

# Access to Medicine: Patent, Price Regulation and Prizes

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## I. Introduction

Developing countries argue that the system of minimum standards enforced by the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) limits access to medicine's in developing countries because strict patent protection leads to increased drug prices. In this system, compulsory licensing which allows access to a patent without the previous authorization of the patent holder is one of the main tools available to developing countries in providing access to medicine. However, even after the World Trade Organization (WTO) decision of August 30, 2003 which implemented paragraph 6 of the Doha Declaration,<sup>1</sup> for countries with insufficient manufacturing capability, the only realistic sourcing mechanism to access to medicine remains importation. Compulsory licensing, in fact, cannot address *per se* the issue of access to medicine with regard to diseases such as HIV/AIDS, malaria and tuberculosis, which are prevalent in developing countries and for which the main obstacle to access is lack of adequate innovation.

With regard to these neglected diseases, the current system of patent protection has not proven to be capable, by itself, to provide an attractive return on investment to pharmaceutical companies in the development of medicine to fight these specific diseases. The purpose of this article is to analyze whether patents can still represent an incentive to research and development (R&D) in developing countries. This article will argue that patent protection is only one of the instruments providing appropriate incentives to the private sector in producing specific kinds of drugs and to assure a minimum

level of quality and quantity. The analysis proposes a long-term tool to treat diseases such as HIV/AIDS, malaria and tuberculosis. This system would be designed by integrating elements from current patent protection mechanisms, price regulation schemes and prizes. The system of price regulation calls for lower drugs prices, correcting the effects of patent protection which increases the price of drugs. A system of prizes would restore private sector's interest in producing low cost drugs, bridging the gap between the needs of developing countries and the necessity of pharmaceutical companies to recover the costs of production and to profit from their investment.

Part II will examine the theory of the commons and anticommons and will analyse the instrument of compulsory licenses. Part III will provide an alternate solution to the issue of access to medicine. This section will analyze the solution adopted by the European Council and will show how patents, combined with a system of price regulation and prizes, could represent an adequate instrument address the issue of lack of innovation and access to medicine with regard to neglected diseases in developing countries. This article will not discuss the different policies of price regulation or prizes but will limit the scope herein to demonstrate that this triple system of patent, price, and prizes can address the double problem of “access” and “incentives” to essential medicine in developing countries.

## II. Background: Intellectual Property Rights and TRIPS Agreement

### A. The Importance of Intellectual Property Rights in Biomedical Research: From the Commons to the Anticommons

In 1968, Hardin published an article in *Science* entitled “The Tragedy of the Commons”<sup>2</sup> in which he introduced the metaphor “tragedy of commons” to help explain overpopulation, air pollution, and species extinction by showing the effects of the overuse of a resource.<sup>3</sup> More specifically, “the tragedy of the commons” showed how the overuse of Earth’s natural resources is the effect of “the tragedy of freedom.”<sup>4</sup> When goods are left unregulated or open to public consumption, they do not belong to anyone and are susceptible to overuse because no one has the right to exclude another from using the resource. Likewise, no one is incentivized to conserve the resource or to invest in its development.<sup>5</sup> The consequence is that the absence of any form of control leads to a lack of adequate incentive to promote further research and development.<sup>6</sup> However, the idea that by ensuring a patent holder an exclusive right over the results of his research represents an answer to the tragedy of commons “can solve one tragedy, but cause another.”<sup>7</sup> The “tragedy of anticommons,”<sup>8</sup> in fact, can be interpreted as a “mirror”<sup>9</sup> of the tragedy of commons. Each one has the right to exclude another, but no one has an effective privilege of use. The resulting effect is the fragmentation of IPRs (Intellectual Property Rights), slowing further development and increasing transaction costs, especially in biomedical research. In 1998, Heller and Eisenberg published in *Science* an article where they claimed that biomedical research is one of several key areas where competing patent rights could actually prevent useful and affordable products from reaching the marketplace because too many property rights could lead to less innovation.<sup>10</sup> Consequently, to avoid the anticommons tragedy, a core bundle of rights has to be conveyed to a single owner rather than fragment the exclusive right among several owners.<sup>11</sup>

In spite of the effects of the anticommons, IPRs seem to have a particular importance in the pharmaceutical industry because they encourage innovation much more than in any other industry.<sup>12</sup> The patent system is built on the premise that a patent provides those incentives for innovation that a common model is not able to provide “by offering the patent holder a limited right to exclude others from using the patented product.”<sup>13</sup>

At this time, the issue is the effect that IPRs can have in developing countries. A response to this issue is that in developing countries IPRs are not able to realize *per se* the same incentives than in developed countries. In particular, developing countries argue that IPRs can block access to medicine in developing countries because strict patent protection increases the price of drugs. Eliminating IPRs

would lead to lower drug prices and increase accessibility of the medicines.<sup>14</sup>

### B. TRIPS Agreement and Compulsory Licenses

The TRIPS agreement, enacted in 1994, is an international framework for protecting trademarks, copyrights, and patents that required all the State Members to provide mandatory minimum standards of intellectual property (IP) protection.<sup>15</sup>

The TRIPS agreement requires patent protection for “any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application.”<sup>16</sup> The broad formulation of article 27 of the TRIPS agreement suggests that the minimum standards of protection required have to be applied also to pharmaceutical invention. The enforcement of the TRIPS agreement displays how, under the pressure of the “Triumvirate,”<sup>17</sup> the only available intellectual property regime is based on a high level of protection of information and technology through the acknowledgement of exclusive IPRs. Yielding to the requests of developed countries to enforce a set of minimum standards to protect IPRs, the TRIPS agreement shows how its design did not allowed for the effective participation of developing countries.<sup>18</sup> Drahos argues that “in the case of TRIPS a basic and well established causal mechanism operated coercion.”<sup>19</sup>

However, the safeguards provided by the TRIPS agreement show how the patent regime granted under the TRIPS agreement is not absolute and is subject to some exceptions. Articles 7, 8 and 31 of the TRIPS agreement provide a framework that addresses access to essential medicines and the public health crisis in developing countries. Article 7 states that “the protection and enforcement of intellectual property rights should contribute not only to the promotion of technology,” but also to the “transfer and dissemination of technology” in a manner conducive to social and economic welfare, and to a balance of rights and obligations.<sup>20</sup> Furthermore, when promoting public interest, article 8 provides that States, should adopt “measures necessary to protect public health” and “to promote public interest in sectors of vital importance to their socio-economic and technology development,” providing that such measures are consistent with the provisions of the TRIPS agreement.<sup>21</sup>

Finally, the main safeguard of the TRIPS agreement is represented by compulsory licenses, a policy tool built to improve access to essential medicines in developing countries.<sup>22</sup> In fact, article 31 of the TRIPS agreement presents an exception to the exclusive rights of the patent holder and grants the use of patents without the previous authorization, allowing developing countries to invoke the public health interest to grant a compulsory license for the domestic production of drugs. In other words, the TRIPS agreement balances the private interest of the patent holder in the exploitation of his

exclusive right with the broader public interest of providing access to medicine and recognizes the supremacy of the public interest over the private.<sup>23</sup>

The negotiating history of compulsory licenses proves the resistance shown by pharmaceutical industry in supporting this instrument. At the present time, Thailand is being pressured to abandon compulsory licenses issued on patents and on drugs for AIDS, heart disease and cancer.<sup>24</sup> Chile is being pressured to not import a generic version of an expensive leukemia drug.<sup>25</sup> Brazil is being pressured not to issue compulsory licenses for the Gilead drug Tenofovir.<sup>26</sup> Moreover in 1998, the U.S. government, supporting the suit brought against the government of South Africa by the South African Pharmaceutical Manufacturers Association, has pressured South Africa to repeal the Medicines and Related Substances Control Amendment Act (“Amendment Act”), which was enacted to increase the availability of affordable medicines in this country.<sup>27</sup>

The main argument against compulsory licenses presented by developed countries is that compulsory licenses could lead to an anti-competitive market and possible disincentives to invention, barring foreign direct investments into local manufacturing facilities and transfer of technology to developing countries.<sup>28</sup> Moreover, the pharmaceutical industry argues that, in the absence of an adequate system of patent protection, compulsory licenses can destroy the incentive for R&D in developing countries.<sup>29</sup> Rozek argues that the use of compulsory licenses by developing countries could create some quality-control problems for local governments and the possibility of facing higher costs necessary to control and regulate the licenses.<sup>30</sup>

In spite of these challenges, compulsory licenses represent a fundamental tool in facilitating the availability of drugs in developing countries and in lowering prices, despite the high royalty and research costs.<sup>31</sup> Brazil has successfully used compulsory licenses to negotiate affordable drugs to treat HIV/AIDS and Thailand’s Ministry of Health has issued new compulsory licenses on patents for the AIDS drug Kaletra and the heart disease drug Plavix.<sup>32</sup>

### *C. Paragraph 6 of the Doha Declaration*

In November 2001, the World Trade Organization Ministerial Conference adopted the Doha Declaration.<sup>33</sup> In this Declaration the WTO Member recognized “the gravity of the public health problems afflicting many developing countries and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”<sup>34</sup> In the Doha Declaration, WTO Members agree that TRIPS agreement should not prevent members from taking measures “to protect public health” and “to promote access to medicine.”<sup>35</sup>

In spite of these resolutions, paragraph 6 of the Doha

Declaration shows awareness of WTO Members that compulsory licenses are not a feasible tool in producing medicine for those developing countries without a specific manufacturing capability in this field.<sup>36</sup> The Declaration recognizes “that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS agreement.”<sup>37</sup> Thus, the system is aware that developing countries without domestic manufacturing capacity would lose its ability to purchase and import lower-priced medicines under a compulsory license scheme.

At the same time, but without any specification, the Declaration recognises compulsory licensing as an instrument to protect public health and to “promote access to medicines for all.”<sup>38</sup> In other words, the Doha Declaration acknowledges the awareness of WTO Members of the difficulty of some developing countries in producing drugs through the tool of compulsory licenses, but failed to define immediately the solution to this problem for those developing countries without specific manufacturing capability.

### *D. The WTO General Council Decision of the 30 August 2003*

The WTO decision of August 30, 2003<sup>39</sup> establishes an adequate mechanism which allows developing countries with insufficient manufacturing capabilities to effectively use compulsory licensing, by trying to overcome the limitation of article 31(f) of the TRIPS agreement that prescribes compulsory licenses are “authorized predominantly for the supply of the domestic market of the member authorizing such use.”<sup>40</sup> In fact, if all the required conditions established by the decision are met, it waives the limitation that production under the compulsory licenses has to be “predominantly for the domestic market.”<sup>41</sup>

This decision states that any member can export generic drugs made under the compulsory licenses to meet the needs of importing countries, providing medicines to address public health problems.<sup>42</sup> In order to benefit from the disposition, the decision requires several limitations such as: limits the amount that can be imported to only the amount necessary to meet the particular needs, and that it must be exported in its entirety.<sup>43</sup> The 30 August decision also provides: that adequate remuneration will be paid for the compulsory license,<sup>44</sup> that importing members should take reasonable measures to prevent re-exportation,<sup>45</sup> and highlight the available legal means by which non-importing member states can prevent diverted pharmaceutical products from being imported into their markets.<sup>46</sup> If all these conditions are met, the requirement to issue a compulsory license predominantly for the supply of the domestic market can be waived.

This mechanism provides a framework ensuring that countries without the manufacturing capacity to purchase antiretroviral medicines. However, under the WTO decision of

August 30, 2003, for countries with insufficient manufacturing capability, the only realistic sourcing mechanism to access to medicine remains importation, considering that at the present time, only about a dozen developing countries such as China, Argentina, Brazil, India, South Africa have the manufacturing capacity to produce generic drugs in a fair quantity and quality.<sup>47</sup> Thus, compulsory licenses allow developing countries to have access to patented drugs-manufacturing procedures, but the absence of manufacturing capability represents an obstacle to produce quality medicines. In fact, after the implementation of the TRIPS agreement, only some countries, such as Zimbabwe (2003) Mozambique (2004) Zambia (2004), Eritrea (2005), Ghana (2005), and Cameroon (2005) have issued compulsory licenses on pharmaceuticals products.<sup>48</sup>

Even if compulsory licenses are one of the main safeguards that provide access to medicine in developing countries, they can be seen only as a short or middle term tool. In fact, compulsory licenses alone do not present an answer to the issue of access to medicine in developing countries because they cannot be effective in addressing those neglected diseases such as HIV/AIDS, malaria and tuberculosis and for which the main problem is still lack of adequate incentive to produce effective drugs.

### **III. Discussion of An Alternative Solution: Patent Protection, Price Regulation and Prizes as a Long Term Tools**

#### *A. First Step: Do Patents Block Access to Medicine? The Case of New Drugs*

Patents and the high prices of drugs are some of the factors that limit the access to medicines in developing countries.<sup>49</sup> However, most of the essential drugs listed by the World Health Organization (WHO) are in the public domain because they are unpatented or because the patents expired.<sup>50</sup> Amir Attaran analyzed how there are only 17 drugs on the 319 listed by WHO that are patentable, although not actually patented, “so that the overall patent incidence is low (1.4 percent) and concentrated in larger markets.”<sup>51</sup> In spite of the free or low cost of the most of the essential drugs, access to medicine is still one of the most important problems in developing countries.<sup>52</sup> In fact, the price of some drugs not covered by a patent can be inaccessible for most people, even at an economical and efficient price.<sup>53</sup> Moreover, the case of new drugs is the example that proves how, even considering that patents can increase the prices of medicine, “the lack of innovation can represent an even greater barrier to access to medicine much more than patent or high prices.”<sup>54</sup>

The lack of adequate innovation and research affects these drugs, who sometimes are a generic formulation of the existing drugs and which do not offer significant improvements. The lack of investment by the pharmaceutical industry suggests

that the new drugs are likely to stall in different stages of development or fail to reach the market in pre-clinical and clinical tests.<sup>55</sup> R&D in new drugs requires significant financial support since it is a costly and risky activity affected by the lack of return on investment. The effect is, consequently, the unavailability of medicines to the people who need them the most.<sup>56</sup>

Although targeted development of new drugs for these neglected diseases should be produced in order to satisfy the needs of the affected populations in developing countries, several factors contribute to the difficulty of providing the quality and quantity of drugs needed.<sup>57</sup> Mainly new drugs for neglected diseases are completely unaddressed because neglected diseases:

- have low mortality;<sup>58</sup>
- occur predominantly in developing countries and, consequently, they do not interest the developed world; and
- do not offer profitable incomes.<sup>59</sup>

Other elements, such as the lack of “R&D in neglected diseases” as well as the lack of “financing and political commitment,” capacity, and health infrastructure can play a more significant role in blocking access to medicine in developing countries.<sup>60</sup>

The issue is that any kind of incentives to produce these kinds of drugs is directly affected by the potential profits that pharmaceutical companies can make by selling the drugs.<sup>61</sup> In fact, different kinds of diseases lead to different kinds of production incentives because pharmaceutical companies invest where they meet the needs of those patients who can ensure the highest profit margins. For this reason, pharmaceutical research is mainly focused on drugs for diseases found in developed countries, whose population is capable of buying the treatments.<sup>62</sup> In contrast, these rare diseases mostly affect people in developing countries, where only a few patients can pay the high prices and where only limited private or public investments are directed to diseases.<sup>63</sup>

The case of new drugs suggests that, in this field, neither patent protection nor high prices of drugs can be considered the obstacle to access to medicine. The solution to this problem is not only “an issue of access, but of production capacity of the developing world”<sup>64</sup> that at the present time is not able *per se* to satisfy its own needs.

#### *B. Second Step: Patent Protection Which is the Role for Patent in Developing Countries?*

In addressing R&D for neglected diseases, patents can still provide an incentive in developing countries. As discussed, in the case of new drugs designed to combat neglected diseases, patent protection cannot be considered an impediment in assuring access to medicine within developing countries. On the other hand, in the cases of neglected diseases, patents

have not proven to be able to effectively stimulate adequate investments. In fact, patent has not ignited R&D in fighting these diseases in developing countries mainly because patents are not capable *per se* to recover the cost of the investments undertaken by pharmaceutical companies when producing these drugs. To reiterate, in developing countries patients are not able to pay the high prices of the drugs and, consequently, pharmaceutical companies are not able to recover the investment in producing these needed drugs only through the patent protection.

Danzon and Keuffel argue that “patent is likely to be an ineffective mechanism to achieve the dynamic efficiency goal of stimulating investment in R&D.”<sup>65</sup> Correa, in particular, points that it is difficult to prove a direct relationship between IPR protection and R&D because IPRs are only one of the several elements that can influence transfer of technology and foreign direct investment (FDI).<sup>66</sup> In contrast, Grabowski finds that patent protection is one of the factors necessary in order to provide incentives to pharmaceutical and biotechnological industries needed “to undertake the long costly and risky investments that characterize the innovative process in these industries.”<sup>67</sup> In fact, patents provides pharmaceutical companies a safeguard which protect their investments since the patents are capable of securing these companies the benefits of their research by covering the cost of their investments.<sup>68</sup>

Even assuming the inability of patents in stimulating R&D *per se* or to address the needs of developing countries, the TRIPS agreement presented IPRs protection as a minimum requirement in promoting research and investment. In fact, by implementing patent protection and creating an international system of minimum standards, the TRIPS agreement shows that IPRs are necessary in order to promote investment in R&D. In other words, the adoption in the TRIPS agreement proves that patent protection is inevitable and the issue of access to medicine cannot be considered without considering patent protection, independently of the positive effects that patent protection can really have on R&D.

The remaining issue is whether it is possible to imagine a system capable of finding a balance between the conflicting interests of the developing countries and the pharmaceutical companies which provides specific medicines to developing countries. In spite of the importance that patent protection can have, it has still not proven to be by itself, the adequate incentive for the private sector. This is noteworthy in regards to neglected diseases, where only a small number of patients are proportionally afflicted by these rare diseases and most of them are in situated in developing countries. On this point, the issue becomes whether a system is able to combine the interests of pharmaceutical companies to keep patent protection and recover the cost of investment in producing drugs for neglected diseases, with the interests of developing countries that are incapable of paying high prices for drugs.

The next section suggests a possible solution to this question and proposes a system that can combine patent protection with price regulation and prizes. Even enforcing a policy of strict patent protection as required under the TRIPS agreement, a system of price regulation can allow developing countries access to medicine at a lower price. A system of public incentives can bridge the gap between the needs of developing countries to lower priced drugs and the necessity of pharmaceutical company to recover the cost of production and to make a profit.

### *C. Third Step: How to Get Access to Medicines? Price Regulation and Public Incentive*

In the case of the new drugs, the lack of R&D for non-profitable diseases requires new legal strategies. Patent protection does not provide by itself the adequate incentive to the R&D and remains liable for the high prices of drugs, consequently affecting access to medicine in poor countries.

Under these circumstances, the protection of IPRs has to be combined with a protection policy that can encourage pharmaceutical industries in providing medicines of the quality and quantity required by developing countries, at a lower price. This policy should allow the availability of drugs for diseases such as HIV/AIDS, malaria and tuberculosis that disproportionately affect developing countries. The strategy should stimulate R&D in the development of drugs to fight these diseases in a market that is incapable to provide adequate profits to pharmaceutical companies and that is not able to provide remarkable investments. The solution is to bridge the gap between the investments of pharmaceutical industries in producing these specific drugs and the low profits that they can expect by selling these low price drugs mainly to the markets in the developing countries.

The following section will show how this can be realized by combining patent protection with a policy of price regulation and public incentives. The first section will analyze the policy of price regulation adopted by the Council of the European Commission with regulation No 953/2003.<sup>69</sup> The second section will discuss the system of prizes as a possible public policy incentive.

#### *a. The Solution Proposed by the Regulation No 953/2003 of the Council of the European Commission: Price Regulation*

One of the solutions in providing cheap medicines in developing countries would be to follow the strategy proposed by the Council of the European Commission with the regulation No 953/2003.<sup>70</sup> The strategy pursued by the European Union (EU) to enhance access to medicines focuses on encouraging differential pricing.<sup>71</sup> To accomplish this, on May 26, 2003 the Council of the European Commission

adopted a regulation that provides for the intervention of the European Commission “to avoid trade diversion into the European Union of certain key medicines.”<sup>72</sup>

The goal of this regulation was to establish a legal instrument that encouraged the pharmaceutical industry to produce specific kinds and specific quantities of medicines that address the needs of developing countries at a lower price.<sup>73</sup> In clause 7 of its *preamble*, the regulation provides that, “there is a need to encourage the pharmaceutical producers to make pharmaceutical products available at heavily reduced prices in significantly increased volumes by ensuring through this Regulation that these products remain on those markets,<sup>74</sup> preventing re-importation into the EU and explicitly prohibiting the importation of “tiered priced products.”<sup>75</sup>

The European Council (EC) tiered pricing regulation creates a framework for exporting medicines at reduced cost from developed countries to developing countries while preventing their re-importation. The Regulation specifically states:

Price segmentation between developed country markets and the poorest developing country markets is necessary to ensure that the poorest developing countries are supplied with essential pharmaceutical products at heavily reduced prices. Therefore, these heavily reduced prices cannot be understood as a reference for the price to be paid for the same products in developed country markets.<sup>76</sup>

Moreover, the regulation No 953/2003 focuses its attention on diseases such as HIV/AIDS, TB (tuberculosis), malaria and related opportunistic infections that do not meet the profitable standard required by pharmaceutical industries.<sup>77</sup> With regard to these diseases the European Council points out that it is necessary “to reinforce safeguards against diversion of low priced pharmaceuticals destined for poor markets and prevent price erosion in developed countries markets”.<sup>78</sup> The regulation lists the developing countries that qualify for this regulation, and it states that many of the poorest countries “are in urgent need to access to affordable essential medicines for treatment of communicable diseases. These countries are heavily dependant on imports of medicines as local manufacturing is scarce.”<sup>79</sup>

In other words, to ensure that developing countries enjoy access to essential and quality medicines in adequate quantities and at a reduced price, the “tiered pricing” regulation provides the following tools:

- “price segmentation” between developed country markets and the poorest developing country markets;<sup>80</sup>
- destination for tiered priced products to specific countries;<sup>81</sup>
- application of the regulation to three specific diseases: HIV, malaria and tuberculosis;<sup>82</sup>
- comprehensive pricing system which lowers the price

of drugs and to facilitates access to affordable medicine.<sup>83</sup>

Article 3 of the regulation establishes fixed price calculations which benefit the provisions requiring that the price either be no more than 25 per cent of the weighted average ex factory price charged or no grater than 15 per cent of the manufacturer’s direct production costs.<sup>84</sup> If the medicine fulfills these pricing requirements the regulation provides a voluntary registration system.<sup>85</sup> Thereafter, re-importation of medicines approved by the Commission and registered under the system into the EU is prohibited.<sup>86</sup> The applicant in exchange receives the protection of the registered product,<sup>87</sup> that is easily identifiable as part of the tiered pricing system through a permanent logo,<sup>88</sup> and an assurance that the customs authorities in the European Community are attuned to any re-importation of its product into the European market.<sup>89</sup> The result of this legal framework, in particular in relation to HIV/AIDS, malaria and tuberculosis, should prevent the diversion of differentially priced products to high-income markets and thus encourage a supply of affordable medicines at a lower price.

A challenge to this regulation would be that this strategy is based on the voluntary adherence of the pharmaceutical industry. The absence of a coercive system which enforces this regulation could be the reason for its ineffectiveness.<sup>90</sup> In fact, the control placed on the production and the distribution channels cannot be sufficient measures that encourage participation by the pharmaceutical industry.

On the other hand, voluntary adherence could foster participation since the goal of the regulation is to protect intellectual property rights. Thus, this system appears to be compatible with the TRIPS agreement provisions.<sup>91</sup> An international regional differential pricing initiative, like the EC tiered pricing regulation, has the advantage of being predictable and subject to systematic controls. Only a limited number of drugs and diseases are targeted and a specified number of countries may take advantage of the system.<sup>92</sup> However, in order to be effective a system of price regulation should be combined with a system of public incentives that can encourage pharmaceutical companies in lowering prices of drugs as a counter effect to the public incentives. On one hand, price regulation may be capable of providing access to medicines at lower prices but, on the other, it may not be able to address *per se* adequate incentives to produce drugs for diseases like HIV/AIDS, TB and malaria listed by the European regulation.

#### *b. Public Incentive: Prizes*

Prizes could represent the public incentive tool that combined with patent protection and price regulation can supplant the incomes that pharmaceutical companies will lose in providing medicines for neglected disease in developing countries.

The Medical Innovation Prize Act of 2007 has already proposed the use of prizes as a tool to resolve the problems of the high cost and the lack of adequate R&D for “non-profitable” diseases.<sup>93</sup> The Medical Innovation Prize Act proposes to reward invention and to provide incentives for investment in R&D with a prize fund. In particular, the Prize Act proposes the elimination of the “exclusivity” conferred by a patent.<sup>94</sup> Section 5 of the Prize Act provides, in fact, that “... no person shall have the right to exclusively manufacture, distribute, sell, or use a drug, a biological product or a manufacturing process for a drug or biological product.”<sup>95</sup> Differently from the Regulation No 953/2003, this mechanism could contrast with the standards required under articles 27 and 28 of the TRIPS agreement, thereby interfering with the intellectual property rights.<sup>96</sup> In fact, not only the TRIPS agreement seems to require patent protection also for pharmaceutical products, but, in addition, this tool would conflict also with the characteristic of “exclusivity” of patents as drawn by the TRIPS agreement.<sup>97</sup>

The prize system has usually been seen as alternative to the patent system or as a counter offer to the patent’s holder for exclusive right.<sup>98</sup> Hollis proposed a “voluntary” prize mechanism that allows pharmaceutical companies to choose between patents or the prize reward system, presenting the system of prizes as an “optional reward” system to the patent.<sup>99</sup> Love and Hubbard, in contrast, have supported a “non-voluntary” prize system that can replace the marketing monopoly produced by the patent system.<sup>100</sup> Moreover, Love and Hubbard suggest “a switch for prizes to prices,” arguing that a system of prizes as an alternative to price discrimination could provide in some cases more incentives for new drugs development.<sup>101</sup>

Why could this system of prizes not be used in conjunction with the model of patent as required by the TRIPS agreement and a system of price regulation? The Prize Act recognizes that patent protection scheme is a way to promote R&D. Clause 8 of section 2 of the Prize Act states that “exclusive rights to market products are one way to reward successful product research and development, but not the only way. Prize funds are another way and have been used successfully to stimulate inventions and solutions to difficult problems.”<sup>102</sup> The *preamble* of the Prize Act also reflects this understanding. Thus, a new system of prizes, which maintains patent protection, would be perfectly compatible with the standards required by the TRIPS agreement.

The proposed prize system would not cause problems with the TRIPS agreement. Moreover, prizes would represent the incentives for pharmaceutical industries to produce those diseases fighting medicines that, for the reasons shown above, are not able to attract R&D. In fact, pharmaceutical companies could cover the cost of medicines that are *per se* not profitable through the system of prices. In order to benefit, pharmaceutical companies should accept the system of price

regulation necessary to produce specific kinds and quantity of drugs and to address these drugs specifically to the market of developing countries at a lower price.

### *c. Price Regulation and Prizes as Effect of a “Compromise”*

Why should pharmaceutical companies accept a system of price regulation and prizes? Price regulation should be the effect of a “compromise”<sup>103</sup> between patent holders and developing countries. Patent holders could maintain the control of the patent and on production of the drugs, have access to prizes and accept a system of price regulation based on the following conditions:

- supply a certain quantity and quality of medicines to an identified list of developing countries;<sup>104</sup>
- separation of the markets in developing countries from markets in developed;<sup>105</sup> and
- free circulation of the drug within the market of the developing countries indicated into the list as it were a unique market.<sup>106</sup> This provision would, in fact, avoid that a country which benefits of the lower price can export the drug to another listed country at a higher price.
- This system could benefit both developing countries and the patent holder. In fact, developing countries could benefit from the regulation of prices and the supply of medicines for diseases like HIV/AIDS, TB and malaria and secure their quality and quantity, thus satisfying their inaccessibility to medicines. In addition, patent holders could cover their investment through a system of prizes while keeping control over the patent and, consequently, the production and distribution channels of the drugs within developing countries. Moreover, maintaining the control of production and redistribution, a patent holder could significantly reduce the risk of the re-importation of drugs to the developed country’s markets avoiding a competing parallel importation.<sup>107</sup>

This article has not discussed different economic policies of price regulation and prizes. The author is aware that the proposed alternative solution to access to medicine must be to create an efficient economic equilibrium between this triple policy of patent, price and prizes in order to not transform this instrument into a tool for further enrichment of the pharmaceutical companies without any advantage for developing countries.

## **IV. Conclusion**

Compulsory licenses can be only one of the tools which enhances access to medicines in developing countries. In the case of new drugs for neglected diseases, the lack of adequate R&D requires new legal strategies to promote investment in medicines to fight HIV/AIDS, malaria and tuberculosis in developed countries who do not present profitable

markets. Pharmaceutical companies do not have incentives for producing drugs for these kinds of diseases because these drugs are needed mainly by the market of developing countries where most of the population is not able to pay high prices.

In spite of the importance that patent protection can have in a system where pharmaceutical companies represent one of the main actors, this system still has not proven to provide by itself the adequate incentive needed. This analysis has demonstrated that patent protection schemes cannot lead *per se* to develop R&D because patents are responsible for the high prices of the drugs and for affecting their availability in poor countries. The TRIPS agreement suggests that the issue of access to medicine cannot be evaluated without considering patent protection, regardless of the positive effects that patent protection may have on R&D.

This article has proposed an alternative solution capable of finding a “compromise” between the position of developing countries and pharmaceutical companies assuring specific kinds and quantities of medicines to developing countries. The alternative solution capable of addressing the double problem of “access” and “incentives” is based on combining elements the system of patent protection as drawn by the TRIPS agreement, and by incorporating elements of price regulation schemes and by awarding prizes. Even by enforcing a policy of strict patent protection as required under the TRIPS agreement, a system of price regulation would lower the price of drugs allowing developing countries access to medicine. The system of prizes would restore the private sector’s interest for the lower incomes related to the regulation of the drugs’ prices and bridge the gap between the needs of developing countries and the necessity of pharmaceutical companies to get profits by their investment.

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1 For an analysis of the WTO General Council decision and of the Doha Declaration see Parts I.C. and D.

2 See Garrett J. Hardin, *The Tragedy of the Commons*, SCIENCE, Dec. 13, 1968, at 1243.

3 See *id.*

4 *Id.* at 1244. In the context of avoiding over-exploitation of common resources, Hardin suggests that “freedom” completes the tragedy of the commons and concludes by restating Hegel’s maxim that “Freedom is the recognition of necessity.”

5 See Michael Heller & Rebecca Eisenberg, *Can Patent Deter Innovation? The Anticommons in Biomedical Research*, SCIENCE, May 1, 1998, at 698, 698-99. Applying the commons model to intellectual property, the effect is a broad dissemination and free availability of “upstream” research in the public domain that can be quickly incorporated into “downstream” products for treating diseases without any power for the inventor to

avoid the appropriation of the research.

6 See Heller & Eisenberg, *supra* note 5, at 698.

7 *Id.*

8 Michael Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 622 (1998). In his article Heller coined the phrase “tragedy of the Anticommons.” After the appearance of Hardin’s article, under a shift of privatization, the area of biomedical research shifted from the commons model to the private system. In Heller’s article, he noted that after the fall of Communism, in many Eastern Europe cities there were a lot of open-air kiosks, but also a lot of empty stores. After investigating, he concluded that because many different agencies and private parties had rights over the use of store space, it was difficult or even impossible for a startup retailer to successfully negotiate for the use of that space. Even though all the persons with ownership rights were losing money with the empty stores, and stores were in great demand, their competing interests got in the way of the effective use of space.

9 Heller & Eisenberg, *supra* note 5, at 698.

10 See *id.*

11 See *id.*

12 See, e.g., Richard P. Rozek, *The Effects of Compulsory Licensing on Innovation and Access to Health Care*, 889-896, J. WORLD INTEL. PROP., 889, 890 (2000).

13 Anna Niesporek, *Compulsory Licensing of Pharmaceutical Products & Access to Essential Medicines in Developing Countries* (2005), [http://www.diva-portal.org/diva/getDocument?urn\\_nbn\\_se\\_liu\\_diva-5488-1\\_\\_fulltext.pdf](http://www.diva-portal.org/diva/getDocument?urn_nbn_se_liu_diva-5488-1__fulltext.pdf).

14 See Ellen ‘t Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, CHI. J. INT’L L. 27, 28 (2002), who argues how the implementation of the TRIPS Agreement is expected to be the cause for further effect on drug prices, while increased R&D investment, despite higher levels of intellectual property protection, is not expected.

15 See Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C art. 8(1), Apr. 15, 1995, *available at* [http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm0\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm) (Marrakesh Agreement Establishing the World Trade Organization) [hereinafter *TRIPS Agreement*]. The TRIPS Agreement was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994 and is an international agreement, administered by the World Trade Organization (WTO), that sets down minimum standards for many forms of intellectual property (IP) regulation. The *TRIPS Agreement* introduced a coherent intellectual property law into the international trading system for the first time, including not only the regulation of different intellectual property rights, but also specific enforcement procedures, remedies, and dispute resolution procedures. For an analysis of the *TRIPS Agreement*, see generally, CARLOS M.

CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS. A COMMENTARY ON THE TRIPS AGREEMENT (2007).

16 *TRIPS Agreement*, *supra* note 15, art. 27 (1).

17 Peter Drahos, *Global Property Rights in Information: The Story of TRIPS at the GATT*, PROMETHEUS, June 1995, 6, 11. Drahos uses the term “Triumvirate” to refer to the action played by United States, Europe and Japan in order to enforce a set of minimum standard against the opposition of developing countries to strict IPRs regime. According to the author, the inclusion of TRIPS into the Uruguay Round was the result of intensive lobbying by the United States, supported by the European Union, Japan and other developed nations.

18 See Thomas W. Pogge, *Human Rights and Global Health: A Research Program*, 36 METAPHILOSOPHY 183, 197-99 (2005). Pogge argues that “participation in the imposition of social rules constitutes a human-rights violation . . . when these rules *foreseeably* and avoidably deprive human beings of secure access to the object of their human rights—only when the imposers of the rules could and should have known that these rules fail to realize human rights insofar as this is reasonably possible, could and should have known that there are feasible and practicable reforms of those rules through which a substantial portion of existing deprivations can be avoided.” From this point of view, the author moves four different objections against the international trade relationship between developed and developing countries. The first one is that people cannot waive their human rights to personal freedom, political participation, freedom of expression, or freedom from torture. The second one is that there is no democratic consent when people consent to the regime that perpetuates their deprivation. The third one is that consent is not justifiable when it was the only escape from continued torture. The last one is that consent cannot justify the severe impoverishment of children. See also Samuel Oddi, *The International Patent System and Third World Development: Reality or Myth?*, 1987 DUKE L.J. 831, 836 (1987).

19 Drahos, *supra* note 17, at 16. Drahos argues that the intellectual property story is a story of “economic coercion rather than military in kind” played by the U.S. that uses a sophisticated process of trade threats and retaliation to coerce some states into complying with its intellectual property objectives. See Duncan Kennedy, *The Three Globalizations of Law and Legal Thought: 1850-2000*, in NEW LAW AND ECONOMIC DEVELOPMENT: A CRITICAL APPRAISAL, 19, 67 (David Trubek & Alvaro Santos eds., 2006). Kennedy argues that the enforcement of intellectual property rights can be read as a reaction of developed countries “against the practices of developing countries that refuse to recognize patents and trademarks or to prevent piracy.”

20 *TRIPS Agreement*, *supra* note 15, art. 7.

21 *Id.* art. 8.

22 See *id.* art. 31. This article lists a set of restrictive conditions that must be satisfied in order to access compulsory licenses.

For an analysis of the compulsory licenses under the *TRIPS Agreement* see generally Jerome H. Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: Historical Prospective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the United States of America* (Case Study for United Nations Conference on Trade and Development (UNCTAD) & International Centre for Trade and Sustainable Development (ICTSD), UNCTAD-ICTSD Project on IPRs and Sustainable Development, Issue Paper No. 5 (2003)); see also Harvey E. Bale Jr., *The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals*, 1 J. INT’L ECON. L. 637 (1998); E. Richard Gold & Daniel K. Lam, *Balancing Trade in Patents: Public Non-Commercial Use and Compulsory Licensing*, 6 J. WORLD INTELL. PROP. 5 (2003); Richard P. Rozek & Renee L. Rainey, *Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy*, 4 J. WORLD INTELL. PROP. 463 (2001); Arvind Subramanian, *The AIDS Crisis, Differential Pricing of Drugs, and the TRIPS Agreement—Two Proposals*, 4 J. WORLD INTELL. PROP. 23 (2001).

23 Reichman & Hasenzahl, *supra* note 22, at 4.

24 See James Love, *Access to Medicine in Developing Countries—Hoping for Change*, HUFFINGTON POST, Feb. 29, 2008), [http://www.huffingtonpost.com/james-love/access-to-medicine-in-dev\\_b\\_89151.html](http://www.huffingtonpost.com/james-love/access-to-medicine-in-dev_b_89151.html) (discussing the U.S. policy against the compulsory licenses, arguing how the U.S. government has been trying to stop World Health Organization (WHO) from offering useful technical assistance on patent issue to poor countries); see also James Love, *Racist and Ignorant Reactions on Thailand Compulsory License*, HUFFINGTON POST, Jan. 25, 2007), [www.huffingtonpost.com/james-love/racist-and-ignorant-react\\_b\\_39618.html](http://www.huffingtonpost.com/james-love/racist-and-ignorant-react_b_39618.html).

25 See *id.*

26 See *id.*; see also James Love, *Brazil Puts Patients Before Patents*, HUFFINGTON POST, May 4, 2007, [http://www.huffingtonpost.com/james-love/brazil-puts-patients-befo\\_b\\_47651.html](http://www.huffingtonpost.com/james-love/brazil-puts-patients-befo_b_47651.html).

27 See *Pharmaceutical Manufacturers’ Association of South Africa v. President of the Republic of South Africa*, No. 4183/98 (Transvaal Provincial Division). The suit was addressed in February of 1998 by the South African Pharmaceutical Manufacturers Association and forty mostly multinational pharmaceutical manufactures assuming that the Amendment Act violated TRIPS and the South African Constitution. After the pressure of the presidential candidate Al Gore, at the end of 1999, the U.S. changed its policy and, in May of 2000, the drug companies dropped the case. On this point see Hoen, *supra* note 14, at 30.

28 See Reichman & Hasenzahl, *supra* note 22, at 892; see also Rozek, *supra* note 12, at 890-92 (arguing that mainly pharmaceutical companies do not support compulsory licenses because patent holders cannot keep control on production). According to Rozek, a compulsory license regime “is a policy that should be used rarely, if at all [because] the instrument

of license can be useful, in particular to realize transfer of technology, but only if based on the voluntary negotiation.” *Id.*

29 See Rozek & Rainey, *supra* note 22, at 464 (arguing that compulsory licenses may encourage a culture of widespread illegal copying of patented products in developed countries markets).

30 See Rozek, *supra* note 12, at 890-91 (arguing that the use of medicines produced in those developing countries without adequate manufacture capability in lack of adequate procedure of control would be “ineffective, wasteful and harmful, because reduced capability to produce the drug means also less quality of the produced medicines”).

31 See FREDERICK M. ABBOTT, QUAKER UNITED NATIONS OFFICE, COMPULSORY LICENSING FOR PUBLIC HEALTH NEEDS: THE TRIPS AGREEMENT AT THE WTO AFTER THE DOHA DECLARATION ON PUBLIC HEALTH (2002), <http://www.cptech.org/ip/health/cl/quano-op9.pdf>.

32 See James Love, Knowledge Ecology International (KEI) Statement on Thailand Compulsory Licenses, Jan. 25, 2007, <http://www.cptech.org/ip/health/c/thailand/kei-thaicl-statement.html>.

33 Press Release, World Trade Organization, Doha Declaration on the TRIPS Agreement and Public Health (Nov. 14, 2001) available at [http://www.healthgap.org/press\\_releases/01/111401\\_WTO\\_TRIPS\\_DECL.html](http://www.healthgap.org/press_releases/01/111401_WTO_TRIPS_DECL.html) [hereinafter *Doha Declaration*]. For an analysis of the history of the Doha Declaration see Ellen ‘t Hoen, *supra* note 14, at 27; see also, CARLOS M. CORREA, WORLD TRADE ORGANIZATION, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH (2002) available at [http://www.who.int/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf](http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf).

34 *Doha Declaration, supra* note 33, para. 1.

35 See *Id.* para. 4 (“We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ rights to protect public health and, in particular, to promote access to medicines for all.”).

36 See *Id.* para. 6 (“We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”); see generally Abbott, *supra* note 31; see also Subramanian, *supra* note 22, at 325 (arguing that compulsory licensing is a “feasible option for large, technologically advanced, developing countries that can easily produce the patented drug, but it is less feasible for the smaller African

Countries, which would have to import drugs”).

37 *Doha Declaration, supra* note 33, para. 6.

38 *Id.*

39 World Trade Organization, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, WT/L/540 (2003), available at [http://www.wto.org/english/tratop\\_e/trips\\_e/implement\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implement_para6_e.htm). [hereinafter *Implementation of Paragraph 6*]. For an analysis of the decision see CARLOS CORREA, WORLD TRADE ORGANIZATION, IMPLEMENTATION OF THE WTO GENERAL COUNCIL DECISION ON PARAGRAPH 6 OF THE TRIPS AGREEMENT AND PUBLIC HEALTH (2004), [https://www.who.int/medicines/areas/policy/WTO\\_DOHA\\_DecisionPara6final.pdf](https://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf).

40 *TRIPS Agreement, supra* note 15, art. 31(f).

41 *Id.*

42 *Implementation of Paragraph 6, supra* note 39.

43 *Id.* para. 2.

44 *Id.* para. 3.

45 *Id.* para. 4.

46 *Id.* para. 5.

47 Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?* 7 J. INT’L ECON. L. 73, 78 (2004); see Eric Noehrenberg, *TRIPS, the Doha Declaration and Public Health*, 6 J. WORLD INTELL. PROP. 379, 380 (2003) (underlining that article 31 of the *TRIPS Agreement* requires member states to follow a previously specified process of negotiation in order to get the license and, in most cases, poor countries are not able to direct a successful negotiation that can lead to an advantageous deal with the patent holder on “reasonable terms” and in a “reasonable time).

48 The list of low income countries that have issue a compulsory license is available at <http://www.cptech.org/ip/health/cl/recent-examples.html>.

49 See Jacques H. Bourgeois & Thaddeus Burns, *Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health: The Waiver Solution*, 5 J. WORLD INTELL. PROP. 838, 839 (2002); see also Rozek, *supra* note 12, at 896; see also Rozek & Rainey, *supra* note 22, at 471.

50 The WHO has compiled a list of over 300 medicines that are considered essential for every country in the world. The “Model Essential Medicines List” (EML) is available at <http://www.who.int>. This list represents a model for determining which drugs are internationally recognized as being needed to address the health care needs of developing countries.

51 Amir Attaran, *How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries*, 23 Health Affairs 155, 155-59 (2004) (concluding that “patents cannot cause essential drugs to be inaccessible in many developing countries because they does not exist 98.6 percent of time.”).

52 Eric Noehrenberg, *supra* note 47, at 381.

53 Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constraint Access to AIDS Treatment in Africa?*, 286 J. AM. MEDICAL A. (2001) (arguing that very poor, low-income developing countries, predominantly in Africa, may spend \$2 or less per person annually on drugs, therefore patents are not a significant barrier to the treatment of HIV/AIDS in Africa, because there are a lot of more significant factors such as poverty, tariffs and sales taxes and a lack of sufficient international financial aid to fund antiretroviral treatment).

54 Bourgeois & Burns, *supra* note 49, at 839; see Rozek, *supra* note 12, at 893 (finding that the idea that IPRs increase the price of products becomes in effect a “misconception” because “IPRs more than to create a monopoly, confer to the inventor only a limited exclusive right”). Consequently, there is no relationship between patent protection and the increase of prices and IPRs cannot be considered liable for the high prices of drugs because the high prices depend on the fact that IPR law remains sometimes ineffective for several years and that governments do not provide adequate instruments to allow free competition. *Id.*

55 HENRY GRABOWSKI, FEDERAL RESERVE BANK OF DALLAS, PATENTS AND NEW PRODUCT DEVELOPMENT IN THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES (2002), <http://www.dallasfed.org/research/pubs/science/grabowski.pdf>. (arguing that only twenty percent of the compounds entering clinical trials survive the development process and gain Food and Drug Administration (FDA) approval.

56 See James Love & Tim Hubbard, *The Big Idea: Prizes to Stimulate R&D for New Medicines*, 82 CHI-KENT L. REV. 1519, 1523 (2007).

57 There are other diseases that have been overlooked in terms of research. For example, the African trypanosomiasis and leishmaniasis can be fatal if untreated, as can chagas diseases, which affects people in central and South America, or diseases such as filariasis, dengue and schistosomiasis. For an overview of this topic see PARLIAMENTARY OFFICE OF SCIENCE AND TECHNOLOGY, FIGHTING DISEASES OF DEVELOPING COUNTRIES (2005), <http://www.parliament.uk/documents/upload/postpn241.pdf>.

58 The reference in this case is in particular to tropical diseases such as, *inter alia*, leishmaniasis, lymphatic filariasis, Chagas' disease, Guinea worm, onchocerciasis and schistosomiasis. According to the 2002 World Health Organization's World Health Report, tropical diseases accounted for only 0.5 percent of deaths in high-mortality poor countries and only 0.3 per cent of deaths in low-mortality poor countries.

59 Less than ten percent of the world's biomedical research funds are dedicated to problems dealing ninety percent of the world's burden of disease. From 1999 to 2000, in neglected diseases only eighteen R&D projects were clinical development compared to the 2100 compounds for all other diseases. Between 1975

and 2004, among the 1556 new molecules of drugs marketed in the world, only 21 were intended for the neglected diseases (eight for malaria, three for tuberculosis and only ten for the whole set of most neglected diseases). Another study found that, of the 1393 new chemical entities marketed between 1975 and 1999, only sixteen were for tropical diseases and tuberculosis, yielding a thirteen-fold greater chance for a drug to be marketed for central-nervous-system disorders or cancer than for a neglected disease. For an overview of this data see Abdesslam Boutayeb, *Developing Countries and Neglected Diseases: Challenges and Perspectives*, INTERNATIONAL JOURNAL FOR EQUITY IN HEALTH, Nov. 26, 2007, [www.equityhealthj.com/content/pdf/1475-9276-6-20.pdf](http://www.equityhealthj.com/content/pdf/1475-9276-6-20.pdf); see also Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 356 THE LANCET 2188, 2188 (2002), available at [http://fieldresearch.msf.org/msf/bitstream/101441/28441/1/Access\\_Trouiller\\_2002.pdf](http://fieldresearch.msf.org/msf/bitstream/101441/28441/1/Access_Trouiller_2002.pdf);

60 Bourgeois & Burns, *supra* note 49, at 838 (showing how prices can be a barrier to access but there are clearly others factors that can effect access to medicine because “developing countries need their local and national government to take more responsibility to obtain needed cooperation and build infrastructure”). Consequently, local political commitment, strong administrative support, and adequate, committed human resources are needed. *Id.*

61 See *The Crisis of Neglected Diseases: Developing Treatments and Ensuring Access*, March 12-14, 2002, Workshop and Conference, New York City, available at <http://www.accessmed-msf.org/resources/key-publications/key-publication-detail/article/the-crisis-of-neglected-diseases-developing-treatments-and-ensuring-access-conference-report/>. This article underlines how the category of neglected diseases can be divided into two sub-categories. On one hand, there are diseases like malaria and tuberculosis that are still able to attract some private R&D. On the other hand, there are other diseases such as leishmaniasis, human African trypanosomiasis, Chagas disease, and lymphatic filariasis that are completely unaddressed. One of the main challenges is that this system represents an effect of failure of any form of public policy because the development process of these kinds of diseases belongs exclusively to the private sector.

62 See *Fighting Diseases of Developing Countries*, *supra* note 57 (discussing how many drugs for neglected diseases in developing countries are toxic and inadequate and many organisms that cause these diseases are becoming resistant to treatment).

63 See Henry Grabowski, Duke University, *Patents, Innovation and Access to New Pharmaceuticals* (2002), [http://levine.sscnet.ucla.edu/archive/grabow-patents\\_innov.pdf](http://levine.sscnet.ucla.edu/archive/grabow-patents_innov.pdf). (arguing how the problem of neglected diseases is substantially similar to the case of orphan drugs where a small numbers of patients are afflicted with rare diseases and those patients are

“uneconomical”)

64 *The Crisis of Neglected Diseases*, *supra* note 61.

65 PATRICIA M. DANZON & ERIC KEUFFEL, UNIVERSITY OF PENNSYLVANIA, REGULATION OF THE PHARMACEUTICAL-BIOTECHNOLOGY INDUSTRY, (2005), [http://www.nber.org/books\\_in\\_progress/econ-reg/danzon-keuffel9-14-07.pdf](http://www.nber.org/books_in_progress/econ-reg/danzon-keuffel9-14-07.pdf).

66 CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 27 (2000); *contra* Rozek, *supra* note 12, at 894 (arguing that there is a strong positive association between countries, IP protection and their R&D investment expenditures because patents proved to be an adequate system to allow innovation and to increase production of drugs as well as to develop local industries and research, attracting foreign investment). For an analysis of the relationship between patent protection, foreign direct investment and technology transfer *see also* Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 Duke J. Comp. & Int'l L. 109 (1998).

67 Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, *supra* note 55, at 88.

68 *See* Grabowski, *Patents, Innovation and access to New Pharmaceuticals*, *supra* note 63, at 3.

69 Council Regulation (EC) 953/2003, To Avoid Trade Diversion into the European Union of Certain Key Medicines, 2003 O.J. (L 135) 5-11, available at [http://trade.ec.europa.eu/antitradediversion\\_html/en.pdf](http://trade.ec.europa.eu/antitradediversion_html/en.pdf). [hereinafter *Regulation on Price Regulation*]. For an analysis of the Regulation *see generally* Kerry Williams, *Pharmaceutical Price Regulation*, 23 SOUTH AFRICAN J. HUMAN RIGHTS 1 (2007), available at <http://www.law.wits.ac.za/sajhr/Williams.pdf>; *see generally* KATHARINA GAMHARTER, ACCESS TO AFFORDABLE MEDICINES. DEVELOPING RESPONSES UNDER THE TRIPS AGREEMENT AND EC LAW (2004).

70 *Regulation on Price Regulation*, *supra* note 69. The regulation, entered into force on June 4, 2003, represents the answer of the European Commission to the pharmaceutical industry's demand to provide instruments in order to avoid trade diversion into developed countries of certain key medicines. Before Regulation 953/2003 other instruments have been provided by the European Union such as Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, available at <http://www.emea.europa.eu/pdfs/human/pmf/2001-83-EC.pdf>. This Directive has subsequently been amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004, available at <http://www.emea.europa.eu/pdfs/human/pmf/2001-83-EC.pdf>. Regulation 953/2005 follows the “Program for Action” of February 2001 of the

European Commission entitled “Accelerated Action on HIV/AIDS, Malaria and Tuberculosis in the Context of Poverty Reduction.” The program addresses the issue of the three major diseases in developing countries in order to develop a policy focused on R&D. It has to be pointed that, on May 17, 2006, the European Commission has enacted the Regulation (EC) 816/2006 of the European Parliament and of the Council “On Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems” 2006 O.J. (L 157), 1-7, available at [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_157/l\\_15720060609en00010007.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609en00010007.pdf). This regulation, concerning the implementation of the WTO decision of August 30, 2003,

71 *See* Williams, *supra* note 69, at 28 (defining the solution proposed by Regulation (EC) 953/2003 as a close approximation of the differential pricing models). For an overview of the different models of price regulations and their effects *see generally* PATRICIA M. DANZON, PHARMACEUTICAL PRICE REGULATION. NATIONAL POLICIES VERSUS GLOBAL INTERESTS (1997).

72 *Regulation on Price Regulation*, *supra* note 69.

73 *See* Williams, *supra* note 69, at 28-31.

74 *Id.* cl. 7 of the *Preamble*.

75 *Id.* cl. 9 of the *Preamble*, arts. 1 (2)(a), 2 (1).

76 *Id.* cl. 5 of the *Preamble*.

77 *Id.* cl. 1 of the *Preamble* and Annex IV.

78 *Id.* cl. 2 of the *Preamble*.

79 *Id.* cl. 4 of the *Preamble*.

80 *Id.* cl. 5 of the *Preamble*.

81 The regulation (Annex II) provides a list of seventy-six developing countries that should benefit from this regulation.

82 *Regulation on Price Regulation*, *supra* note 69, cl. 2 of the *Preamble* and Annex IV.

83 *Id.* art. 3.

84 *Id.*

85 *Id.* art. 4.

86 *Id.* art. 1 (2)(a), 2(1).

87 *Id.* art. 6.

88 *Id.* art. 7.

89 *Id.* art. 8.

90 THE COMMISSION STAFF WORKING DOCUMENT, ANNUAL REPORT 2006/2007 ON THE APPLICATION OF COUNCIL REGULATION (EC) No 953/2003 OF 26 MAY 2003 TO AVOID TRADE DIVERSION INTO THE EUROPEAN UNION OF CERTAIN KEY MEDICINES (2007), [http://trade.ec.europa.eu/antitradediversion\\_html/report2007.pdf](http://trade.ec.europa.eu/antitradediversion_html/report2007.pdf) (addressing this issue, has arguing that “once more funding and better distribution under strengthened health systems in developing countries are in place, sales volumes will increase”).

91 *See* Williams, *supra* note 69, at 30.

92 *Id.* at 28-31.

93 Medical Innovation Prize Act of 2007, S. 2210, 110<sup>th</sup>

Cong. (2007), available at <http://www.ony.unu.edu/seminars/2008/march20merit/S2210.Medical.Innovation.Prize.Act.pdf> [hereinafter *Prize Act*].

94 *Id.* § 5.

95 *Id.*

96 It is questionable that the *TRIPS Agreement* can contain flexibilities that would allow excluding patents for pharmaceutical products, considering the broad disposition of article 27 that provides “patents shall be available for *any inventions*, whether products or processes, in *all fields of technology*, provided that they are new, involve an inventive step and are capable of industrial application” (emphasis added).

97 See *TRIPS Agreement*, *supra* note 15, art. 28 (1).

98 See Joseph E. Stiglitz, *Scrooge and Intellectual property Rights. A Medical Prize Fund Could Improve the Financing of Drug Innovations*, 333 *BRITISH MEDICAL JOURNAL* 1279, 1279-80 (2006) (proposing the prize fund as a solution to promote innovation in crucial diseases such as malaria, HIV and tuberculosis); see also Love & Hubbard, *supra* note 64, at 1520 (arguing that the way to reform the way for R&D is in the “powerful idea that rather than give drug developers the exclusive rights to sell products, award . . . innovators money”). For an overview of the prizes programs see generally KNOWLEDGE ECOLOGY INTERNATIONAL, *SELECTED INNOVATION PRIZES AND REWARD PROGRAMS* (2008), [http://www.keionline.org/misc-docs/research\\_notes/kei\\_rn\\_2008\\_1.pdf](http://www.keionline.org/misc-docs/research_notes/kei_rn_2008_1.pdf).

99 AIDAN HOLLIS, *INSTITUTE OF HEALTH ECONOMICS, OPTIONAL REWARDS FOR NEW DRUGS FOR DEVELOPING COUNTRIES* 4 (2005), <http://www.who.int/intellectualproperty/submissions/Submissions.AidanHollis.pdf>.

100 Love & Hubbard, *supra* note 56, at 1535.

101 *Id.* at 1550; see also Stiglitz, *supra* note 98 (arguing that the prize fund should complement the patent system, which would continue to play a part for applications for which no one offers a prize).

102 *Prize Act*, *supra* note 93, § 2 (10).

103 See GUSTAVO GHIDINI, *ASPEN INSTITUTE ITALIA, L'ACCESSO DEI PAESI IN VIA DI SVILUPPO AI FARMACI ESSENZIALI*, [http://www.aspeninstitute.it/icons/imgAspen/pdf/news/Africa/ghidini\\_it.pdf](http://www.aspeninstitute.it/icons/imgAspen/pdf/news/Africa/ghidini_it.pdf) (identifying the combined system of price regulation and patent protection as an effect of the compromise that allows patent holders to keep the control of drugs).

104 *Id.*

105 *Id.*

106 *Id.*

107 See Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, *supra* note 63, at 12 (discussing that the parallel exportation of drugs from low to high-income countries could undermine the willingness of pharmaceutical firms to continue to provide these products at low price, since

this kind of arbitrage would adversely affect the return on their investment in major markets). See also Rozek, *supra* note 12, at 889.