

# Strong Medicine: Patents, Market, and Policy Challenges for Managing Neglected Diseases and Affordable Prescription Drugs

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## INTRODUCTION

There is a myriad of diseases to which the human body is vulnerable. If an anomaly is due to a malfunctioning enzyme, scientists could use a molecule to correct the errant enzyme, or block the receptor to which the enzyme is attached.<sup>1</sup> In pharmaceutical parlance, the molecule is a compound;<sup>2</sup> however, in lay terms, it is a drug.<sup>3</sup> As one of the most regulated consumer products, it is inevitable that drugs would have a legal definition. Article 1 of the European Union Directive 65/65/EEC defines a drug as any substance designed to prevent or treat diseases in humans or animals.<sup>4</sup> This is in *pari materia* with s. 321(g)(1) of the United States

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<sup>1</sup> See Fran Hawthorne, *The Merck Druggernaut: The Inside Story of a Pharmaceutical Giant*, (Hoboken: New Jersey, 2003) at 72.

<sup>2</sup> For example, more than half of all prescriptions filled in the United States in 1993 consisted of at least one major active compound. See Kerry Ten Kate & Sarah A. Laird, *The Commercial Use of Biodiversity, Access to Genetic Resources and Benefit-Sharing*, (London: Earthscan Publications Ltd., 1999) at 34.

<sup>3</sup> Molecules are traditionally found in microorganisms that live in soil, sludge, decayed plants, etc. For instance, penicillin was derived from mold, while Merck's anticholesterol statins are fungus-based. Today, compounds are increasingly made chemically rather than derived from natural sources. According to Kate and Laird, research for products derived from natural sources has become unappealing to many pharmaceutical researchers because it is slow and expensive. Consequently, rather than seeking new chemicals existing in nature, most companies often prefer to screen libraries of synthetic compounds for basic inorganic and petroleum-based chemicals. See *ibid.* at 50 and 56.

<sup>4</sup> See Article 1 of Directive 65/65/EEC on the Approximation of Provisions laid down by Law, Regulation or Administrative Action relating to Proprietary Medicinal Products, Official Journal 022, 09/02/1965P 0369-0373, (26 January 1965).

*Federal Food, Drug and Cosmetic Act*;<sup>5</sup> s. 2 of the Canadian *Food and Drugs Act*;<sup>6</sup> and s. 3(6)(b) of the Indian *Drugs and Cosmetics Act, 1940*.<sup>7</sup>

As the statutory definition shows, the term “drug” or, “medicinal product” has strict purposive and functional connotations for “cure” or, “disease prevention” in humans and animals. This strict legal conception is of significant policy<sup>8</sup> and jurisprudential<sup>9</sup> relevance in differentiating a drug from borderline products that are not *stricto sensus* drugs, despite their possible therapeutic effects. These include parapharmaceutical products such as personal hygiene and cosmetic products, functional foods, and foodstuffs.<sup>10</sup> For example, the *Indian Drugs and Cosmetic Act* expressly differentiates ayurvedic medicine from the conventional drug,<sup>11</sup> while legislative constructs of “drug” in the European Union, Canada, and the United

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<sup>5</sup> See the *Federal Food, Drug and Cosmetics Act*, U.S.C. tit. 21 s. 321(g)(1) (1938), as am. 2002. It defines drugs as articles, other than food, that are meant to be used in diagnosis, cures, mitigation, treatment, or prevention of disease in man or other animals.

<sup>6</sup> See *Food and Drugs Act*, R.S.C. 1985, c. F-27, s.2. It defines “drug” as follows: “drug includes any substance or mixture of substances manufactured, sold or represented for use in (a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals, (b) restoring, correcting or modifying organic functions in human beings or animals, or (c) disinfection in premises in which food is manufactured, prepared or kept.”

<sup>7</sup> See *The Drugs and Cosmetics Act, 1940* Act No. 23 of 1940 as amended. It defines “drug” as all medicines intended for the treatment, diagnosis and prevention of diseases in human beings and animals. “Drug” has been branded as an essential commodity since 1955. See section 2(iv) of *The Essential Commodities Act, 1955* No. 10 of 1955.

<sup>8</sup> Special policy and regulatory decisions regarding production, safety, distribution, and sales are especially targeted at drugs. Distinctions are made between prescription drugs that cannot be sold across the counter and patent medicines that can freely be sold over the counter without a physician’s prescription. In the European Union for example, Directive 2001/83/EC sets out a broad range of rules concerning production, marketing and distribution of medicinal products (including labeling, packaging and advertising rules).

<sup>9</sup> The courts have had to define “drug” or “medicinal product” in a number of civil and criminal cases. In Europe, examples of such cases by the European Court of Justice are E.C.J., 30 November 1983, *van Bennekom* case 227/82, E.C.R 1983, 3902; E.C.J., 16 April 1991, *Upjohn*, case C-112/89, E.C.R., 1991, I-1741, r. 17; 21.

<sup>10</sup> For discussion, see Stefaan Callens *et al.*, *Chapters on Pharmaceutical Law*, (Antwerpen, Groningen & Oxford, Intersentia: 2000) at 3.

<sup>11</sup> See s. 3(2)(a) of the Indian *Drugs and Cosmetic Act, 1940*, *supra* note 7. It defines Ayurvedic, Siddha or Unani drugs separately from conventional drugs as including “all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb systems of medicine, specified in the First Schedule.”

States expressly differentiate “drug” from cosmetics and foodstuffs.<sup>12</sup> However, despite statutory distinctions between drug and other para-pharmaceutical products, the differences are often not as clear-cut in real life, and courts have had to decide whether or not a product or substance falls within the statutory remit of “drug” or “medicinal product.”<sup>13</sup>

Aspirin, the world’s first synthetic drug, was introduced in 1897.<sup>14</sup> It is the precursor of a string of innovative life-saving drugs that are currently on the cusp of genomics revolution.<sup>15</sup> However, innovative drugs are at a premium and invariably take several years to manufacture.<sup>16</sup> It has been observed that the characteristically extensive pre-clinical and clinical trials preceding drug approval and market

<sup>12</sup> For example, the third recital of the European Union Directive 65/65/EEC on medicinal products, *supra* note 4, puts foodstuffs and hygienic products outside of its regulatory remit. They are, however, subject to a different regulation under Council Directive 76/768/EEC on the approximation of the laws of the Member States on cosmetics. See Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetics, O.J., L 262/169, 27 September 1976. The Directive defines cosmetics as “any substance or preparation intended for placing in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or principally to cleaning them, perfuming them or protecting them in order to keep them in good condition, change their appearance or correct body odors.” *Ibid.*

<sup>13</sup> In the European Union, for example, the European Court of Justice has had to make recourse to certain criteria in determining whether or not a substance is a medicinal product. These include the article’s manner of production, its function, its pharmacological properties in the context of current scientific knowledge, its usage, the extent to which the article is sold, and consumers’ familiarity with the article. See generally Article 1 of Directive 65/65/EEC *supra* note 4; *van Bennekom’s case*, *supra* note 9 at 17; *Upjohn*, case C-112/89, E.C.R., *supra* note 9 at 18. In *Upjohn*, the Court held, *inter alia*, that any substance capable of having an effect on the actual functioning of the body is a medicinal product. *Ibid.* at 21.

<sup>14</sup> See Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, (Aldershot, Burlington: Ashgate 2003) at 89.

<sup>15</sup> See Arti K. Rai, “The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Costs, and Access in the Post-Genomics Era” (2001) *University of Illinois Law Review* at 174-175. The author canvasses the theory that the application of genomics science to pharmaceuticals production could potentially usher in a new era of pharmaceutical innovation defined by efficient, faster targeting and analysis of genes, proteins, and biochemical pathways that cause particular diseases.

<sup>16</sup> See Arthur Lim, *Global Medical Dilemma, Health Cost: The Billion Dollar Crisis of the 21<sup>st</sup> Century* (Singapore: Continental Press Ltd., 2001) at 20.

debut,<sup>17</sup> and the huge costs of advertising,<sup>18</sup> are considerably upping prescription drug overheads.<sup>19</sup> The cumulative costs are invariably passed on to consumers, with the effects that the poor and the uninsured are priced out of the market.<sup>20</sup> Market trappings also shape a disproportionate focus of pharmaceuticals research and development on diseases that are prevalent in rich countries with the most commercial promise, relative to diseases endemic in poor-resource and low-income

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<sup>17</sup> See William Francis Crowley Jr., “Drug Development and clinical research in the UK” (2007) 369 *The Lancet*, online: *The Lancet* <<http://www.thelancet.com>>; Michael A. Santoro, “Introduction to Part I” in Michael A. Santoro & Thomas M. Gorrie, eds., *Ethics and the Pharmaceutical Industry*, (Cambridge: Cambridge University Press, 2005) at 15 (notes that long and large clinical trials contribute considerably to drug overheads); Michael D. Rawlins, “Cutting the cost of drug development?” (2004) 3 *Nature Reviews Drug Discovery* at 360–364.

<sup>18</sup> In 2006, for example, the United States pharmaceutical industry spent approximately \$12 billion on advertising and marketing (\$5 billion and \$7 billion on DTC and professional spending respectively). See Pharmaceutical Research and Manufacturers of America, *New Medicine, New Hope*, 2007 Annual Report, (Washington: August 2007) at 13; Thomas Abrams, “The Regulation of Prescription Drug Promotion” in Michael A. Santoro & Thomas M. Gorrie, eds., *Ethics and the Pharmaceutical Industry*, *supra* note 17 at 153–168 (notes the spiraling expenditures for prescription drug promotion); Catherine Matraves, “Market Structure, R&D and Advertising in the Pharmaceutical Industry” (1999) 47:2 *The Journal of Industrial Economics* at 169–194 (notes that pharmaceutical was both R&Dx and advertising intensive).

<sup>19</sup> Note the countervailing argument that advertising decreases rather than increases drug prices in: Merrill Matthews, “Who’s Afraid of Pharmaceutical Advertising? A Response to a Changing Health Care System” (May 2001) *Institute for Policy Innovation, Policy Report 155* at 16, online: Institute for Policy Innovation <<http://www.ipi.org>>.

<sup>20</sup> See Rai, *supra* note 15 at 176–177 (the author notes that spiraling prescription drug costs were particularly problematic for the elderly and the uninsured in the United States).

countries.<sup>21</sup> The result is an agglomeration of a multitude of debilitating ailments generically known as “neglected diseases.”<sup>22</sup>

The aphorism that patent is the engine of innovation<sup>23</sup> is arguably truer for pharmaceuticals than for most technologies.<sup>24</sup> Patents grant exclusive monopoly to pharmaceutical rights holders, and serve as the critical incentive for crucial investments in pharmaceutical research and development. In that context, patents are the *de facto* building blocks for prescription drug economics.<sup>25</sup> This truism is clearly exemplified by the general reluctance of the pharmaceutical industry to invest in unpatentable, albeit promising compounds.<sup>26</sup> The pharmaceutical industry makes

<sup>21</sup> See “A Dose of Innovation: How to Encourage the Development of Drugs for ‘Neglected Diseases’”, Editorial, *The Washington Post*, (29 March, 2007) at A18 (laments the endemic incidence of neglected diseases, and welcomes a recent collaboration between a non-profit organization and Sanofi-Aventis to develop a new anti-malaria drug); Jurgen Drews, “Drug Research: Between Ethical Demands and Economic Constraints” *supra* note 17 at 21–36 (notes that as the costs of drug R&D spiraled from the 1960s, the mutual coexistence of medical, scientific, and economic motivations for drug R&D was substituted with strategic targeting of specific markets — those with the most commercial promise); Michael Perelman, *Steal This Idea: Intellectual Property Rights and the Corporate Confiscation of Creativity*, (New York: Palgrave Macmillan, 2004) at 140–144 (notes how the market dictates pharmaceutical research focus on diseases that produce the most profits, at the expense of diseases prevalent in poor resource countries).

<sup>22</sup> Neglected diseases are mainly tropical diseases, ranging from malaria to tuberculosis, AIDS, leishmaniasis, sleeping sickness, to chagas disease. They are otherwise known as tropical diseases (TDR), and the World Health Organization for Research and Training in Tropical Diseases is collaborating with the World Bank and UNDP to establish affordable and improved treatments. See the World Health Organization for Research and Training in Tropical Diseases, online: WHO <<http://www.who.int/tdr/>>.

<sup>23</sup> See Paul Herrling, “Patent Sense: Protecting Intellectual Property Saves Lives in the Developing World” (2007) 449 *Nature* at 174–175 (notes that a patent is crucial to securing the massive financial base required for financing innovative pharmaceuticals. He argues further that, absent a patent, the pharmaceutical industry would be unable to produce innovative life-saving drugs); *Patlex Corp. v. Mossinghoff*, 758 F.2d 594 (C.A.Fed. (Pa.), 1985), at 599 (where the United States Court of Appeals for the Federal Circuit held, *inter alia*, that patents created incentives for innovation).

<sup>24</sup> See John H. Barton, “Intellectual Property, Biotechnology, and International Trade: Two Examples” in Thomas Cottier & Petros C. Mavroidis, eds., *Intellectual Property: Trade, Competition, and Sustainable Development* (Ann Arbor: The University of Michigan Press, 2003) at 285–301 (the author notes that pharmaceutical patent is the poster child of the patent system, and “the undisputed example of success of the intellectual property system in encouraging innovation”). *Ibid.* at 286.

<sup>25</sup> See Rai, *supra* note 15 at 177 (notes that prescription drug economics is profoundly shaped by patent monopoly power, which could extend patentees’ stranglehold on price, even after the emergence of similar, or me-too drugs).

<sup>26</sup> For instance, the pharmaceutical industry is reputedly reluctant to invest in a promising, but unpatentable, anti-cancer compound. The drug is known as dichloroacetate

no secret of the patent's indispensability to the trade. In their 2007 Annual Report, for instance, the Pharmaceutical Research and Manufacturers of America listed achieving "strong intellectual property incentives" in the United States and worldwide as a core policy objective.<sup>27</sup>

However, there is a proven nexus between patent monopoly and high prices for pharmaceuticals,<sup>28</sup> to the end that generic drugs are notoriously cheaper than their patented and branded counterparts.<sup>29</sup> Nevertheless, undermining pharmaceutical patents with a view to securing affordable prescription drugs could most certainly imperil investments in innovative life-saving drugs.<sup>30</sup> Herein lays one of the pharmaceutical policy challenges for governments around the world. Significantly, the internationalization of the minimum standards for patents protection by the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) makes it a lot harder for member states to derogate from pharmaceutical patents other than as is possible under the narrowly construed legally allowable exceptions.<sup>31</sup>

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(DCA), and has been used for years to treat a rare metabolic disorder. However, further clinical trials and research is needed in order to ensure its efficacy and safety for cancer treatment. As a well-known compound, the drug is unpatentable, making it highly unattractive for the pharmaceutical industry to invest in, and fueling speculations that charities, universities, and governments, may have to step in to fund expensive clinical trials. See Andy Coghlan, "Cheap, 'Safe' Drug Kills Most Cancers" 2587 *New Scientist* (20 January 2007) 13; Helen Pearson, "Cancer Patients Opt for Unapproved Drug" (2007) 446 *Nature* at 474-475.

<sup>27</sup> See *Pharmaceutical Research and Manufacturers of America*, *supra* note 18 at 5 (notes that the strong intellectual property system in the U.S. explains why it produces 70 per cent of the new drugs that enter the market annually).

<sup>28</sup> Patents are deemed crucial for innovative prescription drugs, and patented drugs are relatively more expensive than out-of-patents generic drugs. See Oxfam, "Fatal Side Effects: Medicine Patents Under the Microscope" in Brigitte Granville, ed., *The Economics of Essential Medicines* (London: Royal Institute of International Affairs, 2002) at 81-99; Kumariah Balasubramaniam, "Access to Medicines: Patents, Prices and Public Policy — Consumer Perspectives" in Peter Drahos & Ruth Mayne, eds., *Global Intellectual Property Rights: Knowledge, Access and Development* (New York: Palgrave Macmillan, 2002) at 90-107.

<sup>29</sup> See Aidan Michael Hollis, "How do Brand's 'Own Generics' Affect Pharmaceutical Prices?" (2005) 27:4 *Review of Industrial Organization* at 329-350.

<sup>30</sup> See David Vaver & Shamnad Basheer, "Popping Patented Pills: Europe and a Decade's Dose of TRIPS" (2006) *European Intellectual Property Review* at 282-291 (the authors note that the underlying principle driving European patent policy is the conventionally presumed patents' indispensability to the survival of the pharmaceutical industry).

<sup>31</sup> Intellectual property protection was inexorably linked with trade via the World Trade Organization's TRIPS Agreement, signed at Marrakesh in 1994. The Treaty which took effect in 1995 generally sets the minimum level of protection, while its Article 27 specifically obliges member states to make patent protection available for all kinds of invention, including pharmaceuticals. Non-compliance could lead to the WTO dispute

Price regulation offers an ostensibly attractive solution to the spiraling prescription drug prices and, with the exception of the United States, has been fairly successfully used to rein in prices in most developed countries under national insurance schemes.<sup>32</sup> However, the downside of capping prescription drug prices is its concomitant propensity to stifle investments in innovative life-saving drugs.<sup>33</sup> For example, analysts believe that the U.S. pharmaceutical industry owes much of its relative competitiveness vis-à-vis its European counterpart, to the lack of an officially mediated price regime that is prevalent in Europe and other developed economies.<sup>34</sup> Moreover, a regulated price regime will not necessarily deliver all prescription drugs needed, as evidenced in Britain, where the national health insurance scheme often excludes “drugs of last resort” because they are deemed too expensive despite their proven clinical benefits.<sup>35</sup>

The pertinent considerations, therefore, are how to best resolve the twin problems of neglected diseases and the spiraling prescription drug costs without stifling innovative pharmaceuticals. In other words, how best to steer prescription drug production towards meeting societal health needs, while maintaining a steady

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settlement procedure and possible trade sanctions. See the Agreement on Trade-related Aspects of Intellectual Property Rights, 1994, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994, online: WTO <[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)>; Donald G. Richards, *Intellectual Property Rights and Global Capitalism: The Political Economy of the TRIPS Agreement* (New York & London: M.E Sharpe Inc., 2004) at 141–166.

<sup>32</sup> With the exception of the United States, pharmaceutical price regulation is used extensively under national health plans in Europe, Canada, and in much of the developed world in order to rein in run-away prices. See Barton, *supra* note 24 at 292.

<sup>33</sup> See Allan Earl-Slater, “Can We Afford to Lose the Pharmaceutical Industry in the EU?” (1996) 96:4 *European Business Review* at 18–25 (the author argues that Europe was losing its competitiveness in the pharmaceutical industry due to price control).

<sup>34</sup> See Madhu Agrawal, *Global Competitiveness in the Pharmaceutical Industry: The Effect of National, Regulatory, Economic, and Market Factors* (New York & London: Pharmaceutical Products Press, 1999) at 18–20, 33–35 (notes that the European pharmaceutical firms were less competitive vis-à-vis the U.S. due to price regulation policy, which the U.S. does not have).

<sup>35</sup> For instance, in 2007, the United Kingdom medicine watchdog, the National Institute for Clinical Effectiveness, rejected a “last resort” drug (Abatacept) for the debilitating condition of severe arthritis. Although the watchdog found that the drug showed strong evidence of clinical benefit, it found its price for an average dose, at 9,333 pounds per person per year, too expensive. See Jeremy Laurance, “Arthritis Sufferers’ Anger as Drug is Denied on NHS” *The Independent* (26 October, 2007), online: *The Independent* <<http://news.independent.co.uk/health/article3098865.ece>>; Merrill Matthews, “Prices, Profits and Prescriptions: The Pharmatech Industry in the New Economy” (2000) *Institute for Policy Innovation, Policy Report 157* at 8–9 (notes that European countries routinely ration, and would often refuse to pay for, expensive prescription drugs).

stream of innovative life-saving medicines. Drawing on empirical data and relevant literature, the article proffers workable policy options, while critically reviewing the legal and socio-economic externalities that underpin current monocultural and market orientated prescription drug economics. The article highlights the inherent weaknesses in the current global pharmaceutical production regime, and canvasses for its supplementation with a normative, non-market oriented, internationally coordinated, pharmaceuticals production paradigm that is cognizant of societal health needs.

The article is divided into six parts. Part one deals with the introduction, part two discusses the evolution of modern medicine and the socio-economic dynamics that shape the current prescription drug economics, part three discusses the pharmaceutical costs conundrum, part four analyses neglected diseases and the scale of the problem, part five discusses the role of patents on the pharmaceuticals costs trajectory and reviews literature on possible alternatives to promoting incentives for pharmaceuticals R&D, and part six sums up the discourse and reiterates the solutions to the problems identified.

## I. FUNDAMENTALS OF PRESCRIPTION DRUG ECONOMICS

An analysis and review of the evolution and history of modern medicine is crucial to understanding the legal and socio-economic dynamics that shape the current market oriented pharmaceuticals production paradigm. The history of drug discovery and development is synonymous with the history of the pharmaceutical industry itself. However, the idea that illnesses could be averted is ancient, and predates orthodox medicine.<sup>36</sup> But, at that early time, treatments of illnesses were steeped in religious and magical practices.<sup>37</sup> These practices have tarried and are still tenaciously held on to in places like Africa and Latin America, where voodoo practices abound, and where sorcery and witchcraft are inexorably linked to illnesses and cures.<sup>38</sup> For instance, some 70 per cent of South Africans still consult

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<sup>36</sup> For instance, acupuncture is an integral component of Chinese healthcare, which dates back at least 2,500 years. See National Institutes of Health Consensus Development Statement, online: Health World Online <<http://www.healthy.net/LIBRARY/Articles/NIH/Report.htm>>; M. Weatherall, *In Search of a Cure: A History of Pharmaceutical Discovery* (Oxford: Oxford University Press, 1990) at 3.

<sup>37</sup> For instance, the mythological Asklepios, better known in Latin as Aesculapius, was the head of a cult of temple-medicine to which the sick could go for medical treatment. See *ibid.* Moreover, belief in witchcraft and its association with illness, death and cure is rife. It is believed that witches and sorcerers can inflict illnesses and cures. See "Does Witchcraft Deserve a Bad Name?" *BBC News* (6 August 2004), online: BBC News <<http://news.bbc.co.uk/1/hi/world/africa/3538912.stm>>.

<sup>38</sup> See, online: Voodoo: From Medicine to Zombies <<http://www.nando.net/prof/caribe/voodoo.html>>. The website has a detailed description of Voodoo altars, and a mythological dictionary.



traditional healers — an estimate of about 200,000 people.<sup>39</sup> In Thailand, the proliferation of faith healers prompted the government to establish a register of faith healers in 2004 in order to educate people on the rights and wrongs of supernatural beliefs.<sup>40</sup>

However, Hippocrates of Cos championed a more rational approach to medical practice by concentrating on observation and experience, thereby eschewing religion and magic.<sup>41</sup> The recognition or discovery of the healing properties of medicinal plants ushered in the “age of the botanicals”,<sup>42</sup> and greatly radicalized medical practice.<sup>43</sup>

Evidence of actual usage of medicinal plants in early times abound. For instance, the curative effect of foxglove on certain diseases was an integral part of European plant folklore, while the use of glycoside yielding plants and toad’s skin

<sup>39</sup> In 2004, the South African Parliament passed a bill to regulate the country’s burgeoning traditional healers. See “Healers Licensed in South Africa: A Bill to Regulate South Africa’s 200,000 Traditional Healers has been Adopted by Parliament” *BBC News* (9 September 2004), online: BBC News <<http://news.bbc.co.uk/1/hi/world/africa/3640270.stm>>.

<sup>40</sup> See Simon Montlake, “Thai to curb supernatural excess” *BBC News* (13 October 2004), online: BBC News <<http://news.bbc.co.uk/1/hi/world/asia-pacific/3740830.stm>>.

<sup>41</sup> Hippocrates introduced the ideas of different temperaments based on four “humors” associated with the body: fluid essences named the sanguine, the phlegmatic, the choleric, and the melancholic. According to Weatherall, these terms have had influence on medical practice till date. Aristotle refined the idea after his observation of dissected animals. He classified the special properties of living organisms into hot, cold, wet, and dry. These resonated with Hippocrates’ humors, and persisted until the growth of modern chemistry. See Weatherall, *supra* note 36 at 3.

<sup>42</sup> See John C. Somberg, “The Evolving Drug Discovery and Development Process” in Peter G. Welling, Louis Lasagna, & Umesh V. Banakar, eds., *The Drug Development Process: Increasing Efficiency and Cost-Effectiveness* (New York: Marcel Dekker Inc., 1996) at 3.

<sup>43</sup> *Ibid.* at 4. For instance, the following plant drugs were known before 1800: Opium from *Papaver somniferum* was discovered in ancient Greece and used for pain relief; Hemlock from *Conium maculatum* was discovered in ancient Greece and used for state poison; Mandragora from *Mandragora officinatum* was discovered in ancient Greece, and used for soporific magic; Belladonna from *Atropa belladonna*, discovered in 1500 and used as a cosmetic and poison; Ipecacuanha from *Cephaelis ipecacuanha* was discovered in Brazil in 1600 and used for bloody fluxes; Jesuit’s Bark from *Cinchona species* was discovered in Peru in 1630 and used for tertian and quartan agues; Coca leaves from *Erythroxylon coca*, were discovered in Bolivia and Peru in 1688 and used to prevent fatigue; Ma-Huang from *Ephedra species* was discovered in China BC and the U.S. in 1924 and used for asthma and as a stimulant; Foxglove from *Digitalis species* was discovered in England in 1775 and used for dropsy and heart disease. See Weatherall, *supra* note 36 at 4.

for medicinal purposes goes back to ancient Egypt.<sup>44</sup> The practice currently provides a limited alternative to orthodox medicine, and is popularly referred to as herbal medicine.<sup>45</sup> It is axiomatic that the use of botanicals was the first step in modern drug discovery and development,<sup>46</sup> and that botanicals are still indispensable to modern medicine,<sup>47</sup> as evidenced by the current bioprospecting activities of pharmaceutical companies.<sup>48</sup> Moreover, the use of traditional knowledge about the medicinal properties of plants and other genetic resources has yielded most conventional plant-based pharmaceuticals.<sup>49</sup> In fact, the modality for the protection of

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<sup>44</sup> Somberg, *supra* note 42 at 4; See also Stephen Pain, “The Pharaoh’s Pharmacists” *New Scientist* (15 December 2007), at 40–43 (reports on the findings that 64 per cent of prescriptions made in ancient Egypt had therapeutic value at par with drugs used in the past 50 years).

<sup>45</sup> Its wide usage has been documented and researched by medical scholars. See N.K. Mubiru, O.W. Maganyi & D.D. Soejarto, “Strength from Traditions: A Selection of Medicinal and Toxic Plants of Uganda for a Joint Public Health Effort” in John R. Stepp, Felice S. Wyndham & Rebecca K. Zarger, eds., *Ethnobiology and Biocultural Diversity* (Athens, Georgia: The International Society of Ethnobiology, 2002) at 229; Joerg Gruenwald, “The Emerging Role of Herbal Medicine in Health Care in Europe” (1998) 32:1 *Drug Information Journal* at 151–153.

<sup>46</sup> The isolation and characterization of plant-based compounds facilitated the scientific use of plant-based remedies that had hitherto been exploited as drugs themselves. See Jacalyn Duffin, *History of Medicine: A Scandalously Short Introduction*, (Toronto: University of Toronto Press, 2001) at 3.

<sup>47</sup> For instance, pharmaceuticals global sales are worth an estimated US\$300 billion annually. Of these figures, botanical pharmaceuticals account for between US\$75 billion and US\$150 billion. See Kate & Laird, *supra* note 2 at 9. The botanical medicine industry has been projected to rise by 10–20 per cent in most countries. *Ibid.*

<sup>48</sup> For example, Merck, Pfizer, and other giant pharmaceutical companies have made it their corporate policy to discover and develop pharmaceuticals from botanical sources. They often form special alliances with botanical gardens and biodiversity-rich countries in Africa, Asia and Latin America. See Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions For Drug Research, Access And Benefit Sharing*, (Tokyo, New York & Paris: United Nations University Press, 2005) at 1–11. However, bioprospecting is often derided by critics as “biopiracy”. For instance, India, China, Brazil, and nine other countries of the world’s most biodiverse countries signed an alliance on 18 February 2002 to fight biopiracy and ensure the preservation of their peoples’ right to their genetic resources. See Virginia Gewin, “Poor Nations Seek New Biodiversity Deal” (2002) 415 *Nature* at 949; Vandana Shiva, “Biopiracy: The Theft of Knowledge and Resources” in Brian Tokar, ed., *Re-designing Life? The Worldwide Challenge to Genetic Engineering*, (New York: Zed Books 2001) at 283–289.

<sup>49</sup> See Kate & Laird, *supra* note 2 at 61. It is said that, of the 120 pharmaceutical products derived from plants in 1985, 75 per cent were discovered through the study of their traditional medical use. *Ibid.*

traditional knowledge of medicinal plant cultivation and uses is now a recurring subject of legal scholarship and institutional discourse.<sup>50</sup>

The advent of chemistry marked a significant paradigm shift in drug development, as emphasis shifted from botany to the exploration of chemical substances as a new frontier of drug development. The publication of the first pharmacopoeia, *De Materia Medica* in 1839-40,<sup>51</sup> epitomized this paradigm shift.<sup>52</sup> Plant and animal substances were isolated and purified, and found to contain carbon, hydrogen, oxygen and other elements.<sup>53</sup> For instance, quinine, an effective malaria drug, was isolated from cinchona bark in 1820 at the Royal College of Chemistry in London.<sup>54</sup> Attempts to produce the drug synthetically failed<sup>55</sup> until the 1944 breakthrough in Germany.<sup>56</sup> This phase marked the beginning of what became organic chemistry.<sup>57</sup> The discovery of dyes spurred new findings of chemicals,<sup>58</sup> and the dyestuff indus-

<sup>50</sup> See Madhavi Sunder, "The Invention of Traditional Knowledge" (2007) 70 *Law & Contemporary Problems* at 119; Peter-Tobias Stoll & Anja von Hahn, "Indigenous Peoples, Indigenous Knowledge and Indigenous Resources in International Law" in Silke von Lewinski, ed., *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore* (The Hague, London & New York: 2004) at 29-43; *WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge* (1998-1999), WIPO Publication No. 768E, ISBN 92-805-0968-3, at 1; Peter Drahos, "Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?" (2000) 6 *European Intellectual Property Review* at 245-250.

<sup>51</sup> This comprised a list of 600 drugs and discussed how to acquire and prepare them. See Jonathan Pereira, *Elements of Materia Medica and Therapeutics* (London: Longman, 1839-40).

<sup>52</sup> See E.J. Shellard, "The Life and Work of Jonathan Pereira 1804-1853" (1981) 227 *Pharmaceutical Journal* at 631-3. Pereira identified four ways by which medicinal effects could be ascertained: first, by the sensible qualities of medicines; second, by the natural historical properties; third, by the chemical properties; and fourth, by the dynamical properties. See Weatherall, *supra* note 36 at 19.

<sup>53</sup> *Ibid.*

<sup>54</sup> The experiment was performed by Pelletier and Caventou, and the composition was eventually established. *Ibid.*

<sup>55</sup> *Ibid.* The nineteenth century experienced some major pharmacological breakthroughs, especially in the purification of the active ingredients of plant-based drugs. Pharmacists and doctors were able to sell and administer powerful alkaloid substances such as morphine, codeine, quinine and cocaine whose purity, strength and dosage could now be regulated. See Roy Porter, *The Greatest Benefit to Mankind: A Medical History of Humanity from Antiquity to the Present*, 1st American Edition, (New York: W. W. Norton, 1998) at 304.

<sup>56</sup> See R.B. Turner & R.B. Woodward, "The Chemistry of Cinchona Alkaloids" in R.H.F. Manske & H.L. Holmes, eds., *The Alkaloids: Chemistry and Physiology*, vol. 3 (New York: Academic Press, 1953) at 1-63.

<sup>57</sup> *Ibid.*

<sup>58</sup> *Ibid.*

try soon gave way to drug production, especially in Germany and Switzerland.<sup>59</sup> Bayer, a German chemical company, was arguably the world's first modern pharmaceutical company, when in 1888 it marketed an anti-pyretic drug that was sold as Phenatin.<sup>60</sup> By 1897, aspirin had been introduced as the world's first synthetic pharmaceutical.<sup>61</sup> The existence of viable chemical industries was the critical linchpin for the subsequent growth and development of the pharmaceutical industry.<sup>62</sup> In fact, modern medicine has been dated from 1928 when Alexander Fleming discovered penicillin,<sup>63</sup> while the birth of modern research-based pharmaceutical industry has been anchored in the 1930s when Prontosil and Penicillin were first commercialized.<sup>64</sup> The advent of biotechnology opened up access to new compounds from human proteins other than the traditional sources of soil collection and organic chemistry.<sup>65</sup> Currently on the cusps of genomics revolution, the industry is primed for greater efficiency in drug research and development.<sup>66</sup>

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<sup>59</sup> *Ibid.*

<sup>60</sup> See Dutfield, *supra* note 14 at 89. While commenting on Bayer's feat and its significance as the template for future pharmaceutical companies, Charles Mann and Mark Plummer said as follows: "For the first time, a drug had been conceived, developed, tested, and marketed, all by a private company. It marked the creation of the modern drug industry, the marriage of science and business that has transformed this century, making huge profits even as it saves lives." See Charles C. Mann & Mark L. Plummer, *The Aspirin Wars: Money, Medicine, and 100 years of Rampant Competition*, (New York: Knopf, 1991) at 10.

<sup>61</sup> See Dutfield, *supra* note 14 at 89.

<sup>62</sup> Many of the chemical companies in Germany and Switzerland found out that the technology for making synthetic dyes was easily transferable to pharmaceuticals. This led to the production of a new number of pharmaceuticals between 1908 and World War II. See Agrawal, *supra* note 34 at 2-4.

<sup>63</sup> Alexander Fleming was a Scottish Microbiologist. He had been searching for years for a therapeutic agent that could kill bacteria without harming the tissue of the host. While he was on vacation, a green mold had drifted in through the window of his laboratory at St. Mary's Hospital in London, contaminating a culture growing in one of his Petri dishes. To his surprise, he found that microbes on the mold were sucking up the bacteria. Fleming named the germ-fighting contaminant penicillin. In October 1945 Alexander Fleming, Howard Florey & Ernst Chain were awarded the Nobel Prize in medicine. See Linda Marsa, *Prescription for Profits: How the Pharmaceutical Industry Bankrolled the Unholy Marriage Between Science and Business* (New York: Scribner, 1997) at 22.

<sup>64</sup> See Carsten Fink, *Intellectual Property Rights, Market Structure, and Transnational Corporations in Developing Countries* (Berlin: Mensch & Buch Verlag, 2000) at 123.

<sup>65</sup> See Barton, *supra* note 24 at 286 (the author notes that biotechnology has changed both the research and structural paradigm of the pharmaceutical industry by enabling a shift from reliance on traditional compounds sourced from organic chemistry and soil collection, to human proteins).

<sup>66</sup> See Arti K. Rai, "Pharmacogenetic Interventions, Orphan Drugs, and Distributive Justice: The Role of Cost-Benefit Analysis" (2002) 19:2 Social Philosophy & Policy at

A notable feature of this narrative is that pharmaceutical innovation is historically transnational, co-operative, incremental and cumulative. This is exemplified by the 1820 isolation of quinine, a malaria drug, from cinchona bark in London by the Royal College of Chemistry, and its subsequent synthesis in Germany in 1944.<sup>67</sup> However, the co-operative element of modern pharmaceutical R&D has been radically redefined by proprietary rights via the instrumentality of the patents regime.<sup>68</sup> A classic example for which patent is the critical linchpin is the public private partnerships, a pharmaceutical research and development paradigm, premised on co-operation between publicly funded research institutions and the pharmaceutical industry.<sup>69</sup>

### (a) Strength in Numbers: The Transnational and Mega-Pharmaceutical Industry

One of the fundamentals of prescription drug economics is the pharmaceutical industry's transnational presence.<sup>70</sup> In spite of the concentration of the largest pharmaceutical companies in relatively few countries,<sup>71</sup> establishment of international manufacturing outposts in nations that import pharmaceuticals is rife and crucial to achieving desired economies of scale.<sup>72</sup> For instance, Pfizer reputedly had twenty-

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246 (posits that the mapping of the human, and over one hundred animal genomes, has yielded an exponential increase in data on genes, proteins, and biochemical pathways associated with various diseases that could be manipulated and specifically targeted by designer drugs, thus improving drug efficiency).

<sup>67</sup> See R.B. Turner & R.B. Woodward, "The Chemistry of Cinchona Alkaloids" in R.H.F. Manske & H.L. Holmes, eds., *The Alkaloids: Chemistry and Physiology*, vol. 3 (New York: Academic Press, 1953) at 1–63.

<sup>68</sup> See Janet Hope, *Biobazaar: The Open Source Revolution and Biotechnology* (Cambridge, Massachusetts and London, England: Harvard University Press, 2008) at 28–67 (the author notes that while patents have been instrumental to the dramatic privatization of biotechnology and its phenomenal growth from the early 1980s, they may also have hindered innovations in the field, resulting in a "tragedy of the anticommons").

<sup>69</sup> See Ron A. Bouchard & Trudo Lemmens, "Privatizing Biomedical Research: A Third Way" (2008) 26:1 *Nature Biotechnology* at 31–38 (the authors observe that the wave of privatization that swept the U.S. pharmaceutical industry in the 1990s was predicated on the twin pillars of transnational research and public-private partnerships). *Ibid.* at 31.

<sup>70</sup> See Bouchard & Lemmens, *supra* note 69 at 31 (the authors note that transnational research is an integral pillar of modern pharmaceuticals R&D); Agrawal, *supra* note 34 at 1.

<sup>71</sup> See Stuart O. Schweitzer, *Pharmaceutical Economics and Policy* (Oxford, New York: Oxford University Press, 1997) at 12.

<sup>72</sup> Economies of scale refers to the costs saved by a firm as a result of expansion. Typically, but not necessarily, when a firm increases its output, the total costs of input decreases with consequential savings. See Joachim Silvestre, "Economies and Diseconomy of Scale" in John Eatwell, Murray Milgate & Peter Newman, eds., *The New*

one manufacturing plants located in developing countries, with four out of its six R&D laboratories located outside of the United States.<sup>73</sup> This is further exemplified in Mexico, which is home to almost all of the major multinational research-based pharmaceutical companies producing 84 per cent of the total value of Mexican pharmaceutical sales in 2003 and investing an estimated \$200 million in 2004.<sup>74</sup> Similarly, crucial research and development activities are often carried out outside of a firm's national borders by foreign surrogates or affiliates, as typified by the Pfizer business model and explicated by the Mexican case. For instance, in 1994, an estimated \$4.5 billion worth of pharmaceutical R&D was executed in the United States by affiliates of foreign firms mainly from the United Kingdom and Switzerland, and \$1.9 billion worth of R&D was executed outside of the United States by foreign associates of U.S. pharmaceutical firms.<sup>75</sup> Moreover, the industry also owes its trans-nationality to periodic mergers and acquisitions, often necessitated by competitiveness imperatives.<sup>76</sup> For example, GlaxoSmithKline evolved through mergers and acquisitions to become the second-largest pharmaceutical company in the world.<sup>77</sup>

Although the pharmaceutical industry has a transnational presence, it tends to concentrate in certain regions of the world; the United States, Canada, Germany, the United Kingdom, Switzerland, France, Belgium, Sweden, and Japan.<sup>78</sup> The industry's locational disequilibrium has been attributed to its inherent competitive-

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*Palgrave Dictionary of Economics*, vol. 2 (London & New York: Macmillan and Stockton, 1987) at 80–84.

<sup>73</sup> See Peter Drahos & John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy* (New York: The New Press, 2002) at 66.

<sup>74</sup> See Pierre Moise & Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Mexico* OECD Health Working Papers No. 25, DELSA/HEA/WD/HWP(2007) 1(13 February, 2007), 1–65, at 35.

<sup>75</sup> See Barton, *supra* note 24 at 290.

<sup>76</sup> Mergers in the industry are imperative for a stronger financial base for the capital-intensive R&D, and for thwarting impediments generated by the inherent competition in the industry. See Somberg, *supra* note 42 at 11. Most often, the mergers or acquisitions transcend firms' nationalities. For instance, in 2000, Glaxo Wellcome, a UK firm, merged with SmithKline Beecham, which was jointly owned by UK and U.S. firms. Other firms that merged between 1989 and 2000 were: in 1989, Dow (US) and Marion (US); Bristol-Myers (US) and Squibb (US); in 1990, Rhone-Poulenc (France) and Rorer (US); Roche (Swiss) and Genentech (US); in 1996, Ciba-Geigy (Swiss) and Sandoz (Swiss) merged to form Novartis; in 1999, Hoechst (Germany) and Rhone-Poulenc (France) merged to form Aventis; Astra (Swedish) and Zeneca (UK). See G. Owen, *From Empire to Europe: The Decline and Revival of British Industry Since the Second World War* (London: HarperCollins, 1999) at 382.

<sup>77</sup> See GlaxoSmithKline, Annual Report, "Answering the Questions That Matter" (2007), online: GlaxoSmithKline <<http://www.gsk.com/investors/reps07/annual-report-2007.pdf>>.

<sup>78</sup> See Owen, *supra* note 76 at 382.

ness in those countries, relative to that in other regions of the world.<sup>79</sup> The competitive advantages that pharmaceutical firms gain from being in these regions range from the ability to develop innovative products, to the availability of sound infrastructure and finance for research and development, to auspicious regulatory framework.<sup>80</sup>

Barring entry barriers such as shortage of skilled labour or weak finances,<sup>81</sup> it is axiomatic that every country would prefer to produce all its pharmaceutical needs locally.<sup>82</sup> The advantages to the real prospects of kick-starting an industrial economy are very obvious, ranging from adequate provision for local health care needs, an R&D focus on country-specific diseases, assured employment in the pharmaceutical sector, adequate quality control of pharmaceuticals production processes, and foreign exchange augmentation with pharmaceuticals exports.<sup>83</sup>

However, because the industry is technology intensive,<sup>84</sup> few countries have the technological resources to truly compete.<sup>85</sup> As noted earlier, while research-based foreign firms produced 84 per cent of Mexican pharmaceuticals in 2003, Mexican firms were confined to producing generics and patented copy drugs.<sup>86</sup> Nevertheless, it has been posited that, despite skeptical views to the contrary, least developed countries, that lack pharmaceutical local production capacity, could benefit from the new exceptions and flexibility in the WTO TRIPS Agreement to es-

<sup>79</sup> See Agrawal, *supra* note 34 at 8–38; John K. Iglehart, “Good Science and the Marketplace for Drugs: A Conversation with Jean-Pierre Garnier” (2003) 22:4 Health Affairs at 119–127.

<sup>80</sup> See Agrawal, *ibid.*

<sup>81</sup> See Mirjam Schiffer & Beatrice Weder, “Firm Size and the Business Environment: Worldwide Survey Results.” International Finance Corporation, World Bank Paper No. 43 (2001), online: International Finance Corporation <[http://ifcln1.ifc.org/ifcext/economics.nsf/AttachmentsByTitle/dp43/\\$FILE/dp43.pdf](http://ifcln1.ifc.org/ifcext/economics.nsf/AttachmentsByTitle/dp43/$FILE/dp43.pdf)>.

<sup>82</sup> See Warren Kaplan & Richard Laing, “Local Production of Pharmaceuticals: Industrial Policy and Access to Medicines: An Overview of Key Concepts, Issues, and Opportunities for Future Research” Health, Nutrition, and Population (HNP) Discussion Paper No. 32036 (January 2005). The International Bank for Reconstruction and Development/The World Bank (the authors note that local production of pharmaceuticals by many countries would not necessarily lead to improved access due to the consequential reduction in the economies of scale).

<sup>83</sup> See Gary Gereffi, *The Pharmaceutical Industry and Dependency in the Third World* (Princeton, N.J.: Princeton University Press, 1983) at 167.

<sup>84</sup> See Agrawal, *supra* note 34 at 1–38.

<sup>85</sup> Some developing countries, notably India, Brazil, Argentina, South Korea, Mexico, and China have been able to reverse engineer and manufacture generics drugs, which require less intensive pharmaceutical technological wherewithal. See Balasubramaniam, *supra* note 28 at 90–107.

<sup>86</sup> See Moise & Docteur, *supra* note 74 at 35.

establish a Mexican or Indian type generic pharmaceutical production base.<sup>87</sup> Enhanced capability for local generics production could potentially make prescription drugs cheaper and thus, affordable<sup>88</sup> and open the door to mainstream pharmaceutical production in the long term. Although not all countries are involved in pharmaceutical manufacturing, most brand names have morphed into global household names, and pharmaceuticals are now truly ubiquitous public goods. From the common antibiotic to the complex AIDS drug, their ubiquity is a testament to their indispensability and the commonality of humanity's quest for adequate health care.<sup>89</sup>

**(b) Public-Private Partnerships: Should Pricing Reflect Public Money in Privately Owned Pharmaceuticals?**

Although the modern pharmaceutical industry depends largely on private equity funding for R&D activities,<sup>90</sup> public private partnerships and a collaborative

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<sup>87</sup> See Frederick M. Abbott & Jerome H. Reichman, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions" (2007) 10:4 *Journal of International Economic Law* at 921–987 (notes that despite skepticism, least developing countries could use TRIPS's flexibility and the comparative advantages provided to them by biogenetic diversity and traditional knowledge to establish viable local generic pharmaceutical production before the 2016 TRIPS deadline for enforcement of pharmaceutical patents: at 978).

<sup>88</sup> For example, India is said to be building on the critical mass of its generic drug production to an established research-based pharmaceutical industry. See Padmashree Gehl Sampath, "India's Product Patent Protection Regime: Less or More of 'Pills for the Poor'?" (2006) 9:6 *The Journal of World Intellectual Property* at 694–726 (notes that Indian pharmaceutical firms produced 22 per cent of all generic drugs worldwide. However, foresees that the introduction of product patents protection in 2005 will have mostly likely lead to a decline in the output of the generic drugs. Indian pharmaceutical firms have thus commenced investing in R&D, which had grown from US\$80 million in 2001 to US\$170 million in 2004: at 700–702).

<sup>89</sup> Health is a basic human need. Good health is no less important than good food. The right to health has even been viewed as a key human right. For a discussion, see Danwood Mzikenge Chirwa, "The Right to Health in International Law: Its Implications for the Obligations of State and Non-State Actors in Ensuring Access to Essential Medicines." (2003) 19:3 *South African Journal on Human Rights* at 541; Zita Lazzarini, "Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the case of Brazil" (2003) 6 *Yale Human Rights & Law Development Law Journal* at 117–118 (Lazzarini posits that a careful reader will not find "[no] right to access to pharmaceuticals" in the International Bill of Human Rights or in any subsequent modern human rights instruments. However, such obligation - although not a defined human right itself — is firmly grounded in the implications of existing substantive provisions and in the special needs created by the current circumstances); *Ibid.*

<sup>90</sup> See Carlos Maria Correa, "Ownership of Knowledge: the Role of Patents in Pharmaceutical R&D" (2004) 82:10 *Bulletin of the World Health Organization* at 784–787 (notes that private firms invest the largest part of global funds for pharmaceutical R&D).



new drug research and production paradigm between publicly funded research institutions and the pharmaceutical industry is an integral element of prescription drug economics.<sup>91</sup> Notable pioneering and breakthrough innovative drugs are often rooted in basic research conducted at publicly funded universities in Canada, Europe and the United States.<sup>92</sup> In the U.S. for example, universities conducting basic research for new drugs are often funded by the National Institutes of Health (NIH),<sup>93</sup> although the universities do hold patent rights, and can commercialize their basic research under the *Bayh-Dole Act*.<sup>94</sup> Specifically, the NIH's contributions to the U.S. pharmaceutical industry drug development programs in 2005, 2006 and 2007, were \$28.7 billion, \$28.5 billion, and \$28.6 billion respectively.<sup>95</sup>

In Canada, the U.S. style public-private partnerships research paradigm for new pharmaceuticals was formalized in 2000, when the Canadian Institutes for Health Research (CIHR) was established.<sup>96</sup> An equivalent of the U.S. National Institutes of Health, the CIHR has a mandate to organize, co-coordinate, and fund health research at the Federal level, and ensure the commercialization of publicly

<sup>91</sup> See Bouchard & Lemmens, *supra* note 69 at 31; Rebecca S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research" (1996) 82 Virginia Law Review at 1663-1727 (reviews the history of the legal framework that facilitated the transfer of publicly funded research results from the public domain to private industry for commercialization via the instrumentality of patents licensing and technological transfer agreements in the United States).

<sup>92</sup> See Dutfield, *supra* note 14 at 98, 102 (the author notes that governments often fund a great deal of basic pharmaceutical research; especially in the United States, the industry has benefited tremendously both from direct government funding, and collaborations with publicly funded universities); Barton, *supra* note 24 at 286.

<sup>93</sup> See Eric G. Campbell *et al.*, "Inside the Triple Helix: Technology Transfer and Commercialization in the Life Sciences" (2004) 23:1 Health Affairs at 64-76; Barton, *supra* note 24 at 286.

<sup>94</sup> See University and Small Business Patent Procedures P.L. 95-517, 12 December 1980, codified at *Bayh-Dole Act*, 35 U.S.C. ss. 200-212 (2004); Radio Broadcast with Professor Paul A. David, "Innovation and the Role of Universities in Commercializing Research Results" (2006) 2 University of Illinois Journal of Law, Technology, & Policy 101 at 103 (notes that wealth creation was injected into the U.S. universities' objectives by the *Bayh-Dole Act*); William M. Sage, "Funding Fairness: Public Investment, Proprietary Rights and Access to Health Care Technology" (1996) 82 University of Virginia Law Review at 1737-1752 and 1749 (notes that the *Bayh-Dole Act* was instrumental to the development of strategic alliances between academics and industry, and that the former had earned large sums from patents royalties and joint venture payments).

<sup>95</sup> See Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry's Profile 2007*, (Washington DC: PhRMA, March 2007) at 2.

<sup>96</sup> See *Canadian Institutes of Health Research Act*, R.S.C. c. 6 (2000) as am. 2006. The CIHR was a successor of the Medical Research Council of Canada.

funded research through patents licensure to pharmaceutical companies.<sup>97</sup> On the contrary, the UK does not have the Bayh-Dole or CIHR type legislation. Perhaps, this partly accounts for the relative lack of enthusiasm for research commercialization expressed by the UK higher education sector. For instance, 26 per cent of UK universities had no formal policy of intellectual property exploitation,<sup>98</sup> while 90 per cent were more interested in publishing research in order to improve research assessment exercise ratings rather than applying for patents.<sup>99</sup> Nevertheless, the UK has a government-backed technology transfer policy, albeit with weak, but beneficial Bayh-Dole effects for UK universities and research institutions.<sup>100</sup>

Generally, collaborations between publicly funded research institutions and for-profit private technological companies are often mutually beneficial.<sup>101</sup> For instance, in the 2006 financial year, U.S. academic centers received \$45 billion of public money in research funding,<sup>102</sup> while joint public-private collaborative research efforts in the U.S. led to the introduction of 697 new products into the market, the launching of 553 new start-up companies, and the management of 12,672 licenses and options.<sup>103</sup> Specifically, biopharmaceuticals public-private collaborative research efforts often lead to breakthrough prescription drugs. A notable example is Xalatan, the best selling eye drop for Glaucoma, which originated from basic research conducted at the laboratory of Columbia University in the 1970s, aided by a \$4 million National Institutes of Health grant.<sup>104</sup> The Xalatan example typifies the collaborative public private partnerships drug research paradigm, between non-profit publicly funded research universities and the profit-orientated pharmaceutical industry.

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<sup>97</sup> See Ron A. Bouchard, "Balancing Public and Private Interests in the Commercialization of Publicly Funded Medical Research: Is There a Role for Compulsory Government Royalty Fees?" (2007) 13:2 Boston University Journal of Science & Technology Law at 120-192 (the author notes that commercialization and public-private partnerships are central to the CIHR mandate). Bouchard, *ibid.* at 122-123.

<sup>98</sup> See Hannah Fearn, "A Penny for Your Thoughts: Academics are at the Very Heart of the Knowledge Economy, but Just How Far Should They and Their Institutions Go in the Commercial Exploitation of Their Ideas?" *Times Higher Education* (28 February-5 March 2008) at 31-35.

<sup>99</sup> *Ibid.* at 31.

<sup>100</sup> See Mark Van Hoorebeek, "Government Policy and University Technology Transfer Practices in the UK" (2005) 4:4 International Journal of Technology Transfer and Commercialization at 500-517.

<sup>101</sup> See Sage, *supra* note 94 at 1749.

<sup>102</sup> See Association of University Technology Managers, AUTM U.S. Licensing Activity Survey FY 2006, online: Association of University Technology Managers <[http://www.autm.net/AM/Template.cfm?Section=FY\\_2006\\_Licensing\\_Activity\\_Survey&Template=/CM/ContentDisplay.cfm&ContentID=1804](http://www.autm.net/AM/Template.cfm?Section=FY_2006_Licensing_Activity_Survey&Template=/CM/ContentDisplay.cfm&ContentID=1804)>.

<sup>103</sup> *Ibid.*

<sup>104</sup> See Jeff Gerth & Sheryl Gay Stolberg, "Drug Makers Reap Profits on Tax-Backed Research" *The New York Times* (23 April 2000) at 1.1.

However, critics have queried the propriety of using public money to fund a profit-orientated industry whose products are often too expensive for the average citizen.<sup>105</sup> For instance, at an average cost of between \$40 and \$50 for a tiny bottle, Xalatan was priced out of reach of low-income Americans who had no prescription drug coverage.<sup>106</sup> It has been observed that the distributions of the benefits of commercialization of publicly funded research are skewed in favour of private companies and universities, and against the public interest.<sup>107</sup> This is exemplified in the United States where, despite the billions of public dollars poured annually into pharmaceutical basic research via public research institutions,<sup>108</sup> millions of mostly uninsured seniors still stream across the border into Canada and Mexico for cheaper prescription drugs.<sup>109</sup>

This has rekindled debates on whether it is appropriate that taxpayer-funded pharmaceuticals are often beyond taxpayers' purchasing power. According to Rebecca Eisenberg, while there is a compelling case for granting patents exclusivity to firms for privately funded research, allowing private firms to hold exclusive rights to inventions that have been generated at public expense would be tantamount to requiring the public to pay twice for the same invention.<sup>110</sup> However, as Eisenberg notes, advocates of "private appropriation" of publicly funded research are quick to argue that further investments are necessary to refine, test, commercialize, and market publicly funded inventions, and that the government lacks the expertise and recourses for those activities.<sup>111</sup> Nevertheless, even if private funds had to supplement public money in getting a product refined and into the market, the pertinent question is: should not taxpayers' contributions to the underlying research and development be factored into product pricing? In other words, should the pharmaceutical industry account for public funding of the underlying basic research in pre-

<sup>105</sup> See Bouchard, *supra* note 97 at 125-126.

<sup>106</sup> A tiny bottle of Xalatan lasted six weeks, on average, and was sold for between \$45 and \$50, an average cost of \$1 per day — one that Albert Russell, a retiree who had no prescription drug coverage, could not afford. See Gerth & Stolberg, *supra* note 104 at 1.1.

<sup>107</sup> See Bouchard, *supra* note 97 at 125-126.

<sup>108</sup> See Pharmaceutical Research and Manufacturers of America, *supra* note 95 at 2 (notes that the U.S. National Institutes of Health contributed \$28.7 billion, \$28.5 billion, and \$28.6 billion in 2005, 2006, and 2007, respectively, to new drug development).

<sup>109</sup> Most purchases are made via the internet. See John A. Vernon, Stephan Goupil, & Joseph H. Colec, "The Internet and Pharmaceutical Importation: Economic Realities and Other Related Issues" (2006) 16:3 Albany Law Journal of Science & Technology at 545-564 (the authors note the findings of a Minority Staff Report of the U.S. House of Representatives that "uninsured seniors in Maine pay 72 [per cent] more . . . than individual purchasers in Canada, and 102 [per cent] more than individual purchasers in Mexico"); *Ibid.* at 556; Jeremy W. Hochberg, "Nailing Jell-O to a Wall: Regulating Internet Pharmacies" (2004) 37 Journal of Health Law at 445-446.

<sup>110</sup> See Eisenberg, *supra* note 91 at 1663.

<sup>111</sup> *Ibid.*

scription drug pricing? It would seem equitable and fair for them to do so. However, it is most unlikely that they would do so voluntarily due to the lure of the market, which is made all the more lucrative by a patents monopoly that guarantees market exclusivity.<sup>112</sup> It would certainly be in the public interest to make the pharmaceutical industry accountable for underlying public funding via product pricing if doing so would enhance affordability and bridge the access gap to prescription drugs.<sup>113</sup>

It is significant that the propriety of the public's paying twice for the products of patented, yet publicly funded, research was examined in some detail but, the inclusion of a recoupment provision was mooted in the run up to the passage of the U.S. *Bayh-Dole Act* in 1980.<sup>114</sup> However, a recoupment provision, which was initially included in the original Bayh Dole bill, was expunged before the bill was signed into law.<sup>115</sup> The issue however, came to a head in 1989, when most HIV-positive individuals could not afford AZT, the most effective drug at the time.<sup>116</sup> The resultant public outcry led to heated debates in the U.S. Congress on the propriety of a pharmaceuticals price control and the adoption of a "reasonable price" requirement by the NIH for inventions arising from the Cooperative Research and Development Agreement.<sup>117</sup> On 2 December 1992, the U.S. National Institutes of Health convened an advisory meeting on the modality for ensuring that drugs developed with public funds were priced to reflect "public investment in the product, and the health and safety needs of the public".<sup>118</sup> Although the NIH could legally look into the issue of whether drug pricing should reflect public investments under the boilerplate provisions of the NIH-industry cooperative R&D agreements,<sup>119</sup> the

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<sup>112</sup> See Richard G. Frank, "Prescription Drug Prices: Why Do Some Pay More Than Others Do?" (2001) 20:2 Health Affairs at 115–128 (notes that brand-name drugs have market power conferred upon them via the patent system). For instance, the Xalatan patent is due to expire in 2011. This allows the Pharmacia Corporation to corner the market for glaucoma drugs and charge monopoly prices until patent expiration. See Gerth & Stolberg, *supra* note 104.

<sup>113</sup> It is certainly in the public interest to have an affordable prescription drug regime. This arguably explains why most countries regulate prescription drug prices.

<sup>114</sup> See Bhaven N. Sampat, "Patenting and the US Academic Research in the 20<sup>th</sup> Century: The World Before and After *Bayh Dole Act*" (2006) 35:6 Research Policy 772 at 777.

<sup>115</sup> *Ibid.*

<sup>116</sup> See Sage, *supra* note 94 at 1742.

<sup>117</sup> *Ibid.*

<sup>118</sup> See "NIH Drafting Interim Pricing Policy Statement for Congressional Hearings" *F-D-C Reports* (7 December 1992) at 7-8, cited in F.M. Scherer, "Pricing, Profits, and Technological Progress in the Pharmaceutical Industry" (1993) 7:3 Journal of Economic Perspectives at 108.

<sup>119</sup> *Ibid.* at 108.

NIH was reluctant to assume a role in price control despite pressures from the U.S. Congress to the contrary.<sup>120</sup>

It is submitted that a policy geared towards reflecting public investments in prescription drug pricing is not a price control mechanism per se, as the United States National Institutes of Health had feared.<sup>121</sup> Rather, it is an equitable measure that would take due account of taxpayers' contribution to financing of the basic research leading to useful prescription drugs. Critics of this proposition might argue that it would amount to a double taxation on the pharmaceutical industry, which would normally have paid licensing fees to universities and publicly funded research institutions for access to patented basic research. Though a valid and credible argument, it is arguably weakened by the findings that revenues generated from licensing fees by universities and publicly funded research institutions are often comparatively paltry and disproportionately small relative to the pharmaceutical industry's profits.<sup>122</sup> This is again exemplified by Xalatan, the best selling eye drug for Glaucoma.<sup>123</sup> While Columbia University reportedly received an estimated one-off \$20 million royalties fee from Pharmacia Corporation, a Swedish Pharmaceutical company to whom the research was licensed,<sup>124</sup> Pharmacia Corporation reportedly earned an estimated \$507 million (mostly pure profits) in annual sales of Xalatan.<sup>125</sup>

Moreover, even if adequate royalties or licensing fees were paid by the pharmaceutical industry for the use of patented publicly funded research, the real social value of life-saving drugs that originated from publicly funded research is unquantifiable, and cannot arguably be fully accounted for by licensing fees. In this view,

<sup>120</sup> *Ibid.* at 108; Christopher Anderson, "Government-Industry Collaboration: NIH Panel Rejects Pricing Clause" (1994) 265:5172 *Science* at 598 (reports on the NIH Panel's rejection of government participation in the pricing of products developed from government-private funded research). Significantly, the recoupment issue would not go away and it resurfaced again in 2001, fueled by public concerns over whether taxpayers' interests were being adequately taken care of. The NIH, nevertheless, rejected recoupment on grounds that it would undermine medical research, reduce funds for academic development, discourage faculty members from engaging in technology transfer, and interfere with industry agreements with academic institutions. See Bouchard, *supra* note 97 at 175.

<sup>121</sup> See F. M. Scherer, "Pricing, Profits, and Technological Progress in the Pharmaceutical Industry" (1993) 7:3 *Journal of Economic Perspectives* at 97.

<sup>122</sup> See Campbell, *supra* note 93 at 70-71 (notes that, of the total \$1.7 billion in licensing revenues earned by the 140 respondents to the 1999-2000 annual survey of the Association of University Technology Managers (AUTM), the top ten income producing universities generated \$1 billion, or 60 per cent of all licensing revenues, and that the bulk of the top ten's licensing revenues derived from a small band of highly lucrative licenses); *Ibid.*

<sup>123</sup> See Gerth & Stolberg, *supra* note 104.

<sup>124</sup> Pharmacia Corporation merged with Monsanto in 2000. See *ibid.*

<sup>125</sup> Most of the \$507 earnings were said to be pure profits, as it costs pennies to make latanaprost — the key ingredient of the compound used in making Xalatan; *Ibid.*

the society could rightfully claim a “social lien” on drugs emanating from publicly funded research.<sup>126</sup>

The pertinent consideration, therefore, is how best to account for the public money invested in pharmaceutical research and development. The most practical and cost-effective solution would appear to be the inclusion of recoupment provisions in licensing agreements for publicly funded patented research that is transferred to the pharmaceutical industry.<sup>127</sup> It has been suggested that technological transfer laws such as the *Bayh-Dole Act* should be reassessed to accommodate such recoupment provisions.<sup>128</sup> This would allow the government to recoup public money spent on developing pharmaceutical products. However, the recoupment proposal is beset with an inherent weakness: the possibility that authorities might not be able to recoup any more than the actual value of public investments in a successful pharmaceutical product. Consequently, the money recouped could be so disproportionately small to industry profits, or diminished by inflation, that it would make little or no difference when ploughed back into the pool of funds dedicated to subsidising prescription drug purchases.

This obstacle could be overcome if the government’s recoupment right is expressly coupled with other entitlements, as might be agreed upon by the parties in the licensing contracts. These would range from royalty payments to, and or stock options for the research institution concerned, or the government. The vesting of right or entitlement to a percentage of accruable profits from product sales in the government or the research institution concerned is also an option. Alternatively, the inherent weakness in recoupment rights could, however, be overcome by generally levying “a compulsory government royalty” on publicly funded, successful commercial products.<sup>129</sup> A compulsory government royalty could be legally, broadly and flexibly interpreted to exceed the original research grant, while taking into account variables such as inflation, the product’s commercial success, accruable profits from the product’s sales, etc. Accruable revenues from the said compulsory government royalty could then be ploughed back into funds dedicated to subsidising prescription drug coverage.<sup>130</sup> However, institutionalizing the measure would require a regulatory framework akin to the one enacted by the state of California.

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<sup>126</sup> In this context, “social lien” is not analogous to a lien, and it is not intended to import its legal meaning. Rather, “social lien” is used to invoke societal moral claim to pharmaceuticals from publicly funded research. The pharmaceutical industry would be morally obliged to reciprocate the claim by easing access to drugs funded with public money.

<sup>127</sup> See Sage, *supra* note 94 at 1737–1752.

<sup>128</sup> *Ibid.* at 1751.

<sup>129</sup> Bouchard, *supra* note 97 at 173–188.

<sup>130</sup> *Ibid.* at 173. Bouchard believes that the measure would operate “to balance public and private interests in the privatisation of innovative research and thus ensures taxpayers’ interests in securing an appropriate return on federally funded research are protected.”

### (c) Public Private Partnerships: The California Regenerative Medicine Research Policy Model

The state of California is bucking the national stem cell policy trends.<sup>131</sup> California is not only funding stem cell research, contrary to the federal stem cell policy, but has come up with a unique intellectual property policy for recouping its funding, and spreading the benefits of regenerative medicine amongst its citizens. The policy is thus radically different from the national intellectual property policy on federally-funded research that was analyzed in the preceding paragraph.<sup>132</sup>

In early 2005, the state of California established the California Institute for Regenerative Medicine (CIRM).<sup>133</sup> The CIRM was empowered to make grants and provide loans for stem cell research.<sup>134</sup> In February 2008, the CIRM published its intellectual property policy to govern the ownership of patents arising from CIRM-funded research<sup>135</sup> and revenue sharing modalities between the state of California and for-profit organizations researching stem cells.<sup>136</sup> According to the policy, for-profit grantees must annually report to CIRM and have all patents applications filed, including any licensing agreements relating to any inventions arising from CIRM-funded research, and accruable revenues from licensing agreements.<sup>137</sup>

It is also required of a for-profit grantee to submit a plan to the CIRM outlining how uninsured Californians would access a drug produced wholly or partly from CIRM-funded Research.<sup>138</sup> Significantly, the drug must be sold at a price

<sup>131</sup> The Bush administration is reluctant to use federal money to fund stem cell research on ethical and religious grounds. The federal government's policy is premised on grounds that the research would harm embryos. See Charles Babington, "Stem Cell Bill Gets Bush's First Veto" *The Washington Post* (20 July 2006) at A04 (comments on President Bush's veto of U.S. Congress's bill to lift funding restrictions on human embryonic stem cell research. President Bush is opposed to stem cell research on ethical grounds).

<sup>132</sup> See para. B, above.

<sup>133</sup> CIRM was established in 2005 through the passage of Proposition 71, the California Stem Cell Research and Cures Initiative. The statewide ballot measure was approved by voters on 2 November 2004. It provided \$3 billion in funding for stem cell research at California universities and research institutions. See, online: California Institute for Regenerative Medicine (CIRM) <<http://www.cirm.ca.gov/>>.

<sup>134</sup> *Ibid.*

<sup>135</sup> CIRM-funded patented invention is defined as "An invention that has been patented under Title 35 of the *United States Code*, and that resulted wholly or in part from CIRM-funded Research, except in the event the patent has expired, been abandoned or found to be invalid or otherwise unenforceable (unless noted otherwise in these regulations)." See c. 4, s. 100401(b), 17 *California Code of Regs. Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations*, online: <<http://www.cirm.ca.gov/faq/pdf/ForProfitOrg.pdf>>.

<sup>136</sup> *Ibid.* at ss. 100400–100410.

<sup>137</sup> *Ibid.* at s. 100402 (a)(d)(e).

<sup>138</sup> *Ibid.* at s. 100407(a).

provided for under the California Discount Prescription Drug Program.<sup>139</sup> This provision arguably, clearly borders on price control, and most probably explains why it is followed up by the following caveat:

This regulation is not intended, and this regulation shall not be construed, to preempt or prevent any other requirement under state or federal law or regulation, or agreement or contract, that would result in selling a Drug at a lower price than provided hereunder.<sup>140</sup>

Ostensibly, the caveat is aimed at deflecting the perception that the statute could preempt federal patent law and allied legislations. Under the Dormant Commerce Clause of the United States Constitution, only Congress could regulate international and interstate commerce.<sup>141</sup> Thus, states are implicitly prohibited from passing legislation that could affect interstate commerce, or impinge on Congress's authority to regulate interstate commerce within the federation.<sup>142</sup> It remains to be seen how well the California law regulating the price of CIRM-sponsored drugs can hold out under the scrutiny of the Dormant Commerce Clause of the United States Constitution.<sup>143</sup>

There are, without doubt, conceivable scenarios for the possible invocation of the commerce clause against the CIRM-sponsored drug price control policy. For instance, if there was evidence that the California price control policy interfered with Congress's authority to regulate prescription drug prices, or that the California measure was depressing prescription drug prices in other states, or making pharmaceutical firms in other states less competitive, or interfering with the way their businesses were run under the laws of their respective states, or that the policy was weakening the pharmaceutical patents monopoly conferred by Congress via the *Patents Act* of 1976, then there could be a valid constitutional ground for challenging the policy.

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<sup>139</sup> *Ibid.* at s. 100407(b)(c).

<sup>140</sup> *Ibid.* at s. 100407(d).

<sup>141</sup> See *United States Constitution* Art. 1, s. 8, cl. 3.

<sup>142</sup> See for example, *Healy v. Beer Institute, Inc.*, 491 U.S. 324 (U.S. Conn., 1989). The U.S. Supreme Court struck down provisions of a Connecticut statute that required out-of-state shippers of beer to affirm that their posted prices for products sold to Connecticut wholesalers were no higher than the prices at which those products were sold in States bordering Connecticut. The Healy Court found that Connecticut's price affirmation statute violated the dormant Commerce Clause because it discriminated against brewers and shippers of beer engaged in interstate commerce, and directly controlled commerce occurring wholly outside the state of Connecticut. Healy, *ibid.* at 491.

<sup>143</sup> Generally, whether or not a state statute would be held violative of the dormant commerce clause, and therefore unconstitutional, would depend on the facts of each case. For a discussion, see Taiwo A. Oriola, "Regulating Unsolicited Commercial Electronic Mail in the United States and the European Union: Challenges and Prospects" (2005) 7 *Tulane Journal of Technology & Intellectual Property* 113 at 134–140 (extensively reviews the case law on the dormant commerce clause of the *United States Constitution*.)



These scenarios are exemplified by the analogous District of Columbia's *Prescription Drug Excessive Pricing Act of 2005*.<sup>144</sup> The Act prohibited any patented drug from being sold in the District of Columbia for an excessive price.<sup>145</sup> However, the Act was successfully challenged in 2005 before the United States District Court for the District of Columbia by the Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America.<sup>146</sup> The Federal District Court held, *inter alia*, that the statute preempted pharmaceuticals monopoly rights vested in the Federal patent law.<sup>147</sup> In a subsequent appeal by the District of Columbia to the U.S. Court of Appeals for the Federal Circuit, the Court of Appeals, by its decision of August 2007, affirmed the judgment of the Federal District Court on grounds, *inter alia*, that the *Prescription Drug Excessive Price Act* was preempted by the Federal patent law.<sup>148</sup>

However, whether or not a state law purporting to regulate prescription drug prices, would preempt federal law, would depend on the factual circumstances underpinning the statute in question. This is exemplified by the case of *Pharmaceutical Research and Mfrs. of America v. Walsh*,<sup>149</sup> where the U.S. Supreme Court affirmed a Court of Appeals decision, allowing for the implementation of the state of Maine's *Act to Establish Fairer Pricing for Prescription Drugs*.<sup>150</sup> Maine had sought to use the statute to extract a discount on prescription drugs purchased on the Medicaid program.<sup>151</sup> Maine intended to use savings from the discount to fund its uninsured residents.<sup>152</sup> Drug manufacturers who did not cooperate risked having their products made available to the recipients of Maine Medicaid on prior authorization with a consequentially potential loss in market share for the recalcitrant manufacturers.<sup>153</sup> The U.S. Supreme Court held, *inter alia*, that the Maine statute did not interfere with interstate commerce, and was therefore consti-

<sup>144</sup> See the District of Columbia *Prescription Drug Excessive Pricing Act of 2005*, codified at *D.C. Code* ss. 28-4555.

<sup>145</sup> The operative section of the Act provides that "It shall be unlawful for any manufacturer or licensee thereof, excluding a point of sale retail seller, to sell or supply for sale or impose minimum resale requirements for a patented prescription drug that results in the prescription drug being sold in the District for an excessive price". See *D.C. Code*, ss. 28-4553, *ibid*.

<sup>146</sup> See also *Pharmaceutical Research and Mfrs. of America v. District of Columbia*, 406 F.Supp.2d 56 (D.D.C., 2005) [*Pharm. Research*].

<sup>147</sup> Patents monopoly rights necessarily include the right to dictate the price of patented products; *Ibid*.

<sup>148</sup> See *Biotechnology Industry Organization v. District of Columbia*, 505 F.3d 1343 (C.A.Fed. (Dist.Col.), 2007) [*Biotechnology*].

<sup>149</sup> *Pharmaceutical Research and Mfrs. of America v. Walsh*, 123 S.Ct. 1855 (U.S., 2003).

<sup>150</sup> *Ibid*.

<sup>151</sup> *Ibid*.

<sup>152</sup> *Ibid*.

<sup>153</sup> *Ibid*. at 1863-64.

tutional.<sup>154</sup> The Court found further that Pharmaceutical Research Manufacturers did not prove that the Maine program impinged on the Medicaid statute by imposing a state requirement devoid of a “Medicaid purpose.”<sup>155</sup>

It is interesting that Maine was allowed to extract compulsory discounts from drug manufacturers, while the District of Columbia was denied the right to cap prescription drug prices. Although clearly distinguishable, Maine and District of Columbia statutes arguably had a similar objective: to reduce the cost of prescription drugs purchased in their respective states. Thus, the cases underscore the view that the preemption doctrine operates on the nature and factual circumstances of each statute. *A fortiori*, it is conceivable that CIRM price control policy for sponsored prescription drugs might escape the preemption trap. This is especially so because it is specific to CIRM-sponsored prescription drugs, rather than prescription drugs generally, or prescription drugs sponsored with equity funds, as the terms of the District of Columbia legislation ostensibly provided for.<sup>156</sup>

Furthermore, for-profit grantees, who had subscribed to price control terms at the time of award from CIRM funds, might not be able to renege on their agreement, as they would be legally obliged to abide by the terms of their contract. It is trite that valid contractual obligations acquiescing to diminished rights, or waivers thereof, would trump subsequent claims to untrammelled intellectual property rights.<sup>157</sup>

Another key provision of the CIRM intellectual property policy is a revenue sharing formula between the state of California and for-profit grantees.<sup>158</sup> A grantee must share with the state of California a fraction of any ‘Net Licensing Revenue’ it receives under a license agreement for a CIRM-funded patented invention.<sup>159</sup> ‘Net Licensing Revenue’ is defined as “[g]ross revenue derived from a license agreement minus the direct costs incurred in the prosecution and protection of a CIRM-funded patented invention.”<sup>160</sup> A for-profit grantee is obliged to pay 25 per cent of Net Licensing Revenue in excess of \$500,000 to the state of California for deposit in the state’s general fund.<sup>161</sup> The threshold amount of \$500,000 shall be adjusted annually by a multiple of a fraction, the denominator of which is, *inter alia*, the Consumer Price Index.<sup>162</sup> Furthermore, if there were other sources of funding for the development of a CIRM-funded patented invention, then the return

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<sup>154</sup> *Ibid.* at 1870-71.

<sup>155</sup> *Ibid.* at 1867-70.

<sup>156</sup> See *supra* note 144.

<sup>157</sup> For example, a European patent is an object of property, and may be assigned, licensed, or contracted out under terms agreeable to the parties concerned. See Articles 71, 72, 73, and 74 of the European Patent Convention, October 5, 1973, (as amended).

<sup>158</sup> See *supra* note 135 at section 100408.

<sup>159</sup> See *ibid.* at s. 100408(a).

<sup>160</sup> See *ibid.* at s. 100401(m).

<sup>161</sup> See *ibid.* at s. 100408(a)(1).

<sup>162</sup> See *ibid.*

to the state of California on Net Licensing Revenue in excess of \$500,000 shall be calculated by dividing CIRM grants to the patented invention by the totality of all funding provided from all sources — that fraction shall be multiplied by 25.<sup>163</sup> The resultant numeral shall be the percentage of Net Licensing Revenue due to the state of California.<sup>164</sup>

Additionally, a for-profit grantee must share with the state of California a fraction of any “Net Commercial Revenue” it receives from a self-commercialized product resulting from its CIRM-funded research.<sup>165</sup> Net Commercial Revenue is defined as “income from commercial sales of a product(s) resulting from CIRM-funded research. . . .”<sup>166</sup> Net Commercial Revenue is designed as a payback of the original CIRM grants in the form of a royalty. A grantee must pay royalties to the state of California on Net Commercial Revenue exceeding the threshold amount of \$500,000.<sup>167</sup> However, total payments shall not exceed three times the total amount of the CIRM grants.<sup>168</sup> The precise rate of payback in the form of a royalty shall be negotiated between the grantee and the CIRM, but it shall not be less than two per cent or more than five per cent of the annual Net Commercial Revenue from the invention, unless the product achieves a blockbuster status.<sup>169</sup>

Moreover, if the invention was a blockbuster, and the accruable Net Commercial Revenue exceeded the milestones of \$250 million and \$500 million per year, then upon the occurrence of each of these milestones, the grantee should pay to the state of California a one-time blockbuster payment of three times the total amount of the grant.<sup>170</sup> However, in addition to any other amount due under the regulation, where a CIRM-funded patented invention fetched Net Commercial Revenue in excess of \$500 million in a year, and where CIRM funds of up to \$5 million were made in support of the said invention, then the grantee would pay the state of California one per cent of Net Commercial Revenue in excess of \$500 million for the life of the patent.<sup>171</sup>

Thus, the California law not only ensures that all grants in support of patented inventions or research are recouped, but also lays claims to a percentage of net

<sup>163</sup> See *ibid.* at s. 100408(a)(2).

<sup>164</sup> *Ibid.*

<sup>165</sup> See *ibid.* at s. 100408(b).

<sup>166</sup> “Net Commercial Revenue excludes the following (as they pertain to the making, using or selling of products resulting from CIRM-funded research): (1) import, export, excise and sales taxes, and customs duties; (2) costs of insurance, packing, and transportation from the place of manufacture to the customer’s premises; (3) credit for returns, allowances or trades; and (4) pre-commercial revenues received in connection with research and development and/or clinical activities.” See *ibid.* at section 100401 (n).

<sup>167</sup> See *ibid.* at s. 100408(b)(1).

<sup>168</sup> See *ibid.*

<sup>169</sup> *Ibid.*

<sup>170</sup> See *ibid.* at s. 100408(b)(2).

<sup>171</sup> See *ibid.* at s. 100408(b)(3).

licensing revenues and net commercial revenues while adjusting for inflation and accruable profits.

Additionally, it caps the price at which California-sponsored pharmaceuticals could be sold to Californian citizens. Moreover, grantees have an obligation to draw up a workable modality for facilitating access to California-sponsored prescription drugs by uninsured Californians. The law unequivocally represents a new era of responsible and equitable public private partnerships, and it is highly recommended to governments around the world. However, it remains to be seen whether for-profit grantees would find the underlying contractual obligations attractive or repugnant, or whether the pharmaceutical industry would challenge the law on grounds ranging from preemption to restraints of trade.

## II. PHARMACEUTICAL RESEARCH AND DEVELOPMENT COSTS: A CONUNDRUM

New drug development is, globally, an expensive and research intensive business.<sup>172</sup> For example, the U.S. pharmaceutical industry reputedly spent \$43 billion on pharmaceutical research and development in 2006.<sup>173</sup> Moreover, a study published in 2003 by the Tufts Centre for the Study of Drug Development, estimated the costs of manufacturing a new drug at \$802 million (2002 U.S. dollars).<sup>174</sup> According to Light D. W. et al., these estimates have been widely cited and accepted as an authoritative fact by the highest national and international policy circles.<sup>175</sup> However, the real costs of manufacturing new drugs are as elusive as they are polemical, the Tufts Study notwithstanding.

Notably, the methodology used, and the validity and accuracy of the data that underpin the Tufts Study has been challenged.<sup>176</sup> The Tufts Study has been especially criticized for inflating or overestimating the costs of developing a new drug, by the inclusion of “capitalized” or opportunity costs (the revenue that would have been generated over the period of development, had the out-of-pocket expenses been invested in the equity market), and the failure to account for tax breaks and

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<sup>172</sup> Pharmaceutical R&D is said to be one of the most research intensive and expensive businesses in the U.S. See Pharmaceutical Research and Manufacturers of America, *supra* note 95 at 2.

<sup>173</sup> *Ibid.* at 2-3.

<sup>174</sup> Joseph A. DiMasi, Ronald W. Hansen & Henry G. Grabowski, “The Price of Innovation: New Estimates of Drug Development Costs” (2003) 22 *Journal of Health Economics* at 151–185.

<sup>175</sup> Donald W. Light & Rebecca N. Warburton, “Extraordinary Claims Require Extraordinary Evidence” (2005) 24 *Journal of Health Economics* at 1030-1033. The figures are also cited in the 2007 Pharmaceutical Research and Manufacturers of America’s Profile, *supra* note 95 at 5.

<sup>176</sup> W. Light & N. Warburton, *ibid.*

government subsidies.<sup>177</sup> However, despite the Tufts Study's apparent flaws and incompleteness, the inclusion of the "opportunity costs" accruable during the lengthy period of new drug development has been defended as a standard accounting practice.<sup>178</sup> It has also been argued that although tax relief could provide financial advantage to a drug developer, it would not alter the estimates of the out-of-pocket costs.<sup>179</sup>

It is submitted, however, that any estimates that discount tax relief, or add bogus opportunity costs to the cost of developing a new drug would be grossly inaccurate. Ascertaining the exact costs of pharmaceuticals R&D, absent public funding, tax-breaks, government subsidies, advertising expenditures, etc., is in the public interest. Accurate estimates are also crucial for an objective evaluation and rationalization of the spiraling prescription drug prices, which are often justified by high R&D costs.<sup>180</sup> However, ascertaining the real costs of new drugs absent government subsidies and tax breaks, etc., is notoriously problematic as the pharmaceutical industry is generally reluctant to "comment on gross margins on individual products".<sup>181</sup>

Alarmed by the increasingly high costs of prescription drugs in the U.S., critics have charged that R&D costs actually had no link to the relatively high costs of prescription drugs.<sup>182</sup> According to Uwe Reinhardt, a University of Princeton economics Professor, the price of drugs "has nothing to do with cost of research. It's whatever the drug companies can get. If they have a drug for which there is really no good alternative that is what they will hit with high prices."<sup>183</sup> As such, critics maintain that the pharmaceutical industry's profits are too excessive and that it could make prescription drugs affordable by slashing prices.<sup>184</sup>

However, while the real cost of developing a new drug is polemical, it is certainly not cheap, and there appears to be a general consensus that high R&D costs may be partly responsible for the spiraling prescription drug prices.<sup>185</sup> The perti-

<sup>177</sup> Frank Clemente *et al.*, "America's Other Drug Problem: A Briefing Book on the Rx Drug Debate" *Public Citizen* (2002) at 46–48, online: Public Citizen <<http://www.citizen.org/documents/drugbriefingbk.pdf>>.

<sup>178</sup> Rawlins, *supra* note 17 at 360–364 (the author, while noting the study's incompleteness, reluctantly accepts the \$802 million Tufts figures for manufacturing a new drug).

<sup>179</sup> *Ibid.* at 360.

<sup>180</sup> Gerth & Stolberg, *supra* note 104.

<sup>181</sup> When asked about Xalatan's gross-profit margin, Dr. Anders Harfstrand, the then vice president for ophthalmology at Pharmacia Corporation, reportedly said: "We never comment on gross margins on individual products". *Ibid.* However, the information he declined to offer was crucial to ascertaining approximate costs of R&D, clinical trials, tax breaks, and government subsidies for Xalatan.

<sup>182</sup> Clemente, *supra* note 177 at 40–48.

<sup>183</sup> Cited in Hawthorne, *supra* note 1 at 176.

<sup>184</sup> *Ibid.* at 176.

<sup>185</sup> Rawlins, *supra* note 17 at 360–364 (notes that extensive clinical trials and attendant regulatory hurdles were responsible for the high costs of developing new drugs).

nent question, therefore, is: can anything be done to mitigate the spiraling costs of pharmaceutical research and development? A string of commingled legal and socio-economic externalities governing pre and post research and development phases have been implicated in the steep research and development costs and consequential run-away prescription drug prices.<sup>186</sup> They range from the legally required extensive and expensive pre-clinical and clinical trials and the delay in the review and approval process for new drugs, to the huge costs of advertising and marketing.<sup>187</sup> The following paragraphs will critically review the literature on these externalities in relative detail, and discuss how they could best be managed to mitigate the costs of developing new drugs and curb the run-away prescription drug prices. Certainly, the reduction of pharmaceutical products' development costs is imperative to achieving the goal of affordable and accessible drugs.<sup>188</sup>

### (a) Clinical Trials and the New Drug Approval Process: Analysis of Impacts on Drug Development Overheads

Pharmaceuticals are arguably one of the most regulated consumables.<sup>189</sup> Drug safety and efficacy imperatives are the arrow-heads of the drug regulatory regime.<sup>190</sup> However, drug regulation is said to contribute to delays in drug approval and market debut, and in that context, it comes at a price that is ultimately paid by consumers.<sup>191</sup>

The regulation with the most direct impact on drug development is, perhaps, the one on mandatory pre-clinical and clinical trials.<sup>192</sup> In the U.S., as in Europe, pre-clinical and clinical trials are legally mandated by law<sup>193</sup> and are often drawn out over a period of years — this considerably adds to the costs of drug develop-

<sup>186</sup> *Ibid.* at 361–363 (notes how the extensive pre-clinical and clinical trials are upping the costs of new drug discovery).

<sup>187</sup> *Ibid.*; Frank Clemente *et al.*, *supra* note 177 at 27–29 (notes the impact of advertising expenditures, amongst other factors, on prescription drug prices).

<sup>188</sup> World Health Organization, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health, Public Health, Innovation and Intellectual Property Rights* (Geneva: WHO Press, 2006) at 18 (notes the imperatives of rethinking the strategies for pharmaceutical product cost reduction to ensure drug availability and affordability in developing countries).

<sup>189</sup> Santoro, *supra* note 17 at 15.

<sup>190</sup> Agrawal, *supra* note 34 at 5 (notes that the Thalidomide disaster was the catalyst for tighter regulatory reforms in the pharmaceutical industry in the U.S.).

<sup>191</sup> *Ibid.* (notes that tighter regulatory reforms have made pharmaceutical research more expensive and time-consuming); Rawlins, *supra* note 17 at 362 (notes that the regulatory policies on the quality and quantity of data required for drug approval do determine the size of a clinical program).

<sup>192</sup> *Ibid.*

<sup>193</sup> Carl C. Peck, Donald B. Rubin, & Lewis B. Sheiner, “Hypothesis: A Single Clinical Trial Plus Causal Evidence of Effectiveness is Sufficient for Drug Approval” (2003) 73:6 *Clinical Pharmacology & Therapeutics* at 481–490.

ment.<sup>194</sup> Pre-clinical and clinical trials are integral elements of the drug approval process and occur in three phases.<sup>195</sup> Phase one studies compare the pharmacological effects in animal experimentation with those expressed in human subjects, and seek to provide crucial information on dosage regimen.<sup>196</sup> Phase two studies generally seek to establish the amount of dosage required to achieve a new drug's anticipated therapeutic benefits and to provide preliminary evidence of its safety for human use.<sup>197</sup> Phase three studies generally seek to confirm a new drug's therapeutic efficacy and safety in a wider patient population at the dosage proposed for marketing and could include studies of comparative efficacy.<sup>198</sup> Thus, the conventional clinical trials are evidence based, providing the needed assurance of drug efficacy and safety to regulators and the public.<sup>199</sup>

However, conventional clinical trials are equally expansive and invariably expensive,<sup>200</sup> leading to suggestions that alternatives should be explored if costs are to be minimized.<sup>201</sup> One of the proposals for cutting costs without prejudice to drug safety and efficacy suggests a reduction in the time taken to conduct clinical studies and a reduction in the number of patients enrolled for pre-marketing clinical trials.<sup>202</sup> Invariably, authorities seeking to cut time and the number of patients in clinical programs would have to balance the cost effectiveness of reduced clinical programs vis-à-vis the socio-economic and legal imperatives of drug safety and efficacy.<sup>203</sup> Obviously, drug safety and effectiveness are paramount, and it would be ludicrous to sacrifice that for short term costs savings. Moreover, rushing new drugs through clinical trials could potentially compromise the rights of human re-

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194 Crowley Jr., *supra* note 17 at 174-175.

195 Rawlins, *supra* note 17 at 362.

196 *Ibid.*

197 *Ibid.*

198 *Ibid.*

199 *Ibid.*

200 Santoro, *supra* note 17 at 15 (noting that drugs are more expensive because of long and large clinical trials).

201 Rawlins, *supra* note 17 at 362.

202 *Ibid.*; Peck, Rubin & Sheiner, *supra* note 193 at 481-490 (notes that multiple clinical trials could be reduced into one without compromising safety and efficacy).

203 For instance, a recent analysis of 25 anti-cancer drug trials, over a period of eleven years, showed that a drug's early release into the market could be affecting its efficacy. The study also suggested that, although stopping the trials early could be beneficial to patients who would have early access, it appeared that shorter trials were motivated by the industry's commercial interests rather than the patients' interests. See F. Trotta, G. Apolone, S. Garattini & G. Tafuri, "Stopping a Trial Early in Oncology: For Patients or for Industry?" (August 2008) 19 *Annals of Oncology* at 1512-1513.

search subjects. This is especially so following high-profile drug mishaps ranging from the thalidomide disaster,<sup>204</sup> to the more recent Vioxx debacle.<sup>205</sup>

Another possible means to cost reduction is to expedite the new drug review and approval process. In the U.S. for example, the Federal Food and Drug Agency is statutorily obliged to review new drug applications within 180 days from the time of submission.<sup>206</sup> However, it often takes the FDA over three times the statutory limit to approve a new drug for the market due to work overload and related logistics problems.<sup>207</sup> On the whole, the process of rigorous and painstaking pre-clinical and clinical trials that precede marketing approval for a new drug means that it takes an average of twelve years to progress from the commencement of a new drug's development to FDA approval in the U.S.<sup>208</sup>

However, while pre-clinical and clinical trial processes cannot be compromised, a new drug review and approval process could certainly be expedited in order to cut patients' waiting time for crucial prescription drugs. In the U.S., for example, two major obstacles to an expedited new drug review and approval process have been identified. The first is the dearth of resources along with concomitant work overload for FDA personnel, creating huge backlog of new drug applications.<sup>209</sup> The second is the FDA's desire to safeguard its reputation for protecting the public's health, and secure its organizational legitimacy;<sup>210</sup> it is perceived that every time the FDA approves a new drug, it takes a chance with its reputation due to the inherent uncertainty in the new drug review process.<sup>211</sup> Under the circumstances, the FDA is liable to make two types of errors: approving a bad drug, or failing to approve an effective and safe drug that should be approved.<sup>212</sup> Cutting

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<sup>204</sup> Agrawal, *supra* note 34 at 5. Thalidomide was developed as a sedative and anti-anxiety medication. No teratogenicity studies were carried out before its release in Europe in 1957 and, at the time, it was widely prescribed during pregnancy. By the time McBride & Lenz published the drug's side effects in *The Lancet* in 1961, more than 10,000 infants had been born with deformities; See "The Thalidomide Disaster", online: <<http://www.obgyn.nus.edu.sg/maxdata1/The%20thalidomide%20disaster.htm>>.

<sup>205</sup> Santoro, *supra* note 17 at 13–16 (details the safety fears that led to Merck's 2004 withdrawal of Vioxx, its best selling pain inhibitor that was used by over 20 million people worldwide, from the market. There was evidence linking Vioxx to heart attack and stroke risks).

<sup>206</sup> Pharmaceutical Research and Manufacturers of America, *supra* note 18 at 12.

<sup>207</sup> *Ibid.*

<sup>208</sup> *Ibid.* at 6 (notes that U.S. patients often had to wait for twelve years, on average, for the approval of a new drug, and that many drugs had to be approved abroad before becoming available to U.S. patients).

<sup>209</sup> *Ibid.* at 12.

<sup>210</sup> Daniel P. Carpenter, "The Political Economy of FDA Drug Review: Processing, Politics, and Lessons for Policy" (2004) 23:1 *Health Affairs* at 52–63.

<sup>211</sup> *Ibid.* at 55 (the author notes that the most successful clinical trials could not eliminate the possibility that a new drug might turn out to be unsafe or inefficacious).

<sup>212</sup> *Ibid.*



drug approval times is a possible solution to delays in the new drug review and approval process, but one that could likely come at a higher marginal cost.<sup>213</sup> Outsourcing of a new drug review to a third party or the privatization of a new drug approval process has also been floated as a possible solution.<sup>214</sup>

In 2005, The European Medicines Agency resolved to grant conditional approvals and shorten the scientific review of new drugs to 150 days.<sup>215</sup> Similarly, through the *Prescription Drug User Fee Act* of 1992, the U.S. aimed to expedite the FDA's new drug review and approval process in mandating that payment of fees by pharmaceutical companies filing for new drug applications be made to the FDA.<sup>216</sup> Prior to the enactment of the Act, on average, it took the FDA thrice the statutory 180 days to review new drug application for the market, due to their huge backlog and workload.<sup>217</sup> Fees paid to the FDA under the Act are dedicated to boosting its resources and expediting the review of new drug applications.<sup>218</sup> Early market entry of new drugs could provide the crucial competition needed to reducing prices of drugs of comparative therapeutic values and clinical benefits. However, a crucial balancing act would have to be exercised on a case by case basis. Drug safety and efficacy is paramount and should not be sacrificed in favour of early market debut.

### **(b) Advertising Expenditures: Impacts on Prescription Drug Pricing**

The second potential contributor to prescription drug expenditures and consequential high prices is the huge cost of prescription drug promotion and advertising.<sup>219</sup> Unlike clinical trials and the drug approval process, which offer little wiggle room, advertising expenditures can arguably be managed and contained.

There are two types of advertising: the first is professional spending, which includes marketing and promotion aimed at doctors, and the second is direct-to-

<sup>213</sup> *Ibid.* at 60.

<sup>214</sup> *Ibid.* at 61.

<sup>215</sup> The European Medicines Agency, *The European Medicines Agency Road Map to 2010: Preparing the Ground for the Future*. Doc. EMEA/H/34163/03/Final (4 March 2005) at 36–45, online: European Medicines Agency <<http://www.emea.europa.eu/pdfs/general/direct/directory/3416303enF.pdf>>.

<sup>216</sup> See S.R. Shulman & K.I. Kaitin, “The Prescription Drug User Fee Act of 1992: A 5-Year Experiment for Industry and the FDA” (1996) 9:2 *Pharmacoeconomics* at 121–133.

<sup>217</sup> See Pharmaceutical Association of America, *supra* note 18 at 12. Congress reauthorized FDA to continue to charge drug manufacturers fees for new drug applications in September 2007. The re-authorization was done via *The Federal Food, Drug, and Cosmetic Act* as amended by the Prescription Drug User Fee Amendments of 2007 (FDAAA) (PDUFA IV). See 72 Fed. Reg. 58103 (2007).

<sup>218</sup> See Shulman & Kaitin, *supra* note 216 at 121–133.

<sup>219</sup> See Thomas Abrams, “The Regulation of Prescription Drug Promotion” in Michael A. Santoro and Thomas M. Gorrie, eds., *Ethics and the Pharmaceutical Industry* (Cambridge: Cambridge University Press, 2005) at 15.

consumer (DTC) advertising.<sup>220</sup> Drug advertising expenditures are usually hefty. For instance, the Pharmaceutical Research and Manufacturers of America spent an estimated \$7 billion and \$5 billion respectively on professional and direct-to-consumer advertising in the United States in 2006.<sup>221</sup> However, these figures would appear modest relative to what used to be the norm.<sup>222</sup> While this might be evidence that the industry's recently avowed self-censorship is working,<sup>223</sup> it is arguably too steep for the indispensable public goods that prescription drugs are.

While the costs of professional advertising, which targets physicians is, within reason, generally more acceptable,<sup>224</sup> DTC advertising has drawn the most criticism.<sup>225</sup> Notably, only the U.S. and New Zealand allow DTC advertising in the industrialized world.<sup>226</sup> In the U.S., the surge in DTC advertising has been mainly

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<sup>220</sup> See Matthews, *supra* note 19 at 16.

<sup>221</sup> See Pharmaceutical Association of America, *supra* note 18 at 13.

<sup>222</sup> According to Frank Davidoff, in 1999, the U.S. pharmaceutical industry spent \$13.9 billion on promotion alone, \$2 billion on direct-to-consumer advertising, over \$7 billion in free drug samples, and \$80 million per year on lobbying. See Frank Davidoff, "The Heartbreak of Drug Pricing" (2001) 134:11 *Annals of Internal Medicine* at 1068–1070.

<sup>223</sup> In 2005, the U.S. Pharmaceutical Association's Board of Directors unanimously approved the establishment of the "Guiding Principles" to govern DTC advertisements. The new principles, which became effective in 2006, directed the industry to create an Office of Accountability to accept comments from the public regarding DTC advertisements, and to appoint an independent Review Panel. See Pharmaceutical Research and Manufacturers of America, *supra* note 18 at 19; See however Kurt C. Stange's view that the industry's self-censorship and FDA oversight were not working. See Kurt C. Stange, "Time to Ban Direct-to-Consumer Prescription Drug Marketing" (2007) 5:2 *Annals of Family Medicine* at 101–104.

<sup>224</sup> For example, paragraph 47 to the preamble to Directive 2001/83/EC of the European Parliament and the Council, on the Community code relating to medicinal products for human use, (as amended) allows for professional advertising targeting physicians subject to strict conditions and effective monitoring. See OJL 311, 28/11/2001 P. 0067-0128. Para. 48, *id.*, provides that monitoring mechanisms shall be in accordance with the provisions of Directive 84/450/EEC concerning misleading advertising OJL 250, 19/9/1984, at 17–20.

<sup>225</sup> Stange, *supra* note 223 at 101–104 (canvasses for a ban on DTC in order to protect public health and the quality of health care). Some of the most articulated objections to DTC are its propensity to shift the physician's prescription responsibility to the consumer and mounting evidence that it is detracting from the clinical quality of care; See W. David Bradford *et al.*, "How Direct-To-Consumer Television Advertising for Osteoarthritis Drugs Affects Physicians' Prescribing Behavior" (2006) 25:5 *Health Affairs* at 1371–1377; Michael S. Wilkes, Robert A. Bell, & Richard L. Kravitz, "Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications" (2000) 19:2 *Health Affairs* at 110–128.

<sup>226</sup> Erin J. Asher, "Lessons Learned From New Zealand: Pro-Active Industry Shift towards Self-Regulation of Direct-To-Consumer Advertising Will Improve Compliance with

attributed to generous health insurance benefits, which transfer the burden of paying for prescription drugs to insurers.<sup>227</sup> However, the literature on the effects of DTC advertising on prescription drug pricing is far from unanimous. While Merrill Matthews contends that there is no nexus between DTC advertising and rising drug prices,<sup>228</sup> Michael S. Wilkes et al., posit that DTC could indeed increase drug costs to the consumer in the absence of competition, or decrease drug prices by promoting competition, if there were competing drugs on the market.<sup>229</sup>

However, if we accepted DTC expenditures as part of prescription drug overheads, it is inconceivable that these expenditures would not get passed on to the consumers through pricing. It is rational economic behaviour of for-profit firms to pass on overhead costs to consumers through product pricing, and there is no basis for exempting pharmaceutical firms from such a natural trajectory induced by market dynamics. Even then, advertising that is not DTC is as likely to increase drug pricing as is DTC advertising.<sup>230</sup> It has been posited that the pharmaceutical industry is by nature advertising intensive, and that advertising is an inherent competitive market structure determinant tool.<sup>231</sup> According to Catherine Matraves, as pharmaceutical firms' market shares increase, there is an intuitive incentive to gain market share through escalation of advertising and, or research and development expenditures, with a corresponding rise in overhead costs and an increase in the degree of economies of scale.<sup>232</sup> *A fortiori*, even in nations in which DTC advertising does not occur, professional or physician-directed advertising remains an integral feature of prescription drug economics due to its apparent indispensability to shaping the pharmaceuticals market share for competitors.<sup>233</sup>

The pertinent question therefore is: should authorities cap advertising expenditures? For a start, the U.S. would do well to scrap DTC advertising as most industrialized countries have done. I find it inconceivable that DTC advertising expenditure would not escalate prescription drug overheads and aggravate prescription drug costs. As for professional advertising, it should certainly be capped if there was irrefutable evidence that it contributed to prescription drug prices. Arguably, such evidence is not hard to find at all; it is apparent in the \$7 billion 2006 figures, which comprised approximately 16 per cent of the \$43 billion spent on research

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the FDA" (2006) 16:3 Albany Law Journal of Science & Technology at 599–627; Stange, *supra* note 223 at 102.

227 Matthews, *supra* note 19 at 2.

228 *Ibid.* at 16.

229 Wilkes, Bell & Kravitz, *supra* note 225 at 122.

230 Matraves, *supra* note 18 at 169–194.

231 *Ibid.*

232 *Ibid.*; However, see also the countervailing argument that advertising did not increase prescription drug price in any discernible way, in Merrill Matthews, "Who's Afraid of Pharmaceutical Advertising? A Response to a Changing Health Care System" *supra* note 19 at 6–9.

233 Matraves, *supra* note 18 at 169–194.

and development in the U.S. If the \$5 billion spent on DTC advertising is thrown into the bill, it would raise the total advertising expenditures to approximately 28 per cent of the 2006 R&D budget. While capping professional advertising expenditures could raise free speech issues, such narrow concerns should arguably be trumped by the overarching public interest. After all, there is no absolute right as such, as evidenced by the limits placed on property rights by eminent domain rules in the United States.<sup>234</sup>

### (c) The Propriety of Prescription Drug Price Regulation

Spiraling prices increasingly make prescription drugs an object of regulatory concern in both developed and developing countries.<sup>235</sup> Drug prices are generally higher in the U.S. than in other countries, which is partly due to the absence of a price control regime.<sup>236</sup> For instance, in 2003 a month's supply of the antidepressant, Zoloft, retailed for \$82 in the U.S., but sold for \$42 and \$29 respectively in Canada and France.<sup>237</sup> The U.S.'s traditionally non-restrictive prescription drug price policy regime has been partly credited with fueling the country's pharmaceutical industry's relative competitiveness vis-à-vis its European and Japanese counterparts.<sup>238</sup> The rationale for the U.S. non-interference policy in pharmaceuticals pricing was epitomized by former FDA Commissioner McClellan's view that "price controls discourage the R&D needed to develop new products."<sup>239</sup>

However, in lieu of price control, the U.S. sought to bridge the rich and poor prescription drug divide via the 2003 *Medicare Modernization Act*.<sup>240</sup> The Act added prescription drug coverage to the Medicare benefits, with the objective of alleviating the costs of medications for people with low annual incomes or high out-of-

<sup>234</sup> See e.g. *Kelo v. City of New London, Conn.*, 545 U.S. 469 (U.S. Conn., 2005) at 478. It was held that confiscating private property for use as part of a redevelopment plan that could be economically beneficial to the entire community was a permissible public use under the Takings Clause of the Fifth Amendment. See generally Charles E. Cohen, "Eminent Domain After *Kelo v. City of New London*: An Argument for Banning Economic Development Takings" (2006) 29 *Harvard J.L. & Pub. Pol'y* at 491 (discusses the *Kelo* decision).

<sup>235</sup> F. M. Scherer & Jayashree Watal, "The Economics of TRIPS Options for Access to Medicines" in Brigitte Granville, ed., *The Economics of Essential Medicines* (London: Royal Institute of International Affairs, 2002) at 49.

<sup>236</sup> Iglehart, *supra* note 79 at 119–127.

<sup>237</sup> John Carey *et al.*, "Commentary: Drug R&D: Must Americans Always Pay?" *Businessweek* (13 October 2003), online: Business Week <[http://ads.businessweek.com/magazine/content/03\\_41/b3853059.htm](http://ads.businessweek.com/magazine/content/03_41/b3853059.htm)>.

<sup>238</sup> Agrawal, *supra* note 34 at 33–35.

<sup>239</sup> Cited in Donald Light & Joel Lexchin, "Will Lower Drug Prices Jeopardize Drug Research? A Policy Fact Sheet" (2004) 4:1 *The American Journal of Bioethics* at W1-W4.

<sup>240</sup> *Medicare Prescription Drug, Improvement, and Modernization Act* of 2003, Pub. L. No. 108-173, 117 STAT. 2066 (2003).

pocket medication costs.<sup>241</sup> In the same vein, the U.S. pharmaceutical industry teamed up with public and private organizations in 2005 to create Partnership for Prescription Assistance (PPA).<sup>242</sup> The PPA provides a parallel prescription drug assistance program to the *Medicare Modernization Act*, and has helped over three million patients find programs that provide free or nearly free medication.<sup>243</sup> However, while the two parallel programs have helped in easing access to prescription drugs for low-income groups, a vast number of uninsured and ineligible patients are still left in the cold,<sup>244</sup> and some have resorted to Canada and Mexico for cheaper prescription medicine.<sup>245</sup>

Canadian pharmacists estimated that at least one million Americans buy prescription drugs in Canada by post or over the internet annually.<sup>246</sup> In 2004, as the annual internet pharmacy sales to Americans reached the \$600 million mark, the then Canadian Health Minister, Ujjal Dosanjh, informed an audience at Harvard University that it would be an illusion to think that Canada would continue to be the drugstore for the United States.<sup>247</sup> However, the prescription drug purchases in Canada are dwarfed by the \$2 billion purchases made annually by Americans in Mexico.<sup>248</sup>

The battle for importation of cheaper prescription drugs, especially from Canada, has since moved into the U.S. Congress, where the House of Representatives passed a bill in 2007 permitting the importation of cheaper prescription drugs from

<sup>241</sup> Dawn E. Havrda *et al.*, “Impact of the Medicare Act on Low-Income Persons” (2005) 143:8 *Annals of Internal Medicine* at 600–608.

<sup>242</sup> See Pharmaceutical Industry Profile 2007, *supra* note 95 at 19.

<sup>243</sup> *Ibid.* Significantly, a 2005 study found that the Partnership for Prescription Assistance program offered considerable savings and was superior to the Medicare drug discount cards; See Dawn E. Havrda *et al.*, *supra* note 241 at 600–608.

<sup>244</sup> The focus of Medicare drug discount cards and of the Partnership for Prescription Assistance program is the low-income group. However, not everyone in the low-income group is eligible; the pharmaceutical industry cannot realistically provide free medicines for all indigent patients in the United States.

<sup>245</sup> In October 2004 for instance, a 68 year old Pennsylvania woman took a 600-mile train ride to Toronto to buy medicines. The trip saved her thousands of dollars. See Robyn Shelton, “Trains Roll to Canada to Buy Cheaper Drugs; The Publicity Trip to Toronto Will Offer Some Prescription Price Relief for 25 U.S. Passengers” *Orlando Sentinel* (30 September 2004) online: Orlando Sentinel <<http://www.consumerwatchdog.org/healthcare/nw/nw004645.php3>>. President Clinton once argued that no American should be forced to get on the bus to Canada in search of cheaper prescription drugs; See Andrew Phillips, “America’s Bitter Pills” *Maclean’s* (20 December 1999) at 98, online: Maclean’s.ca <<http://www.macleans.ca>>.

<sup>246</sup> “Cheaper Prescription Drugs” *The Economist* (18 October 2003) at 32.

<sup>247</sup> J. Cooper, “Canada to US: We’re Not Your ‘Drugstore’” *Jordoncooper.com, a weblog of faith, culture, & technology* (10 November 2004) online: jordoncooper.com <<http://www.jordoncooper.com/2004/11/10/canada-to-us-were-not-your-drugstore>>.

<sup>248</sup> “Border Line Drugs” *The Economist* (29 January 2004) at 60.

Canada.<sup>249</sup> The Bush administration was widely expected to veto the bill on grounds that the importation measure could open doors to unapproved, counterfeit and unsafe drugs.<sup>250</sup> In the same vein, states faced with crippling prescription drug bills are pressuring the U.S. Federal government to mitigate spiraling drug prices.<sup>251</sup> This is evidenced by the State of Vermont lawsuit filed in August 2004 against the Secretary of State for Health and Human Services and the FDA, in the U.S. District Court for the District of Vermont. The lawsuit sought a reversal of the FDA's refusal to allow Vermont employees to establish a prescription drug importation program from Canada.<sup>252</sup> Similarly, in 2005, the District of Columbia enacted the *Prescription Drug Excessive Pricing Act*.<sup>253</sup> The Act prohibited any patented drug from being sold in the District of Columbia for an excessive price.<sup>254</sup> However, the Act was successfully challenged in 2005 before the U.S. District Court for the District of Columbia, by the Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America.<sup>255</sup> A subsequent appeal to the U.S. Court of Appeals for the Federal Circuit affirmed the judgment of the Federal District Court on grounds, *inter alia*, that the *Prescription Drug Excessive Pricing Act* was preempted by federal patent laws.<sup>256</sup>

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<sup>249</sup> Ed Silverman, "House Passes Bill Allowing Importation" *Pharmalot* (August 2007), online: Pharmalot <[http://www.pharmalot.com/2007/08/house-passes-bill\\_allowing-importation](http://www.pharmalot.com/2007/08/house-passes-bill_allowing-importation)>.

<sup>250</sup> *Ibid.*, the pharmaceutical industry was also opposed to the bill, and had lobbied the U.S. Congress to defeat similar bills in the past.

<sup>251</sup> Ram Kamath, Pharm. D & Scott McKibbin, "The Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies", online: (27 October 2003) Office of Special Advocate for Prescription Drugs, Illinois Department of Central Management Services <<http://209.85.229.132/search?q=cache:j07xP3CLvNkJ:www.affordabledrugs.il.gov/pdf/SpecialAdvocateCanadian10-27-03Final.pdf+The+Report+on+Feasibility+of+Employees&hl=en&ct=clnk&cd=10&gl=uk>>.

<sup>252</sup> Pam Belluck, "Vermont Will Sue U.S. for the Right to Import Drugs" *New York Times* (11 August 2004) at 13. The FDA justified its opposition to drug importation on grounds that it rendered the country vulnerable to terrorist attacks; See "Already Against Drug Imports, FDA Raises Specter of Terror" *USA Today* (12 August 2004), online: USA Today <[http://www.usatoday.com/news/health/2004-08-12-fda-crawford\\_x.htm](http://www.usatoday.com/news/health/2004-08-12-fda-crawford_x.htm)>.

<sup>253</sup> *Prescription Drug Excessive Pricing Act of 2005*, *supra* note 144.

<sup>254</sup> *Ibid.*

<sup>255</sup> Pharm. Research, *supra* note 146. The District Court held, *inter alia*, that the Act was pre-empted and facially unconstitutional because it did not "square with the congressional purpose and objectives" of the patent laws; *Ibid.* at 65-66.

<sup>256</sup> *Biotechnology*, *supra* note 148.

The reason that prescriptions drugs are cheaper in Canada<sup>257</sup> and Mexico<sup>258</sup> than they are in the U.S. is because of price control. Canada has reined in drug prices for years, and has famously had some of the cheapest medicines in the industrialized world between 1969 and 1987 by means of a compulsory licensing law for patented pharmaceuticals.<sup>259</sup> This strategy purportedly saved the country an estimated \$211 million annually.<sup>260</sup> On the contrary, the U.S. largely leaves pharmaceuticals pricing to market forces.<sup>261</sup> A U.S. pioneering pharmaceutical price mitigating regulatory regime, the *Hatch-Waxman Act* of 1994 that allows for a smooth berth of generic drugs with a view to fostering competition in the pharmaceutical marketplace, has yet to have any salutary impacts on the efforts to rein in soaring pharmaceutical prices after more than a decade of its existence.<sup>262</sup>

Britain was confronted with the imperatives of a restrictive drug pricing policy option when it introduced, for the first time, a national health insurance policy in 1911.<sup>263</sup> By 1951 when free medical care was extended to the entire population,

<sup>257</sup> OECD Health Working Papers “Pharmaceutical Pricing and Reimbursement Policies in Canada” by Valerie Paris & Elizabeth Docteur, No. 24, DELSA/HEA/WD/HWP(2006)4 (15 February 2007) at 1-89 (notes that the Patented Medicine Review Board was created in 1987 to ensure that prices of patented drugs are not excessive).

<sup>258</sup> Moise & Docteur, *supra* note 74 at 1-66 (notes that regulation of pharmaceutical prices dated back to the 1950s). *Ibid.* at 14-15.

<sup>259</sup> The system allowed a manufacturer of generic drugs to produce patented drugs in Canada by merely notifying the patentee and paying a fixed four per cent royalty fee. See Christina Del Valle, “Intellectual Property Provisions of NAFTA” (1992) 4:11 *Journal of Proprietary Rights* at 8; John F. Burns, “Canada Split on Drug Patents” *The New York Times* (24 August 1987) at D1, online: *The New York Times* <<http://query.nytimes.com/gst/fullpage.html?res=9B0DE5DE143DF937A1575BC0A961948260>>. The author notes that Canada’s compulsory licensing allowed “so-called generic drug manufacturers . . . to copy brand-name products in Canada and sell them for as much as 50 per cent less than the originals.”; Michael Halewood, “Regulating Patent Holders: Local Working Requirements and Compulsory Licenses at International Law” (1997) 35 *Osgoode Hall Law Journal* 243 at 246; Christopher Scott Harrison, “Protection of Pharmaceuticals as Foreign Policy: The Canada-US Trade Agreement and Bill C-22 Versus the North American Free Trade Agreement and Bill C-91” (2001) 26 *North Carolina Journal of International Law and Commercial Regulation* at 457; Drahos & Braithwaite, *supra* note 73 at 68 (comments on Canada’s interference in the investment equation of pharmaceutical companies via compulsory licensing).

<sup>260</sup> The estimated savings through compulsory licensing was given by a University of Toronto economist, Harry Eastman. See David Crane, “New Debate over Generic Drugs Looms” *The Toronto Star* (9 June 1987) at A18.

<sup>261</sup> Barton, *supra* note 24 at 292.

<sup>262</sup> The *Drug Price Competition and Patent Restoration Act* of 1984, 21 U.S.C. 355.

<sup>263</sup> The Liberal government introduced the 1911 *National Health Insurance Act*. The aim was to assist people below certain minimum income levels in receiving medical bene-

the number of prescriptions under the National Health Service had ballooned to 200 million, upping government financial commitments and precipitating an undue government pre-occupation with price regulation, to the chagrin of the pharmaceutical industry of the early post World War II Britain.<sup>264</sup> In the circumstances, the British government either resorted to compulsory licensure to neutralize undue market exclusivity<sup>265</sup> or outright price curbs.<sup>266</sup> In the 1970s, there was a notable standoff between the British department of health and the drug firm, Hoffmann-LaRoche.<sup>267</sup> The latter was selling its patented tranquilizers Librium and Valium at high monopoly prices.<sup>268</sup> The UK Monopolies Commission recommended very substantial price cuts on grounds that the drugs were sold at monopoly prices.<sup>269</sup> Most recently, tensions between the British government and the pharmaceutical industry flared up again following the Office of Fair Trading 2007 Report, which found that prescription drug prices in Britain had crept above the European average.<sup>270</sup> The health secretary then began talks with the pharmaceutical industry, with a view to reducing the latter's profit margins, amidst claims that they had been overcharging the National Health Service by hundreds of millions of pounds.<sup>271</sup>

Even with price regulation, Britain's National Health Service is often unable to provide expensive prescription drugs "of last resort" despite their clinical benefits. For instance, in 2007, the British National Institute for Clinical Effectiveness denied abatacept, an arthritis drug with strong clinical benefits, to 3,500 arthritis patients on grounds that the drug was too expensive, with a high price tag of £9,000 per person per year.<sup>272</sup> Prescription drug price regulation is the norm in Europe, and Britain is not an exception. The practice was given a tacit legal imprimatur by

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fits through national insurance for sickness funded by statutory contributions from the employer, the government and the employed. See John Abraham, "The Political Economy of Medicines Regulation in Britain" in Helen Lawton Smith, ed., *The Regulation of Science and Technology* (New York: Palgrave Publishers, 2002) at 230.

<sup>264</sup> *Ibid.* at 236.

<sup>265</sup> Under the compulsory license regime preceding the *1977 Patent Act*, food and drug patents could be licensed almost as of rights, albeit on conditions to be first settled by the Patent Office. See William Cornish, *Intellectual Property: Omnipresent, Distracting, Irrelevant?* (Oxford: Oxford University Press, 2004) at 24–26.

<sup>266</sup> *Ibid.*

<sup>267</sup> *Ibid.* at 27.

<sup>268</sup> *Ibid.*

<sup>269</sup> *Ibid.*

<sup>270</sup> John Carvel & Marianne Barriaux, "Johnson Moves to Curb Firms Overcharging NHS for Drugs" *Guardian* (3 August 2007), online: [Guardian <http://politics.guardian.co.uk>](http://politics.guardian.co.uk).

<sup>271</sup> *Ibid.*

<sup>272</sup> Laurance, *supra* note 35.



article 4(3) Directives 2001/83/EC (as amended) regulating medicinal products for human use as follows:

The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.<sup>273</sup>

*A fortiori*, if developed economies in Europe and Canada find expensive prescription drugs a burden so much so as to evolve regulatory strategies for its mitigation,<sup>274</sup> developing economies and low-income countries would understandably be more pressed to do so, in view of the paucity of resources.<sup>275</sup> This was the context in which South Africa, faced with a public health crisis precipitated by the HIV/AIDS pandemic, intervened to curb the prices of key prescription drugs.<sup>276</sup> In India, the National Pharmaceutical Pricing Authority, through the provisions of the Drugs (Prices Control) Order, was empowered to revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of medicines.<sup>277</sup> This underscores the perceived need for a regulatory intervention, rather than the whims of the market in pharmaceutical pricing governance.

Prescription drug cost-effectiveness pricing policy, which requires insurance coverage of drugs that provide significant benefits relative to their costs, is generally accepted as the best way to get value for money, and is widely used in the United States, Europe, Canada, and Australia, as costs control mechanism.<sup>278</sup> Health benefits are usually measured in units known as quality-adjusted life years (QALYs), while costs are generally measured from a societal perspective to comprise all current and future costs on the prevention and treatment of disease, and

<sup>273</sup> Directive 2001/83/EC (as amended).

<sup>274</sup> Devidas Menon, "Pharmaceutical Cost Control in Canada: Does It Work?" (2001) 20:3 Health Affairs at 92–103 (notes that price control had worked to a certain extent in Canada, but prescription drug expenditures continued to rise).

<sup>275</sup> World Health Organization, supra note 188 at 2 (notes that there is a compelling evidentiary link between poverty and a high disease burden in developing countries, as evidenced by stunted purchasing power, which in turn, diminishes the degree of interest that for-profit firms take in diseases specific to poor countries).

<sup>276</sup> *South African Medicines and Related Substances Control Act 1965*, as amended by the *Amendment Act*, No. 90 of 1997.

<sup>277</sup> The power is granted pursuant to India, *Drugs (Prices Control) Order 1995*, Part 2, s. 3(ii) (6 January 1995) *The Gazette of India — Extraordinary*. For a discussion on the history of the Drug Control Order and the controversies on its implementation by the National Pharmaceutical Pricing Authority, see Mansi B. Shah & Amit S. Patel, "Drug Price Control in India: An Overview" (2004) 12:2 *Journal of Pharmaceutical Finance, Economics & Policy* at 123–131.

<sup>278</sup> Donald J. Birkett, Andrew S. Mitchell & Peter McManus, "A Cost-Effective Approach to Drug Subsidy and Pricing in Australia" (2001) 20:3 Health Affairs at 104–114; Peter J. Neumann, "Evidence-Based and Valued-Based Formulary Guidelines" (2004) 23:1 Health Affairs at 124–134.

any consequential savings that could arise from disease treatment and prevention.<sup>279</sup> Evidence of a drug's cost-effectiveness is often required as a condition for inclusion in the national formulary by national authorities.<sup>280</sup> Limiting prescription drug insurance coverage to cost-effective drugs is said to be a veritable instrument for controlling drug costs,<sup>281</sup> as it could be used to filter out 'imitator' or 'me-too' drugs that do not provide better value for money than existing drugs in national formularies. However, it has been noted that 'me-too' drugs could potentially curb prices by providing needed competition and diluting monopoly power of patented drugs.<sup>282</sup> In this regard, cost-effectiveness analyses' results are mixed.

Moreover, it's been argued that cost-effective drug therapies, while providing medical benefits, do not necessarily save money.<sup>283</sup> Only treatments that are cost-saving, i.e., more clinically effective, and less costly than comparator treatment, would actually save money.<sup>284</sup> However, the pharmaceutical industry is said to be strenuously opposed to cost-effectiveness analyses, which it perceived as constraints on drug costs.<sup>285</sup> This is symptomatic of the pharmaceutical industry's opposition to any prescription drug costs mitigating initiative that is short of the whims of the market.

However, American officials are rankled by pharmaceutical price control, especially by affluent nations.<sup>286</sup> The general refrain amongst American officials and the United States pharmaceutical industry, is that countries with a price cap on patented pharmaceuticals are undermining future research and innovation in ethical pharmaceuticals<sup>287</sup> and shifting the burden of global pharmaceuticals research and development on the American taxpayers.<sup>288</sup> The Bush Administration had reportedly sought to bring the price of patented pharmaceuticals in Australia, Canada,

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279 Rai, *supra* note 15 at 205.

280 National drug formularies comprise the list of prescription medications approved for routine use by governments. See Neumann, *supra* note 278 at 125.

281 Rai, *supra* note 15 at 205.

282 *Ibid.*, at 206 (notes that the characteristic significant reduction in prescription drug prices upon the introduction of a generic drug).

283 Davidoff, *supra* note 222 at 1069.

284 *Ibid.*

285 *Ibid.*

286 Light & Lexchin, *supra* note 239 at W1-W4 (notes the former FDA Commissioner, Mark McClellan's displeasure with pharmaceuticals price control by the Europeans).

287 *Ibid.*; John E. Calfee, "Pharmaceutical Price Controls and Patient Welfare" (2001) 134:11 *Annals of Internal Medicine* at 1060–1064 (notes that pharmaceuticals price control would undermine innovation).

288 John Carey *et al.*, *supra* note 237; Davidoff, *supra* note 222 at 1068–1071 (notes the general perception that the U.S. pharmaceutical industry was subsidizing drug development in other countries, which could not afford development costs).

Europe, and other affluent countries to the United States level, in order to counter the growing clamor for price control in the United States.<sup>289</sup>

Notably, claims that price control in the United Kingdom and other countries undermines pharmaceuticals research and development, and the notion that Americans are financing the bulk of the global pharmaceutical R&D burden have been debunked.<sup>290</sup> According to Donald Light et al., audited financial reports of major drug firms in the United Kingdom and Canada, showed that all research costs were paid for with substantial profits, based solely on domestic sales at British and Canadian domestic prices.<sup>291</sup> Critics of America's relatively high pharmaceuticals prices argued that cutting prices in half or bringing prices down to the Canadian or European levels would not in any way derogate from pharmaceutical R&D budgets, if drug companies were prepared to reduce marketing expenditures, cut back luxurious managerial allowances, or high profits.<sup>292</sup> The perception is rife that pharmaceutical industry profits are excessive and that price control is justifiable to safeguard the public interest.<sup>293</sup> Analysts argued that the pharmaceutical industry could hardly justify the drug prices that fueled huge advertising and promotion expenditures on the post-development costs of manufacturing pills, which was about 20 to 30 per cent of the overall sales price.<sup>294</sup>

It has been speculated that prohibitive prices could force the United States to impose price regulation, with a view to stemming the widening medical divide be-

<sup>289</sup> See Donald W. Light & Joel Lexchin, "The International War on Cheap Drugs" (2004) 18 *New Doctor: Journal of the Doctors' Reform Society of Australia* at 1.

<sup>290</sup> Light & Lexchin, *supra* note 239 (notes that there was no evidence to verify the claims that price control undermines pharmaceutical R&D in Europe and Canada. He argues further that Americans consumed more than their share of global R&D expenditures, and that other nations were paying for the largely inefficient US pharmaceutical R&D).

<sup>291</sup> *Ibid.*, the findings were based on the reports submitted by 79 Canadian research drug companies, showing that their R&D expenditures had risen by more than 50 per cent since 1995, and that all research expenditures were paid for by domestic sales.

<sup>292</sup> *Ibid.*

<sup>293</sup> Davidoff, *supra* note 222 at 1068–1070 (notes that the U.S. pharmaceutical industry posted a larger profit margin than most other sectors of the economy in 1999, and that the pharmaceutical industry was one of the most profitable industries in the world); *Ibid.*, at 1068; Additionally, the District of Columbia's *Prescription Drug Excessive Pricing Act of 2005*, was predicated on the findings that "[t]he excessive prices of prescription drugs in the district of Columbia is threatening the health and welfare of the residents of the District as well as the District government's ability to ensure that all residents receive the health care they need, and these excessive prices directly and indirectly cause economic harm to the District and damage the health and safety of its residents. . . . [I]t is incumbent on the government of the District of Columbia to take action to restrain the excessive prices of prescription drugs", see *supra* note 144 at s. 28–4551.

<sup>294</sup> Davidoff argues that the marginal cost of making an extra batch of pills was "close to zero", *supra* note 222 at 1068.

tween the rich and the poor.<sup>295</sup> So far, attempts by the Congress and some states to force a price control regime have failed mainly because the Federal government was unwilling to allow prescription drug price control. In order to stave off or preempt the United States' government possible intervention, analysts believe that the industry should embrace a voluntary price reduction strategy, which could benefit the consumer, improve cost-effectiveness of pharmaceutical therapies, and boost the pharmaceutical industry's flagging image.<sup>296</sup> However, industry expert opinions are insistent that pharmaceuticals price control policy would substantially impede research and development.<sup>297</sup> The standard industry view is that while price control could save money in the short term, it would result in a long term loss of lives due to consequential reduction in innovative life-saving drugs.<sup>298</sup> Whilst safeguarding innovative pharmaceuticals has become the industry's standard response to clamors for a price cut, it is extremely doubtful that countries with price control regimes would scrap them.

### III. THE EPIDEMICS OF NEGLECTED DISEASES: THE SCALE OF THE PROBLEM

*We have never had such a sophisticated arsenal of technologies for treating diseases, yet the gaps in health outcomes keep getting wider. This is unacceptable.*<sup>299</sup>

The above statement by the Director General of the World Health Organization (WHO)<sup>300</sup> aptly captures the plight of over one billion people, about one-sixth of the world's population, who are susceptible to tropical diseases (TDR) that predominate in the poorest parts of the world.<sup>301</sup> Tropical diseases range from malaria, tuberculosis, leishmaniasis, sleeping sickness, to chagas, and are otherwise

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<sup>295</sup> "High Cost of New Cancer Drugs Too High for Some?" online: (2004) 25 *Pharmaceutical field* 179 <<http://www.pharmafield.co.uk/article.aspx?issueID=25&articleID=179>>.

<sup>296</sup> Davidoff, *supra* note 222 at 1070.

<sup>297</sup> Calfee, *supra* note 287 at 1060–1064 (notes that price control policy could perpetuate vested interests, become non-objective, and could well go below levels sufficient to reward pharmaceuticals innovation); *Ibid.* at 1060.

<sup>298</sup> Robert Goldberg, "Pharmaceutical Price Controls: Saving Money Today or Lives Tomorrow?" *Institute for Policy Innovation Report* No. 123, online: Institute for Policy Innovation <<http://www.ipi.org>>.

<sup>299</sup> Margaret Chan, Director General of the World Health Organization (WHO), cited in David O'Connell, "Neglected Diseases" (2007) 449 *Nature Outlook* at 157.

<sup>300</sup> *Ibid.*

<sup>301</sup> *Ibid.*

known as ‘neglected diseases’.<sup>302</sup> They are so characterized not because of a lack of high-quality basic research, but due to a dearth of investments for successful translation of basic scientific research and discoveries into crucial drugs.<sup>303</sup> The pharmaceutical industry would not invest if there is no viable market and prospects for recouping their investments.<sup>304</sup>

However, most of the countries where neglected diseases predominate are poor, lack the requisite purchasing power, and are bereft of the key ingredient necessary to spur pharmaceutical investments and innovation: viable commercial markets. For instance, developing countries, which comprise more than 80 per cent of the world population, only account for about ten per cent of global pharmaceuticals sales.<sup>305</sup> *A fortiori*, due to the strategic behavior of market actors, pharmaceuticals R&D is skewed in favour of drugs for which there is a ready and lucrative market.<sup>306</sup>

According to the WHO Commission on Macroeconomics and Health Report,<sup>307</sup> approximately less than five per cent of global pharmaceutical research and development funds are devoted to diseases that predominantly affect developing countries.<sup>308</sup> Indeed, mectizan, Merck’s drug for river blindness, (a disease which affects millions of people in Africa due to poor living conditions) was discovered by pure accident. The company had been working on parasites in farm animals, when scientists stumbled upon a compound (ivermectin) which happened to cure river blindness.<sup>309</sup> In order to underscore the serious health crisis neglected dis-

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<sup>302</sup> Neglected diseases are mainly tropical diseases ranging from malaria, tuberculosis, AIDS, leishmaniasis, sleeping sickness, to chagas disease. They are otherwise known as tropical diseases (TDR), and the World Health Organization for Research and Training in Tropical Diseases is collaborating with the World Bank and UNDP to establish affordable and improved treatments. See the World Health Organization for Research and Training in Tropical Diseases, *supra* note 22.

<sup>303</sup> Jurgen Drews, “Drug Research: Between Ethical Demands and Economic Constraints”, in Michael A. Santoro & Thomas M. Gorrie, eds., *Ethics and the Pharmaceutical Industry*, *supra* note 17 at 21–36 (notes that, as the costs of drug R&D spiraled from the 1960s, the mutual coexistence of medical, scientific, and economic motivations for drug R&D was substituted with strategic targeting of specific markets — those with the most commercial promise).

<sup>304</sup> Perelman, *supra* note 21 at 140–144 (notes how the market dictates pharmaceutical research focus on diseases that would produce the most profits at the expense of diseases prevalent in poor resource countries).

<sup>305</sup> WHO, *supra* note 188 at 15.

<sup>306</sup> Sebastian Buckup, “Global Public-Private Partnerships Against Neglected Diseases: Building Governance Structures for Effective Outcomes” (2008) 3 *Health Economics, Policy and Law* at 31–50.

<sup>307</sup> World Health Organization, “Macroeconomics and Health: Investing in Health for Economic Development”, online: WHO <<http://www.who.int>>.

<sup>308</sup> *Ibid.*

<sup>309</sup> Hawthorne, *supra* note 1 at 15.

eases pose to poor countries, sleeping sickness, a tropical disease that is peculiarly specific to countries with poor resources, will be examined as a case study in the following paragraph.

**(a) Human African Trypanosomiasis: A Case Study of Sleeping Sickness**

*Sleeping sickness is perhaps the most vivid example of the disconnect between the world's pharmaceutical giants and the fatal or debilitating disease of the third world's poor.*<sup>310</sup>

Human African Trypanosomiasis, commonly known as sleeping sickness, is a classic case of one of the developing countries' neglected diseases. The disease is caused by the parasite *trypanosoma brucei gambiense*, and transmissible by the tsetse fly.<sup>311</sup> The disease manifests itself in two stages.<sup>312</sup> The early stage occurs soon after infection, and is characterized by fever, headaches, lymphadenopathy, and organomegaly.<sup>313</sup> The second stage could set in several months or even years after infection, and is characterized by central nervous system breakdown and ultimate fatality if left untreated.<sup>314</sup> The disease affects 36 countries in sub-Saharan Africa,<sup>315</sup> has killed 66,000 in 1999, and remains a threat to 60 million people, only seven per cent of whom have access to diagnosis and treatment.<sup>316</sup>

Pentamidine is currently the standard recommended treatment for the early stage of the disease, but is not suitable for treatment of the disease in the second stage.<sup>317</sup> If the disease progresses to an advanced stage before treatment begins, it can only be treated with melarsoprol, an archaic drug that was first introduced in 1949.<sup>318</sup> The drug contains arsenic, is extremely painful when injected, and kills

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<sup>310</sup> See Donald McNeil Jr., "Medicine Merchants, Drug Companies and the Third World: A Case Study in Neglect" *The New York Times* (21 May 2000), online: *The New York Times* <<http://www.nytimes.com/library/national/science/health/052100drug-merchants.html>>

<sup>311</sup> Manica Balasegaram *e. al.*, "Treatment Outcomes and Risk Factors for Relapse in Patients with Early-Stage Human Trypanosomiasis (HAT) in the Republic of Congo", (2006) 84:10 *Bulletin of the World Health Organization* at 777-782.

<sup>312</sup> *Ibid.*

<sup>313</sup> *Ibid.*

<sup>314</sup> *Ibid.*

<sup>315</sup> The Campaign, Target Diseases, Sleeping Sickness, online: Access to Essential Medicines <<http://212.109.85.26/campaign/slp01.shtm>>. The account on sleeping sickness in this paper is drawn from materials on the MSF website, detailing their campaign against the disease.

<sup>316</sup> *Ibid.*

<sup>317</sup> Balasegaram *et al.*, *supra* note 311 at 777.

<sup>318</sup> The Campaign, Target Diseases, Sleeping Sickness, *supra* note 315.

outrightly three to ten per cent of patients treated.<sup>319</sup> A safer drug, known as eflornithine or DFMO, ran out of production in 1995, just five years after it first reached the market.<sup>320</sup> Like Merck's river blindness drug, eflornithine was discovered purely by chance. It was originally designed to treat cancer, and its production was abandoned when it could not.<sup>321</sup>

It is significant that while research continues on sleeping sickness's sister ailment, which afflicts cattle, there has been no significant improvement in 50 years for melarsoprol, the human version. According to Medecins Sans Frontieres, the veterinary industry appears to hold out the only hope of a final cure for sleeping sickness through their research to unravel the cattle version of the disease.<sup>322</sup> The sleeping sickness case is characteristic of the skewed results of prescription drug economics and the implacable market logic that drives pharmaceutical innovation. It simultaneously underscores market failure and the limitations in the quest for proportionate research investments in drugs for all known diseases. Francois Gros, an Aventis spokesman, summed up the workings of the pharmaceutical market logic:

We can't deny that we try to focus on top markets . . . cardiovascular, metabolism, anti-infection, etc. But we're an industry in a competitive environment. . . . We have a commitment to deliver performance to shareholders.<sup>323</sup>

Getting pharmaceutical companies to invest in drugs for neglected diseases is one of the greatest public health care challenges facing the developing countries. It would, however, take a new kind of public-private partnerships, which would not be entirely dictated by market logic or imperatives, to deliver some of the sorely needed medicines for neglected diseases.

### **(b) A New Regime of Global Public-Private Partnerships Against Neglected Diseases**

A new regime of global, collaborative public-private partnerships governance has evolved to manage neglected diseases.<sup>324</sup> The new regime differs radically from the conventional public-private partnerships paradigm between publicly funded universities or research institutions and the pharmaceutical industry.<sup>325</sup> While the latter is defined solely by ownership rights, oiled by patents, and driven

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<sup>319</sup> *Ibid.*

<sup>320</sup> *Ibid.*

<sup>321</sup> McNeil, *supra* note 310.

<sup>322</sup> *Ibid.*

<sup>323</sup> Cited in McNeil, *ibid.*

<sup>324</sup> *The Washington Post*, *supra* note 21 at A18 (laments the endemic incidence of neglected diseases and welcomes a recent collaboration between a non-profit organization and Sanofi-Aventis to develop a new anti-malaria drug).

<sup>325</sup> See generally Section IIB, above, for discussion.

by market logic and imperatives,<sup>326</sup> the former is an ad hoc coalition of NGOs, charities, pharmaceutical firms, and the WHO,<sup>327</sup> and is driven by altruism.

The emergence of the non-market oriented, global public-private partnerships for neglected diseases has been attributed to new paradigm shifts in development discourse<sup>328</sup> and new perceptions regarding global security threats.<sup>329</sup> Globalization and the concomitant liberalization of trade in goods and services are directly implicated in the current surges in trans-border and trans-national travel,<sup>330</sup> which make the trans-national spread of communicable diseases such as avian influenza, SARS, multi-drug tuberculosis, or any neglected diseases inevitable.<sup>331</sup> It also underscores the urgency of a global public health policy that transcends national borders since communicable and infectious diseases have no respect for national frontiers.<sup>332</sup>

The WHO has consistently provided leadership and been at the forefront of the campaigns to draw attention to, and facilitate treatment for neglected diseases since the 1970s<sup>333</sup> Currently, the World Health Organization for Research and Training in Tropical Diseases is collaborating with the World Bank and United Nations Development Program to establish modalities for affordable and improved treatments for neglected diseases.<sup>334</sup> In May 2000, the World Health Assembly,<sup>335</sup>

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<sup>326</sup> The conventional public-private partnerships for pharmaceuticals R&D are forged by publicly funded universities and the pharmaceutical industry. It is an integral element of prescription drug economics, and it is clearly defined by property rights through the instrumentation of the patent regime. See Section IIA, above.

<sup>327</sup> Backup, *supra* note 306 at 31-32.

<sup>328</sup> WHO, *supra* note 188 at 173 (notes that the preponderance of poverty and sickness in poor countries has gained global prominence since the beginning of the twenty-first century, because it affronts commonly-held basic human values, and the recognition of the interdependence of the global community, and the potentially serious consequences of the failure to tackle the problem).

<sup>329</sup> *Ibid.*

<sup>330</sup> Obijiofor Aginam, "International Law and Communicable Diseases" (2002) 80:12 Bulletin of the World Health Organization 946 at 947.

<sup>331</sup> Thomas M. Gorrie, "Evolving Approaches to Healthcare Challenges" in Michael A. Santoro & Thomas Gorrie, eds., *Ethics and the Pharmaceutical Industry*, *supra* note 17 at 369 (notes that increase in long-distance travel could facilitate larger outbreaks of infectious diseases).

<sup>332</sup> Taiwo A. Oriola, "Against the Plague: Exemption of Pharmaceutical Patents Rights as a Biosecurity Strategy" (2007) 2 University of Illinois Journal of Law, Technology & Policy 287 at 297-309.

<sup>333</sup> World Health Organization for Research and Training in Tropical Diseases, *supra* note 22.

<sup>334</sup> *Ibid.*

<sup>335</sup> The World Health Assembly is the supreme decision-making body for the World Health Organization, and meets up once a year. It comprises delegates from the current 193 Member States, and is responsible for the appointment of the Director General of



the supreme decision-making body for the WHO, called on international organizations, non-governmental organizations, donors, foundations, and the international community to forge a global partnership for the elimination of tuberculosis.<sup>336</sup>

There are now numerous NGOs, charitable organizations, and even pharmaceutical firms<sup>337</sup> in a new global coalition against neglected diseases that are bereft of the traditional market trappings.<sup>338</sup> A major initiative in this regard is the Global Fund to Fight AIDS, Tuberculosis and Malaria, a new international financing mechanism championed by the United Nations.<sup>339</sup> Leading the pack of philanthropic, non-governmental organization initiatives against neglected diseases is the Bill & Melinda Gates Foundation. To date, the Foundation has committed more than \$7.8 billion in support of global health efforts, prioritizing AIDS, malaria, tuberculosis, child and newborn health, and reproductive health.<sup>340</sup> There is also the Global Network for Neglected Tropical Disease Control (GNNTDC), a coalition of health organizations dedicated to controlling and eliminating neglected diseases through a program of advocacy, resource mobilization, and access to essential drugs and vaccines.<sup>341</sup>

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the World Health Organization. See, online: WHO  
<<http://www.who.int/governance/en/index.html>>.

336 J.W. Lee, E. Loevinsohn & J.A. Kumaresan, "Response to a Major Disease of Poverty: the Global Partnership to Stop TB" (2002) 80:6 *Bulletin of the World Health Organization* at 428.

337 It has been observed that pharmaceutical firms have made substantial contribution in kind to public-private product-development partnerships and, that despite a lack of market incentive, about half of the current research projects focusing on neglected diseases are conducted by pharmaceutical firms. See Andrew L. Hopkins, Michael J. Witty & Solomon Nwaka, "Mission Possible: One Billion People Worldwide Suffer from Tropical Diseases" (2007) 449 *Nature Outlook Drug Discovery* at 166–169.

338 Backup, *supra* note 306 at 35–36 (notes that, since the mid 1990s, a number of global health partnerships between public and private actors have emerged to bridge the investments gap for neglected diseases created by market failures).

339 Robert Walgate, "Global Fund for AIDS, TB and Malaria Opens Shop" (2002) 80:3 *Bulletin of the World Health Organization* at 259 (notes that the Fund had its first board meeting in January 2002, and was in a position to disburse between \$700 million and \$1 billion against malaria, AIDS, and TB in 2002).

340 Bill & Melinda Gates Foundation, Media Release, "Annual Report 2006" at 14–20, online: <<http://www.gatesfoundation.org/nr/public/media/annualreports/annualreport06/assets/GatesFoundationAnnualReport2006.pdf>>.

341 GNNTDC is a new collaborative organization that is formalized by the Clinton Global Initiative to facilitate the fight against neglected diseases, through short term and long term strategies. It comprises the Schistosomiasis Control Initiative, Imperial College of London, International Trachoma Initiative, Lymphatic Filariasis Support Centre, Liverpool School of Tropical Medicine, The Task Force for Child Survival and Development, Helen Keller International, The Earth Institute, and Columbia University. On 8 March 2007, the body announced that it had been awarded a \$8.9 million grant via Geneva Global Inc. to fund a campaign to control and eliminate seven neglected dis-

Given the current array of resources, institutional, governmental and non-governmental supports, it has been opined that, over the next decade, it should be possible to produce a new generation of safe, effective and inexpensive medicines for many of the neglected diseases afflicting the poor.<sup>342</sup> This could be accomplished by scaling up investments in research and development of new drugs, building a more efficient and more open mechanism for new drug discovery, and through the provision of crucial political leadership to align public health funding with philanthropic funding.<sup>343</sup>

Already, the new public-private partnerships are being put to the test, as exemplified by a 2007 project, using Advance Market Commitments (AMCs) for the development of a vaccine against pneumococcal disease, with a \$1.5 billion commitment by a consortium of five European countries and the Bill & Melinda Gates Foundation.<sup>344</sup> Similarly, a partnership between the Drugs for Neglected Diseases Initiative<sup>345</sup> and the Paris-based pharmaceutical company, Sanofi-Aventis, recently announced that it had developed, and would produce at cost, a new anti-malaria drug.<sup>346</sup> Sanofi-Aventis reportedly agreed not to seek a patent for the medication, allowing generic drug manufacturers to join in and further reduce the drug's price.<sup>347</sup> This underscores the central and indispensable role that pharmaceutical firms could play in the new non-market oriented public-private partnership regime.

Arguably, these new partnerships would have to contend with the challenges of maintaining their momentum, credibility, and achieving long term viability and effectiveness. However, concerns have been raised about the prospects for long term sustainability of global health partnerships as a new governance structure.<sup>348</sup> There is, however, optimism and confidence that the new global health partnerships would survive due to their potential to minimize the characteristically high costs of the complex transaction required by collaborative new drug R&D.<sup>349</sup>

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eases in two East African countries of Rwanda and Burundi. See, online: Global Network for Neglected Tropical Disease Control <[www.gnntdc.org](http://www.gnntdc.org)>.

<sup>342</sup> Benedicte Callan & Iain Gillespie, "The Path to New Medicine" (2007) 449 *Nature* at 164-165.

<sup>343</sup> *Ibid.*

<sup>344</sup> *Ibid.* Advance market commitments are assurances that the drug under development will be purchased upon production. It's a strategy to remedy the characteristic lack of viable market for drugs on neglected diseases.

<sup>345</sup> The Drugs for Neglected Diseases Initiative (DNDi) is a non-profit initiative driven by the public sector. It aims to research and develop new, improved, effective, affordable, and field relevant drug for neglected diseases. See, online: [dndi <www.dndi.org>](http://www.dndi.org).

<sup>346</sup> *The Washington Post*, *Supra* note 21 at A18.

<sup>347</sup> *Ibid.*

<sup>348</sup> Backup, *supra* note 306 at 31-50 (asks whether global health partnerships are a passing fad or a stable pillar of governance in an emerging global public domain); *Ibid.* at 32.

<sup>349</sup> *Ibid.*, Sebastian Backup opines that the problem of incomplete contract, and the complexity of jointly produced outcomes, could up the costs of market transactions. This provides the rationale for the existence of a global health alliance governance structure

However, with so many actors and players, it is imperative to co-ordinate resources and actions, sometimes across national borders, in order to avoid duplication and the waste of resources. For instance, the planned malaria-vaccine project, backed by the Bill & Melinda Gates Foundation and some European countries,<sup>350</sup> might have to be reassessed in light of the new Sanofi-Aventis anti-malaria drug project<sup>351</sup> — unless, of course, a malaria vaccine would be more cost-effective, or possess superior clinical advantages over existing drugs that are already accessible. A collaborative open innovation network of industry and public laboratories on ongoing drug research of neglected diseases could both eliminate duplication of efforts and maximize the effectiveness of public private partnerships.<sup>352</sup> Open innovation networks would necessarily entail sharing of research tools, data, and patents pooling.<sup>353</sup> Collaborative research tool sharing is a classic non-market oriented template for pharmaceutical innovation and is guaranteed to reduce the costs of new drugs for neglected diseases. It is also the antithesis of the conventional, patents-dependent, and market oriented public/private partnerships that created the neglected diseases phenomenon.

#### IV. THE PRICE OF PATENTS: WHAT ARE THE PROSPECTS FOR WORKABLE ALTERNATIVES TO THE PATENT SYSTEM?

There is no denying the significance of patents to the pharmaceutical industry.<sup>354</sup> The patent monopoly ensures that the pharmaceutical industry recoups their huge financial investments by keeping out competitors during the pendency of crucial patents, which is usually 20 years.<sup>355</sup> Primarily, the societal quid pro quo for patent exclusivity is the expected concomitant rise in research and development

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as a cost cutting strategy despite reservations in some quarters on its political legitimacy as a governance structure.

350 Callan & Gillespie, *supra* note 342 at 164.

351 *Ibid.*

352 *Ibid.* at 164-165.

353 *Ibid.*

354 Andrew Beckerman-Rodau, "Patent Law — Balancing Profit Maximization and Public Access to Technology" (2002) 1 *The Columbia Science & Technology Law Review* at paras. 14-15, online: *Colum. Sci. & Tech. L. Rev.* <<http://www.stlr.org/cite.cgi?volume=4&article=1>>.

355 Dutfield, *supra* note 14 at 98, 107; Harvey E. Bale Jr., "Patents and Developing Countries: Access, Innovation and the Political Dimensions of Trade Policy" in Brigitte Granville, ed., *The Economics of Essential Medicines*, *supra* note 28 at 100; Richard C. Levin *et al.*, "Appropriating the Returns from Industrial Research and Development" in Edwin Mansfield & Elizabeth Mansfield, eds., *The Economics of Technical Change*, (Aldershot, England, Brookfield, Vermont: 1993) at 243.

investments and the public disclosure of the invention,<sup>356</sup> which is expected to assure conditions for competitive, innovative and beneficial products.<sup>357</sup>

Whilst it is beyond the remit of this article to join the fray on the role of patents in promoting innovation,<sup>358</sup> it is instructive to note the counter argument — that patents generally stifle, rather than boost innovation.<sup>359</sup> With regard to medical innovations for example, concerns have been raised about patenting tools of medical research, especially gene sequences.<sup>360</sup> The proliferation of patented genes raises the real prospects of legal barriers to the development of a range of medical products.<sup>361</sup> While licensing, (both voluntary and compulsory) is theoretically a great mechanism for accessing patented tools,<sup>362</sup> the costs could be too prohibitive,

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<sup>356</sup> Beckerman-Rodau, *supra* note 354 at para. 17; Stanley M. Besen & Leo J. Raskind, “An Introduction to the Law and Economics of Intellectual Property” (1991) 5:1 *Journal of Economic Perspectives* 3 at 5.

<sup>357</sup> Frederick M. Abbott, “The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at WTO” (2002) 5 *Journal of International Economic Law*, 469 at 472-473 (the author notes the pharmaceutical industry’s argument that patent was indispensable to continual funding of research and development of innovative pharmaceuticals).

<sup>358</sup> There is a preponderance of polemical literature on this topic. For discussion see Edwin Mansfield, Mark Schwartz & Samuel Wagner, “Imitation Costs and Patents: An Empirical Study” (1981) 91 *The Economic Journal* at 907-918 (the authors ask some firms, the bulk of which are pharmaceutical companies, “what proportion of innovations would be delayed or not introduced at all if they could not be patented?” The firms’ replies show that about one-half of the patented innovations would not have been introduced without patent protection). It is said, for instance, that the relative paucity of development in the Indian pharmaceutical sector vis-à-vis the software and film sectors, was due to a lack of pharmaceutical patent protection. See Harvey E. Bale Jr., “Patents and Developing Countries: Access, Innovation and the Political Dimensions of Trade Policy” in Brigitte Granville, ed., *The Economics of Essential Medicines*, *supra* note 28 at 103.

<sup>359</sup> See e.g. Michael Perelman, *supra* note 21 at 45-73 (the author cites instances where patents stifled innovation rather than promoted it).

<sup>360</sup> John H. Barton, “Research-Tool Patents: Issues for Health in the Developing World” (2002) 80:2 *Bulletin of the World Health Organization* at 121-125; Gerard N. Magliocca, “Blackberries and Barnyards: Patent Trolls and the Perils of Innovation” (2007) 82 *Notre Dame Law Review* at 1809 (the author uses the example of blackberry patent disputes to illustrate the perils of patent trolls for innovation. Patent troll describes the use of patent strategically to extract settlements rather than license or manufacture technology. It is a classic case of using patent abuse and where patent could be used to obstruct innovation pathway).

<sup>361</sup> Barton, *supra* note 360 at 121-125.

<sup>362</sup> *Ibid.*, this would include voluntary and compulsory licensure. National and international patents regimes have compulsory licensure provisions. For example, Article 31 of the TRIPS Agreement incorporates the conditions under which a WTO member may use patented technologies without the authorization of the owner; See Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 31.

leaving researchers no choice, but to design around existing patents.<sup>363</sup> Even if licensing fees were low, enormous negotiation costs and the attendant delay could ultimately lead to an abandonment of the project.<sup>364</sup> For example, the Indian government's attempt to negotiate a compulsory license for a patented drug in the 1970s was mired in endless negotiations, and ended up in a stalemate and consequential abandonment of the project.<sup>365</sup>

Another key criticism against the premise that patents are indispensable to pharmaceutical innovation points out that the number of patents for genuinely innovative pharmaceutical products is negligible; there are thousands of patents for 'upstream' pharmaceutical inventions, or mere scientific discoveries, but there is a trivial amount of patents for technical solutions.<sup>366</sup> The end result is the proliferation of largely non-innovative 'me-too' drugs with no genuine therapeutic results, which is due to the industry's failure to produce "fundamentally new small molecule drugs that work against new targets."<sup>367</sup> This has led analysts to suggest that the pharmaceutical industry should tread a co-operative, rather than the well-worn route, of patents exclusivity to innovative pharmaceuticals.<sup>368</sup> This is not, however, discounting patents' relevance to pharmaceutical innovation. Rather it is a call for a

<sup>363</sup> Barton, *supra* note 360 at 121–125.

<sup>364</sup> *Ibid.*

<sup>365</sup> The Indian government had, in the 1970s, requested a compulsory license. However, the patentee only agreed to a voluntary license. The parties got stuck on royalty disputes as the patentee insisted on a royalty of 25 per cent. After four years of prolonged negotiations, the patentee agreed to accept a ten per cent royalty, which the government still found higher than its five per cent royalty limit. The protracted process of negotiation was too costly for the government, leading to the consequential abandonment of the project. See Biswajit Dhar & K.M. Gopakumar, "Post-2005 TRIPS Scenario in Patent Protection in the Pharmaceutical Sector: The Case of the Generic Pharmaceutical Industry in India" *Intellectual Property Rights and Sustainable Development* (November 2006) at 22, n. 38, online: IPRonline.org <<http://www.iprsonline.org/unctadictsd/docs/Dhar%201Indian%20Pharma%20November06.pdf>>.

<sup>366</sup> Correa, *supra* note 90 at 784–785.

<sup>367</sup> *Ibid.* at 785; Arti K. Rai, Jerome H. Reichman & Paul F. Uhlir, "Pathways Across the Valley of Death: Novel Intellectual Property Strategies for Accelerated Drug Discovery" (2008) 8:1 *Yale Journal of Health Policy, Law, & Ethics* at 55–89 (notes that pharmaceutical firms have largely failed to find fundamentally new small molecule drugs, especially those that work against new targets. They note further that, on the average, only three drugs that act on novel targets have reached the market annually in recent years. This has led to the proliferation of 'me-too' drugs, new products that represent mere incremental innovation over existing molecules).

<sup>368</sup> Rai, Reichman & Uhlir *Ibid.*, at 56, the authors suggest models for multi-firm and public-private collaboration for boosting innovative drugs. This would entail "intensive large-scale collaboration between academics, who possess unique skills in designing assays that can identify targets, and pharmaceutical firms that hold libraries of potentially useful small molecules as trade secrets, making them largely off limits to these academic scientists."

creative use of patents to build co-operative alliances on the pathway to innovative pharmaceuticals.<sup>369</sup>

While collaboration, rather than the current, largely closeted pharmaceutical research and development paradigm, is crucial to innovative pharmaceuticals, it is undeniable that the pharmaceutical industry is highly vulnerable to cheap imitations and piracy because chemicals are easily replicable.<sup>370</sup> Empirical study has established that cheap imitations of original products could adversely affect incentive for further innovation.<sup>371</sup> This is, arguably, one of the reasons the pharmaceutical industry is ever keen on promoting stronger patent protection for pharmaceuticals<sup>372</sup> and quick to fend off generic drugs prior to patent expiration.<sup>373</sup>

However, most developing countries lack a comparative research and development base for innovative drug production<sup>374</sup> and tend to focus on producing generics of patented drugs as exemplified by Mexico, India and Brazil.<sup>375</sup> Basic research into new molecules by India's burgeoning pharmaceutical industry accounts for a

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<sup>369</sup> *Ibid.* at 57.

<sup>370</sup> Paul R. Paradise, *Trademark Counterfeiting, Product Piracy, and the Billion Dollar Threat to the U.S. Economy* (Westport, Connecticut, London: Quorum Books, 1999) at 175. Counterfeit drugs often lead to therapy failures and sometimes tragic consequences. This was exemplified by the tragic deaths of an estimated 2,500 people following the administration of counterfeited meningitis vaccine in Niger Republic in April 1995.

<sup>371</sup> Tim Philips, *Knockoff: The Deadly Trade in Counterfeit Goods: The True Story of the World's Fastest Growing Crime Wave* (London and Sterling, VA: Kogan Page, 2005) at 187–217 (the author catalogues horror stories associated with the flourishing trade in counterfeited drugs).

<sup>372</sup> The pharmaceutical industry was reputedly a key member of the multinational consortium that pressed for stronger international patent protection in the context of the International Trade Agreement. This culminated in the 1994 WTO-Marrakech Trade-Related Agreement in Intellectual Property (TRIPS). See M.B. Rao & Manjula Guru, *Understanding TRIPS: Managing Knowledge in Developing Countries* (New Delhi, Thousand Oaks & London: 2003) at 20–22; Robert Weissman, "A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries" (1996) 17 *University of Pennsylvania Journal of International Economic Law* 1069 at 1077 and 1083–1084. The author, *inter alia*, notes the strong influence of the pharmaceutical industry on the U.S.'s drive for stronger international patent law.

<sup>373</sup> Generics copies are fashioned after brand copies and have been empirically proven to be cheaper than brand copies. See "Reports: Generics Offers Savings Over Imports, Price Controls" (2004) 3:249 *Drug Industry Daily*.

<sup>374</sup> Most developing countries such as Mexico, Brazil and India do better at producing generics than innovative drugs. See Balasubramaniam, *supra* note 28 at 90–107.

<sup>375</sup> Jorge Bermudez, "Expanding Access to Essential Medicines in Brazil: Recent Economic Regulation, Policy Making and Lessons Learnt" in Brigitte Granville, ed., *supra* note 28 at 178 (notes that Law 9.787/99 of October 1999 established the basic legal framework for generic drugs manufacturing in Brazil. The law established technical

fraction of R&D activities carried out by Western pharmaceutical companies in 2000.<sup>376</sup> Indian pharmaceutical firms have thus resorted to producing generics of patented drugs.<sup>377</sup> This often leads foreign pharmaceutical firms to challenge local firms in India for patents infringement.<sup>378</sup> A notable recent example was the case of *Novartis AG v. Union of India and Others*,<sup>379</sup> involving patent disputes between Novartis and Indian pharmaceutical companies at a Chennai court.<sup>380</sup> The former had sought patent protection for Gleevec, a modified form of its leukemia drug under the 2005 *Indian Patent Act*, while the latter contended that the modified cancer drug constituted mere “incremental innovations”, and suffered from prior publication, lack of inventive step and insufficient description. It did not, *inter alia*, represent a new “improved efficacy” or significant improvement on the original, off patent leukemia drug, and therefore was not eligible for protection under the *Indian Patent Act*.<sup>381</sup> Significantly, the Indian generic version of Gleevec retailed for only about a tenth of the \$2,600 that Novartis charged for a month’s course of treatment<sup>382</sup> — an indication of a direct nexus between patents and high pharmaceutical prices.

In the context of access to essential medicines in developing countries, the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Doha Declaration on Public Health<sup>383</sup> provides for special measures ranging from parallel import, government use, to compulsory licensure to facilitate and improve access to affordable life-saving medicines.<sup>384</sup> However, it has been noted that Article 31bis, the arrowhead of the new amendment to TRIPS, which is specially crafted to facili-

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standards and norms that defined the concepts of bio-availability and bio-equivalence of generic drugs vis-à-vis branded medicines); *Ibid.* at 187.

<sup>376</sup> Anna Thomas, “Street Price: A Global Approach to Pricing for Developing Countries” in Brigitte Granville, ed., *supra* note 28 at 278.

<sup>377</sup> Sampath, *supra* note 88 at 694–726 (notes that Indian pharmaceutical firms produced 22 per cent of global generic drugs and that the *Indian Patent Act* of 2005 has greatly facilitated the production of generics); *Ibid.* at 699–700.

<sup>378</sup> Khozem Merchant, “Drugs Makers Fear Patent Abuse in India” *Financial Times* (12 May 2002) at 4.

<sup>379</sup> *Novartis AG v. Union of India and Others*, W.P. No. 24754 (2006) and W.P. No. 24759 (2006) [RNF] cited in K.D. Raju, “The Debacle of Novartis Patent Case in India: Strict Interpretation of Patentability Criteria Under Article 27 of the TRIPs Agreement” Social Science Research Network (2007), online: SSRN <<http://ssrn.com/abstract=1030963>>.

<sup>380</sup> Amelia Gentleman, “Battle Pits Patent Rights Against Low-Cost Generic Drugs” *The New York Times* (30 January 2007), online: *The New York Times* <[http://www.nytimes.com/2007/01/30/business/worldbusiness/30novartis.html?\\_r=1&oref=slogin](http://www.nytimes.com/2007/01/30/business/worldbusiness/30novartis.html?_r=1&oref=slogin)>.

<sup>381</sup> Gentleman, *ibid.*; See also Dhar & Gopakumar, *supra* note 365.

<sup>382</sup> Gentleman, *supra* note 380.

<sup>383</sup> See Para. 6 of the Doha Declaration on the TRIPS Agreement and Public Health, online: WTO <[http://www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm)>.

<sup>384</sup> Abbott & Reichman, *supra* note 87 at 929–957.

tate access to essential drugs by developing countries with limited or no manufacturing capacity, is encumbered with administrative hurdles that could hamper its effectiveness.<sup>385</sup> Furthermore, the proliferation of bilateral trade agreements requiring stronger intellectual property protection than TRIPS does, are generally perceived as obstacles to the implementation of TRIPS's flexibilities by developing countries.<sup>386</sup>

This arguably informed the recent report by the Commission on Intellectual Property Rights, Innovation and Health (CIPIH) of the World Health Organization, urges developing countries to, *inter alia*, devise appropriate national legal frameworks to facilitate access to affordable prescription drug.<sup>387</sup> The report also reiterates, *inter alia*, the virtues of the rewards or prize system as well as that of open source approaches to pharmaceutical innovation with a view to easing the stranglehold of patents on pharmaceuticals.<sup>388</sup>

### (a) Prize or Reward Contests as Primers for Innovation

Prize or reward contests are competitions specifically designed to rally experts into solving particular technological needs or problems for a named prize or award.<sup>389</sup> The idea and use of a prize or reward as incentive for innovation has been around for a long time. For example, the British Parliament enacted the *Longitude Act* in 1714,<sup>390</sup> announcing up to £20,000 in rewards for the development of a "practicable and useful" method for accurately determining longitude at sea.<sup>391</sup> Most recently, Sir Richard Branson and Al Gore announced "The Virgin Earth Challenge".<sup>392</sup> It is a \$25 million Global Science and Technology Prize "for whoever can demonstrate to the judges' satisfaction a commercially viable design which results in the removal of anthropogenic, atmospheric greenhouse gases so as to contribute materially to the stability of Earth's climate."<sup>393</sup>

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385 *Ibid.*, the authors, however, argue that the said administrative huddles could be overcome by "skillful lawyering, political determination and coordinated planning."

386 Carlos Maria Correa, "Implications of Bilateral Free Trade Agreements on Access to Medicines" (2006) 84:5 Bulletin of the World Health Organization at 399–404.

387 See *supra* note 188 at 175–188.

388 *Ibid.*

389 Clayton Stallbaumer, "From Longitude to Altitude: Inducement Prize Contests as Instruments of Public Policy in Science and Technology" (2006) 1 University of Illinois Journal of Law, Technology & Policy at 118.

390 *An Act for Providing a Public Reward for Such Person or Persons as Shall Discover the Longitude at Sea*, 1714, 12 Ann., c. 15 (Eng.) cited in Clayton Stallbaumer, *ibid.*

391 The announcement followed the tragic sinking of a fleet of Royal Navy warships, crewed by two thousand sailors, on the Isles of Scilly — roughly twenty miles off southwest of England. The sailors had misjudged their position due to poor navigational equipment. One John Harrison, a clock maker, received the £20,000 top prize in 1773, some 59 years after the tragic accident. See Stallbaumer, *ibid.* at 117.

392 See, online: Virgin Earth Challenge <<http://www.virginearth.com>>.

393 *Ibid.*



In the context of pharmaceutical innovation, the prize or reward contest has been floated, not as a substitute for, but as a compliment to the patent system.<sup>394</sup> For example, in February 2007, Canada, Italy, Norway, Russia, the United Kingdom, and the Bill & Melinda Gates Foundation, announced a \$1.5 billion “Advance Market Commitment” (AMC) for pneumococcal vaccines.<sup>395</sup> The money is dedicated to subsidizing the purchase of eligible vaccines for use in developing countries.<sup>396</sup> The fund guarantees that any useful vaccines developed for the disease would be purchased, and provides a critical incentive for pharmaceutical firms to invest in R&D leading to effective vaccines for the disease. Such vaccines could also be cheaper and affordable due to the economies of scale inherent in advance market commitment to bulk prescription drug purchases.

Another major initiative for institutionalizing the prize system for pharmaceutical innovation was the U.S. *Medical Innovation Prize Act* of 2005.<sup>397</sup> The Act was intended to revolutionize medical research and development in the United States.<sup>398</sup> According to the bill’s sponsor, Representative Bernard Sanders:

[r]ather than rely[ing] on high drug prices as the incentive for R&D, the bill would directly reward developers of medicines, on the basis of the incremental therapeutic benefit to consumers, through a new Medical Innovation Prize Fund. Prices for prescription drugs to consumers would be at low generic prices immediately upon entry to the market. By breaking the link between drug prices and R&D, it would provide more equitable access to medicine, end rationing and restrictive formularies, and manage overall R&D incentives through a separate mechanism that can be increased or decreased, depending on society’s willingness to pay for medical R&D.<sup>399</sup>

Unfortunately the bill had no co-sponsors and never became law because no further action was taken on it.<sup>400</sup> The bill does, however, represent deep yearnings for an alternative to the patent system and the potential promise of the reward system as a

<sup>394</sup> James Love & Tim Hubbard, “The Big Idea: Prizes to Stimulate R&D for New Medicines” (2007) 82:13 *Chicago-Kent Law Review* at 1520–1550; Marlynn Wei, “Should Prizes Replace Patents? A Critique of the *Medical Innovation Prize Act* of 2005” (2007) 13:1 *Boston University Journal of Science & Technology* at 25–45 (notes that the benefits of the prize system were untested, and unlikely to dislodge the entrenched patent regime).

<sup>395</sup> HM Treasury, Press Notice, “Launch of the First Advance Market Commitment for New Vaccines” (28 February 2007) online: HM Treasury <[http://www.hm-treasury.gov.uk/press\\_18\\_07.htm](http://www.hm-treasury.gov.uk/press_18_07.htm)>.

<sup>396</sup> *Ibid.* Arguably, the measure is a direct response to the market’s failure to channel investments into neglected tropical diseases specific to developing countries.

<sup>397</sup> See H.R. 417, *Medical Innovation Prize Act* of 2005, online: OLPA <<http://olpa.od.nih.gov/legislation/109/pendinglegislation/medicalinnovation.asp>>.

<sup>398</sup> *Ibid.*

<sup>399</sup> *Ibid.*

<sup>400</sup> *Ibid.*

primer for pharmaceutical innovation. It has been noted that, if implemented properly, the use of prizes can potentially help the industry

make inventions freely available to competitive suppliers, leading to lower prices and greater access, avoid waste on unimportant “me-too” products that do not improve health outcomes, reduce incentives for excessive spending on marketing and promotion of irrational drug use, and stimulate R&D to benefit populations with low purchasing power.<sup>401</sup>

Significantly, whilst the prize system has succeeded in other fields of innovation, it remains largely untested for pharmaceutical innovation.<sup>402</sup> Notable obstacles to its implementation include institutional impediments, ascertaining who has the authority to award prizes, the measure of award, and who pays for the prize.<sup>403</sup> However, James Love, while noting that the aforementioned obstacles are not insurmountable, opines that the system of prices is ingrained in many areas of the economy, and that “there is a reluctance to abandon a system of prices determined by actual market transactions as the method of determining the value of knowledge good, because there is a concern that prizes will be difficult to administer, or [will be] inadequately resourced.”<sup>404</sup>

Additionally, some analysts believe that if patents operate in parallel to the prize system, contestants could be tempted to apply for patents, thus truncating the welfare benefits inherent in the prize system.<sup>405</sup> Since it is safe to assume that we are stuck with the patent system for the foreseeable future, subsequent patenting of inventions entered into prize contests would be inevitable, unless, of course, it is expressly forbidden by statutes or contractual obligations. Even if contestants were forbidden from subsequently applying for patents, the likelihood that the contestants’ invention might infringe existing patents is ever present.<sup>406</sup> In which case, the contestant would be forced to withdraw, invent around the patents, or enter into a licensing agreement with the patentees.<sup>407</sup> *A fortiori*, the patent system remains a potent obstacle to the prize or reward system.

Despite the apparent obstacles, authorities should seriously explore institutionalizing the prize or reward system to supplement the patent regime as a primer for pharmaceutical innovation. It has been posited that where public policy goals are in

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401 James Love, “The Role of Prizes in Stimulating R&D: Comment to WHO IGWG” *Knowledge Ecology International* (30 September 2007), online: Knowledge Ecology International <[http://www.who.int/phi/public\\_hearings/second/contributions\\_section2/Section2\\_JamesLove-KEL\\_prizes.pdf](http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_JamesLove-KEL_prizes.pdf)>.

402 Wei, *supra* note 394 at 25–45.

403 See Love, *supra* note 401.

404 *Ibid.*

405 Jerome Davis & Lee N. Davis, “Patents, Inducement Prizes, and Contestant Strategy: Do Patents ‘Crowd Out’ Prizes?” (Paper presented to the DIME IPR workshops in London, England, 23–24 March 2006), online: (2006) (Working Paper No. 12) at 15 <[http://www.dime-eu.org/files/active/0/IPR-W\\_12-DavisDavis-mai03-1.pdf](http://www.dime-eu.org/files/active/0/IPR-W_12-DavisDavis-mai03-1.pdf)>.

406 *Ibid.* at 9–15.

407 *Ibid.*

synch with prize contests objectives, the latter would flourish and compliment public policy efforts.<sup>408</sup> It would be hard to find a government or authority that would not want a regime of affordable and accessible prescription drugs for its population. What is needed is a concerted international effort, borne out of strong political will, to forge viable prize or reward contests as a complimentary route to innovative pharmaceuticals. The prize system has great potential to generate affordable and accessible prescription drugs.<sup>409</sup>

### **(b) Could Open Source Biology Ease the Patents Pains?**

Open source biology is a concept modeled on open source software. Prior to the advent of proprietary software, which now dominates global operating systems, open source software was the norm.<sup>410</sup> However, the normative order of the non-proprietary software regime began fizzling in the late 1970s and early 1980s as spin-off companies began commercializing software.<sup>411</sup> Proprietary software actors soon became dominant, forcing a resurgence of the “free” software movement and culminating in the launch of the “GNU” operating system in 1984.<sup>412</sup>

However, the increasing use of non-proprietary software in proprietary applications forced the advent of “copyleft” license, or the GNU “General Public License” (GPL), designed to protect software users rather than software owners, whose interests are well secured via intellectual property and licensing agreements.<sup>413</sup> The terms of GPL allow users to use, study, and modify the source code of a licensed program, and freely exchange both modified and unmodified versions.<sup>414</sup> The collaborative climate fostered by the GPL soon culminated in the creation of “Linux”. Now the putative flagship of the open source movement is big enough to rattle established proprietary software leaders.

The open source software template has been canvassed for adoption in the context of biotechnology in order to foster collaborative research and development of crucial life-saving drugs, which the market-oriented patent system fails to de-

<sup>408</sup> Stallbaumer, *supra* note 389 at 149.

<sup>409</sup> See Aidan Hollis, “An Efficient Reward System for Pharmaceutical Innovation” *Department of Economics, University of Calgary* (17 January 2005), online: Department of Economics, University of Calgary <<http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf>>.

<sup>410</sup> See Hope, *supra* note 68 at 7 (notes that in the early days of computing, proprietary restrictions on access to, or use of source code were rare. Most users made their own programming and freely exchanged source code).

<sup>411</sup> *Ibid.*

<sup>412</sup> *Ibid.* at 8-9.

<sup>413</sup> *Ibid.* at 10-11; Sapna Kumar, “Enforcing the GNU GPL” (2006) 1 *University of Illinois Journal of Law, Technology & Policy* at 1-36.

<sup>414</sup> Kumar, *ibid.* at 3.

liver equitably and proportionately.<sup>415</sup> While noting that the open source licensing strategy is necessarily predicated on the existence of a proprietary right, Janet Hope observes that a non-proprietary transfer strategy need not use the open source template, but could instead rely on “straightforward free revealing.”<sup>416</sup> However, some scholars have queried the suitability of the open software template for biotechnological inventions and argued that it was no more than an abuse of patents.<sup>417</sup>

Nevertheless, it has been canvassed that the opportunity costs for pharmaceutical firms seeking to adopt open source strategy for exploiting drug patents is extremely high.<sup>418</sup> However, because not all drugs are blockbusters, the real opportunity cost of an open source strategy for pharmaceutical firms could be “substantially lower than the apparent or perceived cost.”<sup>419</sup> Whilst acknowledging industry’s established proprietary culture as a putative obstacle to the widespread adoption of open source biotechnology, Janet Hope notes that it is possible for the biotechnology industry to implement the open source business model.<sup>420</sup>

Indeed, the international HapMap Project that sequenced the human genome was predicated on “copyleft-style click-wrap conditions” in order to facilitate access to “haplotype mapping information.”<sup>421</sup> Other putative evidence that shows open source biotechnology at work includes its adoption by organizations such as

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<sup>415</sup> Katherine M. Nolan-Stevaux, “Open Source Biology: A Means to Address the Access and Research Gaps?” (2007) 23 Santa Clara Computer & High Technology Law Journal at 271-316; Stephen M. Maurer, Arti Rai & Andrej Sali, “Finding Cures for Tropical Diseases: Is Open Source an Answer?” (2004) 6:1 Minnesota Journal of Law, Science & Technology at 169-175.

<sup>416</sup> This connotes straight forward publication without any licensing requirement. See Hope, *supra* note 68 at 158.

<sup>417</sup> Robin Feldman, “The Open Source Biotechnology Movement: Is It Patent Abuse?” (2004) 6 Minnesota Journal of Law, Science, & Technology at 117-167 (notes that the open source template largely uses the power of the patent system in order to ensure the availability of the core technology or innovation for free access. He notes, further, that open source license agreement, which requires advances in technology to remain open as the original technology, may amount to patent abuse or misuse).

<sup>418</sup> Hope, *supra* note 68 at 268.

<sup>419</sup> The author argues that in considering the opportunity cost of an open source strategy, pharmaceutical firms should distinguish between patents on drugs and patents on research tools. This is especially so because most pharmaceutical firms are reluctant to sell research tools invented in-house. *Ibid.* at 268.

<sup>420</sup> *Ibid.*

<sup>421</sup> *Ibid.* at 308.

The BioBricks Foundation<sup>422</sup> and the CAMBIA.<sup>423</sup> The BioBricks Foundation uses BioBrick standard DNA parts that encode basic biological functions, and any individual or organization is welcome to design, improve, and contribute BioBrick standard biological parts to the registry.<sup>424</sup> As of 2007, over 600 students and instructors from over 60 universities around the world have made, shared, and used BioBrick standard biological parts as part of the International Genetically Engineered Machine competition.<sup>425</sup> On the other hand, the CAMBIA uses BiOS (Biological Open Source) to facilitate the making and sharing of biotechnological knowledge, with a view to eradicating “inequities in food security, nutrition, health and natural resource.”<sup>426</sup>

Open source software demonstrates the virtues of openness and technological freedom. Although still in a nascent state, open source biology has the potential to extend the benefits of medical biotechnology to both the rich and the poor. Certain government institutions and agencies are beginning to show leadership in the concept of open science. For instance, the U.S. National Institutes of Health’s recent open access policy is a significant development in institutional participation in the open science project.<sup>427</sup> The new NIH policy mandates public access to research published by NIH-funded scientists within 12 months of appearing in a peer-reviewed publication.<sup>428</sup> The California’s Intellectual Property and Revenue Sharing Requirements for For-Profit Organizations, similarly mandates scientists funded by the state of California to make a 500 word abstract available to the general public within 60 days of publication.<sup>429</sup> Additionally, a copy of each publication of research funded by California must accompany the annual progress report.<sup>430</sup>

The fledging open science policy in the U.S. is, however, still a far cry from the real thing: open source biotechnology. It is suggested that governments around the world should adopt both open science and open source templates for the diffusion of publicly funded biotechnological knowledge. The current proprietary platform is exacting and could potentially block upstream research, drain research expenditures, and up the costs of pharmaceutical research and development.

422 The BioBricks Foundation is a non-profit organization founded by engineers and scientists with significant experience in both non-profit and commercial biotechnology research. See, online: The BioBricks Foundation <<http://bbf.openwetware.org>>.

423 The CAMBIA is an independent, international non-profit institute, dedicated to creating tools to foster collaboration and life science enabled innovation. See, online: CAMBIA Homepage <<http://www.cambia.org/daisy/cambia/home.html>>.

424 The BioBricks Foundation, *supra* note 422.

425 *Ibid.*

426 The CAMBIA, *supra* note 423.

427 Bob Grant, “Open Access Lives in NIH Bill” *The Scientist* (18 December 2007), online: The Scientist <<http://www.the-scientist.com>>.

428 *Ibid.* Such funded research shall be made available on the agency’s publicly accessible digital archive, PubMed Central, within twelve months of publication.

429 *Supra* note 135 at s. 100403(a).

430 *Ibid.* at s. 100403(b).

Institutional and governmental leadership is crucial and could broaden the community of open source biologists and provide a viable alternative to the proprietary model. Whilst the dynamics and economics of biotechnology and software differ in certain fundamental respects, open source biotechnology could, with time, enjoy comparable success with open source software; BioBricks and CAMBIA have proven the viability of such potential and possibilities. It is hoped that biopharmaceutical firms will join in the open source revolution, which could dramatically close up the scientific information deficit in poor countries and greatly improve public health.<sup>431</sup>

### (c) Patent Pools: A Cooperative Approach to Innovation

Patent pools are co-operative arrangements between a consortium of at least two companies that agree to cross-license their patents to one another or to third parties.<sup>432</sup> Patent pooling has a long history, and has been used strategically by rival firms to pool resources together in order to, inter alia, achieve competitiveness.<sup>433</sup> It is also a potentially potent anti-competitive tool that can be used by firms to corner the market or crowd out other competitors through strategic licensing.<sup>434</sup> For instance, in *Standard Sanitary Mfg. Co. v. United States*, the U.S. Supreme Court had to dissolve a patent pool that fixed prices and blocked unlicensed manufacturers.<sup>435</sup> Also, in *Hartford-Empire Co. v. U.S.*,<sup>436</sup> the U.S. Supreme Court similarly dissolved patents pool of major glass manufacturers that covered 94 per cent of all the glass manufactured in the United States.<sup>437</sup> They had used their dominant position to unreasonably inflate glass prices.<sup>438</sup> In his judgment, Justice Hugo Black remarked that “this country has perhaps never witnessed a more completely successful economic tyranny over any field of industry than that accomplished by the appellants.”<sup>439</sup>

<sup>431</sup> Virginia Barbour, Paul Chinnock, Barbara Cohen & Gavin Yamey, “The Impact of Open Access Upon Public Health” (2006) 84:5 *Bulletin of the World Health Organization* at 339-340.

<sup>432</sup> See Ted J. Ebersole, Marvin C. Guthrie, and Jorge A. Goldstein, “Patent Pools as a Solution to the Licensing Problems of Diagnostic Genetics” (2005) 17:1 *Intellectual Property & Technology Law Journal* at 6-13.

<sup>433</sup> David Serafino, “Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures” *Knowledge Ecology International* (June 2007), online: Knowledge Ecology International <[http://www.keionline.org/index.php?option=com\\_content&task=view&id=69](http://www.keionline.org/index.php?option=com_content&task=view&id=69)>.

<sup>434</sup> For a discussion of patent pooling as a potential anti-competition tool, see Steven C. Carlson, “Patent Pools and the Antitrust Dilemma” (1999) 16 *Yale Journal on Regulation* at 359-373.

<sup>435</sup> *Standard Sanitary Mfg. Co. v. United States*, 226 U.S. 20 (U.S., 1912)

<sup>436</sup> *Hartford-Empire Co. v. U.S.*, 323 U.S. 386 (U.S., 1945).

<sup>437</sup> *Ibid.*

<sup>438</sup> *Ibid.*

<sup>439</sup> *Ibid.* at 436-37.

Nevertheless, patent pooling has potential benefits in the field of biotechnology, which primarily exploits “the biological templates of DNA and RNA.”<sup>440</sup> The proliferation of patents on genetic information could potentially create obstacles for upstream research if patentees are unwilling to license, or if license fees are prohibitive.<sup>441</sup> This is especially so for medical research tools, which the pharmaceutical industry often treats as trade secrets and is reputedly reluctant to license them.<sup>442</sup> Even in cases where companies were willing to license their biotechnological patents, the transactional costs of technological transfer could potentially drain research expenditures.<sup>443</sup> There is, thus, a strong incentive for firms to enter “into a co-operative dynamic that facilitates more cost-effective common access to vital technology, while preserving competitive business practices sufficient to thwart anti-trust implications.”<sup>444</sup> Such collaborations could solve the problems often posed by patented genetic diagnostics, which could potentially block upstream research or product development, up research and development costs, and make medical innovation more expensive. *A fortiori*, patent pooling is potentially a great cost-cutting collaborative tool for pharmaceutical firms and other alliances and partnerships. Its wide adoption by the biopharmaceutical industry could lead to an overall reduction in research and development costs and prescription drug prices.

**(d) Supplementing the Monocultural Prescription Drug Economics with Non-Market Oriented Public-Private Partnerships Regime**

In section III.B. of this article, the burgeoning new regime of non-market, not-for-profit, public-private partnerships against neglected diseases is analyzed.<sup>445</sup> It should be possible to replicate the regime’s governance structure, finance, and objectives for dealing with all manner of diseases generally. A non-market oriented public-private partnership would not have to necessarily sell prescription drug at costs, but it should not operate a profit-maximizing policy as is currently the case for most pharmaceutical firms.

A non-market public-private partnership paradigm is feasible if pharmaceutical firms would moderate advertising and promotional expenditures and recognize government subsidies and tax rebates in prescription drug pricing. As discussed in section III.B. of this article, the WHO has done an excellent job championing the battle against neglected tropical diseases. It has provided the crucial leadership

<sup>440</sup> Lawrence M. Sung & Don J. Peltó “The Biotechnology Patent Landscape in the United States as we enter the New Millennium” (1998) 1:6 *The Journal of World Intellectual Property* 889 at 895.

<sup>441</sup> Ebersole, Guthrie & Goldstein, *supra* note 432 at 6–13; Barton, *supra* note 360 at 121–125.

<sup>442</sup> Hope, *supra* note 68 at 268.

<sup>443</sup> Barton, *supra* note 360 at 121–125; Sung & Peltó, *supra* note 440 at 889–901.

<sup>444</sup> Sung and Peltó, *supra* note 440 at 893; Ebersole, Guthrie & Goldstein, *supra* note 432 at 11.

<sup>445</sup> See Section IVB, above.

needed for galvanizing the international coalition of governmental and non-governmental organizations, and charities against neglected diseases. However, it is crucial that similar international non-market oriented public-private partnerships are replicated to tackle the spiraling prescription drug costs, not only in poor countries, but across the world. Making prescription drugs affordable for all and sundry, irrespective of nationality or place of residence is arguably within the constitutional remit of the World Health Organization.<sup>446</sup>

### (e) The Case for a Global Convention on Neglected Diseases and Affordable Prescription Drugs

The twenty first century ushers in the awareness that national and international health is inseparable.<sup>447</sup> The threats posed by communicable diseases, such as the avian flu and SARS, and the real prospects of bioterrorism, reinforce the perception that geographical boundaries are no bulwark against global pandemic diseases.<sup>448</sup> Significantly, international law has been historically crucial to global communicable disease surveillance,<sup>449</sup> and is arguably the most suited tool for managing neglected diseases and affordable prescription drugs globally.

However, the transnational law on global health governance is largely disparate and ad hoc. These range from the World Health Organization's International Health Regulations 2005,<sup>450</sup> international human rights law,<sup>451</sup> the WTO TRIPS

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<sup>446</sup> See generally the *Constitution of the World Health Organization*, (Geneva: World Health Organization, 1948). The preamble to the constitution provides, *inter alia*, that "[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition." A lack of access to affordable prescription drug clearly derogates from this provision.

<sup>447</sup> Allyn L. Taylor & Douglas W. Bettcher, "International Law and Public Health" (2002) 80:12 Bulletin of the World Health Organization at 923.

<sup>448</sup> Oriola, *supra* note 332 at 297–309.

<sup>449</sup> Aginam, *supra* note 330 at 946 (notes that communicable diseases governance did not come within the normative confines of international law until the mid-nineteenth century, specifically in 1851, when France conveyed the first international sanitary conference).

<sup>450</sup> World Health Organization International Health Regulations (1969) as amended in 2005 and in force since June 2007, online: <<http://www.who.int/csr/ihr/WHA58-en.pdf>>. This is a legally binding agreement on international public health security, and provides a legally binding framework for coordinating the management of global public health emergency.

<sup>451</sup> Roberto Andorno, "Biomedicine and International Human Rights Law: In Search of a Global Consensus" (2002) 80:12 Bulletin of the World Health Organization at 959 — 963 (notes how international human rights principles have been integrated into biomedicine and cites, in particular, the UNESCO Universal Declaration on the Human Genome and Human Rights, and the Helsinki Declaration); David P. Fidler & Lawrence O. Gostin, "The New International Health Regulations: An Historic Development for International Law and Public Health" (2006) Journal of Law, Medicine & Ethics at



Agreement on Public Health,<sup>452</sup> UNESCO Universal Declaration on Human Genome and Human Rights,<sup>453</sup> Council of Europe Convention on Human Rights and Biomedicine,<sup>454</sup> to the Constitution of the World Health Organization.<sup>455</sup> Significantly, none of these conventions directly addresses the twin problems of neglected diseases and affordable prescription drug procurement as such. Although WHO is loosely and generally mandated by its constitution to oversee global health governance,<sup>456</sup> there is neither a specific mandate to effect crucial changes in the market oriented global pharmaceutical research paradigm,<sup>457</sup> nor a mandate to ensure affordable prescription drug globally. In fact, WHO has often been criticized for exceeding its remit and meddling in matters reserved for the World Trade Organization, whenever it ventured into the challenges posed by intellectual property to global public health.<sup>458</sup>

Moreover, although WHO is an important partner in the burgeoning public private partnerships regime against neglected diseases, it is a governance structure that lacks normative order — its membership is voluntary, its aims are altruistic, and its legitimacy is open to legal challenge.<sup>459</sup> Moreover, it has been observed that the current high level interests of the international community and NGOs in health

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85–94 (notes the incorporation of human rights principles into the new International Health Regulations).

452 WHO, *The Doha Declaration on the TRIPS Agreement and Public Health*, (01-5860) WT/MIN(01)/DEC/2 (2001), online: WHO <[http://www.who.int/medicines/areas/policy/doha\\_declaration/en/print.html](http://www.who.int/medicines/areas/policy/doha_declaration/en/print.html)>.

453 UNESCO, *Universal Declaration on Human Genome and Human Rights*, (1997), online: UNESCO <<http://www.unesco.org/ethics>>.

454 Council of Europe, *Council of Europe Convention on Human Rights and Biomedicine*, Doc. 36ILM817 (1997), online: Council of Europe <<http://fds.oup.com/www.oup.co.uk/pdf/bt/cassese/cases/part3/ch16/1121.pdf>>.

455 *Constitution of the World Health Organization*, (Geneva: World Health Organization, 1948), online: WHO <<http://www.who.int>>.

456 Frank P. Grad, “The Preamble of the Constitution of the World Health Organization” (2002) 80:12 *Bulletin of the World Health Organization* at 981–984 (comments on the significance and strength of the preamble to the WHO Constitution).

457 Jurgen Drews, “Drug Research: Between Ethical Demands and Economic Constraints” in Michael A. Santoro & Thomas M. Gorrie, eds., *Ethics and the Pharmaceutical Industry*, *supra* note 17 at 21 — 36.

458 ICTSD, “WHO Committee on Drug Innovation and Prices Underway in Geneva” (7 November 2007) 11:38 *BRIDGES Weekly Trade News Digest*, online: ICTSD <<http://ictsd.net/i/news/bridgesweekly/7636>> (notes that the WHO Director-General was aware of critics’ objections that the WHO was usurping WTO territory by meddling in intellectual property matters).

459 It is clearly conceivable that the new regime of public-private partnership is vulnerable to legal challenges bordering on the legitimacy of its authority.

problems afflicting poor countries would wane or fizzle overtime, as “the international community exhausts its limited attention span and resources”.<sup>460</sup>

Arguably, this informed the signing of a petition in 2005 by a coalition of non-governmental organizations, academics and politicians, urging WHO members to adopt a Kyoto-style global medical treaty.<sup>461</sup> The underlying principle of the proposal was to extract governmental commitments to spending a certain proportion of their national income on medical research and development.<sup>462</sup> This would obviate a complete reliance on private equity for financing of pharmaceutical innovation.<sup>463</sup> While governments are morally obliged to cater to the health of their citizens, and are already obliged under numerous international treaties on social and economic rights (albeit unenforceable), having a global medical treaty would provide the necessary legal imprimatur and incentive for governmental responsibility and transparency, especially in non-democratic regimes.

The proposed global medical treaty should institute a legal framework that would vest in the WHO, an express power to manage neglected diseases and affordable prescription drugs globally. Undoubtedly, WHO has the expertise, the credibility, the global reach, and the experience to carry out the tasks. The proposed treaty should expressly indicate what the powers of WHO are with regards to intellectual property rights and public health issues. It should also stipulate financial obligations of member states to supporting global public health governance. The treaty should also have room for NGOs to participate in global public health issues, and accord them the legal backing and protection necessary. Under the auspices of the proposed treaty, WHO should have the mandate to work with national governments, pharmaceutical firms, and investors to encourage prize contests, open source biology, and patents pooling to boost pharmaceutical innovation.

## CONCLUSION

This article notes the significance of access to affordable prescription drugs, and the eradication of neglected diseases to achieve a wholesome global public health status. It observes that the twin issue of spiralling prescription drug prices and neglected diseases pose serious policy challenges for governments around the world. It reviews the literature and empirical studies on the dynamics of the market-oriented prescription drug economics, and canvasses for non-market public-pri-

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<sup>460</sup> Lawrence O. Gostin, “A Proposal for a Framework Convention on Global Health” (2007) 10 *Journal of International Economic Law* 989 at 992-3 (canvasses for the establishment of a Framework Convention on Global Health, that would have legally binding commitments from member states to meeting the basic survival of the world’s least healthy people).

<sup>461</sup> Andrew Jack, “WHO members urged to sign Kyoto-style medical treaty” *Financial Times* (25 February 2005), online: [Financial Times <http://www.ft.com>](http://www.ft.com).

<sup>462</sup> *Ibid.*

<sup>463</sup> *Ibid.*

vate international partnerships to rein in spiraling prescription drug prices and manage neglected diseases.

While noting that regimes that overly implement price control, in an effort to rein in run-away prices, could be counter-productive, the article notes the inevitability of price controls, as already implemented in Canada, European countries, Mexico, and India. The article canvasses for the acceleration of clinical trials and a regulatory approval process for new drugs in order to achieve early market debut, ensure competitiveness of comparative products and ensure competitive pricing. However, the suggestion is made subject to the caveat that abridged clinical programs, and to an early approval process that would not prejudice the right of human research subjects or jeopardize drug safety and efficacy.

There is a strong nexus between patents and high pharmaceutical prices. This article notes the problems with the market-oriented prescription drug economics and canvasses for non-market oriented public-private partnerships to supplement the current system. The article supports the call for a global medical treaty and notes that it is best suited to set the agenda and provide a crucial legal framework for managing neglected diseases and affordable prescription drugs.