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Patents and Pharmaceutical R&D: Consolidating Private–Public Partnership Approach to Global Public Health Crises

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Intellectual property (IP) is a reward and incentive market-driven mechanism for fostering innovation and creativity. The underlying, but disputed, assumption to this logic is that without IP, the wheel of innovation and inventiveness may grind to a halt or spin at a lower and unhelpful pace. This conventional justification of IP enjoys, perhaps, greater empirical credibility with the patent regime than with other regimes. Despite the inconclusive role of patents as a stimulant for research and development (R&D), special exception is given to patent's positive impact on innovation and inventiveness in the pharmaceutical sector. This article focuses on that sector and links the palpable disconnect between the current pharmaceutical R&D agenda and global public health crises, especially access to drugs for needy populations, to a flaw in the reward and incentive theory of the patent system. It proposes a creative access model to the benefits of pharmaceutical research by pointing in the direction of a global treaty to empower and institutionalize private–public partnerships in health care provisions. Such a regime would restore balance in the global IP system that presently undermines the public-regarding considerations in IP jurisprudence.

Keywords pharmaceutical patents research and development; intellectual property; access to medicine; global public health

Among the competing and sometimes overlapping justifications for intellectual property (IP) is the argument premised on reward and incentive.[1] At the center of this reasoning is that IP regimes, including those at the core and periphery, are incentive mechanisms directed at rewarding innovation and creative endeavors. The logic of this justification and, indeed, other justifications for IP is that rewarding innovators and creators alike will foster innovation and will guarantee a healthy public domain (Drahos, 1996). The latter is like the water in the swimming pool of creativity. Without a robust public domain, the pool of creativity will dry and humanity will be worse off. This justification for IP is strong and persuasive in terms of its logic. It is also compelling in regard to its appeal to common sense. But it is highly problematic in terms of its underlying assumptions and biases (Oguamanam, 2009).

First, there is a presumption that without IP-forms of reward and incentives, the wheel of creativity will falter or ultimately grind to a halt. Second, the reward and incentive narrative of IP is premised on the primacy of economic and profit considerations as the fundamental drivers, promoters and determinants of innovation and creativity. Despite the reservations against it, the preeminence of the reward and incentive narrative is palpable in relation to patents, perhaps, more than other regimes of intellectual property rights (IPRs). The credibility of this justification for IP is stronger in the specific arena of pharmaceutical research and development (R&D) and innovation than in any other industrial category (Barton, 2003; Mgbeoji, 2006).

This article focuses on the patent regime in the pharmaceutical sector to interrogate the reward and incentive justification of IP. It explores the direction in which the patent regime promotes pharmaceutical R&D and innovation. The article builds on the backdrop of identified misalignment in the focus of pharmaceutical R&D and the public health crises in developing countries as evidenced, in part, by access freeze to essential drugs and pharmaceutical R&D's lack of interest in diseases endemic to less privileged and poor segments of the global population (Oxfam, 2008).[2] I reflect on the symbolic implication of the emerging interventionist role of non-market actors in filling the gaps in the global public health system in regard to public health and the access to essential drugs crises. I propose a vision of patent-based pharmaceutical R&D and innovation system that is driven by global need and demand—and backed by a treaty on pharmaceutical R&D that provides legal framework for the non-market actors while affirming the balancing role of IP in negotiating social relations.

Patent and Pharmaceutical R&D

The pharmaceutical sector is research-driven and research intensive. As the engine of health services delivery and general health promotion, it is also strategic for the overall economic well-being of society. As an export-based and transnational industry, the pharmaceutical sector is equally strategic in economic competitiveness and trade relations among states. R&D in the pharmaceutical sector, perhaps, compares to no other such experience in any readily identifiable industrial sectors. Pharmaceutical R&D involves broad and concerted disciplinary collaborations. The process of innovation in the pharmaceutical sector is quite expensive, traversing upstream activities in the nature of platform research to downstream activities, including clinical trials, regulatory approvals, drug manufacturing, marketing, branding and other capital-intensive promotional activities. Industry estimates, albeit contested, of the cost of bringing a new drug into the market is in the region of the US$800 million mark.[3] Also, the elongated time frame for introducing a new drug into the market is estimated, on the average, at between a 10- and 15-year period (DiMasi, 2001a, pp. 286–96).

The research-intensive nature is an inherent feature of the pharmaceutical enterprise. There is no end yet to the diseases that afflict humanity. New diseases continue to be discovered. Known diseases mutate, finding their way around drugs. All of these necessitate inquiry into new drugs and new methods of treatment. Even when cures are found, the imperative for a more economic approach to disease control as well as for the mitigation, or elimination of the side effects of existing drugs compel a continuing quest for pharmaceutical innovation. In addition, changing life patterns, environmental dynamics, demographics, social dynamics (e.g. globalization), technologies (e.g. digitization and biotechnologies) and epistemic interactions (e.g. between formal science and local knowledge) are factors that warrant inquiry into new therapeutic regimens (Oguamanam, 2006). In the contemporary epoch of biotechnologies, genomics and proteomics research, the imperative for pharmaceutical innovations continues to re-assert itself in palpable terms.

Despite the capital-intensive and complex landscape for pharmaceutical innovation or R&D, stakeholders argue that there is not much guarantee for profitability of investment in breakthrough drugs.[4] For a number of reasons this appears to be true. First, if there is no tight control or legal assurance regarding the exclusivity of both process and resulting product; it is quite easy for second comers or free riders to replicate the breakthrough drugs in a generic version. For instance, with the right information, a second comer can put into the market within a period of about six months a product that took over ten years of pharmaceutical R&D.[5]

Second, even if there is legal assurance of exclusivity for the manufacturer of a breakthrough drug, such an assurance does not necessarily guarantee market exclusivity. For example, it does not foreclose the entrance of follow-on drugs in the same class, often derogatorily referred to as ''me too drugs''. Although the latter term is now used in different ways, according to DiMasi and Paquette (2004), it refers to ''a new drug entrant to a therapeutic class that has already been defined by a separate drug entity that was first in the class to obtain a regulatory approval for marketing''.

It needs to be mentioned that unlike generic drugs, follow-on drugs can enter the market during the life of the patent on breakthrough drugs (Jaffe and Lerner, 2004, p. 11; Mgbeoji, 2006, pp. 21–2). This is hardly an aberration. Essentially, follow-on drugs, even though approved for a class with an existing breakthrough drug, are not in all material terms the same as breakthrough drugs in the same therapeutic class. They bring additional values worthy of patent protection. For example, as an added benefit, they may involve a simplified and cost-effective delivery or dosage regimen; they may also target a specific population group hitherto vulnerable to extreme side effects of a breakthrough drug in the same class. They assist in making drug prices competitive. Generally, they tend to represent viable alternatives to breakthrough drugs capitalizing on the latter's shortcomings.

In addition, research on follow-on drugs often starts at the same time or even earlier than the research that yielded a breakthrough drug in the same class. So, the entry date of a breakthrough drug in a class is neither indicative of priority of research initiative nor a warrant for patent or market exclusivity in the class. Despite the added social benefits of follow-on or me too drugs, viewed only from the prism of breakthrough drug manufacturer, the economics of multiple drugs in one class is not good for investment in pharmaceutical R&D.

Third, in addition to its expensive nature and elongated duration, pharmaceutical R&D is a particularly risky venture from both an investment and a health perspective (DiMasi, 2001b). In regard to the former, apprehension about drug failure is a constant cause for worry. A combination of scientific and economic reasons, not to mention safety considerations, accounts for high failure rates for new drugs. This can happen at any stage in the drug development process (Stein, 2006). In any event, when drug failure happens or when drug development research is terminated prematurely, this underscores the risky and expensive nature of the economics of pharmaceutical R&D.[6]

The three considerations enumerated above combine with others outside the scope of this article to emphasize the unique nature of pharmaceutical R&D and the process of innovation around new drugs. Given its unique nature, it is often argued that without a strong patent protection, innovation in the pharmaceutical sector would be difficult to sustain. Of all regimes of IP, patent is the most relevant to pharmaceutical research both in regard to the subject matter of pharmaceutical innovation and in consideration to the imperative in that industry for a stronger and more exclusive protective regime. Similarly, of all the alternatives and competing mechanisms for rewarding innovation in the pharmaceutical sector, none appears to enjoy serious patronage in comparison with the patent regime.[7]

For many pharmaceutical industry advocates, the patent regime is not entirely satisfactory as a guarantor of risk capital for pharmaceutical innovation. They have continued to push for longer patent terms to leverage market competition in the industry and to delay the entrance of generic drug makers to the market.[8] They are unrelenting in their campaign for proprietary protection of ancillary information and regulatory data generated from downstream protocol for the approval of new drugs.[9] Also, they have sought additional rights and privileges as condition precedent for conducting R&D in orphan diseases.[10] In all of these and many more counts they have been immensely successful, as we demonstrate later. Indeed, today the only significant reward and

incentive mechanism in pharmaceutical innovation is patent-based pharmaceutical R&D. In relation to alternative schemes to encourage innovation, the patent system has endured as a resilient mechanism (Mossoff, 2001). For instance, an alternative scheme such as the parliament-backed prize system did not seem to have quite survived its tainted history on the basis of justified skepticism over government's ability to redeem its commitment once an invention was made (Jaffe and Lerner, 2004, p. 85). Not to mention the politics of resolving multiple claims to prize entitlements. As persuasive as the claims of its advocates may be, it requires examining in what direction patent has facilitated innovation and inventiveness in the pharmaceutical sector. To do that, we begin by exploring the global landscape for patent-based pharmaceutical R&D.

The Global Landscape for Patent-Based Pharmaceutical R&D

The world is in a dire public health crisis. And the international community is not insensitive to this problem, or so it seems. Global awareness of the public health crisis of our time and public health advocacy has heightened in diverse fora among variegated combinations of stakeholders since the 1990s.[11] There is no scarcity of symbolic illustrations of inter-linked global responses to the extant public health challenges. One such example will be adequate for now. In 2000, the 189 member states of the United Nations signed the UN Millennium Declaration. The Declaration provided the bases for eight Millennium Development Goals (MDGs) for development and poverty eradication (United Nations Development Programme, 2008). It is instructive that three to five of the eight MDGs focus directly or indirectly on health inequality in regard to developing countries. Specifically, they highlight the targeted reduction, by 2015, of child mortality, improvement of maternal health and combating HIV/AIDS, malaria and other tropical diseases that afflict the world's poor (Travis *et al*., 2004).

The emphasis on health of the poor and vulnerable in developing countries in MDGs reflects the general lack of access to health care delivery and essential medicines for over 90% of the global population. Less than 10% of global spending on health R&D is applied to diseases that mainly afflict the poorest 90% of the world population, a statistic which analysts deride as the "10/90 [health] gap" (Oxfam, 2008; Torreele *et al*., 2004; World Health Organization [WHO], 2006a; compare Pogge, 2005).[12] Similarly, according to a 2004 study report, "[o]f the 1393 new medicines marketed between 1975 and 1999, less than 1% are destined to treat tropical diseases which are responsible for almost 10% of global disease burden" (Torreele *et al*., 2004, p. 6). According to Isabel Hilton, "[o]f the thousands of new compounds drug companies have brought to the market in recent years, fewer than 1% are for tropical diseases" (Hilton, 2000). The 2004 report also found that in 2000,

> [O]ver 17.7 million people died from communicable diseases and nutritional deficiencies, which represents one third of the total deaths in the world. The large majority of these people live in the third world countries. Some of these diseases could be preventable and/or curable with existing drugs, but others have no treatment available (Torreele *et al*., 2004, p. 8).

Overall, the "R&D for neglected tropical diseases receives only $1 of every $100,000 spent worldwide on biomedical research and product development" (Oxfam, 2008, p. 1).

These statistics may attract skepticism for one reason or another. However, literatures on global public health are unequivocal regarding the misalignment of pharmaceutical R&D and global health needs of 90% of the global population (Abbott and Reichman, 2007; Drahos and Mayne, 2002; Lim, 2001; Oriola, 2009; Portman, 2003). This trend calls to question the impact of

patent-based pharmaceutical R&D on global health. From the foregoing state of affairs, it is plausible that the patent system may not have delivered on its promise, that is provision of reward and incentive to secure or facilitate inventiveness or innovation for the ultimate benefit of humankind. Despite the rapport between the patent system and the pharmaceutical industry, 90% of the global population has yet to access the benefits of innovations in the pharmaceutical arena. Put in a slightly different way, pharmaceutical R&D has as yet to find sufficient motivation to realistically address the health challenges of over 90% of the global population. We will turn to the reward and incentive theory of patent for insight into the possible basis for this glaring lack of need-based approach to pharmaceutical R&D and innovation.

In recent times, patent-based innovation in pharmaceutical R&D has been on the increase.[13] According to DiMasi and Paquette, technological advances in basic biomedical sciences, the growth of the biotechnology sector and the emergence of scientific networks resulting in the expansion of scientific opportunities combine to foster greater innovation in patent-based pharmaceutical R&D (2004, p. 11). Traditional pharmaceutical companies have increased R&D spending and have taken advantage of the connectedness of scientific networks and expansion of research opportunities to transition "from random screening toward a more targeted rational drug design approach" (2004, p. 11). Taking recent advances in personalized medicine, genomics and the burgeoning sub-industrial sector in pharmacogenomics as an example, there is hardly a doubt that pharmaceutical R&D is alive, but it may not be well.

As already noted, the R&D in the pharmaceutical sector caters to the needs of 10% of the world's global population, the world's wealthiest (Oxfam, 2008; Torreele *et al*., 2004). The reason for this is not necessarily because of the concentration of pharmaceutical corporations in the industrialized or developed countries. Indeed, the extant globalized economic order has overridden any spatial barriers to trade. Rather, it is because the 10% has the ability to pay for the cost of new drugs as compared with the neglected 90% (Oxfam, 2008; Torreele *et al*., 2004). Patent is the guarantor for profitability of new R&D products. And the priority of pharmaceutical companies is to seek a more efficient and effective way of recouping their investment dollar within the shortest possible time (Pugatch, 2004). Thus, a critical target of pharmaceutical companies is to match need with affordability (Torreele *et al*., 2004). It is a mindset that questions the value of a need when the needy can ill afford what is needed. Here, there is an unfortunate separation between need and market (Drahos and Braithwaite, 2003, pp. 167–8).

Giving an insight into the psychology of the pharmaceutical establishment, Roy Vagelos, a former CEO of Merck, was quoted as saying, "[a] corporation with stockholders [Merck] can't stoke up a laboratory that will focus on Third World diseases because it will go broke. That's a social problem and industry should not be expected to solve it" (Silverstein, 1999).[14] Similarly, his Novartis counterpart notes that "we have no model which would meet the need for new drugs [for the poor] in a sustainable way . . . you can't expect for profit organizations to do this on a large scale".[15] As a market-based incentive, pharmaceutical patents do not cater to the health needs of poor people in developing countries.[16] According to the Report of Working Group (2) of the WHO Commission on Macroeconomics and Health, chaired by Richard G. A. Feachem and Jeffrey D. Sachs, health needs of the poor in developing countries are "public goods, which are types of goods that markets undersupply because market-based incentives [e.g. IP/patents] are not adequate" (WHO, 2002). They observe that many global public goods would need to be provided by concerted international initiatives "since national governments acting individually lack the incentive to provide such efforts at sufficient level for global wellbeing" (WHO, 2002).

Echoing the same sentiments from a more critical perspective than the Feachem and Sachs Report, Drahos and Braithwaite identify knowledge as a public good that ought to be accessible by

all. They blame IP for robbing "much knowledge of its public-good qualities" and creating avoidable scarcity in a manner that aggravates the needs of the world's poor. In their words, "when knowledge becomes a private good to be traded in the markets the demands of many paradoxically go unmet. Patent-based R&D is not responsive to demand, but to ability to pay" (Drahos and Braithwaite, 2003, pp. 167–8).[17] In making strategic commercial decisions regarding the direction of patent-based R&D, pharmaceutical companies undermine the interest and needs of 90% of the global population because of artificial dichotomy between market and need.

The neglect of the health needs of the 90% of the global population and the apparent disconnect in patent-based pharmaceutical R&D between need and market is instructive. It shows that the impact of the reward and incentive narrative of the patent system on promotion of inventiveness and innovation is, like the overall market economic system, unable to optimally extend the benefits of innovation to the most needy. Put differently, as a reward and incentive approach to innovation, patent-based pharmaceutical R&D does not even push or explore the frontiers of innovation to accommodate needs of the most vulnerable.[18] It is then tenable that as against the promotion of inventiveness and innovation, in the pharmaceutical context, what appears more convincing is the link between patent and the commercialization of products of pharmaceutical R&D (Oguamanam, 2009). Given the capital-intensive nature of pharmaceutical R&D, patent provides investors and inventors alike much needed comfort to invest risk capital and genius in the pursuit of innovation.[19]

Just two convenient examples demonstrate the skewed nature and logic of the patent-driven pharmaceutical R&D agenda. First, Aventis (now Sanofi-Aventis) was the original producer of the only safe medicine that treated the usually deadly late stage of sleeping sickness (Shah, 2007), a.k.a. Human African Trypanosomiasis (HAT).[20] The company stopped making the drug in 1995 because it was not profitable. However, in 2000, Bristol Myers Squibb under license from Aventis found a new use or application for the drug, namely as an ingredient in a hair removing cream, a product which was successful in developed countries (Torreele *et al.*, 2004). According to Anup Shah, Aventis was pressured, following the backlash of legal action against South Africa by 39 pharmaceutical companies on the former's compulsory license regime for AIDS drugs (Gathii, 2002; Mirabile, 2002), to donate the drug to the WHO and to commit research funds and treatment programs for sleeping sickness. Meanwhile, the lesson is not lost that pharmaceutical companies would prefer to invest in a hair removal cream where there is a viable market as opposed to investing in a cure for a disease that "affects 500,000 in 36 African countries" not counting 6 million others at the risk of its spread (Shah, 2007). This is, simply, because the need does not match the market.

Second, the average annual per capita health expenditure in sub-Saharan Africa is said to be US$6.00 (Trouiller *et al.*, 2002, pp. 2188–94) whereas, in all the Organization for Economic Cooperation and Development (OECD) countries that figure is well above US$2,000 (OECD, 2008). In the United States, it is over US$3,000 (OECD, 2008). In some cases, the long-term treatment of an orphan disease sufferer in a developed country costs about US$150,000.[21] While per capita health expenditure is not indicative of system efficiency, these figures only demonstrate the unattractive nature of developing countries as a viable target market for pharmaceutical R&D.

Another example of the dichotomous relationship between patent-based pharmaceutical R&D and global health needs is evident in the phenomenon of follow-on drugs, mentioned earlier. According to a study published in 2004, the United States recorded a sharp increase in the rate of entry for competitive drugs resulting in a significant drop in market exclusivity for breakthrough drugs (DiMasi and Paquette, 2004, p. 11). The study found that the mean length of market exclusivity for breakthrough drugs from the 1970s fell from 8.2 years to 1.2 years in 1998 which

translates to 78% (DiMasi and Paquette, 2004, p. 5). This means that entry barriers over new or multiple drug introductions in the same class with a pre-existing breakthrough drug have fallen radically. Without doubt, follow-on drugs have recognized economic and social benefits that I have highlighted above. However, on the backdrop of asymmetrical pharmaceutical R&D resource allocation to neglected diseases, concerns about the wasteful and duplicative nature of follow-on drugs persists as they give credence to the skewed nature of patent-driven pharmaceutical R&D agenda.

The capital-intensive nature of pharmaceutical R&D accounts for the attraction of the patent system as a preferred incentive mechanism. But the market economic focus of the patent system results in significant dichotomy between global public health needs and pharmaceutical innovation. As I demonstrate below, that dichotomy conditions for the increasing role of non-market alternatives in the mitigation of global public health crisis. While not disavowing that pharmaceutical R&D is expensive, the truth is that figures posted by the pharmaceutical establishment to buttress the cost of innovation in that sector are as controversial as they are contested for reasons of accuracy. In order to explore the function and efficiency of non-market actors in the mitigation of global health crisis, including the role, if any, of pharmaceutical companies in support thereof, a critical look at the costing of pharmaceutical R&D is necessary.

Cost of Pharmaceutical R&D: Unaccounted Factors

The economics of drug pricing is outside the scope of this article. However, in posting the figures for the cost of pharmaceutical R&D, pharmaceutical corporations do not account for a number of important factors that are critical for a more realistic appraisal of their claimed costs. In the following paragraphs just a few of those factors that are unaccounted for in the hard and cold economics of pharmaceutical R&D are highlighted. In this highlight, the US pharmaceutical R&D landscape is a convenient default for a number of reasons, a handful of which will suffice. That country is the world's number one drug manufacturing country. Its pharmaceutical corporations are among the biggest and most entrenched in its domestic politics and policy. They operate mainly as transnational entities. The American pharmaceutical industrial sector is manned by perhaps the most powerful, effective and influential industrial interest and pressure group, namely the Pharmaceutical Research and Manufacturers of America (PhRMA).[22] PhRMA is on record as orchestrating the most far-reaching transformation in the global IP landscape, namely the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) (Drahos and Braithwaite, 2003).[23] The latter has enabled PhRMA to leverage the global environment for pharmaceutical patents and their impact on public health. In addition to having comprehensive legislative and incentive mechanisms for the pharmaceutical industry, America is one of the few developed countries in the word that does not regulate drug price. Drug prices in the United States are more than double in comparison to other developed countries, not to mention developing countries (Shah, 2007).[24]

The cold economics of pharmaceutical R&D hardly take into account the impact of public subsidy in the industry or the latter's benefits from publicly funded research, especially in platform or basic sciences. The complex pathways to drugs development are more often than not navigated through some form of reliance on the benefits of basic research which, for the most part, is publicly funded (Bouchard, 2007; Eisenberg, 1996; Sage, 1996).[25] Indeed, "[m]ost innovative medicines emerging from the pharmaceutical industry have their origin in publicly funded research" (Oxfam, 2008, p. 8). In the United States, of the 21 innovative medicines introduced within a 27-year period

(1965–92), 15 of them were made possible through the exploitation of insights from government-funded research (Oxfam, 2008).[26] According to Noam Chomsky,

> a very substantial part of [pharmaceutical] research and development is paid for by the public . . . [and] in a narrow sense in the order of 40–50%. But that is an underestimate because it doesn't count the basic biology and basic science which are publicly funded (Shah, 2007).

In 1980, via the Bayh–Dole Act, the United States sanctioned full-scale private proprietary control of the benefits of publicly funded research, a move that benefited research-intensive industries, including Big Pharma.[27]

Other aspects of legal changes in the United States since the 1980s benefited the pharmaceutical R&D industries in many ways. The impact of such changes does not seem to reflect on the cost of pharmaceutical R&D. During that period, a.k.a. the Reagan years, the United States relaxed its anti-trust laws, and adopted a permissive corporate consolidation regime that resulted in enhanced American competitiveness in the global market (Sell, 2004, p. 369). Specifically, a weaker anti-trust regime paved the way for merger and acquisitions in key industries, notably the pharmaceutical sector.[28] Pharmaceutical companies have continued to capitalize on a weaker anti-trust regime to consolidate patent, brand and market monopolies. By leveraging or mopping up alternative processes, products and brands, this approach progressively eliminated competition in the industry that was hitherto possible under the traditional IP system. According to Susan Sell, "the consequence of this new thinking was to remove most intellectual property licensing from antitrust scrutiny" (Sell, 2004, p. 369).

Another aspect of legal development is the extension of patent protection to life and life sciences (Bagley, 2003; Kelves and Berkowitz, 2001; Knoppers, 2000). This has had a special ramification for biotechnology, and has promoted technological advances in basic biomedical sciences. As I observed earlier, this approach has facilitated research convergences and a research network culture that operate to expand scientific opportunities with cumulative system benefit in pharmaceutical R&D and drug production. For example, random screening is gradually giving way for a targeted and rational approach to drug discovery. Globalization and free trade have continued to facilitate the applications of biotechnology for bioprospecting, which is the screening of genetic resources, mainly in indigenous and local communities, for pharmaceutical compounds of economic value (Oguamanam, 2007). Instead of a scatter-gun approach, pharmaceutical companies increasingly rely on the traditional knowledge of local communities to screen for viable compounds. This approach has transformed the success rate in drug discovery by 78% (Oguamanam, 2004). The cost-effective benefit of this bioprospecting hardly translates to reducing the cost of pharmaceutical R&D. As influential architects of a global patent regime designed to free ride on the knowledge of local communities, pharmaceutical companies have continued to secure questionable patents at the expense of local knowledge holders, a practice known as biopiracy.[29] Nonetheless, the prevalence of such practice has as yet to mitigate or impact in any way the costs claimed for pharmaceutical R&D.

Perhaps nowhere are the claims for the cost of pharmaceutical R&D more questionable than the amount expended by the industry for advertisement and lobbying. In virtually all developed countries, but more notoriously in the United States, "[d]rug companies spend more on advertising and marketing than on research, more on research on lifestyle drugs than on life saving drugs, and almost nothing on diseases that affect developing countries only" (Stiglitz, 2006, p. 1279). As a sampler, in 2006, US pharmaceutical companies spent an estimated US$12 billion on advertising and marketing compared with US$43 billion spent on R&D that year (Oriola, 2009, p. 84). As we

have noted, patent-based pharmaceutical R&D is essentially a market-driven enterprise. Next to obtaining patents, marketing and branding top the list of priorities in pharmaceutical innovation (Pugatch, 2004). The industry spends an enormous amount of resources in ''creating'' new diseases, finding new indications for old drugs, in targeting new consumer populations and in identifying new markets. For pharmaceutical corporations, in practice, a product's market is narrowly construed as the playing field meant for only those who can afford it.

Next to marketing and advertising, the pharmaceutical industry has remained a major political pressure group in the United States and the rest of the developed world. In the United States in particular, the industry traditionally outspends others lobbying the federal government. In 1997 alone it spent US$74.8 billion on that score; the following year, it spent almost US$12 million in campaign contributions (Silverstein, 1999). These figures normally increase in subsequent years. Clearly, the advertising, marketing and lobbying expenditures of pharmaceutical companies are mind boggling. Even a slight downsizing of these budgets would result in significant reduction in the cost of pharmaceutical R&D, and ultimately the cost of drugs (Oriola, 2009, p. 91).

The enormous political exposure and entrenchment of the pharmaceutical industrial establishment in the corridors of power have helped to ingratiate it to the politicians of all ideological shades (Drahos and Braithwaite, 2003). Their successes are evident in legislative and policy outcomes that show them as a most favored industrial sector. A few examples of those successes include legislative support for investment in orphan drugs, protection for regulatory data, specific extensions for pharmaceutical patent terms, a more flexible patent regime that accommodates evergreening and push back of entry dates for generic drugs, just to mention a few.[30] Perhaps more importantly, at a global level, the US pharmaceutical interest group has succeeded through the TRIPS Agreement in establishing a global level playing field for the pharmaceutical market and the patent system. There is paucity of evidence, however, to show that these concessions have made a positive impact on the cost of pharmaceutical R&D. Ironically, pharmaceutical companies continue to post ''the largest legal profits of any industry'' (Silverstein, 1999), a feat supported by the high cost of drugs and a pharmaceutical R&D agenda that does not address the needs of the most vulnerable in the now globalized landscape.

Despite their influential and most favored status, pharmaceutical manufacturers have as yet to make a much needed dent on the escalating global public health inequity. In part, this is as a result of the market-driven approach of the patent system. That approach places premium on the affordability of results of pharmaceutical R&D instead of need. Even within that matrix, it is possible that the cost of pharmaceutical R&D may not be as claimed by the industry. While the jury may still be out on the actual cost of pharmaceutical R&D, meeting the health needs of 90% of the global population remains a matter of urgency. As global public goods (Maskus and Reichman, 2004), non-market mechanisms provide the best guarantee for addressing these needs. In this section, we explore the framework for the non-market mechanisms.

Emergence of Non-Market Interventions

There are multiple ways in which the non-market approaches to access to drugs or products of pharmaceutical R&D for the needy entered the global public health policy space. In terms of impact, this trend strikes at the heart of the conceptual framework of the IP system and has resulted in the re-thinking of the relevant global legal infrastructure relating to pharmaceutical patents. Notably, the 2001 Doha Declaration on the TRIPS Agreement and Public Health (World Trade Organization [WTO], 2001) opened the way for a progressive reading and application of TRIPS Agreement in ways that explore compulsory licensing to address public health emergencies

in specific member states, especially those having "insufficient or no manufacturing capacities in the pharmaceutical sector" (WTO, 2001, paragraph 6). The essence of Doha was that the WTO/TRIPS Agreement or, in other words, IP, should not stand in the way of measures by member states to protect public health. Doha has since provided a platform for legislative revisions in some developed countries, notably Canada, to enable the exportation of AIDS drugs, for example, to countries in need under strict contractual terms. Pursuant to Doha, and the post-Doha amendment to TRIPS Agreement, Canada amended its Patent Act with the addition of 20 subsections under the title of "use of patents for international humanitarian purposes to address public health problems" (Patent Act, R.S.C., 1985). The Doha Declaration came on the backdrop of sentiments over the TRIPS Agreement-instigated access freeze to essential medicines in developing countries. It resulted in a push back by the United States, its powerful pharmaceutical lobby and other industrialized country proponents of the TRIPS Agreement from strict application of the letters of the treaty.[31] This was evident in the backpedaling from US-led initial oppositions to South Africa and Brazil's bid to make AIDS drugs affordable to needy populations in those countries (Gathii, 2002; Medicines Act, 1997). Doha has since become the key entry point for the stalled revision of TRIPS Agreement.

Before Doha, however, the United Nations, through its Sub-commission on Human Rights, had as early as 1998 expressed interest in the implication of TRIPS Agreement for human rights (United Nations High Commissioner for Human Rights, 2000). In 2001 the Sub-commission expressed strong reservations over the potential negative impacts of TRIPS Agreement, certainly IP, on human rights especially in regard to access to medicine in developing countries. Following on the heels of the UN's concerns, the WHO has remained proactive in disavowing the negative impact of the WTO/TRIPS Agreement on pharmaceutical R&D and access to essential drugs to the needy. In a broader framework, WHO launched the Commission on Macroeconomics of Health in 2001, charging it with analyzing the impact of health on development, and with exploring ways in which investments in health could promote economic growth (WHO, 2001).

In its 2002 report, the Commission made a case "for a New Global Health Research Fund with an annual funding of US$1.5 billion by 2007 to spur scientific knowledge" vital for addressing "critical underinvestment in basic science, product development, and operational research regarding diseases that mainly hit the world's poor, especially tropical diseases such as malaria" (WHO, 2002, p. xii). The report also canvassed increase in public–private partnerships (PPPs) for "targeted opportunities such as vaccines for HIV/AIDS, TB, and Malaria" (WHO, 2002, p. xii). WHO's proactive disposition in this regard has positioned that organization as key player in multiple partnerships for policy elaboration and as a facilitator of non-market intervention mechanisms in boosting pharmaceutical R&D and access to essential drugs for needy populations (Oriola, 2009).

The momentum thus far generated has led to increasing calls by stakeholders for a global treaty on R&D in health. In 2005 Science and Development Network reported that "[a] group of medical researchers and NGOs, [including] more than 160 scientists, public health experts, and professors of law, economists and members of parliament" signed a petition addressed to WHO urging it to set in motion a machinery for "a global treaty aimed at increasing research into diseases affecting the world's poor".[32] The call argues that the Kyoto Protocol on Climate Change model for trading greenhouse emissions could be used to earn credit by countries via technology transfers to developing countries in lieu of, or toward their funding commitment under the proposed treaty.[33] We explore aspects of this proposal in the last section.

In 2003, pursuant to a decision of the World Health Assembly (WHA), the WHO inaugurated a Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) (WHO).

The Commission was charged with collecting data and proposals from relevant quarters and to prepare an analysis of the intersections of IPRs, innovation and public health (WHA, 2006). More importantly, the Commission's mandate included the incorporation of "the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries" (WHA, 2006). In its 2006 report (WHO, 2006b) the Commission concluded that IP's ability to promote innovation cannot be universally guaranteed. Rather, it is context-specific. In developing countries—where there is no market for profitable innovation—the impact of IP is limited.

The CIPIH report acknowledged progress in the growth of "private–public partnerships and funding [research] from foundations and governments" (WHO, 2006b, p. xi) and recognized strong global awareness of the role of IP in global health inequity, increased prospects of additional funding and progress in science targeted at the problem. It, however, argued that there is need for a synergistic approach by all partners and stakeholders for a sustainable bridging of the gap between pharmaceutical R&D and access to drugs for the world's poor. Following the CIPIH report, the WHO, at the direction of the WHA, established an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) to prepare a global plan of action for pharmaceutical R&D targeting the health needs of developing countries. The IGWG submitted its report in 2008 (WHO, 2007).

The momentum for multiple collaborations, including PPPs in support of pharmaceutical R&D that target neglected regions of the globe, is evident in the proliferation of private foundations, non-governmental organizations (NGOs) and several civil societies groups that are committed to tackling global health inequity and the burden of disease (Oriola, 2009; Oxfam, 2008). These groups have continued to forge new partnerships with diverse stakeholders, including relevant professional groups, big pharmaceutical corporations, universities and allied research institutes and intergovernmental bodies, for funding support, logistics and collaborations. While some of these non-market initiatives have far broader scope in regard to their program of work or mandate, a number of these initiatives are disease-specific in their orientation.

In terms of their operations and pursuant to their specific mandates, these public–private or private–public and other hybrid initiatives participate in a number of collaborations with diverse stakeholders, including pharmaceutical companies, in drug cost cutting and access programs for needy populations. A 2008 Oxfam study, *Ending the R&D Crisis in Public Health* (Oxfam, 2008), identifies and discusses the operational details and mandates as well as the limits of a sample of PPP mechanisms that harness and apply "donor funds to pro-poor [pharmaceutical] innovation" (p. 10).

The first is in the nature of Advanced Market Commitments (AMCs). Under this scheme, donor countries or private foundations/charities guarantee upfront to pay a fixed price for a resulting vaccine that targets needs in select developing countries. This is designed to facilitate commercial development and to expedite introduction of urgently needed health products in target countries, especially vaccines that otherwise may be unfeasible for lack of market there. The second involves Product Development Partnerships (PDPs) in which non-profit entities collaborate with public and private interests, including pharmaceutical industries, to undertake pharmaceutical R&D on one or more of type II and III diseases under the WHO international classification of disease. The third is Priority Review Voucher (PRV) that is deployed mainly by the US Food and Drug Administration (USFDA) to reward pharmaceutical companies or PDP initiatives if they launch a new drug for a neglected disease. In consideration, the USFDA issues a PRV for the PDPs or any applicable party as a reward or incentive. The PRV is transferable to a third party. By way of PRV, USFDA commits to fast-track the review of drug approval process in relation to any

pending drug approval application that the beneficiary of PRV may nominate. Oxfam reports that the estimated value of a PRV, which inevitably increases the value of a patent, to be US$321 million (Oxfam, 2008, p. 15). Other incentives include patent pools, various orphan drug schemes, tax credits and miscellaneous incentives designed to refocus pharmaceutical R&D in directions that would otherwise not be attractive under market economic considerations.

With some measure of success, each of the above schemes has been instrumental in enhancing the supply of critical drugs, including vaccines targeted at needy segments of the global population. The Oxfam study demonstrates that the key drawbacks to these PPP initiatives are that: (1) project funds are not adequately directed at innovation; (2) resulting products may still not be affordable by a significantly high number of people in middle income countries; (3) resulting products tend to be inappropriate for target populations in poor countries; (4) IP constraints sharing of knowledge and consequently limits follow-on innovation and scientific research; and (5) there is poor or inadequate governance structure for the schemes that pose challenges for transparency and design implementation.

Despite these shortcomings, a number of donor countries, including private charities and leading pharmaceutical companies, have continued to partner under the above schemes and other variant initiatives for the extension of the benefits of pharmaceutical R&D to target and needy populations. For example, the supply of diverse drugs ranging from pneumococcal and tuberculosis (TB) vaccines, malaria, to HIV and AIDS have benefited from the above schemes. Examples of leading private charities that have continued to participate in these and other forms of PPP mechanisms include the GAVI Alliance[34] and Drugs for Neglected Diseases Initiative (DNDi), the Bill & Melinda Gates Foundation, the William J. Clinton Foundation, the Wellcome Trust, the Global Network for Neglected Tropical Disease Control (GNNTDC), Doctors Without Borders (Medicins Sans Frontières) and Universities Allied for Essential Medicine (UAEM) initiatives. Other "high-profile global health initiatives" (Travis *et al.*, 2004, p. 900) include the (US) Presidential Emergency Plan for AIDS Relief, the Global Funds to Fight AIDS, TB and Malaria, Stop TB and the Roll Back Malaria Partnership. Needless to mention, this list is only representative or symbolic of a multitude of initiatives, groups and activities that seek a non-market or subsidized approach to addressing global health inequity in order to fill the gap in public goods created especially by patent-driven pharmaceutical R&D.

In the range of two decades or so since these non-market initiatives responded to the TRIPS Agreement-instigated escalation of global health inequity, their impact cannot be overstated. They have pushed hope into the horizon for many in the developing world. Clearly, "investment in health research is greater than it has ever been" (Tallaksen, 2005). In a 2006 article, Stephen M. Maurer captures the impact and prospects of these initiatives as follows:

> We live in an era of hope. Ten years ago, worldwide spending on R&D for tropical disease was a paltry US$50 million. In a world where pre-drug R&D costs averaged US$802 million, substantial progress was almost impossible. The situation today is very different; 5 years from now, [i.e. in 2011] R&D budgets will likely reach US$500 million. This figure is still only about the fifth of the total R&D budget of a large pharmaceutical company, nevertheless, the dream of a new drug for tropical diseases every year or so could now become a reality. Whether or not governments and non-profit organizations . . . achieve this goal depends on how wisely they spend the money (Maurer, 2006).

Thankfully, Maurer's projections may turn out to be conservative and may be exceeded by 2011.[35] But his observations regarding the challenges facing the emerging initiatives are right on

point. Determining the most appropriate incentive strategy to undergird research in neglected diseases is a major challenge in a non-market context (Oriola, 2009, pp. 107–12; Oxfam, 2008).[36] There is no dearth of literature exploring the pros and cons of the multitude of competing options (Oriola, 2009, pp. 107–12; Oxfam, 2008). Here, I highlight a few critical preliminary concerns. First, a conceptualization of an appropriate approach is critical. For instance, a clear distinction must be drawn between two variations of PPPs, namely public–private and private–public models. The former is not new. In the United States, it is a Bayh–Dole approach which essentially "involves transferring of default patents from government to [private] parties with stronger incentives to license invention" (So *et al*., 2008). The latter is basically private sector-driven but relies strongly on public infrastructure for upstream delivery of the objectives of sponsoring institutions. In the global health context, global private–public partnerships (GPPPs)

> are those collaborative relationships which transcend national boundaries and bring together at least three parties, among them a corporation (and/or industry association) and an intergovernmental organization so as to achieve a shared health-creating goal on the basis of a mutually agreed and explicitly defined division of labour (Sell, 2004, p. 371).[37]

Whether the operative model is public–private or private–public, including their modification, there is usually a role for pharmaceutical proprietary interest holders.[38] Thus, if the non-market initiatives are to make any sustainable impact, they must find a strategy for collaboration with patent-driven pharmaceutical R&D concerns. Specifically, non-market initiatives must seek ways to use their goodwill to leverage and negotiate proprietary and other IP arising from or associated with the R&D and products they sponsor. It must always be borne in mind that the imperative for non-market intervention resulted from the failure or deficiencies of the patent-driven pharmaceutical R&D landscape. The influence of Big Pharma in the corridors of power in global capitals, especially Washington, casts strong clouds of suspicion regarding the role of pharmaceutical R&D corporations in PPPs, and perhaps especially in regard to Presidential Emergency Plan on AIDS Relief.[39] The latter is being coordinated by United States Agency for International Development (USAID) under variegated forms of partnerships based essentially on a public–private framework.

Increasingly, the entrenchment of pharmaceutical companies in emerging patterns of PPPs has combined with the former's *ad hoc* donation of drugs, and occasional concessions of their IP rights (for mitigating specific diseases and public health emergencies, or more appropriately targeted at responding to public outrage as a public relations management strategy) have led analysts to accuse pharmaceutical companies of ulterior motives (Shah, 2007). Their visibility in PPPs is perceived as a design "to discourage the use of compulsory license [and other independent initiatives] to facilitate access to essential medicines" (Sell, 2004, p. 371)[40] by needy populations. In other words, pharmaceutical companies have the potential to penetrate the PPPs with their permanent interest in a market-driven agenda. It is in their interest to ensure that PPPs' initiatives represent *ad hoc* and non-permanent interventions. That way, PPPs will not disturb the *status quo* in pharmaceutical R&D that unduly benefits drug companies at the expense of the world's poor.

Given these concerns and several others raised in the critique of non-market models, their sustainability as a permanent feature of global health governance may have to be supported through a global treaty framework. The patent-based pharmaceutical R&D is an integrated aspect of the global IP matrix of which the TRIPS Agreement is the pivot. That regime has failed woefully to cater to the health needs of the majority of the world population. Such needs have been characterized as public goods outside the capacity of the IP-based market economic model. It is then important that an international treaty regime, along the lines envisaged by some interest

groups mentioned above, may be required to lay down the framework for a synergistic and effective operation of multiplicity of prevailing non-market models in pharmaceutical R&D.

Toward a Treaty Regime on Pharmaceutical R&D

As we noted in the last section, the idea of a global medical R&D reform is not new. For example, following the 2005 initiative in which stakeholders petitioned the WHO for a medical R&D treaty framework as an alternative to extant or future trade agreements targeting patents and drug prices; Kenya proposed a resolution to the WHO Executive Board along those lines in late 2005 (Consumer Project on Technology, 2005). The following year, Brazil became a co-sponsor of the resolution which proposed the inauguration of a group of WHO member states to explore the idea of a global medical R&D framework treaty. The WHO has since approved a draft resolution on medical R&D treaty, which the WHA deliberated on in mid-2006 (WHA, 2006).[41] Even though there is no definitive outcome on the treaty initiative, the idea has been introduced at the highest decision making level of the WHO. In late 2006, the WHO's IGWG discussed elements of a global strategy and plan of action aimed at improving medical innovation and R&D for alleviating the health predicament of the world's poor (Consumer Project on Technology, 2005; WHA, 2006).

Thus far, the foregoing initiative on a medical R&D treaty provides some direction in regard to treaty content as part of a global strategy and plan of action to address the health needs of the developing countries. Essentially, the treaty concept broaches a new tradable credit system aimed at rewarding and promoting public-regarding and socially significant research. Akin to the Kyoto Protocol model, member states could apply the credits to meet treaty obligations. Those who exceed their treaty targets can exchange or trade excess credits across borders. The credit targets diverse projects relevant to the health needs of the world's most vulnerable, including R&D for neglected diseases, medical technology transfer, promotion of traditional medical knowledge systems and their dissemination, the concept of open public goods, including free and open source public database for medical and related innovation, other priority research projects and outstandingly useful public goods, etc. The treaty proposal is premised on freeing up any country that meets the treaty benchmark from constraining trade agreements impacting patents or drug prices.

Outside the treaty framework, analysts explore the subject of global medical and pharmaceutical R&D reform. For example, in 2005, Thomas W. Pogge approached the subject from a reform perspective by proposing an alternative to "the way pharmaceutical research into drugs and vaccines is incentivized under the current rules of TRIPS Agreement as supplemented by various bilateral agreements the United States has been pursuing" (p. 197). Pogge examines differential pricing alongside compulsory licensing regimes. He notes these regimes are attractive for the short-term objectives of alleviating access to essential drugs in needy populations; in the long run, however, they are unsustainable and may be counterproductive. Both practices result in product diversion and market failure, especially in regard to undersupply as

> pharmaceutical companies will tend to spend less on the quest for essential drugs when the uncertainty of success is compounded by additional unpredictability of whether and to what extent they will be allowed to recoup their investments through undisturbed use of their monopoly pricing powers (p. 188).

Despite these reservations, compulsory licensing and market differentiation could be effective if they are targeted or limited to trouble-shooting interventions and made a feature of dealing with the global health crisis, under a treaty framework.

Pogge proposes a global public-good strategy in which "results of efforts to develop new essential drugs are to be provided as public goods that all pharmaceutical companies anywhere may use free of charge" (p. 188). The aim is to ensure a global dissemination of the resulting drugs at marginal or below-marginal costs in ways that optimize, on a measurable scale, the impact of the new drug on the reduction of the global burden of disease. The reward for innovators under the global public-good strategy will derive from a global public fund as a proportion to the impact of the invention on the global burden of disease. According to Pogge (p. 190)

> Rewarding pharmaceutical research on the basis of its impact on the global burden of disease [as opposed to monopoly rents] would attract inventor firms toward medical conditions whose adverse effects on humankind can be reduced most cost effectively. This reorientation would greatly mitigate the problem of neglected diseases that overwhelmingly affect the poor. And it would open new profitable research opportunities for pharmaceutical companies.

So far, calls for the reform of the current global medical R&D and IP infrastructure do not seem to accommodate or account for the pervasive role of non-market actors and variety of PPPs in the mitigation of global public health crises. To do so would seem to be only logical at this point in the debate. For example, there is amble room to co-opt non-market actors into the global fund proposed by Pogge. A more holistic approach to the treaty option that builds on ongoing initiatives while incorporating the PPPs and non-market imperative is now warranted. Already elements of the proposed medical R&D treaty and the operational modalities and experiences of the PPPs as well as diverse independent proposals for tackling the negative impact of the TRIPS Agreement on global public health crises explored above provide content and ongoing scheme for the exploration of the features of a treaty regime.

Under the present proposal, a medical or pharmaceutical R&D treaty would, as a matter of priority, among other things, provide the legal anchor for the operation of non-market or social-regarding approach to pharmaceutical R&D, which currently operates on voluntary charitable and extralegal impulses. In a way, it would, along the lines of Pogge's public-good strategy, create much needed balance in IP jurisprudence as symbolized by the TRIPS Agreement's approach which has stood global thinking on IP on a narrow market economic pedestal. That the Doha Declaration brought about the first ever amendment to TRIPS Agreement is symptomatic not only of the limitation or failure of the market economic or strict utilitarian approach to IP. Along with the PPP upsurge in pharmaceutical R&D and drug access to the needy, the Doha initiative underscores the much neglected role of IP as a tool for negotiating social relations and, by extension, for facilitating the supply of global public goods. That project could be advanced via a global treaty on pharmaceutical R&D.

In a 2006 article, Professor Madhavi Sunder (p. 257) writes that IP's

> march to all corners of our lives and to the most destitute corners of the world has paradoxically exposed the fragility of its economic foundations while amplifying its social and cultural effects. Indeed, with full compliance to the TRIPS Agreement now required in all but the world's very least developed countries,[42] bringing with it patents in everything from seeds to drugs, intellectual property law becomes literarily an issue of life and death. Despite the real-world changes, intellectual property scholars increasingly explain their field through the lens of economics alone . . .

IP's march to the most destitute corners of the globe was initiated by the United States and its allies, including Canada, the European Union and Japan via the TRIPS Agreement. According to

Peter K. Yu, TRIPS Agreement came on the terms set by these countries and at a price for developing countries. Specifically, "TRIPS Agreement significantly curtained the ability of less developed countries to design an intellectual property system that is tailored to their local needs, interests, and goals" (Yu, 2007, p. 8).

The United States is the world's leading champion of a market or utilitarian approach to IP. But a social relations theory of property is amply embedded in that country's constitution (Sunder, 2006). Drahos points out that even the natural law tradition recognizes "the right of a state to modify property rights through the enactment of positive law" (Drahos, n.d.). More than three decades before Doha, the court in the United States recognized that even classical property rights are designed to serve and, consequently, to be curtailed by human values such as health and life (*State v Shack*, 227 A.2d 369 (NJ. 1971) p. 372).[43] More so are IP rights constrained by public-regarding considerations even as they do not have the same status as real property (Lessig, 2003).

Beyond Doha, in the copyright realm, the ubiquity and impact of IP on social and cultural relations across borders is also a matter of diverse creative access interventions within and outside the market model. For example, as part of the access to knowledge (A2K) movement under creative commons arrangements, the DevNat license program allows a network of developed country authors to collaborate in a scheme that permits variegated royalty-free uses of their works in third world countries while the authors retain their entitlements to IP rights in relation to users in the developed world. According to Sunder (2006, p. 290) "[m]arket failure alone cannot explain these projects. Concerns for distributive justice and human rights are evident". Under the Doha framework and via the extant mechanisms and operational outlines of the PPPs in pharmaceutical R&D as well as in the example of DevNat and similar projects, it is clear that the market or utilitarian rationale is still central to the dominant thinking and rationale for IP policy. However, these initiatives are equally symptomatic of the gaps in the theory and applications of IP laws in ways that are bereft of social, cultural and development accounts.

As IP rights claims translate into life and death for the most vulnerable in the destitute corners of the globe, a legal regime that emphasizes the social-planning or public-regarding and development elements of IP must come to the rescue because property rights, more so, IPRs, are designed to serve human values. My first preference will be work from within the TRIPS Agreement, to negotiate a single and comprehensive treaty regime that seeks to restore balance to the entire agreement to cover all regimes of IP, avoiding the piecemeal approach that Doha has tried and failed to implement. However, given the enormity of such a task, and not to mention the serial failures of the attempts to revise TRIPS Agreement, I am reluctant to tow that line. Furthermore, taking into consideration the Doha framework already in place and the robust nature of PPP initiatives in the pharmaceutical R&D sector, perhaps a treaty regime that squarely builds on those may be more feasible.

Despite the window opened by Doha and the so-called TRIPS Agreement flexibilities,[44] experience shows that it is still difficult for Doha to deliver on its promises. Canada's embrace of the Doha-induced opportunity—the first by a developed country—to supply AIDS drugs to Rwanda has recently run into troubled waters shortly after takeoff (Valpy, 2009).[45] Indeed, even for developing or middle-income countries with pharmaceutical manufacturing capacity, such as India, it is a Herculean task to resolve legal issues around the production of generic drugs with existing patent law. Not to mention navigating the direct and often subtle pressures, including veiled threats of foreign patent holders and their countries that are unwilling to allow a third party manufacturer to supply drugs to a developing country (Sunder, 2006, p. 295).

The foregoing creates an imperative for a treaty that provides the legal basis for a viable and balanced operation of non-market mechanisms in addressing global health inequity. The major

objective for such a treaty is to lay down the legal and operational scheme for harmonizing the process of PPP initiatives in pharmaceutical R&D. This is with a view for ensuring overall efficiency, including cost reduction for all stakeholders and participants in the delivery of the result of such initiatives. Next to that, the treaty will, in a way, plug the development, distributive and public-regarding gaps in the extant global IP scheme symbolized by the TRIPS Agreement. Overall, the proposed treaty is to be framed as an integral part of the global IP and health governance regime.

Without attempting to be exhaustive, a global treaty on pharmaceutical R&D and access to drugs, in its basic elements, would establish and elaborate on an applicable scheme for IP claims by pre-existing rights holders or, as may be applicable, the nature of other incentives for participating in PPP schemes. This may be in the form of voluntary waiver of patent rights or fixed royalty rates. The treaty would build on the experiences of existing PPP schemes in defining and elaborating on the role of various participants in the project, including country and private charity donors, NGOs, civil society organizations, professional associations, recipient countries, pharmaceutical companies and, perhaps more importantly, intergovernmental organizations such as the WHO.

Also, a global health/pharmaceutical R&D treaty would elaborate on a framework for drug pricing within PPP initiatives, one that ensures a realistic and leaner pricing regime that focuses on a PPP model as opposed to a direct market regime. For instance, such a pricing regime would take into consideration the publicly funded aspect of the innovation, for example, those arising from basic research or applied research. The pricing regime would also discount the marketing/advertising costs which would, more likely than not, be inapplicable in a PPP scheme. The treaty would incorporate operational flexibilities, for example, allowing for *ad hoc* or emergency PPP interventions, especially in cases of pandemic and national or global health emergencies. The proposed treaty would provide a classification scheme for determining beneficiary countries so as to account for progression in economic status and change in demographic. It must encourage technology transfer and the conduct of R&D in recipient countries. Also, it must promote strong governance regime along with a transparent model for managing transborder handling of any applicable drugs.

Conclusions

The connection between the patent system and promotion of innovation may appear to have been over advertised after all. Despite the exceptional relationship between patent and pharmaceutical R&D, patent appears to aggravate global health inequity. Critical examination of the pharmaceutical industrial complex warrants a distinction between the role of patents in promoting invention and innovation and its role as a guarantor of risk capital for the profitability of invention. Thus, because of its focus on 10% of the world's affluent located in the developed world, the patent-based pharmaceutical R&D does not cater to the needs of 90% of the global population. Thus, while it is plausible to argue that patent promotes innovation and inventiveness, as a market economic mechanism, it is not concerned with innovation that caters to the needs of the majority because such needs do not guarantee viable markets for products of R&D. Instead, pharmaceutical companies specifically target the market for those who can afford the results of R&D rather than those in need. It is apparent that global pharmaceutical R&D potential has as yet to be optimized. Frustrated, actors in global health governance are quick to dismiss the health needs of 90% of the global population as vital global public goods, defined as types of goods that markets undersupply because market-based incentives such as patents are inadequate.

While the public-good argument is not in dispute, there has as yet to be a realistic evaluation of the cost of pharmaceutical R&D and by extension new drugs in order to determine the extent of the gap in global health for the poor. Indications from the United States, which can be extrapolated for convenience and with caution to other developed countries, are that pharmaceutical R&D concerns enjoy a most favored status. They have not taken into account a number of factors, including the changes in the new scientific research network and landscape, the spate of mergers and acquisition in the industry, advances in biotechnology and the exploitation of local knowledge for bioprospecting, in order to arrive at a realistic cost of R&D. Indeed, the costs of R&D posted by drug companies require serious interrogation.

One of the consequences of the skewed nature of pharmaceutical R&D priority is the emergence of non-market approaches to close the gap in the health needs of the poor as a matter of global public good. Presently, those approaches are being implemented in a multiplicity of formats and conceptual frameworks ambiguously expressed as PPPs. One of the concerns about the PPPs is the role of pharmaceutical R&D corporations given their vested interests in sustaining the *status quo* in global health inequity. The proliferation of non-market actors whose objectives may seem at cross purposes with those of patent-driven pharmaceutical companies requires a coordination to ensure some synergy in the global commitment to address what analysts have tagged the 90/10 gap in global health.

Given that the present inequity in global health is rooted, for the most part, in a TRIPS Agreement-driven global IP framework, a permanent response via a non-market approach may be better supported by a global treaty on pharmaceutical R&D. Such a treaty would be premised on restoration of the balance in IP jurisprudence that has long been skewed by the primacy of utilitarian and market economic thinking over the role of IP in development and in negotiating social relations. The imperative for such a balance could not be more urgent than now when IP impacts the lives of all, especially those in remote parts of the globe as a matter of life and death. The treaty needs to be integral to, or build on, the sentiments expressed in the 2001 Doha Declaration on TRIPS Agreement and Public Health, and be one that will provide a robust legal framework in IP and global health governance to address global health crises. It is easy to envisage the tough challenges that may assail such a treaty, especially given the lack of political and moral will by many stakeholders to effectively deliver on the promises of Doha Declaration and the so-called TRIPS Agreement flexibilities for those in direct need. But that will not detract from the present urgency to begin a conversation on a compelling idea whose time may be due. It is a conversation that will provoke reflection on IP and human values and on "the struggles at the heart of local and global intellectual property law conflicts" (Sunder, 2006, p. 258).

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Notes

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1 For a general review of underlying theoretical justifications for IP, see Drahos (1996).
2 For an overview and general situation report on the disconnect between pharmaceutical R&D and drug needs of the world's poor, see Oxfam (2008).
3 This figure appears to have become the official benchmark supported by the Tuft Center for the Study of Drug Development. Many NGOs and civil society groups use this figure an official industry figure. It provides the basis for their disputation of the cost of drug development. See DiMasi *et al*. (2003); see also Oxfam (2008, p. 13) and Light and Warburton (2005).
4 For stakeholders, drug development is a fluid process that is vulnerable to appropriation at every stage. Save for stringent patent and other peripheral regimes, innovators and investors alike have extremely limited assurances of exclusive exploitation of the products of R&D and, consequently, of the profitability of their innovation.
5 In practical terms, armed with the necessary information, including regulatory approval data, an established generic drug manufacturer with the necessary capacity can manufacture generic versions of brand name drugs in a matter of months, even though the average time frame for the development and marketing of such a breakthrough drug is between 10 and 15 years.
6 For example, in 2006, Pfizer announced that it was terminating further R&D on the drug Torcetrapib, an expected blockbuster drug for the treatment of cholesterol imbalance and mitigation of heart disease. This was after an external expert body determined that taking the drug increased patients' risk of death. It was discovered that 82 patients taking Torcetrapib died, in comparison to 51 who had been taking Lipitor, another cholesterol drug. In the meantime, Pfizer was alleged to have spent over US$800 million in the development of the compound that was acknowledged to raise high-density lipoprotein (see Stein, 2006).
7 This is in accordance with the underlying rationality associated with the IP system within the mainstream law and economic analysis (see Sandeen, 2009) (arguing that economic reward is the presumed rationality undergirding the inventive endeavor such that those operating outside this form of motivation are ''irrational'' actors under the law and economic logic).
8 This is done through direct legislation on patent term extension such as the 1984 US Drug Price Competition and Patent Term Restoration (a.k.a. Hatch-Waxman) Act (1984), Pub. L. No. 98-417, 98 Stat. 1585 (which provides for patent term extension to compensate for delays arising from regulatory approval processes). In Canada, an equivalent process regime derives from the 1993 Notice of Compliance (NOC) Regulation (S.OR./93-1330) which was made pursuant to the Patent Act (R.S.C. 1985, c. P-4). The NOC indirectly compensates for delays in regulatory approval by patent term extension.
9 Article 39.3 of the TRIPS Agreement provides a universal framework for the protection of regulatory data in member states of the WTO. Similarly, article 1711 of North American Free Trade Agreement (NAFTA) provides for a five-year period for regulatory data exclusivity. Indeed, the influence of American pharmaceutical industry lobby on the TRIPS Agreement is well documented (see, e.g., Drahos and Braithwaite, 2003). Canada, the United States, Japan and Australia all have regimes in place for the protection of regulatory approval data. It would seem that the question in regard to TRIPS Agreement provision is whether the standard is one of exclusivity or permissive reliance (see Basheer, 2006). The essence of protection of regulatory data is to maximize the leverage of breakthrough drug patent holders and to delay the entry of generic drug maker into the market.

10 In the United States this is evident in the Orphan Drugs Act, Pub. L. No. 97-414 (1983), which effectively extends patent protection by seven years through the prohibition of the registration of generic versions of orphan drugs (i.e. drugs that target statutorily classified rare diseases) at the expiration of patent term.
11 The 2001 Doha Declaration on the TRIPS Agreement and Public Health marks a paradigmatic epoch not only in the escalation of a global public health crisis in the 1990s and the linking of the phenomena with the transformation in global IP brought about by the TRIPS Agreement.
12 Pogge (2005, n. 190):

> even if common talk about 10/90 gap is now an overstatement, the problem is certainly real: Malaria, pneumonia, diarrhoea, and tuberculosis, which together account for 21 percent of the global disease burden, receive 0.31 percent of all public and private funds devoted to health research (footnotes omitted).

13 See Rai (2001), highlighting the potential of genomics to revolutionize pharmaceutical innovation.
14 See also Oriola (2009, p. 103) citing McNeil (2000), quoting Aventis Inc.'s spokesman, Francios Gros as arguing that pharmaceutical companies "can't deny that [they] try to focus on top markets [in pursuit of] a commitment to deliver performance to shareholders".
15 See Stiglitz (2006).
16 According to Oriola (2009), an estimated less than 5% of the global pharmaceutical R&D are applied to diseases endemic to developing countries (citing WHO, 2002, p. 79); for statistics, see Torreele *et al.* (2004).
17 Also cited in Sell (2004); see generally Maskus and Reichman (2005).
18 The efficiency of patent-based pharmaceutical R&D can be tested on two competing bases: (1) its effect on maximizing return on investment or (2) its ability to prioritize innovation and bring its benefits to the majority of those in need. It would seem that the overarching consideration is directed to the first that is a market-driven approach.
19 This perspective on the patent system is at the core of the mainstream law and economic approach to the IP system. See generally Pugatch (2004); see also Kitch (2000), Cooter and Ulen (2008) and Sandeen (2009) (providing a general critical perspective on the law and economic approach to IP).
20 For more in-depth insight into the struggle to make HAT drug available to needy African population, see Torreele *et al.* (2004, pp. 15–24).
21 This is the figure posted for a lifelong treatment of Gaucher's disease with alglucerase. See Torreele *et al.* (2004, p. 8, n. i). Orphan diseases are a reference to rare kinds of diseases that affect relatively small numbers of people in developed countries and elsewhere. They enjoy special legal categorization in the United States as a result of which they are targets of special non-market incentives designed to support R&D which would not have been viable on the basis of pure market considerations.
22 For general outlook on PhRMA and its activities, see ⟨http://www.phrma.org/about_phrma/⟩ [Accessed January 2010].
23 Highlighting the role of pharmaceutical interest lobby in the US politics and its influence in bringing about the TRIPS Agreement.
24 See also Vernon *et al.* (2006) (cited in Oriola (2009, p. 75) and noting a US House Representatives Report which indicates over 70 and 100 percentage disparity in the cost of procuring prescriptions drugs by uninsured US senior citizens from Canada and Mexico, respectively).
25 All of these articles explore the protection of public interest in the private sector commercial exploitation of research that benefit from public funding.
26 Referring to a 2004 Congress Report and citing Mintzberg (2006).
27 For discussion of the Bayh–Dole Act, see Sage (1996); see also So *et al.* (2008) and David (2006) (providing perspective on the Bayh–Dole Act in the context of European and other historical initiatives).

28 According to Oriola (2009, p. 70), "the [pharmaceutical] industry also owes its trans-nationality to periodic mergers and acquisitions, often necessitated by [anti-]competitiveness imperatives".
29 For a treatise on biopiracy, see Mgbeoji (2006); see also Shiva (1997).
30 *Supra* n. 9.
31 Indeed, Doha Declaration brought about the first ever amendment to the TRIPS Agreement in 2005 by the addition of a new article 31*bis* which relaxes the pre-existing obligation for compulsory licensing by an exporting country in order to accommodate the needs of countries without pharmaceutical manufacturing capacity pursuant to paragraph 6 of the Doha Declaration.
32 See Tallaksen (2005).
33 *Ibid.*
34 Formerly the Global Alliance for Vaccines and Immunizations.
35 This is so given the budgetary figures posted by mega foundations such as the Bill & Melinda Gates Foundation and the William J. Clinton Foundation for sponsoring pharmaceutical R&D and access to critical medicines for neglected diseases in the developing countries. In addition to these initiatives, the expenditures associated with other diverse initiatives and proliferation of non-market regimes help to push expenditure beyond Maurer's projection.
36 Listing the major models to include AMC, PDPs, PRVs, prizes, tax credits and orphan drug schemes.
37 See also *supra* n. 36, Torreele *et al.* (2004, p. 6), and Oxfam (2008) quoting Lee *et al.* (2002). According to Sell, the Global Alliance for Vaccinations and Immunizations established by Bill Gates Foundation in collaboration with WHO, UNICEF, World Bank and Merck Pharmaceuticals is an example of GPPP.
38 Perhaps nowhere is this clearer than in the text of the IGWG's Draft Global Strategy, see WHO (2007).
39 The initiative is a US government-led global interventionist outreach program initiated by President George W. Bush aimed at making AIDS treatment available globally to those in need with emphasis on 15 developing countries. For more details see The President's Emergency Plan for AIDS Relief [online]. Available at ⟨http://www.pepfar.gov/⟩ [Accessed July 2009].
40 Noting that the industry is inclined toward the institutionalization of long-term donations of drugs by pharmaceutical companies.
41 The resolution is titled "Public health, innovation, essential health research and intellectual property rights: towards a global strategy and plan of action" [online]. Available at ⟨http://apps.who.int/gb/ebwha/pdf_files/WHA59/A59_R24-en.pdf⟩ [Accessed December 2009].
42 For least developed countries, full compliance with TRIPS Agreement with respect to pharmaceuticals has been extended by the Doha Declaration to 2016.
43 Also cited in Sunder (2006, p. 291).
44 Stiglitz (2008, p. 1717) alludes to the half-heated nature of the so-called TRIPS Agreement flexibilities by his reference to "inflexibilities of these flexibilities".
45 Valpy reports that Apotex, the generic manufacturer licensed under Canada's Access to Medicines Regime, is not seeking a new licencing agreement because of the difficulties in working under a system which requires extensive and expensive negotiations with the patent holders. They were only able to send an allotment AIDS drugs sufficient to address the needs of 21,000 Rwandans.

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