

GLOBALIZATION AND HEALTH

Challenges for Health Law and Bioethics

Edited By

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TABLE OF CONTENTS

<i>Preface</i>	<i>vii</i>
<i>Acknowledgments</i>	<i>xiii</i>
<i>Contributors</i>	<i>xv</i>

PUBLIC HEALTH: DEVELOPING GLOBAL CONCERNS

BELINDA BENNETT Travel in a small world: SARS, globalization and public health laws.....	1
UDO SCHÜKLENK AND BRAIMOH BELLO Globalization and health: A developing world perspective on ethical and policy issues	13
GEORGE F. TOMOSSY AND JOLYON FORD Globalization and clinical trials: Compensating subjects in developing countries	27
DEBORAH ZION Ethics, disease and obligation.....	47

THE GLOBAL BIO-ECONOMY: CONSENSUS AND INNOVATION

DEREK MORGAN Regulating the bio-economy: A preliminary assessment of biotechnology and law	59
ALAN IRWIN The global context for risk governance: National regulatory policy in an international framework	71
THOMAS ALURED FAUNCE Global intellectual property protection of “innovative” pharmaceuticals: Challenges for bioethics and health law	87
PATRICIA PEPPIN Directing consumption: Direct-to-consumer advertising and global public health	109
TIMOTHY CAULFIELD AND BARBARA VON TIGERSTROM Globalization and biotechnology policy: The challenges created by gene patents and cloning technologies	129

GLOBALIZATION AND HEALTH CARE

KERRY PETERSEN

The rights of donor-conceived children to know the identity of their donor:
The problem of the known unknowns and the unknown unknowns..... 151

JOHN HARRINGTON

Globalization and English medical law: Strains and contradictions..... 169

IAN FRECKELTON

Health practitioner regulation: Emerging patterns and challenges for the age
of globalization..... 187

Index..... 207

PREFACE

Within contemporary society, globalization has emerged as a key concern at the centre of ethical, legal and policy debates relating to health care. Conflicts between public interests and individual rights, the challenge of regulating health professionals and access to health services, and the effects of a global market all feature prominently in these discussions. As a result of globalization, these issues can no longer be understood solely within the political boundaries that define traditional notions of individuals and communities. Rather, solutions demand a global conception of rights and obligations, which in turn requires new approaches to health policy formulation and a reevaluation of existing ethical and legal frameworks. In essence, the impact of globalization on human health is testing the robustness of modern regulatory systems, legal doctrines and ethical paradigms.

PUBLIC HEALTH: DEVELOPING GLOBAL CONCERNS

The interconnectedness of the global economy presents new challenges in public health. While globalization has facilitated improvements in health care, it has also created new hazards and avenues for exploitation. It is becoming increasingly apparent that both national and international responses are required. Indeed, as the chapters in this section convey, public health is rightly a global concern.

Globalization has led to a sharing of both risks and responsibilities in public health. Belinda Bennett reminds us of the ease with which infectious diseases can spread within the global community, given the speed of modern travel and trade. Despite a long history of the impact of infectious diseases on human society, the SARS crisis in 2003 demonstrated the ongoing importance of having efficient public health infrastructures at national *and* international levels. However, as Bennett notes, “the huge disparities in health and health infrastructure that exist between countries continue to undermine the ability of countries to respond rapidly and effectively to outbreaks of infectious disease.”

Bennett’s critique of the SARS crisis also shows how concerns about public health become acute at the interface between the developed and the developing worlds, which raises important questions about the meanings of rights and obligations in an international context. The evolving field of bioethics would play a vital role in addressing such dilemmas. Udo Schüklenk and Braimoh Bello argue, however, that much of bioethics discourse has focused on high-tech issues such as stem cell research and nanotechnologies, and “traditional liberal bread-and-butter issues of informed consent and individual autonomy.” They argue that bioethics should instead focus on issues that affect many more people in the world – issues that address global inequities in health care between developed and developing

countries. To that end, they propose a range of topics that should receive greater attention by professional bioethicists: the 10/90 gap in health research, the transnational organ trade, access to essential medicines, health-based immigration restrictions, international research ethics and the flow of health information. According to Schüklenk and Bello, a refocusing of bioethics as a field of inquiry is essential if it is to have continued contemporary relevance.

The evolution of public health as a global concern invokes questions about global social justice. As argued by George F. Tomossy and Joylon Ford, the quest for cures exposes fundamental deficiencies in legal doctrines insofar as they may prevent access to justice. They examine the plight of developing world subjects who may become injured in the course of first-world sponsored clinical trials, and who face significant legal obstacles when seeking compensation from multinational pharmaceutical corporations. Concerns about distributive justice thus come into conflict with the corporate incentive to pursue profits within a global market. Tomossy and Ford argue that citizens of one jurisdiction should not be exposed to risks of harm in order to benefit others, and would call upon investigators, sponsors and regulators alike to protect developing world subjects. They advocate that access to justice by developing world plaintiffs should be facilitated in first-world courts, which will require correcting procedural and substantive legal impediments that are presently almost insurmountable.

Finally, concerns about global social justice and public health invite consideration of the ethical grounds upon which arguments for obligations on the part of individuals, corporations and governments in the developed world towards developing countries might be based. This theme is explored by Deborah Zion, who analyzes obligations in terms of a duty of beneficence, efficacy, justice and integrity. She proposes that setting up processes to analyze the effects, burdens and benefits of clinical research would be a vital starting point towards relieving global health care inequities.

THE GLOBAL BIO-ECONOMY: CONSENSUS AND INNOVATION

The viability of national regulatory systems is continually being confronted by a global market for health care that is driven by the forces of innovation and health care consumerism. The emergence of a global bio-economy has created the need for transnational regulation of biotechnology and medical products. While generating consensus in health care policy formulation has always been a challenge, it is particularly so against the backdrop of globalization where consensus needs to be located at both national and international levels. And, as in the previous section, ethical issues permeate these discussions.

Derek Morgan argues that “we stand on the threshold of what might be thought to be a new dimension in the relationship of human sciences to biotechnology.” He proposes that the emergent “bio-economy” is set to transform our lives in the same all-encompassing manner brought about by the industrial age and advent of the computer. With the key societal concerns for these stages having related to

environmental degradation and privacy respectively, he predicts that the central issue in the new economy will be ethics. In order to resolve some of the current debates in this regard (for example, cloning, genetic patenting and bio-engineered foods), Morgan argues that the development of international consensus will require the implementation of “biomedical diplomacy,” informed by traditional tools of “rhetoric, persuasion, negotiation, and economic and political leverage.” The rationale for this process, he maintains, must be based on “rethinking equity in health,” without which “all talk about human values, human dignity, human rights and democratic balance will be so much empty rhetoric.”

Our understandings of “the global” and of “risk” help to shape responses to innovative technologies in health. Drawing upon the example of regulatory debates surrounding genetically modified foods in the United Kingdom, Alan Irwin considers the relationship between internationalized patterns of innovation and the development of national policy processes. His analysis reveals how differing conceptualizations of “the global” can exist within public discourses about innovation, and how the interaction between “the global” and “the national” affects the construction of regulatory debates. Irwin argues that these debates present political challenges in the need to formulate “more open cultures of deliberation and reflection,” and that it is important “to move away from simply presenting globalization as an objective (and generally irresistible) force and towards an acknowledgement of its varied manifestations and social constructions.”

Thomas Faunce explores the link between innovation and corporate globalization by examining the intersection of international trade and domestic health policy. His critique addresses the impact of US-derived global intellectual property policies on government pricing of pharmaceuticals in Australia. He traces the evolution of these policies to their corporate origins in the United States and explores their enforcement through both international trade mechanisms and bilateral treaties. Faunce cautions that these policies represent “a significant, emerging problem for global public health,” and urges greater attention to principles in bioethics, public health and international human rights in order to ensure affordable access to essential medicines.

As with trade, advertising is being recognized as a critical force in the global economy. Its relevance is particularly significant in today’s consumer society where advertising plays a vital role in the development and expansion of markets for health products. Patricia Peppin analyzes the challenges associated with regulating advertising of pharmaceutical products through a comparative overview of the regulatory frameworks for advertising of medicines in the United States, Canada, the European Union, Australia and New Zealand. Drawing on semiotic theory, Peppin explores the construction of meanings through the information and images used in advertisements and the interpretation of those meanings by consumers. She warns of “significant public health consequences” associated with passing on advertising costs to health systems and with commodifying the doctor-patient relationship.

Globalization clearly presents significant difficulties for crafting consensus on regulatory policy in the area of biotechnology. This theme is explored by Timothy

Caulfield and Barbara von Tigerstrom. Using the examples of gene patents and laws designed to limit human cloning, they reveal the competing tensions that emerge from global debates surrounding these issues. As they note, the demand for extensive regulatory intervention exists; however, “differing cultural and socio-political positions magnify the policy-making challenge.” The authors acknowledge the difficulties inherent in reaching consensus on contentious issues and the potential for international agreements to limit the scope of national policy making. Their analysis thus yields an important lesson: “there can be no simple template for understanding and addressing the implications of globalization for biotechnology policy.”

GLOBALIZATION AND HEALTH CARE

Having canvassed the implications of globalization for health care on a macro-level, this last section turns to the nexus between health care professionals and consumers. Globalization has had a fundamental effect on rights and obligations at the micro-level through its impact on national policies and legal systems. As these chapters show, the effects of globalization filter through to shape the rights of individuals and practices of the health professions.

Kerry Petersen’s examination of the rights of children conceived using donated gametes to access identifying information about their biological (donor) parent provides a case for the study of individual rights in health care in a global setting. Despite the absence of consistent national or international patterns governing assisted reproductive technologies, common themes and regulatory approaches emerge from international comparisons. Petersen’s critique thus reveals that incremental changes in regulatory reforms in this area favouring openness and disclosure of donor identity demonstrate the influence of human rights discourse on national health policy formulation.

John Harrington analyzes the impact of global market forces on national health systems, and signals the threat to national regulatory systems posed by health tourism and the commodification of human organs. Patients are increasingly travelling abroad in order to access health procedures. He argues that “consumption of health care, just like its provision, is no longer confined by national borders,” with the global trade in human organs continuing to defy attempts to curtail it. Indeed, Harrington notes that the taboo against commodification has started to erode, with the consensus against commodification coming apart “under pressure of the actually-existing market.”

In the final chapter in this collection, Ian Freckelton charts the emerging landscape in the global regulation of health care practitioners. Drawing on the experience of the United Kingdom, Canada, Australia and New Zealand, Freckelton maps the common regulatory trends that are emerging against the backdrop of this changing regulatory environment. He examines the changes caused by increasing consumerism and availability of health information in the age of the Internet, as well as the issues that arise from increased global movement of health professionals, and

the ethical issues arising from the recruitment of developing world health professionals to meet the needs of health systems in developed countries.

CONCLUSION

Across the three themes of this volume, globalization has emerged as a fundamental force shaping ethical, legal and policy debates in health. The authors in this volume have shown that all aspects of health care, whether one is speaking of individual rights, professional obligations or governmental policy, are invariably influenced by transnational factors. As has been observed in globalization discourse more generally, these effects have been both positive and negative. The obvious challenge facing all countries, developing or developed, is to embrace the benefits of a global bio-economy while avoiding its harms. As is increasingly evident from attempts to govern innovation in biotechnology and access to health care, however, legal and regulatory mechanisms can only go so far towards achieving this goal. From the collective efforts of our colleagues in this volume, we would therefore derive the conclusion that a sound ethical base is needed upon which to ground policy initiatives, whether at national or international levels, and regardless of the difficulties obtaining political consensus might present. Such a base, we suggest, must ultimately be grounded in global considerations about equity and respect for human rights.

*Belinda Bennett and George F. Tomossy
Sydney, July 2005.*

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CHAPTER SEVEN

THOMAS ALURED FAUNCE

GLOBAL INTELLECTUAL PROPERTY PROTECTION OF “INNOVATIVE” PHARMACEUTICALS

Challenges for Bioethics and Health Law

Multilateral and bilateral trade agreements have become important vehicles by which US multinational corporations, through close collaboration with government officials, are striving, amongst other objectives, for increasingly stringent global intellectual property protection (GIPP), particularly over what they term “innovative” pharmaceuticals.

This chapter explores the evolution and structural dynamics of GIPP. It particularly considers the hypothesis that GIPP represents a corporate-driven ideology whose legitimacy in a democratic polity is undermined by its uncertain foundation in public health research and inadequate integration with norms of bioethics and health law, including international human rights.

This analysis begins with consideration of the domestic evolution of GIPP from within the US patent system. This may reveal how many of its important structural features had their roots in a domestic profit-making ideology. The chapter then examines the critical initial globalization role of the US *Trade Act* 1974, particularly section 301. This permitted US industry to request an investigation by the US International Trade Commission of foreign nations whose practices allegedly caused it material injury. The *Agreement on Trade Related Intellectual Property Rights* (TRIPS) is analyzed as a mature component of GIPP by which increased intellectual property rights, in particular over pharmaceuticals, were linked with strong trade sanctions. The sophisticated contribution to GIPP made by the *Medicare Prescription Drug Improvement and Modernization Act* 2003 (US) is then evaluated, particularly its prohibition of Federal Government medicine price setting and its requirement for a study of pharmaceutical price controls in other developed countries.¹ In each case the extent to which GIPP attempted or failed to integrate its corporate-designed principles with basic norms of bioethics, public health law and international human rights is discussed.

B. Bennett & G.F. Tomossy (eds.), Globalization and Health: Challenges for Health Law and Bioethics, 87-107.

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An important GIPP case study briefly presented here involves provisions in the US-Australia Free Trade Agreement (AUSFTA) attempting to “eliminate” Australia’s medicines cost-effectiveness pricing system known as the Pharmaceutical Benefits Scheme (PBS).

THE DOMESTIC ORIGINS OF GIPP IDEOLOGY

The rules and laws of intellectual property have traditionally been designed to achieve optimal balance between two ends: reward of innovation and diffusion of knowledge to the public. The philosophy underpinning them was once described as emerging from the normative traditions of natural law theory, or utilitarianism (Hettinger 1989). Such claims, as we shall see, are rarely made with any frequency or authority in relation to pharmaceuticals today.

In the late 1960s Nordhaus demonstrated that optimal duration of patent protection balanced incentives for innovation against the social losses of monopoly exploitation. He attempted to show how optimal patent life over a product is longer if price elasticity of demand is lower and its social benefit is reduced relative to research and development costs (Nordhaus 1969).

Gradually, however, such utilitarian attempts to weigh social benefit of patent monopolies, particularly over pharmaceuticals, appear to have been replaced with a more purely profit-driven economic analysis. This conceptual shift created one of the basic preconditions for the globalization of intellectual property enforcement. It is unlikely that any particular group of pharmaceutical executives devised, at one time, the complete strategy for GIPP. Rather, the hypothesis explored here is that GIPP’s evolution was the outcome of a network of corporate thinking inexorably committed to maximizing profit from pharmaceuticals. The related corporate institutions, lacking institutional incentives to reward moral responsibility or ethical thinking, may have gradually eroded the confidence of ambitious individual employees to champion such non-commercial norms. The first step appears to have involved developing a strategy to favorably influence domestic economic policy, then exert greater control over the structures creating relevant US intellectual property law.

Research subsequent to Nordhaus attempted to show that optimal patent duration should be longer for economic reasons where enforcement is costly or incomplete (Scherer 1984). Likewise, the case was made that the economic incentive of patent life should be shorter where competitors wasted resources with “window dressing” inventions merely to improve market share (Gallini 1992). The traditional Nordhaus model was also contentiously modified to include what is referred to as “cumulative” or “incremental” innovation (Scotchmer 1991).

Some argued, prophetically given later globalization developments, that if such reasoning was accepted, the patent monopoly over pharmaceuticals would become a form of rent pursued by competing investors until much relevant and anticipated social benefit had been dissipated through duplication (Grady and Alexander 1992). One underemphasized line of analysis considered that much pharmaceutical

innovation proceeds in public-funded institutions partly as a result of researchers' motivation to facilitate equitable dispersal of knowledge and promotion of public goods (Eisenberg 1992). Of the twenty-one drugs with greatest therapeutic effect introduced between 1965 and 1992, all but five were based on a discovery made in the public sector (Cockburn and Henderson 1997). This type of socially-focused patent law reasoning involves a strong implicit emphasis on distributive justice, a foundational principle of both bioethics and public health law (Faunce 2005). It is an approach, as we shall see, rarely engaged with as protection of pharmaceutical intellectual property became a global exercise.

In 1959 the Kefauver committee found evidence of substantial abuse of monopoly power in the US pharmaceutical industry (Comanor 1966). As a result of its recommendations, the US Food and Drug Administration (FDA) commenced a more rigorous evaluation of efficacy as well as bioequivalence in new pharmaceutical applications (Comanor 1986). Counter arguments were raised that the decline in communally valuable new drugs began well before any increase in regulatory stringency and was particularly related to tranquilizers whose supply and demand were adversely affected by the thalidomide tragedy (Temin 1980). Further, the increased regulatory requirements appeared to have no dampening effect on pharmaceutical research and development spending, which continued to rise during this period (Grabowski and Vernon 1983).

Nevertheless, the US pharmaceutical industry now promoted what was to become a common tactic in its later efforts at globalization. It blamed recently enhanced government regulation for the decreased number of innovative molecular entities it was able to introduce in subsequent years (Peltzman 1973). They argued, ultimately successfully, that FDA burdens should be relaxed and patent lives extended to compensate for market time lost in regulatory review (Wiggins 1983). Here too we see the origins of a linked accountability diversion and patent extension technique that lead to globally problematic relations between government regulators and the pharmaceutical industry.

On 9 July 1982, Barry MacTaggart, then chairman and president of the pharmaceutical company Pfizer International, published an op-ed piece in the *New York Times*. This document represented a pivotal point in the shift of pharmaceutical intellectual property protection toward a global strategy. It crystallized much initial industry thinking concerning a new target to blame for its domestic failures on the "innovation" front.

MacTaggart alleged that US knowledge and inventions were being stolen by particular foreign governments by means of specifically designed laws. The World Intellectual Property Organization (WIPO) was criticized for "trying to grab high-technology inventions for underdeveloped countries" and for contemplating treaty provisions that would "confer international legitimacy on the abrogation of patents" (Drahos and Braithwaite 2002, 61). Ominously in terms of subsequent developments, no attempt was made in this brief but seminal tract to consider how such a free market approach should mesh with exceptions to patent rights in the interest of community benefit.

Significant in the domestic background of this influential public enunciation of GIPP was the 1980 decision of the US Supreme Court in *Dawson Chemical Company v. Rohm and Haas*.² This overruled prior decisions where judges deprecated patents as disguised, socially disadvantageous monopoly rights. The court now declared that “the policy of free competition runs deep in our law...but [that] of stimulating invention...underlies the entire patent system [and] runs no less deep.” In *Haas*, reward of “innovation” through State grant of protectionist monopoly rights achieved the status of “equal footing” with the previously antagonistic concept of “free market competition” (Kastriner 1991, 7).

In 1982, another important element in GIPP arose from the creation of the Court of Appeals for the Federal Circuit (CAFC). This Court’s ostensible purpose was to centralize patents, tariff and custom, technology transfer, trademarks, government contracts and labor disputes within one specialist jurisdiction. Critics feared the new court would be prone to isolation from broader normative systems and to influence by corporate interest groups (Lever 1982). Yet these were probably two of the main reasons for its creation. For GIPP to begin to launch itself upon the world it first required a solid and consistent basis in domestic patent law, one that unequivocally emphasized the paramount importance of the rights and profits of the innovator.

The CAFC has since, as expected, developed an extremely pro-patent jurisprudence rarely mentioning the word “monopoly,” readily granting large scale compensatory damages and permanent injunctions, whilst consistently upholding the interests of alleged innovators over purported copiers or generic suppliers. The adverse social impacts of such decisions, and the extent to which they conflict with basic principles of bioethics or public health law are rarely, if ever, discussed in this new patent court jurisprudence (Sell 2003, 67-72). Between 1982 and 1990, the CAFC upheld on appeal 90 percent of patents initially determined to be valid and infringed, compared with 62 percent in the various relevant courts between 1953 and 1978. It reversed on appeal only 28 percent of patents held invalid at first instance, compared with 12 percent previously (Jaffe 2000). The CAFC later produced many decisions that appeared very advantageous to the development of GIPP. Also assisting the nascent GIPP ideology was industry lobbying for a Federal economic policy positing level of output, rather than amount of competition as the dominant regulatory end point. This allowed pharmaceutical companies in particular to promote high levels of market concentration as efficiencies, rather than price-distorting monopolies and cartels that conflicted with ethical and legal obligations to promote competitively low prices in the public interest (Sell 1998). GIPP was beginning to emphasize that intellectual property rights provided such corporations with a strategy to protect investments and increase revenue, if need be by excluding competition from the market. This was quite different from earlier conceptions, which stressed the role of patents in social diffusion of knowledge (Sell 2003, 13-4).

In 1983 the US Government passed the *Drug Price Competition and Patent Restoration Act* (commonly known as the *Hatch-Waxman Act*). This legislation gave pharmaceutical patent holders an additional five years of patent life, allegedly to compensate for the period of pre-market testing and FDA evaluation. It allowed, as a

response to the CAFC decision in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,³ generic competitors to use original brand-name data to prepare bioequivalence and other testing provided those activities were reasonably related to securing regulatory approval and “springboarding” on originator patent expiry. The statute provided an incentive for rapid generic market entry by according the first such entrant 180 days of market exclusivity. Brand name manufacturers were allowed to request a thirty-month injunction against marketing approval of generic drugs alleged to be infringing valid patents (Gallini 2002). This last provision in particular, by linking marketing approval (previously based primarily on safety and quality issues) with patent validity, established the profitable practice, known as “evergreening,” by which the patent monopoly over large sales volume brand name pharmaceuticals could be tactically extended. The techniques of “evergreening” developed here were set to be transported, by their incorporation into bilateral trade deals, into public health systems around the world as a key component of GIPP.

The next important development in GIPP ideology appears to have involved the search for an effective mechanism to widen the global markets over which pharmaceutical intellectual property rights could be enforced (Sell 2003, 17). To do this, US pharmaceutical companies successfully prosecuted the argument that any form of State restriction on their prices in foreign countries was an unjustified interference in the marketplace, rather than an ethically and legally legitimate public health restraint on a protectionist market distortion (Drahos and Braithwaite 2002, 13). This again was largely an ideological debate. Very little objective evidence of public health impact was adduced either for or against GIPP.

Section 301 of the *Trade Act 1974* (US) provided GIPP with an initial, largely unsuccessful, global enforcement mechanism. Between 1975 and 1979, eighteen corporate petitioners filed section 301 cases, but in none managed to induce the US to take retaliatory action, six being settled by bilateral resolution (Coffield 1981). Section 301 of *Trade Act 1974* (US) was amended in 1984 to permit the US President, through the office of the US Trade Representative (USTR), to deny trade benefits or impose duties on products or services of countries unjustifiably restricting US commerce. In 1987, the US Pharmaceutical Research and Manufacturers Association or PhRMA (then called the PMA, or US Pharmaceutical Manufacturers Association), demanded trade retaliation against Brazil under section 301, for the latter’s lack of adequate patent protection for US pharmaceuticals. No serious attempt was made by the US to balance the ethical and public health law obligations of the Brazilian government to provide affordable, essential medicines for its citizens. When Brazil refused on social justice grounds to alter its policy, the US placed a large retaliatory tariff on imports of Brazilian pharmaceuticals. Brazil filed a complaint with the GATT, but withdrew this when US sanctions were dropped in return for a commitment to increased pharmaceutical patent protection (Mossinghoff 1991).

In 1987, the US also denied trade benefits to Mexico because of that country’s failure to adequately protect US pharmaceutical patents. The Mexican government refused to buckle to this pressure, holding instead to a longstanding public health

commitment to provide affordable, essential medicines to its people. This persistent refusal lost Mexico \$500 million in Generalised System of Preferences (GSP) benefits (Sell 2003, 90-1). The GSP scheme, set up under the United Nations Conference on Trade and Development provided for preferential tariff treatment for developing country exports of manufacturing and semi-manufactured goods. In 1988, an amendment called “Special 301” was made to section 182 of the *Trade Act* 1974 (US) by the *Omnibus Trade and Competitiveness Act* 1988 (US). Special 301 became the principal statutory authority under which the US investigated and, if need be, threatened trade sanctions against foreign countries that maintained acts, policies and practices that violated, or denied US corporations rights or benefits under trade agreements, or, through otherwise being unjustifiable, unreasonable or discriminatory, burdened or restricted US commerce. Unjustifiable acts, policies and practices were defined as those that violated, or were inconsistent with, the international legal rights of the US, including denial of national treatment or most-favored nation (MFN) treatment to US exports or limiting protection of US intellectual property rights.

The USTR was now required under the *Trade Act* 1974 (US), to mention, in its annual review, a “Special 301 Report Priority Watch List.” Corporations could petition the USTR to investigate and, ultimately, threaten trade sanctions against a particular unjustifiable, unreasonable or discriminatory policy or practice of a foreign country so listed. The Special 301 Report Watch List will probably remain a classic example of public law at the service of private corporations (Drahos and Braithwaite 2002, 89). The 2004 list includes, for example, these comments about Canada’s attempts to restrain pharmaceutical prices for social justice reasons in the public interest: “systemic inadequacies in Canadian administrative and judicial procedures continue to allow the early and often infringing entry of generic versions of patented medicines into the marketplace” (USTR 2004).

Croatia is likewise criticized because of its “lack of co-ordination between the patent and health authorities to prevent patent infringement by the grant of marketing approval for copycat pharmaceuticals, and failure to provide expeditious and timely judicial remedies to parties seeking to stop infringing activities” (ibid.). Ecuador is similarly impugned because “the number of copy products granted marketing approval by the health authority continues to increase, due to the lack of any linkage system between the health and patent agencies” (ibid.).

The policies of the Italian government were attacked on the USTR “Priority Watch List” at US multinational corporate insistence. The USTR reasoned that the policies “may adversely affect the prior practice of patent term extension for pharmaceuticals” (ibid.). Malaysia is denigrated for failing to link “the marketing approval process to the patent registration process” for pharmaceutical products (ibid.). Poland is criticized for permitting the commercial availability “of generic versions of patent protected pharmaceutical products” (ibid.). Vietnam is castigated because “counterfeit pharmaceuticals are common in the marketplace” (ibid.).

The USTR Priority Watch List consistently avoids opportunities to consider the human cost of the more stringent patent protections they so stridently advocate as a

global legislative priority. No attempt, for example is made, in any such Special 301 report, to balance the public health cost of requiring the impoverished citizens of these mostly developing nations to pay higher prices for pharmaceuticals. The available income, or burden of disease in these countries is not mentioned as a relevant factor. No effort is made here to address obligations flowing from bioethics and public health law (particularly distributive justice) or international human rights (the right to health). The next stage in GIPP's evolution involved linkage to an even stronger method of global intellectual property enforcement.

GIPP'S LINKAGE WITH TRADE

From 1981, Edmund Pratt, then CEO of the Pfizer pharmaceutical company, in his capacity as chair of the Advisory Committee on Trade Negotiations (ACTN) had been consulting directly with the US President about placing foreign intellectual property protection on the US trade agenda (Ryan 1998). At this time, the US commenced a series of bilateral negotiations on patents, copyright and trade with countries such as Korea, Mexico, Singapore, Hungary and Taiwan. US intellectual property negotiators apparently discovered, however, that financially more effective outcomes emerged once their trade colleagues did most of the bargaining (Enyart 1990, 54).

The task of making GIPP a primary object of US trade policy was skillfully executed. Pharmaceutical company lobbyists, as mentioned earlier, had previously sowed the idea of linking trade and intellectual property rights in various levels of the relevant US bureaucracy, government and academia. At the same time, they increased the size of their contributions to the election campaign funds of the two major US political parties. The World Intellectual Property Organization (WIPO) seems to have been by-passed in the task of promoting GIPP, perhaps because the US and other OECD nations considered it lacked sufficient enforcement tools or motivation (Abbott 2002, 315).

In the mid to late 1980s, when GIPP was increasingly being expressed in TRIPS negotiations, very little empirical or theoretical research existed concerning the effects of increasing intellectual property rights in a country (*id.*, 313). Some evidence had emerged that stronger patent rights appeared to encourage incremental improvements by the originator, but also to create hindrance from prior inventors and freeze out future radical inventors (O'Donoghue, Scotchmer and Thisse 1998). Lerner (2001), for example, studying 177 policy shifts in sixty countries over 150 years, found an "inverted-U" relationship between patent strength and innovation. He suggested that strengthening patents had a positive effect on innovation when intellectual property protection was initially low, but a negative impact if patent protection was initially high (*ibid.*). The limited research that did support the trade-IP linkage with pharmaceutical innovation was generally written by drug company-funded institutes and academics (Bekelman and Gross 2003). This too appears to have become a consistent tactic of GIPP proponents. When counterarguments to GIPP are raised by academics or policy makers, a paper is rapidly published

allegedly either confirming their lack of economic rationality, or supporting the GIPP position.

The TRIPS Agreement was a manifestation of GIPP developed by senior executives at twelve US corporations including, in particular, the pharmaceutical giant Pfizer (Drahos and Braithwaite 2002, 61). Its standards were designed to obtain rent for developed nations from two great emerging technologies, digital technology (through copyright, patents and protection for layout designs) and biotechnology (through patents and trade secrets) (id., 10). Developing countries, led by India and Brazil, both of whom had large generic drugs industries catering to the essential needs of impoverished populations, fought against TRIPS in the 1986 Uruguay Round mandate of the WTO. Amongst their objections were suspicions that increased intellectual property protection would burden the task of providing universal access to affordable, essential medicines. The US negotiators bargained that they at least be allowed to place the issue “on the table.” Eventually, a Senior Officials meeting was convened in Geneva in April 1989 that announced a “framework text” to provide the basis of substantive negotiations whilst not considering issues of institutional implementation (id., 11).

The US, European Community and Japan, however, signified that subsequent economic co-operation between their nations and the developing world was dependent on TRIPS Agreement being reached. The US negotiators made quite open threats about trade sanctions under Special 301 of the *Trade Act* 1974 (US), or even abandoning GATT altogether (id., 193). Developing countries were promised the developed parties to TRIPS would strive to reduce their domestic agricultural subsidies and alleviate restrictions on the import of tropical products. Although it was clear that TRIPS would have a major impact on public health particularly in developing countries, the World Health Organization was not included in the negotiations (ibid.).

The developing countries, led by India, strove to achieve explicit concessions under TRIPS to allow liberal use of compulsory pharmaceutical licensing. They also sought to specifically reduce restrictions on the parallel importation of drugs from countries where the price was cheaper, as a result, for example, of national bargaining strategies (Abbott 1998, 500). Neither goal was fully achieved; Article 30 instead conferring an ambiguous general right of “limited exceptions to the exclusive rights conferred by a patent.” Article 7 recognized that the protection of intellectual property should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of its users and producers in a manner conducive to social and economic welfare and to a balance of rights and obligations. A clarification would be needed, however, to determine the extent to which this Article allowed public health exceptions to pharmaceutical patent rights.

Developing nations agreeing to TRIPS were asked to renounce a large portion of their sovereignty over areas of intellectual property that would be crucial to ensuring justice and fairness dominated the policies that shaped their subsequent economic progress. The first reason they did so, nevertheless, may have arisen from the belief

that this would accord them greater agricultural access to developed world markets. Ironically, the developing nations actually obtained little such advantage from TRIPS in the agricultural sector. Instead, the TRIPS regime increased developed nation intellectual property rights over agricultural plants and seeds, facilitated direct competition with biotechnologically superior developed nation farmers, allowed US and EU farmers to continue benefiting from large farm subsidies and permitted developed nations to use phytosanitary restrictions as a de-facto means of protection against developing nation agricultural imports (Drahos and Braithwaite 2002, 11).

The second reason developing nations may have agreed to TRIPS is that they were somehow convinced that higher intellectual property standards would eventually benefit them. Yet, then and now, developing nations hold a minute proportion of the world's patents. Further, industrialization had begun to occur in Singapore, Brazil, India and South Korea well in advance of a globalized intellectual property regime (id., 143).

TRIPS eventually emerged as one of the twenty-eight agreements in the *Final Act of the Uruguay Round of Multilateral Trade Negotiations* leading to the WTO in 1994. It required all signature countries to adhere to minimum levels of intellectual property protection (including pharmaceutical patents). It was the first broadly subscribed multilateral IP agreement enforceable between governments and allowed them to resolve international intellectual property disputes more readily through the WTO dispute mechanism. Developed countries were required to fully implement TRIPS by 1 January 1996, while developing and least developed countries were given staggered compliance periods (Gathi 2002).

TRIPS and the GIPP ideology it appeared to implement, may historically be viewed as a triumph of corporate lobbying over democratic bargaining. "A small number of US companies, which were established players in the knowledge game, captured the US trade-agenda-setting process, and then, in partnership with European and Japanese multinationals, drafted intellectual property principles that became the blueprint for TRIPS" (Drahos and Braithwaite 2002, 11).

In 1997 the South African government, as the result of the HIV/AIDS crisis affecting 50 percent of its citizens in some districts and its inability to respond with cheap anti-retroviral medications, passed its *Medicines and Related Substances Control Amendment Act*. Section 15C permitted the relevant Minister to "prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public." It expanded the conditions for compulsory licenses and parallel importation to facilitate the capacity of more poor South African citizens gaining access to cheap anti-HIV/AIDS pharmaceuticals.

As a result, South Africa was placed on the USTR Priority Watch List. The US Department of State, Department of Commerce, Patent and Trademark Office, USTR, National Security Council and Office of the Vice President commenced an assiduous, concerted campaign to persuade the Government of South Africa to withdraw or modify aspects of section 15C which were considered inconsistent with its commitments under TRIPS (USTR 1999).

The US threatened to bring the South African legislation before a WTO Dispute Settlement Body. The US (and the PhRMA interests it represented) claimed that the South African public health and equity interpretations of TRIPS compulsory licensing and parallel importation articles were inconsistent with TRIPS. As one commentator pointed out, however, such a view is repugnant to basic principles of moral responsibility:

One would truly have to lack a moral compass to render a legal opinion condemning millions of people to a premature death because Pfizer, Pharmacia & Upjohn, Glaxo SmithKline or Novartis would not be able to engage in their optimal pricing strategy. The WTO, in my view, could not survive such a decision. (Abbott 2002, 321)

Nevertheless, in 1998, as is now well known, forty-one pharmaceutical companies commenced litigation, partly based on TRIPS, against the South African *Medicines and Related Substances Control Amendment Act*. President Nelson Mandela was named as first defendant. In April 2001, the action was withdrawn after a campaign by members of the international civil society including Médecins Sans Frontières, relying in particular on basic norms of bioethics and the international right to health. Other nations (for example Brazil and Venezuela) brought and won similar cases based on their constitutional rights to health (Drahos and Braithwaite 2002, 6). These conflicts were the inevitable result of GIPP's prior refusal to engage with norms of bioethics, public health law, or international human rights.

Partly in response to lobbying by such NGOs at the WTO Doha Ministerial Conference in November 2001,⁴ WTO Ministers issued a separate *Declaration on the TRIPS Agreement and Public Health*.⁵ Paragraph 6 of this equity clarification permitted WTO Members with "insufficient or no manufacturing capacities in the pharmaceutical sector" to issue compulsory licenses for the production, or importation, of medicines without consent from the patent holder, where necessary to protect public health (such as to combat the HIV/AIDS crisis) and promote "access to medicines for all." After a further WTO decision of 30 August 2003, Members could unequivocally waive Article 31(f) of TRIPS and respond to compulsory licenses to export to markets (other than domestic ones) where that other country does not have the capacity to manufacture medicines itself. This practical extension of the international human right to health was not restricted to situations of national emergency. The Ministerial Declaration stressed the importance of "implementing and interpreting" TRIPS "in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines." But if the *Doha Declaration* appeared to provide an obstacle to GIPP, this was only temporary.

At the start of the twenty-first century GIPP continued to be fuelled by the lavish expenditure of US pharmaceutical companies on marketing, administration and lobbying. In the fiscal year July 2003-June 2004, the US drug industry (brand-name, generic and biotech drug makers, biomedical device makers, pharmacy benefit managers and distributors) spent US\$108.6 million chiefly on funding 824 lobbyists (many of whom had previously worked for government) to influence public policy

(in 2002 \$91.4 million for 675 lobbyists) (Public Citizen 2004). The CAFC decision in *Madey v. Duke University*⁶ was also very useful to GIPP proponents. They were increasingly attempting to argue that pharmaceutical research and development leading to product innovation could only consistently arise not due to public-funded efforts at universities, but from corporate profit motive in a context of strong IP protection. The CAFC held in *Madey* that any experimentation into a pharmaceutical compound at a university potentially breaches a patent, because these institutions are profit-making.⁷ The decision was unsuccessfully appealed to the US Supreme Court by the Association of American Medical Colleges, the American Council on Education, various individual colleges, universities and medical schools, as being contrary to basic ethical principles and inhibiting research into socially important but unprofitable diseases such as malaria, tuberculosis, diarrhoea and pneumonia.⁸

Another example of the way GIPP began to influence regulatory structures concerns its close involvement with the US FDA. A structural conflict of interest increasingly kept FDA safety officials from strongly exercising independent authority because the Office of Drug Safety is part of the section responsible for evaluating and approving new drugs. Many of its own employees consider the FDA now views the drug industry as a financially supportive client to be appeased rather than a potential infringer to be carefully regulated. In an internal survey conducted in 2002 of about 400 FDA scientists, two-thirds said they lacked confidence that the FDA “adequately monitors the safety of prescription drugs once they are on the market” and 18 percent reported they “have been pressured to approve or recommend approval” for a drug “despite reservations about the safety, efficacy, or quality” (Fontanarosa, Drummond and De Angelis 2002, 2648).

The *Medicare Prescription Drug Improvement and Modernization Act 2003* (US) was a significant domestic triumph for GIPP. It had begun as a measure to assist senior citizens and people with disabilities cope with rising US health care costs. It ended up instead a boon for the pharmaceutical industry and managed care corporations. The US government was specifically prohibited from using its bulk buying power for Medicare beneficiaries (as the Australian government does under the PBS) from negotiating medicines price discounts.⁹ This provided the stable conceptual base from which US corporations could begin a concerted program to dismantle reference pricing systems around the world. The 180-day period of market exclusivity designed to be an incentive for generic drug market entry was abolished.¹⁰ Brand name drug companies, by injuncting the first such generic for potentially breaching their claimed patents, had effectively been prolonging their maximum profits over blockbuster (high sales volume) brand name medicines. The legislation commissions a study but fails to make legal the reimportation of prescription drugs from Canada and other industrialized countries where they are approximately half US prices.¹¹

The legislation also directed the Secretary of Commerce, in consultation with the International Trade Commission, the Secretary of Health and Human Services and the United States Trade Representative, to conduct a study and report on drug pricing practices of countries that are members of the Organization for Economic

Cooperation and Development and whether those practices utilize nontariff barriers with respect to trade in pharmaceuticals. The study was required to include an analysis of the use of price controls, reference pricing, and other actions that affect the market access of United States pharmaceutical products. It was also to “estimate of additional costs to U.S. consumers because of such price controls and other such practices, and the extent to which additional costs would be reduced for U.S. consumers if price controls and other such practices are reduced or eliminated.”¹² Pharmaceutical price controls in eleven OECD countries were eventually studied. The resultant report by the US Department of Commerce is replete with classic expressions of GIPP ideology. Increased intellectual property protection is justified here as a necessary prerequisite to ensuring innovative new drugs. US citizens, the study claims, will gain \$5 to \$7 billion per year in benefits from new drugs if the OECD countries had no price controls. The report sets the benchmark for pharmaceutical prices as that in the US, because it allegedly represents a completely “deregulated” market (US Department of Commerce 2004, 7).

A Conference Agreement on the legislation obliged the United States Trade Representative, the Secretary of Commerce, and the Secretary of Health and Human Services to analyze

whether bilateral or multilateral trade or other negotiations present an opportunity to address these price controls and other such practices and shall develop a strategy to address such issues in appropriate negotiations. In so doing, these agencies shall bear in mind the negotiating objective set forth in the Bipartisan Trade Promotion Authority Act of 2002 to achieve the elimination of government measures such as price controls and reference pricing which deny full market access for United States products. In so doing, the agencies shall provide periodic and timely briefings for the Committees of the House and Senate listed above, with an interim briefing no later than 90 days after enactment to address negotiations to establish a U.S.-Australia Free Trade Agreement and, as appropriate, other current negotiations.¹³

GIPP'S SWITCH TO BILATERALS AND THE AUSFTA

Frustrated by public health inroads into the lucrative TRIPS pharmaceutical patent arena, such as the *Doha Declaration on TRIPS and Public Health*, US multinationals now began to forum shift in an effort to promote GIPP. Their strategy was to negotiate tougher intellectual property regimes outside TRIPS, in private Free Trade Agreements (“FTAs”). The AUSFTA which entered into force on 1 January 2005, was in fact merely one of a series of what may more accurately be termed bilateral corporate colonization arrangements (or preferential trade agreements) negotiated with thirty-four countries in the Free Trade Area of the Americas Agreement, five Central American countries, the Dominican Republic, the Southern African Customs Union, Morocco, Bahrain and Singapore.

These FTAs had the following common features that represented core elements of the now mature GIPP. First, governments signing them were required to extend pharmaceutical patent protection beyond the twenty-year period required by TRIPS. Second, compulsory licensing, rare in any event, was nonetheless expressly limited,

unlike TRIPS, to situations such as “national emergencies of extreme urgency.” Third, restrictions were imposed on the parallel importation of cheap medicines. Fourth, generic companies were restricted in their capacity (allowed under TRIPS) to “springboard” by using brand name data. Finally brand name “evergreening” provisions were introduced that linked pharmaceutical marketing approval for generic medicines with notification to relevant brand name manufacturers and an assessment of their existing patent validity (Oxfam International 2004).

With the AUSFTA, however, GIPP achieved a unique breakthrough. For the first time provisions were included in a bilateral trade deal aimed at facilitating the “elimination of government measures such as price controls and reference pricing which deny full market access for United States [pharmaceutical] products.”¹⁴ The particular reference pricing system targeted here was Australia’s PBS. In a now well-rehearsed tactic, Australian negotiators were told that even the limited promised access to the US manufacturing and agricultural markets would be closed unless the PBS was part of the deal (Drahos and Henry 2004).

The Deputy US Trade Representative (USTR), for example, stated that the AUSFTA was the first US bilateral free trade deal that included:

special provisions addressing market access for pharmaceuticals...[which, to address] Australia will [have to] make a number of improvements to its Pharmaceutical Benefits Scheme...the [AUSFTA] also establishes a Medicines Working Group that will provide a forum for ongoing dialogue on Australia’s system of comparing generics to innovative medicines. (Shiner 2004, 2)

PhRMA through its representatives on a committee called IFAC3, worked closely with US trade negotiators to insert strategically planned articles in the AUSFTA (Drahos et al. 2004, 2). The close industry-government relationship which had been so important in the evolution of GIPP, was evidenced here by the fact that a former Australian government staffer had become the Chief Executive Officer of the Australian version of PhRMA, Medicines Australia (Metherell 2002). Simultaneously, a senior advisor to the former Australian Federal Health Minister, had become a PhRMA advisor on AUSFTA strategies in relation to the PBS (Beaumont 2004).

The GIPP attempt to eliminate PBS reference pricing through the AUSFTA had three major overt strategies. First, under the heading of “transparency” Annex 2C incorporated provisions requiring (under the threat of Chapter 21 trade sanctions) that PBS procedures make it more difficult to refuse to “list” any new pharmaceutical. It created an “independent review” process for decisions of the Pharmaceutical Benefits Advisory Committee (PBAC) not to list submitted medicines. It also increased opportunities for lobbying of PBAC members and established a Medicines Working Group tasked with developing procedures related to the above transparency requirements (Drahos et al. 2004).

Second, the intellectual property chapter (Chapter 17) included provisions facilitating brand name drug patent “evergreening” (Article 17.10.4). This provision required that generic drug market entry be notified to a brand name manufacturer and then indefinitely “prevented” whenever a patent was “claimed” over a brand

name drug. Implementing Australian legislation created a notification process, but also imposed damages when brand name manufacturers used this process to “evergreen” their patents over blockbuster pharmaceuticals. Chapter 17 of the AUSFTA included articles that restricted the capacity of the Australian government to compulsorily license medicines in public health emergencies (Article 17.9.8), export them to deal with such crises in neighboring countries lacking their own manufacturing capacity (Article 17.9.6), or parallel import its cheaper medicines back to the vast US market to the benefit of US citizens (Article 17.9.4). Other provisions locked Australia into expanded brand name patent terms, for example in situations of delayed marketing approval that again went beyond what was required under TRIPS (Article 17.9.8).

Perhaps of most concern for the long-term viability of PBS reference pricing were the interpretive principles at the commencement of Annex 2C. These laid bare some of the core principles of GIPP. Three of them emphasized reward of “innovation” in pharmaceutical development and the fourth stressed an expectation that the respective governments would “recognize” research and development in this area. These principles are more important than might first be thought. The chief strategy employed appears to have involved shifting the emphasis of the PBS from the democratically legitimate norm (having specific constitutional and judicial support) supporting universal access to affordable, essential medicines, toward what may be termed a “corporate lobbying principle” requiring State recognition of pharmaceutical innovation and research and development. The expression “corporate lobbying principle” refers to a norm that, despite its incorporation in a trade deal and subsequent avid promotion amongst bureaucracy and government, has no established basis in systems such as bioethics, public health law, or international human rights. “Recognition of pharmaceutical innovation,” “patent-driven research and development,” “transparency” and “market access,” for example, struggle to satisfy a legal rule of recognition in representative democracies. Bilateral trade deals are one of the most effective means by which such principles can insinuate themselves within the recognized decision making systems and regulatory structures of a democracy and alter the thrust of their respective activities toward facilitating the corporate agenda of maximizing profits and reducing costs.

The operation of such “corporate lobbying principles” in Annex 2C is facilitated by the presence in the AUSFTA of a non-violation nullification of benefits article that specifically covers both chapter two (containing Annex 2C on pharmaceuticals) and Chapter 17 (on intellectual property). This provision, Article 21.2(c), permits dispute resolution proceedings to be initiated where the legitimate expectations of a party (as established, for example, by the interpretive principles at the commencement of Annex 2C) have not been fulfilled. Prioritizing reward of innovation and research and development is a dominant goal of GIPP. It is not a goal of the PBS, which instead has the task under section 101 of the *National Health Act* 1958 (Cth) of comparing new medicines against existing ones in that class so as to facilitate government assistance in pricing only for those drugs that are objectively established as having therapeutic benefit.

Comments made before and after the AUSFTA negotiations indicated that the US saw the PBS strategy in this agreement as a valuable precedent for the implementation of GIPP and elimination of medicines reference pricing systems elsewhere in the world (US Department of Commerce 2004, 7). Australian determination to protect the PBS variant of reference pricing may be an act of global health significance.

GIPP, BIOETHICS AND PUBLIC HEALTH LAW

Throughout this chapter it has been emphasized that one of the most distinctive features the GIPP ideology is its lack of engagement with values and principles of bioethics or public health law. One frequent example, ignored by GIPP, has been distributive justice. John Rawls' philosophy has placed the social virtue of distributive justice at the foundation of those principles and rules which evolve in a democratic legal system to equalize, as far as possible, the basic conditions of life available to each of its citizens. Distributive justice and the international right to health require a society to attempt to reduce the burden of illness in its population and, at this point in time, to do so by ensuring that those citizens have equitable access to affordable, essential medicines (Ruger 2004). It is likely to find expression in a new social responsibility provision of the UNESCO *Universal Declaration on Bioethics* (Berlinguer 2004).

The human right to health has become an important feature of constitutional and international human rights jurisprudence (Leary 1994). At its core, expressed in the *Universal Declaration of Human Rights* (Article 25(1)) and the *International Covenant on Economic, Social and Cultural Rights* (Article 12(1)), as well as other international conventions and constitutional provisions, it obliges a State to make effective use of available resources to at least progressively realize its capacity to fulfill public health responsibilities, including the basic preconditions for health (Toebe 1999). Universal access to affordable, essential medicines is arguably now a core element of the international right to health.

Organizations such as Médecins Sans Frontières view equitable provision of essential medicines to the developing world as a core component of their commitment to concepts of distributive justice and international human rights (Médecins Sans Frontières 2005). They state that what they have witnessed since the inception of TRIPS is not an improvement in access in this area, but a deterioration.

Basic principles of bioethics and health law, that should have been taken into account by documents expressing the GIPP ideology, underpinned many core recommendations of the Millennium Summit in September 2000. The four particularly relevant targets were:

- Target Five, by 2015, reduce by two-thirds the mortality rate among children under five;
 - Target Six, by 2015, reduce by three-quarters the maternal mortality ratio;
 - Target Seven, by 2015 halt and begin to reverse the spread of HIV/AIDS;
- and

- Target Eight, by 2015, halt and begin to reverse the incidence of malaria and other major diseases (Singer and Gregg 2004, 25).

In 2000 the World Health Organization (WHO) estimated that one third of the world's population lacked access to essential drugs, with this figure rising to 50 percent in the poorest parts of Africa and Asia (WHO 2000). According to fundamental principles of bioethics and the international right to health, WHO's Model List of Essential Drugs (those which satisfy the core health care needs of the majority of the population), should be affordable and represent the best balance of quality, safety, efficacy and cost for a given health setting (WHO 2000). No core document of GIPP, however, has seriously addressed such targets or recommendations.

Instead, the proponents of GIPP promote attempts to win public relations kudos by expressing dismay at the public health crises in developing nations, while allowing GIPP to proceed unhindered. One particular example was a paper that allegedly discovered that in 65 developing nations covering a population of four billion, patenting is rare for 319 pharmaceuticals on the World Health Organization's Model List of Essential Medicines. This conclusion was said to justify a more "pragmatic" approach, so that public health policy might concentrate instead on "greater causes of epidemic mortality, which now pose unprecedented threats to global peace and security" (Attaran 2004, 157). Academics generally supportive of PhRMA claimed this data "should squash once and for all demands for compulsory licensing of patented medicines in most poor countries and make largely irrelevant the *Doha Declaration on TRIPS and Public Health* (Bate 2005).

Yet, in South Africa, every three-drug antiretroviral (ARV) cocktail is blocked by patents and most ARV drugs in South Africa are patented. There are four to five million HIV positive persons in South Africa and the economy there has more than 40 percent of the GDP for sub-Saharan Africa. Third, entry into the South Africa market is necessary for generic suppliers to reach the economies of scale (volume) needed for the efficient production.

Studies on the effect of GIPP throughout the period of its evolution consistently suggest it has a deleterious effect on public health. It appears that GIPP has had little positive impact on the level of local medicinal research and development whilst substantially increasing medicines prices in the countries forced to introduce it (Nogues 1990). Kawaura and La Croix showed that GIPP's introduction to Korea substantially reduced that country's wealth (La Croix and Kawaura 1996). Conclusions about the impact of GIPP in developed nations such as Japan (Sakakihara and Bransteeter 1988) and Canada (Pazderka 1999) depend on the extent to which generic pharmaceutical competition is permitted to continue, or be fought for. The evidence is weak that increased patent protection will stimulate additional R&D expenditure in countries introducing it (Deardorff 1992). The welfare costs in India may be substantial (Chaduri, Goldberg and Panle 1993). It appears likely, should it continue, that GIPP will lead to at least a 25 percent increase on global spending on patented drugs, even if China is not taken into account (Lanjouw 1997).

Those US academics whose work supports aspects of what has been described here as GIPP, are now well known (CP-Tech 2005). One of the central components of GIPP ideology is that increased pharmaceutical patent protection and prices are justified because of the high research and development costs and vast promised benefits to health care. For example, DiMasi, Hansen and Grabowski provide (2003) a figure of \$800 million for the total pre-marketing approval cost for each new drug, from work performed at the Tufts Center for the Study of Drug Development (DiMasi, Hansen and Grabowski 2003). PhRMA, under the banner “New Medicines, New Hope,” cites these results to claim that pharmaceutical companies rely on government-granted patents to protect their huge investments in researching and developing new drugs (PhRMA 2005). On the other hand, the US National Institutes of Health financed TB Alliance Report, *The Economics of TB Drug Development*, put the cost at between \$115 to \$240 million, including costs of failures (Global Alliance 2001). Others claimed that the Tufts Center calculations failed to adequately account for the substantial contribution of research from public institutions, the government subsidies and tax subsidies and the disproportionate profits of the industry. Further, the figures made controversial assumptions about capital costs, were averaged and did not accurately relate to specific drugs as no such data exists (Corea 2001, 3).

CONCLUSION

For several decades now, US trade policy has oscillated between multilateral agreements, such as the WTO TRIPS Agreement, and bilateral trade deals, in the pursuit of preferentially protectionist ideological objectives. A key component of these objectives has been the strengthening of global intellectual property protection over allegedly innovative pharmaceuticals owned by US corporations. Critical to this strategy has been the capacity to threaten trade sanctions against GIPP non-complying nations.

By the end of 2005, over 300 bilateral free trade agreements will have been notified to the WTO. They are despised by many respected economists as mechanisms whereby small countries are pressured into accepting special interest provisions of GIPP that actually besmirch the name of “free trade” (Irwin 2005). Such deals appear to be turning the world trading regime into a “dog’s breakfast” of constructive ambiguities and preferentially protectionist intellectual property rules, particularly advancing the corporate agendas of pharmaceutical multinationals. It is a tactic that fragments the coalitions of developing countries on core social justice issues in multilateral trade negotiations, to the public health detriment of their citizens.

One hypothesis is that for the US government to have so aggressively sought to implement GIPP, it must have fundamentally shifted its commitment to normative systems which advocate primacy in policy for the concepts of respect for human dignity and the egalitarian relief of human suffering. These systems, bioethics,

public health law and international human rights, have not been engaged with by GIPP, restricting its credibility and legitimacy.

Indeed, a significant, emerging problem for global public health is that the increasingly dominant GIPP ideology has developed no accepted, intrinsic mechanism for weighing considerations of overall community benefit against its desire to maximize profit. Its central articles of faith continue to propound the ideology that anything interfering with free markets makes them less efficient, and that people are best conceived as suppliers and demanders of commodities at the service of manufacturers and investors. Gestures are periodically made and marketed to show the compassionate side of pharmaceutical multinationals (Wehrwein 2002). Yet, carefully orchestrated displays of strategic pharmacophilanthropy are no substitute for corporate acceptance of routine State restrictions on their profit in the interests of community welfare (Davies 2004). If GIPP continues to undermine the benefits of enhanced global trade by pursuing hegemonic objectives in such negotiations, it may eventually be forced to accept preeminent responsibility (financially and morally) for the global public health crisis it is creating.

What is urgently needed now are coordinated research projects in many nations accurately documenting the health and related regulatory impacts of trade-enforced increased intellectual property rights over innovative pharmaceuticals. Perhaps what is also necessary is for nations with pharmaceutical reference pricing systems, to group together to share research data and regulatory strategies that may foster and advance universal access to affordable, essential medicines as part of a basic commitment to bioethics and international public health. Perhaps they might even begin to include provisions facilitating such collaboration in their own bilateral trade deals, so that any subsequent renegotiation of TRIPS hears the many strong social justice and public health claims in this area.

NOTES

- 1 *Medicare Prescription Drug Improvement and Modernization Act* 2003 (US) para 101 (1860D-11(i) (codified as amended at USC para 1395w-111(j), and also paras 1101 and 1123 and conference agreement. Available at: <http://thomas.loc.gov/cgi-bin/cpquery/?&db_id=cp108&r_n=hr391.108&sel=TOC_2588886&> (Last accessed: 11 February 2005).
- 2 (1980) 448 US 176.
- 3 733 F.2d 858, 221 USPQ 937 (Fed Cir 1984).
- 4 World Trade Organization, Ministerial Declaration, Doha (WT/MIN (01)/DEC/1) US. Available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm (Last accessed: 7 April 2005).
- 5 World Trade Organization, Declaration on the TRIPS Agreement and Public Health (WT/MIN (01)/DEC/2) Available at: <http://www.wto.org/english/thewto_e/minist_e/min01_e/min01_e.htm> (Last accessed: 7 April 2005).
- 6 307 F.3d 1351 (Fed Cir 2002).
- 7 *Madey v. Duke University*, 307 F 3d 1351 (Fed Cir 2002).
- 8 Petition for a Writ of Certiorari at 14, *Madey v. Duke University*, 307 F 3d 1351 (Fed Cir 2002) (No. 02-1007).
- 9 *Medicare Prescription Drug Improvement and Modernization Act* 2003 (US) New 42 USC 1860D-11 (i) as added by section 101 of HR1.

- 10 *Medicare Prescription Drug Improvement and Modernization Act* 2003 New 21 USC 355 (j) (5) as added by section 1101(a)(2)(D) of HR1.
- 11 *Medicare Prescription Drug Improvement and Modernization Act* 2003 New 21 USC 804(1) (1) (a) as added by section 1121 of HR1.
- 12 *Medicare Prescription Drug Improvement and Modernization Act* 2003 21 USC 108-173 as added by section 1123 of HR1.
- 13 *Medicare Prescription Drug Improvement and Modernization Act* 2003 21 USC conference agreement House Report 108-391 Title XI-Access to Pharmaceuticals. Available at: <http://thomas.loc.gov/cgi-bin/cpquery/?&db_id=cp108&r_n=hr391.108&sel=TOC_2588886&> (Last accessed: 11 February 2005); *Trade Act* 2002 (US), 107-210 §2102 (b) (8) (D).
- 14 *Trade Act* of 2002, 107-210, 2102(b)(8)(D).

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