Framing and Reframing Global Patent Policy
Implications on Access to Medicine in Developing Countries

Abstract

This paper pursues an analysis of the global pharmaceutical patent policy discourse and the inception of the Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement. It argues that a coalition of pharmaceutical industries and non-governmental organizations (NGOs) each engaged in agenda setting by grafting new frames onto existing ones. The industry framed intellectual property protection as an issue of free trade, while the NGO campaign reframed intellectual property protection as an issue of public health. In both cases, information and the framing of information played a crucial role in the policy debate and ultimately, the policy outcomes.

Introduction

The ways in which information is presented, filtered, and absorbed by people and transformed into knowledge involves the use of frames. Information and the framing of information play a crucial role in agenda setting, policy debates and ultimately, policy outcomes. Frames are the “septic metaphors, symbolic representations and cognitive clues used to render or cast behavior and events in an evaluative mode and to suggest alternative modes of actions” (Zald 1996, 262). More specifically, frames are considered schemes for both the presentation and comprehension of information. Entman differentiates media frames as “attributes of the news itself” and individual frames as “information-processing schemata” (Entman 1991, 7). Media frames can shape the way an individual interprets issues, which through the use of individual frames affect that individual’s perceived legitimacy of particular groups (Edelman 1995, 119; Entman 1993, 53). To Entman, the framing process involves both selection and salience: to frame is to “select some aspects of a perceived reality
and make them more salient in a communicating text...to promote a particular problem definition, causal interpretation, moral evaluation, and/or treatment recommendation for the item described” (Entman 1993, 52).

Framing of information may be used to not only address policy issues generated within a nation’s borders, but also those created through the dynamics of globalization and internationalization. While it is commonly assumed that globalization liberalizes access to goods and services, it may have the opposite effect with respect to access to innovation. A relatively recent example is the internationalization of intellectual property rights. In developed countries the exclusive rights to innovation, by way of patents, provide the pharmaceutical industry with incentives to invest in the costly development process that is necessary to bring innovative new drugs to the market (Grootendorst 2007). In developing countries, on the other hand, patent laws are lax if not non-existent.

As medicines are among the goods traded globally, the World Trade Organization (WTO) has had a profound influence on their exchange in the world. The establishment of the WTO in 1995 concluded with a number of separate agreements, including the agreement on Trade-Related Aspects of Intellectual Property Rights, known as TRIPs. The TRIPs agreement sets out to harmonize the scope and duration of pharmaceutical patent protection as well as the set of exclusive rights conferred across national patent regimes (Eren-Vural 2007), thereby restricting global access to innovation and technology. The establishment of TRIPs at the WTO was seen as a victory for pharmaceutical firms (Sell and Prakash 2004). In an attempt to conform to the requirements of the TRIPs agreement, developing countries have seen a transition in pharmaceutical patent policies from weak or non-existent regulations to strong patent regimes (Eren-Vural 2007). Consequently, one implication of the pharmaceutical industry’s framing of global patent protection is to reduce access to medicine among the world’s poor (Odell 2006; Sell and Prakash 2004). This follows basic economic theory that granting of monopolistic rights results in increased drug costs, since a significant determinant of a manufacturer’s price for a given drug lies in whether it is patented (Love 2007).

An alternative frame was established a few years later by a coalition of non-governmental organizations (NGOs) looking to increase access to life-saving medicines among the world’s poor. NGOs interpreted the implications of the TRIPs agreement on the HIV/AIDS crisis and redirected the policy problem as one of excessively stringent intellectual property rights norms that made HIV/AIDS
medicines unaffordable (Sell and Prakash 2004). The framing promoted by NGOs led to the recently recognized TRIPs “flexibilities,” intended to allow better access to medicines in developing countries.

The central issue revolves around how TRIPs could be used as an instrument to provide incentives for drug companies to innovate while concurrently balancing consumers’ interest in having access to medicines. In the background section, this paper explores this issue by outlining the common history of lax patent policies in today’s developed and developing countries and the forces that led to the stronger patent policies currently observed. It then argues that the balance between innovation and access is, in part, shifted by the ways in which the discourse around the issue is framed. The paper specifically examines the framing of the problem, by pharmaceutical companies and lobbies and by non-governmental organizations, such as Médecins sans Frontières (MSF), in the time periods both leading to and following the establishment of the TRIPs agreement. The paper concludes that both the pharmaceutical industry and the NGOs framed issues and grafted private agendas on policy debates. The campaign used by the pharmaceutical industry framed the protection of intellectual property rights as an issue of free trade, while the NGO campaign framed intellectual property rights into issues of public health. While both campaigns succeeded in producing changes in policy outcomes, the debate on how best to balance innovation and access to medicine in developing countries continues. Thus, in the final paragraph, the report offers a summary of a possible way in which access could be improved.

Background

History of Patent Policies in Developed and Developing Countries

Historically, a nation’s choice in the composition and extent of its patent protection laws reflected the nation’s evaluation of the costs and benefits of a particular level of protection (Furman et al. 2002). The selection of an ideal level of patent protection, from free access to complete protection of intellectual property, is known to change as a country’s economy changes (Eren-Vural 2007). In fact, intellectual property rights in today’s developed countries emerged only after centuries of incremental changes in policies designed to aid economic advancement. The United States, while currently among the most prominent advocators of stringent international patents, was throughout most of the 19th century a net importer of technology: “It offered lax protection for foreigners’ intellectual property and built much of its industrial prowess on British technology” (Sell and May 2001, 486). A New York
*Times* article recalls that “in the 19th century, the United States was both a rapidly industrializing nation and - as Charles Dickens, among others, knew all too well - a bold pirate of intellectual property” (Lohr 2002). As for European countries, full pharmaceutical patent protection was not provided until 1949 in the United Kingdom, 1960 in France, 1968 in Germany, and 1978 in Italy and Sweden (Nogués 1990, 3).

In many of today’s developed countries, weak patent protection had once served as an important driver of technological development as it allowed domestic producers to obtain foreign technology and build-up production capabilities. Weak patent protection on pharmaceuticals was also prevalent due to the importance of drug access to meet the needs of public health (Eren-Vural 2007). For America, the preference for weak protection changed when the country’s firms began to achieve their own technological breakthroughs and as the international trade system became more interdependent (Brenner-Beck 1992).

Similarly, lax intellectual property protection in today’s developing countries has had the compound benefits of ensuring greater access to innovative products in the short run and stimulating industrial development in the form of imitator industries (Cohen-Kohler et al. 2008; Brenner-Beck 1992). These are historically reliable precursors to innovative industrial expansion in the long run (Cohen-Kohler et al. 2008). India's take on patent policies was perhaps best expressed by Indira Ghandi: “The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiting from life and death” (addressing the World Health Assembly in 1982). The 1970 Indian patent law excluded drugs/products from patent protection so that only processes were patented; this meant that as long as generic manufacturers found new ways to make existing products, patent law would not prevent them from doing so (Cohen-Kohler et al. 2008). At the expense of eliminating incentives to create new products, the country saw the emergence of a generic drug industry responsible for manufacturing approximately half of the anti-retrovirals (ARVs) used to treat an estimated 700,000 patients throughout the developing world (Cohen-Kohler et al. 2008). As such, India became a major international supplier of drugs to countries where the products were marketed legally because they had not been patented locally (Barton 2004). As evident in the history of lax patent policies in today’s developed countries, the choice of developing economies for a weak patent system in order to foster industrial and technological development and address the demands of public health was in no way unprecedented (Eren-Vural 2007).
Indicators for Transitioning to Strong Patent Policies

Developed countries have met and overcome the threshold level required for recognition of strong intellectual property laws. Brenner-Beck writes that “Historically, the preconditions for the introduction of patent protection were the presence of some scientific/technical infrastructure, the conversion from agricultural or handicraft production to industrial production, freedom in the conduct of business and the desire and will of the state to advance technical and industrial development” (1992, 103). As patents protect the pharmaceutical industry in developed countries, the social effects of patents on prices in these countries are attenuated by the role that state and social security systems play in securing access to medicines (Correa 2007). It is now well documented that unregulated competition would dissuade firms from innovation in today’s developed countries as innovations would be easily copied once revealed (Varian 2006).

While developed and developing countries share a common history in lax patent policies, the impetus to stronger patent policies is markedly different between these groups of countries. As Brenner-Beck contends, it would be in the interest of developing countries to adopt stringent intellectual property measures only upon reaching a threshold level of economic development (1992). This begs the question, if harmonization of intellectual property forces the developing world to prematurely adopt strong patent policies, what would be the implications of such harmonization on access to medicines within these countries?

Competing Frames on International Patent Policies

The central issue is how harmonization of property rights could serve as a social policy instrument, calibrated to provide incentives for drug companies to innovate while balancing consumers’ interests in having access to medicines (Fitzpatrick 2003). This balance is, in part, shifted by the ways in which the discourse is framed. While framing an issue is not the only method of changing policy - which may also require assembling a large supportive political coalition and taking advantage of opportunities in the political environment - framing remains a significant component that outlines the risks and responsibilities in order to influence policy change (Lawrence 2004). It is argued here that the two competing frames presented by drug companies and NGOs have in part influenced policy change by shifting the balance between innovation and access to medicine.

Framing the Issue: The TRIPs Agreement
The coalition of pharmaceutical firms from developed countries have framed global patent policy as a trade issue, by stating that strong intellectual property rights are necessary to ensuring continued production of new technologies for world growth (Odell 2006). During the Uruguay Round that led to the 1994 TRIPs agreement, drug companies argued that intellectual property protection benefited the developing countries because 1) it promoted successful operation of a system that promoted global innovation, thus benefitting all; 2) promoted the transfer of technology from the developed nations to developing nations, encouraged direct foreign investment in the developing countries, and stimulated R&D to address problems specific to developing countries; and 3) strengthened the incentive of domestic innovation and creativity (Brenner-Beck 1992; Love 2007).

This framing took place at a time when developed countries were devoting one percent to three percent of their annual gross national product (GNP) to the production of technology (Brenner-Beck 1992). Around the time of the Uruguay Round of General Agreement on Tariffs and Trade (GATT) talks in 1986, approximately 23 percent of US exports were comprised of high intellectual property content (Brenner-Beck 1992). This period of booming international trade was seen with an increase in research and development (R&D) costs and advances in copying technology, which influenced the economies of developed nations to demand increased protection for intellectual property (Love 2007). US policymakers’ concerns about competitiveness provided the necessary political opportunity for framing global intellectual property rights as a trade issue. For example, the number of articles in major newspapers on “Competitiveness” and “United States” as archived in Lexis-Nexis saw a steady rise from approximately 100 articles in 1986 to approximately 550 articles in 1992 (Sell and Prakash 2004, 155).

The large coalition of drug companies in developed countries also framed the issue explicitly on ethical grounds, suggesting that strong patent protection must be upheld to prevent developing countries from acts of “piracy” and “thievery.” The US, acting as both judge and jury for the world’s trading system, was reported in the New York Times as accusing certain countries of failing to protect intellectual property rights, naming eight to a “priority watch list” that included Brazil, India, Saudi Arabia, Mexico, China, Thailand, Taiwan and South Korea (Farnsworth 1989). It was also reported that “an important objective of the Uruguay round was to put an end to the piracy of patents and copyrights that costs United States companies billions of dollars” (Farnsworth 1989). The strategy was received with praise from the United States Council for International Business, representing 275 American corporations and lawmakers (Farnsworth 1989). These accusations came at a time when Brazil
and India found themselves increasingly dependent on world trade and vulnerable to any breakdown in the trading system, and while not explicitly excluded from discussions, the countries were silenced under potential talks of sanctions and trade tariffs (Brenner-Beck 1992; Farnsworth 1989).

Using a carrot-and-stick approach, the US and other developed countries met their goal of providing an adequate system of global intellectual property protection. The stick, as alluded to above, was continued unilateral action that threatened the trade and aid flowing from developed countries to those on the "priority watch list" (Mercurio 2004). The carrot for implementing stringent international intellectual property protections came in the form of "several sweeteners in other areas of negotiation, particularly in the area of textiles" (Mercurio 2004). Thus, the way in which drug companies in developed countries framed their arguments towards stricter international patent policies, in part, contributed to the establishment of an international trade regime, the TRIPs agreement (an inseparable part of the WTO package), which affected access to medicines in developing countries.

*The “Trade Issue”: Implications on Access to Medicine*

The TRIPs agreement provides minimum standards for the protection of patents, trademarks, copyrights and other intellectual property rights, and provides remedies for the effective enforcement of the rights (Mercurio 2004). The pertinent sections on patent protection are found in Articles 27-34 (WTO 1994, 319-351). Since the inception of TRIPs, researchers have looked at the potential implications of the agreement on access to medications in developing countries. It has been reported that the agreement, as intended, would create extended barriers to market entry for generics, both through the requirement for 20-year patents, as well as its provisions on exclusive marketing rights and data protection (Cohen-Kohler et al. 2008; Mercurio 2004). The proven impact of generic competition on prices points to an increase in drug prices in absence of such competition (Varian 2006). Given the high drug costs, the possibility of a burgeoning black market for the sale of counterfeit drugs has been suggested, whereby the diseased seize the chance to purchase

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1 TRIPs requires: Patents to be available for any invention, whether product or process, in all fields of technology without discrimination. Patents confer exclusive rights to prevent third parties from non-consensually using patented processes, and from 'making, using, offering for sale, selling, or importing for these purposes' patented products and the products of patented processes. Inventions covered under the patent law must meet the criteria of novelty, inventive step, and industrial applicability. The minimum obligations for pharmaceuticals are: that pharmaceutical products and microorganisms are patentable for up until 20 years from the date the inventor files for the patent application; there is no discrimination permitted against patent rights for imported products; exclusive marketing rights are granted until patent expiry. TRIPS also provides for transitional periods for developing countries without pharmaceutical product patents (WTO 1994).
outwardly legitimate product at discounted prices (Cohen-Kohler et al. 2008; Pecoul et al. 1999).

Another implication of TRIPs on access to medication is derived from Article 31 of the agreement. While Article 31(b) allows waiving the requirement to seek a patent holder’s permission “in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” subsection (f) requires that any such use shall be “predominantly for the supply of the domestic market of the Member authorizing such use” (WTO 1994, 333). In other words, a nation could override valid patent laws so long as that nation ordered the generic drugs from domestic producers. As exporting countries such as India would be constrained to supplying only their domestic market, the ability of a developing country without a drug-producing industry of its own to import a cheaper generic variety of a key patented drug (such as ARVs for HIV treatment) would be limited, even in the case of national emergency (Love 2007).\(^2\) Framed as a trade issue, the drug industry overlooked this glaring implication of the agreement on access to medication.

The final implication of TRIPs considered in this report pertains again to Article 31 and compulsory licensing. While the provision exists and the option is in theory available to developing countries, it is not very feasible in practice. When responding to an HIV/AIDS crisis in 1997, Thailand chose to make use of TRIPs Article 31, which permits compulsory licensing.\(^3\) After Thailand planned to produce a generic version of the AIDS drug ddI, US trade officials, on behalf of the Pharmaceutical Research and Manufacturers Association (PhRMA), decided to threaten sanctions on Thailand’s core exports. Thailand subsequently dropped its compulsory licensing plans (Odell 2006; Cohen-Kohler et al. 2005). In a similar case, several drug companies challenged the legality of the South African Medical and Related Substances Control Act of 1997, which allowed for compulsory licensing of patented pharmaceuticals (Mercurio 2004).

Given such implications on access to medicines in developing countries, the inception of the TRIPs agreement was opposed by a newly formed coalition that comprised of NGOs (such as Oxfam and MSF), AIDS advocates, public health agencies, and governments and drug companies of developing countries (hereafter,  

\(^2\) The Republic of Malawi is a case in point. While the country has a small domestic pharmaceutical industry, it is not yet producing ARV medication to meet the needs of its infected population (Love 2007). It has also been reported, in 2002, that two of the most commonly used ARV were patented in 37 of the 53 countries surveyed (Cohen-Kohler et al. 2005).

\(^3\) Compulsory licensing allows states with manufacturing capacity to produce generic drugs that are more affordable. One of the conditions is that licenses must be used in domestic markets and not for export (Love 2007).
collectively referred to as “NGOs” for simplicity). While drug companies and their governments had framed intellectual property protection as one that would promote trade and investment for mutual benefit and put an end to piracy of consumer goods, the newly formed coalition reframed the issue to gain policy change.

**Reframing the Issue: The TRIPs Flexibilities**

The environment in which public opinion and policies are formed can shift when the health risks are reframed in specific ways. This is in part because reframing assumes that the beliefs of all human beings are influenced in part by the social environment in which they move and are thus “malleable,” subject to the influence of advocacy and persuasion, including framing tactics (Odell 2006, 87). The TRIPs opposition coalition reframed intellectual property protection as a risk to public health. This move was not unprecedented. In a relatively recent report Nathanson contends that the success of the smoking/tobacco control movement may be accounted for by an “ideologically persuasive construction of the relevant health risks, by grassroots mobilization for nonsmokers’ rights” (1999, 422). Nathanson also suggests three dimensions to public health risk framing, which portray risk as “acquired deliberately or involuntarily (and the victim correspondingly as culpable or innocent), as universal (putting us all at risk) or as particular (only putting them at risk), as arising from within the individual or from the environment as visible or invisible” (1999, 446). These types of risk apply strongly to the case of reframing by NGOs in objection to the TRIPs agreement.

NGOs reframed the TRIPs agreement on explicitly ethical grounds, suggesting that medicines that could save or prolong the lives of people with HIV/AIDS, among other diseases, were available but inaccessible from manufacturers who refused to deliver them at marginal cost (Odell 2006). Thus, a public health risk was framed in the form of a deliberate risk, imposed by drug companies, which would cause the suffering and death of innocent people. While the TRIPs agreement never intended to cause unnecessary deaths, the pressures imposed on Thailand and South Africa by the pharmaceutical industry to discourage compulsory licensing provided opportunities for TRIPs opponents to claim exactly that (Odell 2006). NGOs saw a sharp spike in media discussion of possible connections between patent protection and health problems. This is evidenced by the number of articles in major newspapers on “Patents” and “Public Health” as archived in Lexis-Nexis, which was less than 50 articles in 1989, and then rose to approximately 100 articles in 1997, followed by a sudden rise to approximately 400 articles by 2001 (Sell and Prakash 2004, 166).
The following Brazilian case provides a single example of the presence and form of media discussion. Despite relentless pressure from pharmaceutical companies, Brazil chose to pass a patent law that interpreted “local working” (a term used in TRIPs to mean importation) as local production rather than importation (Odell 2006). The threat of compulsory licensing had helped Brazil negotiate reasonable drug prices with global pharmaceutical companies; it used this threat credibly against the pharmaceutical firms Roche and Merck in the quest for affordable AIDS drugs (Mercurio 2004; Odell 2006). The cover story and headline in a New York Times magazine on January 28, 2001, read “Look at Brazil: Patent laws are malleable. Patients are educable. Drug companies are vincible. The world’s AIDS crisis is solvable” (Rosenberg 2001). As a result, the public in developed countries heard of the TRIPs agreement, most for the first time, and heard of it framed as a threat to public health.

The NGO health campaign and the political backlash that it created forced PhRMA to become defensive about intellectual property enforcement and its implications for the HIV/AIDS crisis. In March 2001, PhRMA also chose to end its legal case against the South African government (Odell 2006). However, the US case against South Africa catalyzed the formation of a bargaining coalition in the WTO to seek gains at the WTO’s Doha ministerial conference (Mercurio 2004; Odell 2006). In November 2001 the conference adopted a Declaration on the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health (Kerry and Lee 2007). Kerry and Lee write that “The Doha Declaration affirmed the right of member states of the WTO to interpret and implement TRIPS in a manner supporting the protection of public health and, in particular, access to medicines” (2007). Towards the same aim, the Declaration was followed with additional changes in the Implementation of the Paragraph 6 Decision, in 2003 (Cohen-Kohler et al. 2005). Collectively, these agreements formed the TRIPs “flexibilities.” Thus, global patent policy was reframed as a public health issue by a large, united coalition comprising of members from developing countries and NGOs, to bring about a policy change. The balance between incentives for innovation and access to medicine shifted due to the way in which the discourse had been framed by NGOs. However, the extent of this shift in practice is currently questioned, since the WTO has not explicitly defined the legal status of the Declaration.

**The “Public Health Issue”: Implications on Access to Medicine**

In practice, the TRIPs provisions on compulsory licensing (in the case of a national emergency) were not exercised by governments of developing countries because of
concerns about political ramification (see section 3.11). The TRIPs “flexibilities” partially aimed to address this concern (Cohen-Kohler et al. 2005). The positive impact of the agreement has been evidenced by a decline in the number of complaints by pharmaceutical firms for inadequate intellectual property rights protection, registered by the US Trade Representative, from five in 1999 to one in 2002 (Cohen-Kohler et al. 2005). Oxfam notes that “many developing countries - bolstered by effective civil-society groups and political will - are succeeding in introducing and enforcing TRIPS safeguards” (Oxfam 2006). The outcome the Paragraph 6 Decision temporarily addresses the issue posed by Article 31(f) of the TRIPs agreement, by permitting countries with local manufacturing capacity to issue compulsory licenses to produce and export drugs to countries without adequate manufacturing capacity (Cohen-Kohler et al. 2005). Since domestic capacity and/or technical expertise to manufacture on-patent pharmaceuticals is lacking in a majority of developing countries, the interpretation of this terminology is crucial for ensuring access to medicine for the poor (Cohen-Kohler et al. 2005).

Thus, the outcome of the reframing by NGOs was associated with obvious adjustments to the TRIPs agreement. These adjustments provide some mechanisms to help improve access to medicines, and from a political perspective, make feasible the use of compulsory licensing to address public health concerns (Odell 2006). Notwithstanding, international trade rules have considerably restricted policy options for accessing affordable medicines. Evidence suggests that the harmonization of intellectual property rights has positively impacted innovation, but not access to medication. For example, a recent study estimates that in the absence of any price regulation or compulsory licensing, the total annual welfare losses to the Indian economy from the withdrawal of the four domestic product groups, in the fluoroquinolone segment, would be in the order of US $713 million, and “the overwhelming portion of the total welfare loss therefore derives from the loss of consumer welfare” (Chaudhuri et al. 2003). Another study tips the balance in indicating that since the introduction of product patents, Indian generic companies (such as Ranbaxy) have been motivated to increase their investment in R&D (Kale and Weild 2008; Mandavilli 2007). While global patent protection policies must take into account the pharmaceutical industry’s incentive to create, these policies must also ensure that the interests of the developing world are met.

Conclusion

Campaigns are processes of issue construction comprised of problem identification, cause specification and solution creation, all with the intent of producing substantive
change (Sell and Prakash 2004). During their campaigning, both the pharmaceutical industry and NGOs engaged in agenda setting by “grafting new frames onto existing ones” (Sell and Prakash 2004, 144). The industry campaign framed intellectual property protection as an issue of free trade, while the NGO campaign reframed intellectual property protection as an issue of public health. Both campaigns succeeded in producing changes in policy outcomes. Thus, the ways in which discourse around the central issue – that is, how harmonization of property rights could serve as an instrument to provide incentives for drug companies to innovate while balancing consumers’ interests in having access to medicines – is shifted by the ways in which the discourse is framed. Yet a balance between innovation and access to medication remains out of reach and the global drug gap persists. While there is no single cause of the drug gap, the international trade rules, through market and public sector failures, have exacerbated this inaccessibility.

The pro-access measures resulted from an ad hoc case-by-case approach dependent on an active civil society, and as Brazil demonstrated, the state’s political will. Based on this observation, suggestions for improved access include wider implementation of current TRIPS provisions by states in conjunction with civil society organizations. This would include an intervention that would eliminate compulsory licensing and broaden the scope of voluntary licensing (Cohen-Kohler et al. 2008). The former would entirely remove the barriers to the use of TRIPs “flexibilities.” The latter would allow companies with patented medicines to offer licenses to other manufacturers based in developing countries, if they are able to provide the same quality medicines at lower cost (Cohen-Kohler et al. 2008). Under the voluntary license solution, countries can negotiate with patent holders to manufacture their branded and patented products locally. Legal and ethical orientation of the TRIPs agreement by NGOs – that is, the human rights imperatives of developing countries to access medicines – may serve as the device for the intervention. This implies a framing mechanism, with enforceability offered by the language of international human rights law, for ensuring that domestic and international policy-making on medicines takes account of public health and social welfare implications. However, this serves as an imperfect solution since elimination of compulsory licensing threatens undersupply; for the pharmaceutical industry, the uncertainty of success and the unpredictability of whether and to what extent investments could be recovered, weaken the quest for essential drugs.

Consequently, others have proposed strategies that tackle the fundamental problem of a monopoly-based innovation and access system. Non-exclusive licensing practices has been encouraged and implemented in some instances. A business
model that could be adopted on a much larger scale includes the not-for-profit Drugs for Neglected Diseases initiative (DNDi). The initiative finances R&D up front and offers the outcome of its research on a non-exclusive basis to generic producers allowing for technology transfer and competition among multiple producers (’t Hoen 2009, 94). Similar licensing practices could combat not only monopoly pricing, but also barriers to research when applied to government-funded and university research. Universities currently hold important patents on many life-saving drugs, including the antiretroviral drugs stavudine (Yale University), abacavir (University of Minnesota), lamivudine (Emory University), and enfuvirtide (Duke University) (Kapczynski et al. 2003). In recognition of this, the Universities Allied for Essential Medicines proposes that “when a university licenses a promising new drug candidate to a pharmaceutical company, it should require that the company allow the drug to be made available in poor countries at the lowest possible cost” (UAEM 2009). This proposal is particularly favourable when the inventor is not dependent on sales of the invention to finance his/her work, such as in the case of government, university or otherwise up-front funded research (’t Hoen 2009, 94).

A responsibility lies with researchers, health advocates and policy makers for continued monitoring of the effects of the TRIPs agreement in those countries with the greatest disease burden. It will be important to assess the degree to which discontinuities in the domestic supply of importing countries are due to inherent distributional problems, or to problems arising from the externally imposed requirements of the TRIPs agreement.

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