Power, Politics and Pharmaceuticals

Drug Regulation in Ireland in the Global Context

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CHAPTER 2

The Pharmaceutical Industry and the World Trade Organisation's TRIPs Agreement:

Intellectual Property, Global Governance and Health

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Introduction

Throughout the 1980s and early 1990s, the pharmaceutical industry in the United States accomplished a spectacular victory in policy-making that will have profound consequences for public health policy on a global scale. Although the industry was heavily criticised domestically during the 1980s for maintaining inflated prices on prescription drugs, a coterie of pharmaceutical firms successfully campaigned throughout the decade for the US government to adopt the industry's international objectives in the area of intellectual property rights.[1] Their campaign culminated in the signing of the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPs) by contracting parties to the General Agreement on Tariffs and Trade (GATT)[2] in Marrakech, Morocco, on 15 April 1994. The globalisation of intellectual property rights, as embodied in TRIPs, was the most significant change in intellectual property laws enacted in the twentieth century.

This chapter examines why countries ceded sovereignty over an issue as fundamental as the intellectual property laws which determine who gains control of information and technologies. It also assesses the implications of TRIPs for World Trade Organisation (WTO) member states in the area of public health policy.

Intellectual property and TRIPs

TRIPs is one of the three pillars of the WTO and was negotiated during the Uruguay Round of trade talks that took place from 1986 to 1994

under the auspices of the GATT. TRIPs came into being with the establishment of the WTO on 1 January 1995. Under TRIPs all WTO members[3] must introduce legislation that complies with the provisions of the agreement. For many WTO members, the TRIPs agreement has ushered in a period of profound change as a large number of countries have amended their existing legislation or drafted completely new laws pertaining to intellectual property rights.[4]

Intellectual property rights are the rights given to persons over creations of the mind such as inventions, works of art and literature and designs. Intellectual property rights, such as patents, trade marks and copyright, grant the creators of an object an exclusive right over the use of their creation for a certain period of time, usually twenty years. In order for a patent to be granted, the invention must fulfil the criteria of being novel, innovative and useful.[5]

TRIPs was framed with the intention of protecting intellectual property on a global scale by making the practice of intellectual property piracy punishable by a penalty such as economic or trade sanctions in the WTO's Dispute Settlement Understanding (DSU), a body which effectively acts as the WTO's court of arbitration. In July 2007, the WTO consisted of 151 members. If a member state perceives that a fellow WTO member is transgressing its intellectual property rights, the aggrieved party may bring a case to the DSU and seek redress therein. The DSU is a particularly significant development in global governance, as it gives the WTO enforcement powers that its predecessor institution, the GATT, inherently lacked.[6] Under TRIPs, all members must provide a minimum of twenty-year patents on pharmaceutical processes and products. The holder of the patent has exclusive rights to manufacture, sell and distribute the drug during that time-span. At the time of the WTO's inception, the organisation had ninety-eight 'developing' country members. Twenty-five of those countries did not provide any patent protection for pharmaceutical products. Among those developing country members that had such laws in place, the length of patent protection in fifty-six of them was much shorter than twenty years.[7]

Why the necessity for TRIPs?

Rapid changes in technology and transformations in the structure of global capitalism in the 1980s helped to propel the issue of intellectual property rights from what was 'an arcane area of legal analysis and a policy backwater' to the forefront of global economic policymaking.[8]

International trade in goods embodying intellectual property increased substantially with the rapid expansion of knowledge-based industries from the early 1980s onwards. As the USA's comparative advantage began to shift away from industrial manufacturing to high-technology industries such as pharmaceuticals, the protection of intellectual property became a fundamental tenet of the United States' economic foreign policy.[9] Concomitant to profound technological change was the perception among business leaders in many industrialised countries that inadequate protection of intellectual property (IP) in technology-importing countries was detrimental to their competitiveness.[10] This was an argument that found much resonance in the US Congress throughout the 1980s. Despite the fact that trade in counterfeit goods had been ongoing for centuries, the ease with which intellectual property-embodied goods, such as software and pharmaceutical products, could be replicated led to a call for a global IP protection regime.[11]

Barry MacTaggart, the then chairman and president of Pfizer International, first articulated the pharmaceutical industry's frustration with intellectual property piracy with an opinion piece in *The New York Times* in July 1982. In an article entitled 'Stealing from the Mind', MacTaggart accused a plethora of foreign governments of stealing knowledge and inventions that had been generated in the USA.[12] MacTaggart asserted that, as more and more countries strive to industrialise, it is ironic that little or no respect is accorded the laws and principles that helped to bring about industrialisation, particularly in the area of patent protection, for high technology.[13] The Pfizer chairman neglected to relate how the piracy of intellectual property had been pivotal to the industrial development of countries as diverse as the United States, the Netherlands, Switzerland and the 'Tiger' economies of south-east Asia.[14]

The ire of Pfizer and other major pharmaceutical firms was primarily focused on the Indian Patents Act of 1970, which exempted pharmaceutical products from patenting and provided for compulsory licensing, a strategy which allows a government to issue a licence to a domestic manufacturer to manufacture a drug without the consent of the patent holder.[15] Protection of its intellectual property interests is central to the international economic strategy of the United States, as goods embodying IP have been calculated to comprise almost half of its annual exports. However, intellectual property 'piracy' remains an all-pervasive problem. The International Anti-Counterfeiting Coalition (IACC)[16]

calculated in 1993 that the US economy loses about $US200 billion each year and 750,000 jobs annually from piracy.[17] An earlier study into US losses from intellectual property piracy played a seminal role in fomenting political support for what later became the TRIPs agreement.

In 1987, President Reagan commissioned the United States International Trade Commission (ITC)[18] to undertake a study with the aim of quantifying losses to the US economy from intellectual property piracy. Questionnaires were dispatched to affected industries. Firms with an interest in a trade-based approach to intellectual property rights had, according to Susan Sell, 'plenty of incentive to overestimate the losses knowing that the ITC report would be used by politicians and economists in Washington when they debated whether or not IP should become a major issue in international trade negotiations'.[19] The ITC study found that the cost of all intellectual property violations to US industry was between $US43 and $US61 billion per annum. This figure included not only the cost of generic drugs to US pharmaceutical firms, but also copyright violations and trademark infringements.[20] The findings of the study were particularly crucial because they galvanised the attitudes of policy-makers on Capitol Hill who hitherto had been either ambivalent or ignorant in their attitude to intellectual property. The survey acted as a catalyst to precipitate changes in intellectual property law within both the domestic and global spheres.

The pharmaceutical industry was foremost among those high-tech information-based producers that called for changes in intellectual property rules. The ITC study stated that the cost of piracy to ten major US drug manufacturers was almost $US2 billion per annum. The Merck Corporation estimated the annual losses to the US pharmaceutical industry overall at $US6 billion.[21] Global piracy of pharmaceutical products was estimated to reduce annual R&D investment by US firms by between $US720 million and $US900 million a year.[22]

Bringing new drugs to market requires vast research and development resources. Imitating these products once they are in the marketplace by a process of reverse engineering is eminently easy. Reverse engineering is the process of taking a product apart in order to analyse its workings and then constructing a new product based on that knowledge. According to a much-cited 1991 study, a pharmaceutical product that can cost on average $US231 million to bring to market can be copied for virtually nothing.[23] The Pharmaceutical Research and Manufacturers of America (PhRMA)[24] claimed in 1999 that it costs at least half a billion US dollars to bring a

new chemical entity to market.[25] A study conducted by Arnold Relman and Marcia Angell,[26] however, is sceptical of PhRMA's claim. The authors contend that:

> The average out-of pocket, after-tax R&D cost of most of the drugs upon which the [pharmaceutical] industry's revenue now depends was probably much lower than $266 million (in year 2000 dollars). Tax credits for certain types of R&D would probably reduce that estimate even more.[27]

PhRMA's view was that only a stringent legal agreement such as TRIPs would obviate rampant intellectual property piracy and allow its members to plough back profits into R&D. In return for intellectual property protection, the pharmaceutical industry would bring investment and technology transfer to developing countries.[28] PhRMA is one of the world's most politically influential and well-financed industrial lobbies. The organisation employs 297 full-time lobbyists on Capitol Hill – one for every two congressional representatives.[29] One of the primary sources of PhRMA's power is its influence over the Office of the United States Trade Representative (USTR), which has consistently backed PhRMA's claims with the threat of trade sanctions.[30]

Throughout the 1980s, the veracity of the claim that intellectual piracy was undermining profits and R&D sat uneasily with the pharmaceutical industry's phenomenal performance. The dominance by pharmaceutical corporations of the Fortune 500 was reflected in the fact that Pfizer's return on investment was almost double the median return for Fortune 500 companies, while the group's net income rose from $US103.4 million in 1972 to $US800 million by 1990.[31] Nevertheless, policy-makers in Washington were loath to contradict the industry's claims.

In response to the aforementioned ITC study, the US Congress passed the Omnibus Trade and Competitive Act in 1988. This act contained 'Special 301' legislation requiring trading partners of the United States to extend intellectual property protection to US companies. Failure to comply with the Act would render countries subject to tariff retaliation for 'unreasonable' practices.[32] However, the country-by-country approach inherent in 'Special 301' actions was highly inefficient. Firstly, there were too many countries with lucrative pharmaceutical markets to approach individually.[33] Bringing a 'Special 301' action against each recalcitrant state would therefore prove unwieldy. Also, trying to impose economic or trade sanctions on powerful economies such as China for infringements of US

intellectual property was especially problematic in the face of trenchant opposition to such sanctions from the US automobile and other exporting industries.[34] If pharmaceutical companies' intellectual property rights were going to be protected on a global basis, 'some kind of comprehensive agreement would be necessary'.[35] TRIPs fulfilled all the criteria of such a comprehensive agreement.

Creating new norms in intellectual property

PhRMA saw the globalisation of US intellectual property protection standards as the requisite panacea to intellectual property piracy.[36] In order for its argument to sway policy-makers in the US Congress, PhRMA had to formulate a new normative framework on intellectual property rights (IPRs). One of the strategies undertaken in constructing new norms in the area of IPRs was to link the perceived decline in US competitiveness throughout the 1980s with weakly enforced intellectual property rights in developing countries, and especially in the 'dragon economies' of east and south-east Asia.[37]

The expansion of these Asian economies, and that of Japan in particular, during the 1980s began to erode the industrial foundations of the United States and was seen as a portent of US decline.[38] Public myths were constructed in the US about the provenance of Japan's phenomenal growth. According to one commentator, 'American ideas, American know-how were being stolen by the Japanese, it was widely believed. The trade surplus that Japan had with the US became a rallying cry for protectionist elements within the United States.'[39] When representatives of US intellectual property interests arrived on Capitol Hill in the mid-1980s to relate their grievances, they not only encountered bipartisan congressional sympathy, but also a hardened resolve among policy-makers to stymie America's economic decline by placing the issue of intellectual property rights within a multilateral body with a powerful enforcement mechanism.[40]

Placing intangible intellectual property rights, a concept synonymous with monopoly privileges, within an organisation committed to trade liberalisation, such as the WTO, would require turning this maxim on its head and instead equating the protection of intellectual property with the precepts of the free market. As Edwin J. Prindle of the US Patent Office stated, 'patents represent the best and most effective means of controlling competition. They occasionally give absolute command of the market, enabling their owners to name the price without regard to the cost of

production.'[41] Edmund Pratt of Pfizer continuously stressed that it was necessary to demonstrate to governments abroad that protecting foreign intellectual property was in their enlightened self-interest. The framework successfully promoted by the pharmaceutical industry, that patent protection would lead to greater free trade, economic growth, investment and technology transfer to developing countries, became 'the normative building block of the TRIPs Agreement'.[42] The fundamental reason for embracing intellectual property rights, according to Pratt, was not simply to comply with GATT or WTO rules or avoid trade sanctions, 'but to provide a base for the extension of liberal democratic principles that can lift economies and better lives'.[43]

The formation of two business groupings, the International Intellectual Property Alliance (IIPA) in 1984 and the Intellectual Property Committee (IPC) in 1986, was critical in ensuring that the outcome of the Uruguay Round of trade talks was satisfactory to corporate interests. The IPC, which consisted of thirteen large US corporations such as Pfizer, Merck, Johnson & Johnson, Bristol-Myers and Dupont, set about establishing a global private sector/government network that would lay the ground for what became TRIPs.[44] The IPC's primary achievement was convincing US government officials to take a tough stance on intellectual property issues in trade negotiations. This led to the issue of trade-related intellectual property rights being included on the GATT agenda when negotiations began in Punta del Este, Uruguay, in 1986.[45]

In order to secure a deal on intellectual property in the Uruguay Round, negotiators from the US, European Community and Japan had to make certain trade-offs, but even these reflected the great asymmetries of power in the global political economy. Conditions that exist in order for democratic bargaining to take place, namely full representation, full information and non-coercion, were excluded from the TRIPs negotiations and resistance within the GATT to the agreement becoming part of the new WTO was eradicated.[46] The so-called 'Green Room' procedure was often invoked during TRIPs deliberations, whereby the GATT director-general consulted in confidential surroundings primarily with the major trading powers of the 'Quad', namely the USA, Canada, Japan and the European Community. The findings of this group were then presented to the more formal GATT meetings, effectively as a *fait accompli.*[47]

While the TRIPs deliberations were taking place, PhRMA lobbied policy-makers in Washington to ensure that the North American Free

Trade Agreement (NAFTA) between the USA, Canada and Mexico contained stringent intellectual property provisions. Mike Privatera, public affairs director of Pfizer Inc., stated at the conclusion of the talks: 'The Mexicans gave us everything we wanted.'[48] The TRIPs agreement represented a failure of democratic processes, both nationally and internationally, as a tiny clique of knowledge-based companies was able to capture the US trade agenda-setting process and draft intellectual property principles that were to become the template for TRIPs.[49] Curiously, as Susan Sell writes, 'despite the fact that the TRIPs deliberations focussed on policies that affect virtually everyone on the planet, the GATT Secretariat received no complaints from consumer groups at the time of the negotiations'.[50] The TRIPs agreement came into being on 1 January 1995 with a virtual whimper. Reaction to the agreement only began after its implementation, when the profound implications of TRIPs for public health were assessed. TRIPs moved from being purely a 'trade-related' issue to one of access to life-saving medicines.[51]

Implications of TRIPs

Price is not the only determinant of access to essential medicines. Other vital factors which need to be addressed by policy-makers include providing a well-functioning and efficient healthcare infrastructure, comprehensive reach, adequate medical supplies and the presence of well-trained medical personnel.[52] Nevertheless, price remains a primary component in determining whether people live or die. For this reason, the Indian Drug Manufacturers Association (IDMA) predicts that a 'national health disaster' is imminent with the introduction of the TRIPs agreement.[53] Under TRIPs it is inevitable that twenty-year patents will lead to either monopolistic or oligopolistic practices, with only a tiny coterie of firms controlling the supply and market prices of drugs. As a result, competition will be stymied and prices of medicines will inevitably increase.

A critical examination of the retail prices of drugs in thirty-nine countries around the world by Williem Pretorius suggests that the guiding principle which the pharmaceutical industry adopts when fixing prices is 'to charge what the market can bear'.[54] In most countries of the South, this may result in companies adopting a high-price, low-volume strategy aimed only at those with the ability to pay (as was the case in India prior to the introduction of its 1970 Patents Act). Elsewhere, charging what the market

can bear entails a low-price, high-volume strategy aimed at the bulk of the population. The Delhi-based National Working Group on Patent Laws undertook a comparative study in 1993 which contrasted the price of drugs in India with countries that have patent protection for pharmaceuticals. The findings of the group showed that in several cases drug prices in India were forty-one times lower than those in countries that provided patent protection. Since TRIPs provisions relating to the patenting of pharmaceutical products and processes were implemented in India in 2005, generic pharmaceutical manufacturers are restricted from reverse engineering patented drugs until the twenty-year patents on such drugs expire.

The pharmaceutical industry lobbied successfully for the uniform patent period of twenty years before and during the Uruguay Round. This duration is highly contentious. An optimal patent period should always reflect a balance between the rules of appropriation and the rules of diffusion by providing an incentive to innovate on the one hand and an opportunity to capture benefits on the other. One eminent economist describes the twenty-year patent duration as 'a period so long that few economists of repute can be found who would call it efficient in terms of balancing the two opposing forces [of appropriation and diffusion]'.[55]

Jayashree Watal, Counsellor in the Intellectual Property Division of the WTO, in a study undertaken in 2000, demonstrated how prices of generic medicines in India would rise by at least 26 per cent after the full implementation of TRIPs in 2005. In her study, Watal also verified that the price of patented drugs would rise by between 200 and 300 per cent from 2005 in India.[56] An International Monetary Fund (IMF) survey on the possible consequences of TRIPs highlighted that annual welfare losses to India could range from $US162 million to $US1.26 billion, while the annual profit transfer to foreign firms based in India would be between $US101 million and $US839 million.[57]

The groundbreaking 1970 Indian Patents Act, which did not allow the patenting of pharmaceutical products, was emasculated in order to conform to TRIPs. Indian negotiators to the GATT, who viewed TRIPs as a process befitting the country's programme of economic liberalisation that was initiated in 1991, cannot be exonerated from blame. S. P. Shukla, Indian ambassador to the GATT from March 1984 to February 1989, characterised the Indian capitulation on TRIPs as 'The Geneva Surrender'.[58] India provides a salutary example of how even a powerful developing country can cede sovereignty over its laws governing property rights in pharmaceuticals. The multilateral framework embodied in the

WTO, while allowing for bargaining between members, has, on the issue of TRIPs, disproportionately favoured exporters of intellectual property, with potentially calamitous consequences.

TRIPs-related cases

The TRIPs agreement is liable to have profound implications for national sovereignty, particularly in the area of health policy. While the Doha Declaration on Public Health of 2001[59] allows for the issuing of a compulsory licence in the case of a national medical emergency or threat to public health, test cases illustrate that the issue is laden with complexity and ambiguity. The remaining options for WTO members to circumvent the stringencies of TRIPs include compulsory licensing and/or parallel importation. Although the option of compulsory licensing is permitted under TRIPs, only a few technologically advanced developing countries, such as India and Brazil, have the necessary facilities to undertake the production of generic pharmaceuticals.

Countries without manufacturing facilities for pharmaceutical products can gain access to lower-priced drugs produced in other developing countries, or by generic manufacturers in some developed countries, by using parallel importation. This tactic allows a government to sanction the importation of pharmaceutical products when the price being charged by the patent holder in that jurisdiction is higher than the price being charged elsewhere.[60] Balasubramaniam[61] states that the analysis of empirical data 'supports the position that compulsory licensing and parallel imports are two regulatory tools that should be included in the national legislation of all developing countries'.[62] The cases documented below highlight how the use of parallel imports and compulsory licensing, despite their legality under TRIPs, are still liable to opprobrium.

The cases of South Africa, Brazil and the anthrax crisis of 2001 in the USA highlight how flexibilities within TRIPs can be utilised to implement public health policy in those respective countries, but also serve to illustrate that concessions in the arena of intellectual property rights must be fought for assiduously.

In November 1997, the government of South Africa amended its Medicines Act to allow it to undertake parallel importing and compulsory licensing in order to help it combat the country's burgeoning HIV/AIDS crisis. This would allow the South African government to purchase antiretroviral drugs from a third country instead of buying them from pharmaceutical firms within South Africa. Under TRIPs, this provision

applies only to patented drugs and not to generics. The South African government's amendment was immediately subject to a lawsuit by thirty-nine pharmaceutical firms on the grounds that it breached the obligations South Africa had agreed to under TRIPs. In April 2001, the case was withdrawn in Pretoria by the pharmaceutical companies primarily on account of the bad publicity concerning the case that was generated by groupings such as Treatment Action Campaign, Medicins Sans Frontières and Oxfam.[63] The South African case elucidated how, even when a country adheres to the provisions of TRIPs, it can still become subject to a legal challenge citing a breach of WTO rules. This also proved to be the case with the Brazilian government.

In March 2001, the Brazilian Health Ministry announced that it would issue compulsory licences to local producers in order to manufacture generic copies of two antiretroviral drugs used in the treatment of HIV/AIDS unless Merck and Roche – the patent holders of both drugs – agreed to substantial price decreases. The cost of purchasing both drugs was absorbing half the Brazilian government's AIDS budget. Local producers estimated that they could produce both drugs at half the import price.[64] International pharmaceutical companies had threatened to withdraw investment if the Brazilian government did not remove its threat to use compulsory licensing in order to alleviate the crisis.[65] Under direction from PhRMA, the USA brought a WTO case against the Brazilian government. The suit challenged the latter's attempt to issue a compulsory licence in order to help counter a public health crisis. The case generated such negative publicity that Merck and Roche agreed to drop the prices of their patented antiretrovirals and the United States Trade Representative (USTR) withdrew the complaint against Brazil. Nevertheless, the US government did not concede on the substance of the issue and stressed that it would deal with the issue bilaterally, while Brazil agreed to consult with the USTR over possible future use of its compulsory licensing laws.

The South African and Brazilian cases illustrate the pressures that countries can be subjected to even when their legislation is in compliance with TRIPs. As Brazil and South Africa are advanced developing countries and, to a certain extent, regional powers, the cases against them generated levels of publicity that helped them overcome their respective TRIPs-related crises. Countries lacking the financial resources and political influence of both Brazil and South Africa may incur greater problems in resisting coercion.

The TRIPs agreement contains provisions in Article 31 which allow WTO members to use the subject matter of a patent without the authorisation of the rights holder in certain cases, such as a national emergency or 'other circumstances of extreme urgency or in cases of public non-commercial use'.[66] The USA found itself facing such an emergency in October 2001 when anthrax spores dispatched by post killed a number of its citizens and threatened to cause a major health crisis among a public still convulsed by the 9/11 terrorist attacks. For USA trade officials, the anthrax crisis provoked a dilemma. With a WTO Ministerial Conference due to be held in Doha, Qatar, in November 2001, the USA did not wish to be perceived as malleable regarding patent rules.

Nevertheless, the anthrax deaths provoked the US Secretary of Health and Human Services, Tommy Thompson, to threaten Bayer AG, the producer and patent holder of the anti-anthrax antibiotic ciprofloxacin (Cipro), that if the corporation did not lower its price significantly he would disregard its patent and issue a compulsory licence to domestic manufacturers.[67] Under a 1918 national security law, Thompson had the power to grant a compulsory licence to allow domestic manufacturers to produce generic Cipro to increase the government's dwindling back-up supply of the drug. In response to this threat, Bayer rescinded and dropped the price of Cipro that it had hitherto supplied to the US government by half. Bayer agreed to supply 300 million ciprofloxacin tablets to the US government at the drastically reduced price of 95 cents per tablet, a move which effectively averted the anthrax crisis. This gesture by Bayer served to undermine the US government's position on the sanctity of patents in the lead up to the crucial WTO Ministerial Conference which took place in November 2001 in Doha, Qatar.

The stance taken by the US on the anthrax crisis stressed not only the flexibilities of the TRIPs agreement, but how the US was willing to jettison its standpoint at international level on intellectual property to cope with a domestic crisis.

The US government can be readily eulogised for acting in the public interest when its population was under threat from bio-terrorism. Nevertheless, when Brazil sought to ameliorate its devastating HIV/AIDS crisis utilising the same tactics – i.e. the use of a compulsory licence – it was excoriated by the USTR and threatened with a case against it at the WTO. In the run-up to the Doha WTO Ministerial Conference, and with the anthrax crisis ongoing, the USTR sought to block proposals that would clarify rules to allow developing countries to issue compulsory

licences during a public health crisis.[68] The reach of the USTR's power is highly extensive, not only in developing countries. It was also seen to great effect in dealings with the Irish government throughout the late 1990s.

Ireland and TRIPs

The threat of taking a fellow member before the WTO's dispute settlement panel has proven to be a highly effective means of enforcing TRIPs. Despite the often supine stance taken by successive Irish governments in relation to United States' foreign policy, Ireland was the subject of a TRIPs-infringement case brought against it by President Clinton's United States Trade Representative, Charlene Barshefsky, in 1998. The case related to the Irish government's failure to enforce TRIPs provisions, which allowed the copyright of US software producers and filmmakers to be violated with virtual impunity.

With trade sanctions a very realistic possibility, the Irish government committed itself in February 1998 to adopting a bill that would ameliorate the most apparent TRIPs deficiencies in Irish law by July 1998. As a consequence, the USTR decided to withdraw its case against Ireland. The case did highlight, however, that the US government is capable of enforcing its power by the threat of coercion and is symptomatic of how TRIPs can be used as an effective means of enforcing what John Ikenberry and Charles Kupchan have termed 'socialisation through external inducement'.[69] It was somewhat ironic that Ireland was cited for copyright infringement in a global forum, as the first recorded instance of a judgement on copyright can be traced back to sixth-century Celtic Ireland, when An Breitheamh Diarmuid ruled that Saint Columba had infringed Brehon law by plagiarising the Latin Psalter of Saint Finian of Clonard. Diarmuid's decree that 'as to every cow its calf, so to every book its copy', set the precedent for copyright law worldwide.[70]

Present-day Ireland deposited its ratification of the WTO agreement, together with the annexes thereto, on 30 December 1994 and became an original member of the WTO on 1 January 1995, the date on which the TRIPs Agreement entered into force. Generally, ratification of a treaty or convention or agreement by a state constitutes the consent of that state to be bound by their respective provisions. While it had been deemed flagrant in its stance on software and video piracy, successive Irish governments have been loath to take any standpoint inimical to the interests of the pharmaceutical industry in the area of intellectual property rights. This perspective is perhaps reflective of the fact that sixteen of the

top twenty pharmaceutical companies in the world have established facilities in Ireland and that the Irish pharmaceutical industry consists of 120 companies, which employ more than 24,000 people.[71]

As intellectual property rights are regarded as fundamental to the development and progress of the pharmaceutical industry, Ireland is considered a safe location for investment, not least due to its TRIPs-compliant patent laws. Indeed, when TRIPs came into force in Ireland in January 1995, Irish patent law was already compatible with the agreement: Dáil Éireann had passed the Irish Patents Act on 27 February 1992 and Ireland was a signatory to the European Patent Convention of 1973, both of which rigorously protect the intellectual property of innovators. Provision is made for compulsory licensing in the 1992 Act that allows a government minister to use 'Inventions for the Service of the State'.[72]

The Irish government can issue a compulsory licence to a domestic manufacturer in the case of a national health emergency or 'for the maintenance of supplies and services essential to the life of the community'. However, Article 31(c) of TRIPs prevents the commercial use of a drug for which a compulsory licence has been issued and stipulates that products made under compulsory licensing must be 'predominantly for the supply of the domestic market of the Member authorising such use'.[73] This provision has profound implications for countries that do not have manufacturing capacity and need to import generic drugs, and for WTO members such as Brazil that export generics to other developing countries. Due to the opprobrium generated by Article 31(f) of TRIPs, the WTO agreed to relax this provision in August 2003. Countries that are unable to manufacture medicines required in an emergency or other circumstances of extreme urgency may now import generic copies made under compulsory licence subject to certain conditions. Consequently, any WTO Member may export generic medicines made under compulsory licences to meet the requirements of importing countries.

While all WTO members may import generic medicines *in extremis,* twenty-three 'developed' countries within the WTO, including Ireland, voluntarily declared that they would not avail of this new, relaxed provision. Fifteen of the twenty-three countries are European Union (EU) members. The EU has consistently adopted the US stance on intellectual property, never better exemplified than when the European Commission recommended in September 2002 that it saw 'no reason' to amend the highly contentious Article 27.3(b) of TRIPs, despite the vociferous objections of many developing country representatives.[74]

Ireland's ability to influence EU policy in the area of intellectual property rights was further eroded with the passing of the second Nice Treaty referendum by the Irish electorate in October 2002. Article 133 of Nice transfers competence for the negotiation of issues pertaining to intellectual property to the European Commission. National ratification of intellectual property agreements is no longer required as the EU Council of Ministers will in future decide whether the EU enters a final agreement on the issue. Prior to Nice, voting on intellectual property agreements was subject to unanimity within the EU, which meant that a single EU Member State had the power to block any agreement. Since the ratification of Nice, the issue of intellectual property is decided by qualified majority voting.[75] This aspect of Article 133 of the Nice Treaty severely limits the competence of national governments with regard to intellectual property negotiations and hands enormous powers to the EU Trade Commissioner in WTO negotiations.

Conclusion

Perhaps the most curious aspect of the TRIPs agreement is that it has transformed intellectual property from an area of esoteric analysis by trade lawyers into an issue of pivotal importance in both the global knowledge economy and the developmental strategy of individual nation states. Nowhere is this highlighted more than in the issue of access to essential medicines.

The pharmaceutical industry achieved a remarkable feat by creating new norms in a form of monopoly privileges (i.e. intellectual property) that were inserted into an organisation (the WTO) whose primary aim is the liberalisation of trade. A small coterie of knowledge-based companies was effectively able to enact public law for the rest of the world by linking transgressions of intellectual property rights around the globe with declining US competitiveness and inducing policy-makers and the office of the United States Trade Representative to accept this normative frame.

Nevertheless, the victory of the pharmaceutical industry in bringing TRIPs within the WTO has since been undermined by the global HIV/AIDS crisis, which has provoked a backlash against the industry's stance on intellectual property rights. TRIPs does contain flexibilities such as compulsory licensing and parallel importation to help counter public health emergencies. However, attempts by two powerful developing countries, South Africa and Brazil, to avail of these provisions have been greeted with reproach by PhRMA. The continued use of unilateral

'Special 301' legislation by the United States to counteract piracy acts as a huge disincentive to countries to avail of TRIPs' flexibilities.

The use of so-called 'TRIPs-plus' measures have also undermined the public health safeguards permitted to WTO members in TRIPs. Since the adoption of the TRIPs Agreement, the Clinton and Bush administrations have negotiated numerous bilateral and regional trade agreements that have imposed such 'TRIPs-plus' intellectual property rules on other WTO members. As a result, patented medicines have even higher levels of intellectual property protection than required in TRIPs, a tactic which has delayed the availability of affordable generic medicines. This trend is symptomatic of the Bush administration's tendency to use bilateral and regional agreements to enforce TRIPs rather than utilising the multilateral trade mechanisms in the WTO. For example, while the Clinton administration filed fifteen cases with the WTO from 1996 to 2000 charging other WTO members with violations of US intellectual property, the Bush administration had filed only one intellectual-property-related case with the WTO between 2001 and September 2004.[76]

The ability of WTO member states to avail of the flexibilities within TRIPs will determine if the agreement is to achieve a balance whereby innovators can be rewarded without diminishing accessibility to essential medicines. If the TRIPs agreement fails to achieve this balance, and the WTO ignores the varying exigencies of its member states, the provisions within TRIPs pertaining to public health are likely to provoke even greater opprobrium and discord in the future.