</sup> Available from [http://www.ip.mpg.de/fileadmin/user\\_upload/Principles\\_for\\_IP\\_provisions\\_in\\_Bilateral\\_and\\_Regional\\_Agreements\\_final1.pdf](http://www.ip.mpg.de/fileadmin/user_upload/Principles_for_IP_provisions_in_Bilateral_and_Regional_Agreements_final1.pdf).

<sup>90</sup> Giovanni Dosi and Joseph E. Stiglitz, *op. cit.*, p. 3.

The scenario for innovation in the pharmaceutical sector, discussed above, clearly illustrates that the conception underpinning the TRIPS Agreement was flawed from a global perspective. The rate of innovation has not increased, rather, it has declined and while developing countries struggle with high prices for medicines, R&D necessary to address their particular health needs continues to be marginalized.



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