

Intellectual Property as an ‘Investment’ in International Law: A Case of Access to Medicines versus Access to Justice?

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What is a ‘global wrong’? To a lawyer, the word ‘wrong’ entails something more than just the existence of a situation in which someone may have suffered an undeserved misfortune, even if it was one for which someone else might be said to be factually responsible or morally liable. There must be some kind of legally recognised cause of action in favour of a particular claimant and against an identifiable defendant, justiciable before an appropriate and competent tribunal, with some possibility of redress for the victim or retribution against the wrongdoer. Likewise, the ‘global’ element suggests that the wrong in question should transcend national borders and legal systems, whether in respect of its supranational incidence or by violating rules which constitute part of the global legal order, or both.

Supposing the existence of some kind of (global) wrong, then what about remedies and procedures? For present purposes I propose to examine one particular scenario from one of two different and very contradictory viewpoints, with the proviso that I am not offering any definitive conclusions on either the legal or the philosophical merits of the case for either side. It is simply that the case for one side quite readily lends itself to a kind of globalisation and privatisation of procedure and remedies, whereas the other does not.

This article is concerned with patents, and the identification of patents as ‘intellectual property rights’ is by no means trivial. That the owner of a patent has a bundle of ‘rights’ in some relevant legal sense is both self-evident and uncontroversial. However, the period since negotiations for TRIPs¹ began in 1986 has seen a major change in the rhetoric of such rights. As Robert Weissman comments²:

Characterizing patent protections as a kind of intellectual property ‘right’ was a first step in setting the terms of debate. This characterization is of course not novel; patents, trademarks, and copyrights have long been viewed as intellectual

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¹ The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakech, 1994).

² Weissman, R (1996) ‘A Long, Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Developing Countries’ 17 *University of Pennsylvania Journal of International Economic Law* 1068.

property rights. ... Nor is the characterization, from a legal standpoint, startling or at all surprising. Lawyers commonly understand that the holders of government-authorized powers have 'rights,' without attaching any particular moral force to the term.

In the debate over international patent policy, however, the use of the term 'right' exercised an important influence. As a preliminary matter, it is important to recognize that while 'rights' may be commonplace in legal discourse, the allocation or recognition of a right may nonetheless privilege certain actions or relations. Characterizing something as a right tends to immunize it from challenge both in practice and in the realm of ideas. To transgress a right is to 'violate' it, to commit a wrong. To define something as a right is to remove it, more or less, from political challenge. Even if it is not considered a 'natural' right; in moral terms, a right is supposed to be somewhat inviolate.

PATENTS AND COMPULSORY LICENCES: THE SCENARIO

The power of states to issue compulsory licences under patents which they have granted is regulated on a global basis by two international conventions, the Paris Convention of 1883-1967³ and the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) of 1994. The latter is supplemented by the so-called 'Doha Declaration' of 2001 and the corresponding 'Doha Decision' of 2003.⁴ All these instruments quite expressly contemplate the grant of compulsory patent licences, in particular for medicines needed to meet national emergencies such as the AIDS crisis, so it is difficult to conceive of an objection to such licences in principle. But now imagine a state in which compulsory licences were granted by the dozen, at the whim of a civil servant and at a derisory level of royalties; that the relevant patents were not for life-saving remedies needed locally but for so-called 'lifestyle medicines' which could be profitably exported; that the licensees were friends and cronies of the minister; and that there was no possibility of an independent and impartial judicial review of either the original decision to grant the licence or its commercial terms.

Even without knowing the substantive law of Paris, TRIPs and Doha, there is more than enough here to set alarm bells ringing, not only under the specific provisions of the various agreements⁵ but also in terms of general public international law. However, if there is no prospect of effective and unbiased judicial review in the domestic legal system of the state in question, then any aggrieved patent proprietor will have to look for redress elsewhere, and very probably in an international forum. The breaches of general public international law would be justiciable before the International Court of Justice, as would breaches of the Paris Convention, but only at the suit of a member state with locus standi, and in practice this is an option which need only be mentioned to be rejected.⁶

³ The Paris Convention for the Protection of Industrial Property (Stockholm, 1967).

⁴ Declaration on the TRIPs agreement and public health, adopted on 14 November 2001 (WT/MIN(01)/DEC/2); Implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and public health, Decision of the General Council of 30 August 2003 (WT/L/540 and Corr1).

⁵ See below n 8.

⁶ Art 28 of the Paris Convention confers jurisdiction on the International Court of Justice, but it is optional, many states have entered reservations and it has never been relied on in practice.

Rather more attractive is the possibility of a complaint to the Dispute Settlement Body of the World Trade Organisation (WTO DSB), and once again this would have to be brought by a friendly state party, although the rules of locus standi are considerably more flexible.⁷ The WTO DSB has international jurisdiction over breaches of TRIPs and over breaches of the Paris Convention, insofar as the latter is incorporated into the former.⁸ However, there is a gap in jurisdiction, in that the WTO DSB almost certainly lacks jurisdiction to entertain the claim under customary public international law as such⁹; and (more seriously and somewhat surprisingly) TRIPs does not expressly deal with the ownership of intellectual property rights at all, and is consequently something of a dead letter when it comes to dealing with their expropriation.¹⁰

More attractive than either of these, if the possibility is a real one, is that of invoking international investment law, under which the patent proprietor might, it seems, bring a complaint in its own right against the expropriating state before the International Centre for the Settlement of Investment Disputes (ICSID),¹¹ and obtain full compensation for the expropriation. This very much depends on the expropriating state being party to an appropriate kind of treaty (typically a 'Bilateral Investment Treaty' [BIT]) with the state of which the aggrieved party is a national, and on a number of issues which are currently unresolved. If viable, however, this possibility seems to combine a global theme, insofar as international treaties and customary international law provide the standard by which the rightness or wrongness of the respondent state's conduct is to be adjudged, and private law, insofar as the ICSID jurisdiction and procedure very much resembles an ordinary international commercial arbitration between private parties, except that only the claimant is a private party, with the respondent being a state.

CASE 4183/98 IN SOUTH AFRICA

A brief account of one case from South Africa may help to put the scenario in perspective. On 18 February 1998, the Pharmaceutical Manufacturers' Association of South Africa and about 40 of its individual member companies filed suit¹² against the South African Government to nullify as unconstitutional certain provisions of the Medicines and Related Substances Control Amendment Act 1997,¹³ which would (in effect) have empowered the Government to substitute cheap imported generic medicines for expensive patented ones.

⁷ Understanding on Rules and Procedures Governing the Settlement of Disputes (Marrakech, 1994).

⁸ TRIPs art 2(1) obliges WTO members to comply with relevant obligations under the Paris Convention. TRIPs art 64 provides that arts XXII and XXIII of GATT 1994, and the Dispute Settlement Understanding, apply to disputes arising under TRIPs, with an exception not relevant here. The WTO Appellate Body has adjudicated claims under Paris Convention provisions incorporated into TRIPs, as well as provisions native to TRIPs itself: Appellate Body Report, *United States—Section 211 Omnibus Appropriations Act of 1998*, WT/DS176/AB/R, adopted 1 February 2002, DSR 2002:II, 589.

⁹ The jurisdiction of the Dispute Settlement Body is defined by reference to the 'covered agreements', which are those attached to the Marrakech 'Final Act' of 1994: Dispute Settlement Understanding, art 1.

¹⁰ *United States—Section 211 Omnibus Appropriations Act of 1998* supra n 8.

¹¹ Established by the Convention on the Settlement of Investment Disputes between States and the Nationals of Other States (Washington, 1965).

¹² As Case 4183/98 in the High Court of South Africa, Transvaal Provincial Division. There is no official report of the case, which settled before trial, but the Originating Notice of Motion may be found at www.cptech.org/ip/health/sa/pharmasuit.html.

¹³ No 90 of 1977.

Specific complaints of the plaintiffs were that the legislation, once implemented, would enable the Government to expropriate the plaintiffs' intellectual property without any provision for compensation¹⁴; and that it was discriminatory and contrary to the WTO TRIPs Agreement.¹⁵

The 1997 legislation was general in its coverage, but the pharmaceutical companies' resistance to it was particularly controversial in relation to South Africa's AIDS epidemic, and especially so after a lobby group for AIDS sufferers, the Treatment Access Campaign, was allowed to intervene as an *amicus curiae* on 8 March 2001.¹⁶ In the face of intense international opprobrium the pharmaceutical companies all but admitted defeat, and amid much rejoicing they formally abandoned their case on 19 April 2001.¹⁷

So the good ended happily, and the bad unhappily? Well, perhaps not. In the immediate aftermath of 19 April it may have seemed so, but in the longer term there is little enough cause for rejoicing and plenty of cause for concern. The first concern is simply that the settlement of the litigation seems to have done little or nothing for the South African AIDS sufferers. Nelson Mandela had been succeeded as President in 1999 by Thabo Mbeki, according to whom AIDS could be treated or prevented with garlic, lemon juice and beetroot, or avoided entirely by attention to personal hygiene. As for the HIV virus, the party line was that AIDS had nothing to do with HIV, which was simply a scare-story invented by the foreign pharmaceutical companies to frighten people into buying their hugely expensive and completely ineffective anti-retroviral drugs.¹⁸ This was not the best platform from which to enact a programme for access to the self-same anti-retrovirals as essential medicines.

The second concern is for the rule of law. The pharmaceutical manufacturers had let their case drag on for more than three years, before joinder of the Treatment Access Campaign — or the imminence of trial — galvanised everyone into action, which rather suggests that the litigation was part and parcel of a long-term political campaign against the 1997 Act, rather than a genuine attempt to redress legitimate grievances or challenge the legitimacy of the Act once and for all. Why then did so many lobbyists, foreign governments, NGOs, trade unions and their assorted supporters so vocally insist that the pharmaceutical companies should be shamed into dropping their claims, as if trial of the issues raised by the plaintiffs was a disaster to be avoided at all costs? Surely, it would have been better all round to have waited a few months for an authoritative judicial determination of just how much scope for action the Government really enjoyed, whether as a matter of municipal or international, law?¹⁹ Perhaps it was the imminent prospect

¹⁴ Notice of Motion supra n 12 para 2.3.

¹⁵ Id para 2.4.

¹⁶ See www.cptech.org/ip/health/sa/TACfoc.html.

¹⁷ BBC News Online, Thursday, 19 April 2001, 'Drugs firms drop Aids case', <http://news.bbc.co.uk/1/hi/world/africa/1284633.stm>. For an index to further news reports (some with broken links) see www.cptech.org/ip/health/sa/press04192001.html; as well as www.cptech.org/ip/health/sa/pharma-v-sa.html for other reports and comments.

¹⁸ Cullinan, K and Thom, A (2009) *The Virus, Vitamins and Vegetables: the South African HIV/AIDS Mystery* Jacana.

¹⁹ A highly relevant comparison might be made with the decision of the Constitutional Court in *Minister of Health and Others v Treatment Action Campaign (No 1)* (CCT8/02) [2002] ZACC 16; 2002 (5) SA 703; 2002 (10) BCLR 1075, holding that the policy of restricting the use of the anti-retroviral nevirapine for the prevention of mother-to-child transmission of HIV to a limited number of 'test sites' was unconstitutional, and ordering the government to remove the restrictions and make nevirapine available unconditionally.

of losing badly on the merits that explained why the pharmaceutical companies were so quick to withdraw their claim when the going got tough?

In this particular instance, we need not shed too many tears for the pharmaceutical companies themselves: like masters of the martial arts they chose the right moment to step back by a few inches, and their opponents collapsed in a heap in front of them. But the rule of law requires that litigants — no matter how unpopular or undeserving — should have their day in court, where their rights and obligations should be determined by the voice of reason, not by the clamour of the multitude.

Of course this South African case was a pure example of public law litigation in a national forum, involving the sort of judicial review of the constitutionality of legislation which has been commonplace in the United States for over two centuries and which will soon be increasingly familiar in the United Kingdom. It was not strictly global in any sense other than TRIPs compliance. However, it was certainly global in the extent of the interest and opposition it aroused, and in the issues it raised, one of which was the compatibility of the proposed amended law with the all-but-global TRIPs Agreement. In another sense it raised the question of whether a litigant uncertain of receiving a fair hearing under the normal public law procedures of the national courts could bypass the problem — and perhaps secure some collateral advantages — by invoking a competent global jurisdiction or private law procedures, or both. This will lead us in due course to a more detailed consideration of potential procedures and remedies on the international plane, in particular under the WTO Dispute Settlement Understanding which is directly relevant to TRIPs, and, more speculatively, to examine the jurisdiction of ICSID under the ICSID (or Washington) Convention.²⁰ But first, some more substantive law.

THE GLOBALISATION OF LAWS

The globalisation of laws has a very long history. Here, I am concerned with the interrelationship between four rather disparate bodies of law which have some claim to global status, and their application to this particular situation.

Intellectual Property

My own specialist field is intellectual property law. Nothing flows more easily, under the right conditions, than ideas and information, and the laws of intellectual property protection have been the subject of progressive globalisation since the early 19th century. In the first phase, intellectual property rights were sometimes included in bilateral commercial treaties, such as early treaties of friendship, commerce and navigation. A second phase was characterised by bilateral treaties dealing with intellectual property specifically, but this phase was superseded in the late 19th century by the adoption of the first of two (prospectively) global intellectual property conventions, in the form of the Paris Convention of 1883.²¹ This governed patents, trade marks, designs and other so-called

²⁰ *Supra* n 11.

²¹ *Supra* n 3.

'industrial property rights' and was complemented from 1886 by the Berne Convention, dealing with copyright.²²

The Paris and Berne conventions attracted new members and were revised at more or less regular intervals during the 20th century, until the process broke down in about the 1980s, principally as a result of the increasing polarisation between capitalist and socialist economies on the one hand, and the developed and developing worlds on the other. From this deadlock there emerged the most recent milestone in the globalisation of intellectual property laws, namely the WTO TRIPs Agreement of 1994.²³

The International Law of Human Rights

Next, there is the international law of human rights, which plays a somewhat ambivalent role in this analysis.²⁴ On the one hand, there is the protection of property in human rights law: 'Since property is an inviolable and sacred right, no one shall be deprived thereof except where public necessity, legally determined, shall clearly demand it, and then only on condition that the owner shall have been previously and equitably indemnified.'²⁵ The right to property in general has been reasserted many times since 1789. The recognition of intellectual property as a specific form of property enjoying the status of a human right is more recent and not so unequivocal, but it is well established, whether in specific treaty language, by interpretation or by usage.²⁶ On the other hand, the very nature of intellectual property rights — or at least those, such as patents, which are granted by the state — means that the rights in question are far from absolute. They may be, to varying degrees, contingent, revocable and discretionary.²⁷

While rights talk may have the general effect in legal discourse of elevating the defined conduct or relationship above politics, that effect was particularly strong in the case of patent policy. The vociferous insistence of industry and the US government assumed a moral character. This was an especially notable accomplishment in light of the intangible nature of intellectual property. Additionally, intellectual property is more obviously a creation of the state than other sorts of property and hence it intuitively enjoys less of a moral right. At the practical level, one does not receive a patent until an invention is certified by the state as new, useful and non-obvious. This makes it unusually clear that the state could choose not to grant the right at all. At the conceptual level, patent rights evaporate after a set period. Governments may grant patents for longer or shorter periods, on conditions, or not at all. The

²² Berne Convention for the Protection of Literary and Artistic Works (Paris, 1886-1971). The global nature of these conventions may be demonstrated by the number of member states: Paris 173, Berne 164.

²³ *Supra* n 1. For a recent overview of the process, see Yu, P (2009) 'The Global Intellectual Property Order and its Undetermined Future' *WIPO Journal* 1.

²⁴ See generally, Torremans, P (ed) (2008) *Intellectual Property and Human Rights* Kluwer Law International.

²⁵ Declaration of the Rights of Man (1789), art 17.

²⁶ That intellectual property rights-holders do indeed have 'human rights' in respect of their creations is all too easily ignored, but it is founded on art 27(2) of the Universal Declaration of Human Rights (UDHR), and art 15(1)(c) of the International Covenant of Economic, Social, and Cultural Rights (ICESCR); not to mention art 17(2) of the Charter of Fundamental Rights of the European Union. See eg Yu, P (2007) 'Reconceptualizing Intellectual Property Interests in a Human Rights Framework' 40 *UC Davis Law Review* 1039.

²⁷ Weissman 'A Long, Strange TRIPs' *supra* n. 2 at 1087.

characterisation of an inventor or producer's intellectual property interest as a 'right' works to obscure the contingent nature of the patent.

A very different kind of 'human right' is the right to health, and, ultimately, life itself.²⁸ From this point of view, the continuing prevalence of lethal epidemics such as AIDS, malaria and TB, especially in poor countries such as sub-Saharan Africa, is not only a human tragedy but a breach of human rights. But if there is to be more than a breach of 'human rights' in some abstract sense, then one must identify the relevant legal rule which is the source of these rights and their corresponding obligations, whether in customary international law or in a specific legal instrument such as a treaty or statute. In international law, the main sources are likely to be article 15 of the UDHR, article 12(1) of the ICESCR and article 24 of the Convention on the Rights of the Child. As an example of a rule derived from municipal law, reference may be made again to the South African case *Minister of Health and Others v Treatment Action Campaign (No 1)*,²⁹ in which the Government's conduct was held to have contravened articles 27 and 28 of the South African Bill of Rights.

Finally, for present purposes, there is the right of access to the courts, and of fair process.³⁰

Customary Public International Law

For completeness, one should also briefly mention customary public international law, especially insofar as it deals with the protection of the property of foreign citizens against unlawful expropriation. But it is unnecessary to go into detail here, as the relevant principles are well known and are embodied in the various BITs with which this article is principally concerned.

The Law of International Investments

The other specialist area of law which this article will address is international investment law. Here, the state of play is rather different from that for intellectual property, though the starting point is very similar, insofar as the commercial treaties of the 19th century frequently provided some kind of basic legal protection for foreign investment on a bilateral basis. However, the move from bilateral to global (or at least multilateral) treaties — which for intellectual property began with the Paris and Berne conventions of 1883 and 1886, and proceeded throughout the 20th century — never happened for international investment law. There was an ambitious but unsuccessful attempt to negotiate a multilateral agreement on investment through the OECD in the mid-1990s, but it proceeded no further than a consultation draft.³¹ Investment protection had previously been on the agenda for the Uruguay round of negotiations which resulted in the establishment of the World

²⁸ Hestermeyer, H (2007) *Human Rights and the WTO: the Case of Patents and Access to Medicines* Oxford University Press.

²⁹ *Supra* n 19.

³⁰ Art 10 UDHR; art 13 International Covenant on Civil and Political Rights.

³¹ The Multilateral Agreement on Investment: Draft Consolidated Text (DAFFE/MAI(98)7/REV1 of 22 April 1988). See also Gervais, D and Nicholas-Gervais, V (1999) 'Intellectual Property in the Multilateral Agreement on Investment: Lessons to be Learned' *Journal of World Intellectual Property* 297.

Trade Organisation in 1994, but the only outcome was the Agreement on Trade-Related Investment Measures, which is so unassuming as to be almost trivial.

In the absence of a multilateral agreement on investment or an effective equivalent to the Agreement on Trade-Related Investment Measures, bilateral (and in some cases regional) alternatives have flourished. What one might call the 'classic' BIT is a short and simple document which is relatively consistent in international usage, despite the absence of an agreed international precedent or any relevant global treaty regime, and despite the number of different national variants in use. Briefly, the classic BIT³² protects foreign 'investments' against expropriation by the host state, and guarantees 'fair and equitable treatment' to foreign investors. These are the principal substantive obligations, and they are the ones with which I am principally concerned here. The standard United Kingdom BIT (or IPPA) may serve as an example.³³

If that were all, then it might be objected that the typical BIT did no more than to reduce to paper what are already well-known and widely accepted principles of customary public international law. In fact, the true significance of the typical BIT lies in its procedural provisions. From the point of view of the investor state and its nationals, the most advantageous provision is for the host state to agree to submit to binding arbitration at the suit of aggrieved (private party) investors at the ICSID, which is affiliated to the World Bank.³⁴ If ICSID arbitration is considered too much of a concession, then there is typically provision for arbitration under specific institutional rules, such as UNCITRAL.

The Present State of Play: 'Classic' and 'Trojan' BITs

Somewhat ironically, the latest phase in this brief composite history of intellectual property and investment protection takes us back two centuries to the days of frock coats, powdered wigs, and treaties of friendship, commerce and navigation. It is marked by the emergence (or re-emergence) of two categories of bilateral or regional agreement: the traditional bilateral 'free trade agreement', previously thought to have been rendered extinct by globalisation, and a category which lacks (but very much needs) a name of its own, and which I propose to call the 'Trojan international investment agreement (IIA)'.

Whereas the 'classic' BIT or IIA is very much a one-trick pony, the 'Trojan' or 'viral' variety contains considerably more than the acronym implies, and what it contains may not be entirely innocuous. Without necessarily aspiring to the ambitions of a full 'free trade agreement', the Trojan IIA typically contains obligations of substantive law which have nothing to do with free trade or investor protection in the usual sense, but which further other commercial interests on the agenda of the investor state.³⁵ Highest of all on

³² BIT stands for Bilateral Investment Treaty. IPPA is Investment Promotion and Protection Agreement, the preferred UK form, and BIA is Bilateral Investment Agreement. Others are FTAs (Free Trade Agreements) and IIAs (International Investment Arrangements), the latter being a generic term for all of these. The number of BITs and IIAs in existence runs into thousands, with the UK being party to well over 100: for general background information see www.bilaterals.org/.

³³ For the UK model IPPA, see the UNCTAD IIA Compendium at www.unctad.org/sections/dite/ia/docs/Compendium/en/69%20volume%203.pdf

³⁴ *Supra* n 11.

³⁵ See UNCTAD, IIA Monitor No 1 (2007) Intellectual Property Provisions in International Investment Arrangements (UNCTAD/WEB/ITE/IIA/2007/1).

the list of interests to be propitiated are those modern devotees of the Goddess Athena, the corporate owners of intellectual property rights, whether real or imagined.

To this extent, these Trojan IIAs belong to the category of regional or bilateral 'TRIPs-plus' agreements, so called because the parties to them agree to accept and implement intellectual property norms which are more onerous than those to be found in TRIPs itself, or to abandon flexibilities which TRIPs permitted.

Most of what has been written on the relationship between international investment law and intellectual property,³⁶ particularly in the context of access to medicines,³⁷ concerns these Trojan IIAs, and, in particular, their tendency to reduce or eliminate derogations and exceptions which were expressly permitted under the Paris and TRIPs regimes. Without wishing to challenge that line of argument, the present article addresses an entirely different issue, in so far as it is concerned almost entirely with 'classic' BITs, and with provisions which are only incidentally relevant to intellectual property.³⁸

THE AIDS PROBLEM AND LEGAL RESPONSES TO IT

Access to Medicines

States and individuals affected by the AIDS pandemic need access to effective medicines, in particular anti-retrovirals, most of which are still under patent. As the international prices for patented medicines are typically higher than what states would like to pay, and perhaps higher than they are able to afford, the obvious solution is to find a company ready, willing and able to supply the medicines in question at a much cheaper price, and grant it a compulsory licence under the relevant patents, with a royalty being payable to the patent proprietor in compensation.

Under the Paris Convention regime as it prevailed from 1883 until the adoption of TRIPs in 1994, member states retained almost complete autonomy in formulating and applying policies for intellectual property protection in the medical field. In principle, the Paris Convention did not even require states to have any patent system, though in practice all did. More importantly, Paris did not require patents to be available for any particular category of inventions, and in more than a few member states medicines were not patentable at all. This was not necessarily a rational or enlightened exercise of the legislative function, since in at least some of these cases the prohibition dated back to times when travelling quacks like Donizetti's Dr Dulcamara peddled their (hopefully)

³⁶ Correa, C (2004) 'Bilateral Investment Agreements: Agents of New Global Standards for the Protection of Intellectual Property Rights?' available at: <http://www.grain.org/briefings/?id=186>; Drahos, P (2000) 'BITs and BIPs, Bilateralism in Intellectual Property' *Journal of World Intellectual Property* 791; Mercurio, B (2006) 'TRIPs-Plus Provisions in FTAs: Recent Trends' in Bartels, L and Ortino, F (eds) *Regional Trade Agreements and the WTO Legal System* Oxford University Press.

³⁷ Matthews, D (2005) 'TRIPs Flexibilities and Access to Medicines in Developing Countries: the Problem with Technical Assistance and Free Trade Agreements' 27 *European Intellectual Property Review* 420; Lin, T-Y (2009) 'Compulsory Licenses for Access to Medicines, Expropriation and Investor-State Arbitration under Bilateral Investment Agreements – Are There Issues beyond the TRIPs Agreement?' 40 *International Review of Intellectual Property and Competition Law* 152.

³⁸ Literature specifically dealing with the possible status of intellectual property rights as an 'investment', and on the consequent relevance of BITs and other IIAs, is less plentiful; but see Drahos 'BITs and BIPs' supra n 36; UNCTAD, IIA Monitor No 1 (2007), supra n 35; Lin 'Compulsory Licenses' supra n 37.

innocuous and (invariably) inefficacious nostrums to ignorant peasants, and legislators understandably recoiled from endorsing these impostures with the dignity of a patent.

Elsewhere (as in Germany, for instance) inventions in the pharmaceutical field might be protected only as processes, or (as in the United Kingdom) be subject to a specific compulsory licensing regime. India entered the post-Colonial period with a Patents Act on the British model, but curtailed patent protection for pharmaceuticals as a deliberate instrument of policy in the 1950s in order to encourage an indigenous generic chemical industry, as did Canada too.

The TRIPLe Whammy

One of the most important items on the agenda of the TRIPs negotiators was to require pharmaceutical inventions to be protected on the same terms as any others,³⁹ and this was achieved by TRIPs article 27(1). Another item of almost equal importance was to reduce, compared to the Paris Convention, the circumstances in which compulsory licences of patents could be awarded. In particular, TRIPs article 31(f) provided in respect of all uses not authorised by the right-holder: 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'. There were other provisions requiring, inter alia, that each authorisation should be considered on its own merits (so no blanket authorisations); that negotiations with the right-owner were to precede the authorisation, except in cases of national emergency; that the scope and duration of the use were to be limited to the purpose for which it was authorised⁴⁰; and so on. TRIPs also provided for independent judicial review of the original decision to authorise the use, and the terms of compensation.⁴¹

At first sight the compulsory licensing provisions which TRIPs still permitted should have been more than adequate to deal with emergencies such as the AIDS pandemic. Indeed, the mere possibility of a compulsory licence being granted might have been thought to place the state in a sufficiently strong negotiating position vis-à-vis the rights-owner, as seems to have been the case when the United States decided to stockpile millions of doses of Bayer's patented antibiotic ciprofloxacin against the perceived threat of an anthrax attack by Al-Qaeda.⁴²

However if this analysis were true at all, then it was really only relevant for developed countries with sufficient internal manufacturing capacity to produce the necessary medicines for their own consumption, since TRIPs explicitly forbade compulsory licensing for manufacture for export,⁴³ and there were few countries (if any) which had the necessary manufacturing capability but which were not members of the WTO.⁴⁴ This meant that the combined Paris-TRIPs regime was manageable for the internal needs of the likes of India,

³⁹ Sell, S (2003) *Private Power, Public Law: the Globalisation of Intellectual Property Rights* Cambridge University Press.

⁴⁰ Respectively art 31(a), (b), (c).

⁴¹ Art 31(i) and (j).

⁴² BBC News Online 'America's anthrax patent dilemma' 23 October 2001, <http://news.bbc.co.uk/1/hi/business/1613410.stm>].

⁴³ Art 31(f).

⁴⁴ At any rate, not after the accession of China to the WTO, on 11 December 2001.

China, and the major South American and South-East Asian countries which were rapidly emerging from developing into developed status.

The countries which felt the triple-whammy effect of TRIPs worst were those where AIDS was endemic but which lacked a sufficiently advanced industrial base to manufacture appropriate medicines for themselves. If the relevant medicines were patented locally (which was not always the case) then those countries could, at least in principle, issue compulsory licences for local production for local consumption, supposing local manufacture to be possible in practice. But for undeveloped countries local manufacture of advanced pharmaceuticals was (and is) simply not an option. Those countries could issue compulsory licences to import, but according to the territorial nature of patents, a licence to import into one country could not confer a corresponding right to manufacture in another country. So could a compulsory licence to import be matched with a corresponding compulsory licence to export from a country whose pharmaceutical industry was sufficiently developed to manufacture for export, such as India or Canada? No, because TRIPs expressly prohibited just this possibility.⁴⁵

The Doha Declaration

The supposed solution to this state of affairs was the so-called Doha Declaration of November 2002, together with a package of formal and informal measures taken to implement it. In general terms, Doha contained a reassertion of priorities and flexibilities which were already inherent in TRIPs, and gave a pro-health 'steer' to the interpretation of certain fundamental terms, such as what constituted a national emergency. To that extent, Doha involved a political realignment of the interpretation and application of TRIPs, rather than any derogation from it.

Where Doha did depart from TRIPs was over the problem of licensing exports. Here, it provided something which was entirely lacking in TRIPs, namely a legal mechanism for matching compulsory licences in undeveloped importing countries with ones in developed countries which had the capacity to manufacture and export the medicines needed at the scene of the emergency.⁴⁶ The system may be illustrated by the arrangements for the supply of 260,000 packs of the composite anti-retroviral TriAvir from Canada to Rwanda. Rwanda's notification pursuant to paragraph 2(a) of the Doha Declaration was recorded by the WTO on 19 July 2007,⁴⁷ and contained a declaration by Rwanda of its intent to import 260,000 packs of TriAvir⁴⁸ over two years, to be manufactured by Apotex, Inc in Canada. The corresponding declaration by Canada was dated 8 October 2007,⁴⁹ and contained as an annex an authorisation from the Canadian Commissioner of Patents dated 19 September 2007, permitting Apotex to manufacture for export to Rwanda 15,600,000

⁴⁵ Art 31(f).

⁴⁶ See the Doha Declaration and Decision, *supra* n 4, as well as Rott, P (2003) 'The Doha Declaration – Good News for Public Health?' *Intellectual Property Quarterly* 284; Matthews, D (2004) 'WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?' 7 *Journal of International Economic Law* 73; Abbott, F and Reichman, J (2007) 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions' 10 *Journal of International Economic Law* 921.

⁴⁷ IP/N/9/RWA/1.

⁴⁸ A fixed-dose combination product of zidovudine, lamivudine and nevirapine.

⁴⁹ IP/N/10/CAN/1.

tablets of a fixed dose combination of the three active components, which required licences under no fewer than nine Canadian patents.⁵⁰

And that is as far as it goes. There is no other known case of the Doha mechanism being invoked.⁵¹

TRIPs versus ICSID

So far, this discussion of the AIDS problem has concentrated on the needs of developing countries and their populations, who cannot afford to pay market rates for imported patented anti-retroviral medicines. But there is another point of view, which is that the owners of intellectual property rights, such as patents, have rights too. These rights may be put at various levels of ambition and abstraction, but at the very least they include the right not to have their 'property' expropriated without adequate compensation, fairly determined. They are also entitled to expect compliance with the specific provisions of the Paris Convention and the TRIPs Agreement, except to the extent that those provisions may have been changed by agreement or over-ridden by legal principles of greater force.

Moreover, and whatever the social, medical, political and economic merits of the Doha Declaration (and these seem to lessen with familiarity), there are certain purely legal objections which can be taken against it, or which at least deserve further investigation.⁵² First, there is the question of whether the relevant parts of the Doha Declaration had (and were intended to have) legal effect, or were they merely political? If they were intended to be legally effective, then were they intended to take effect by way of treaty amendment, binding interpretation, waiver or what? And in any of those cases, did the relevant and necessary powers exist, were the correct procedures followed, or (if not) with what consequences? Finally, might individual member states have gone beyond what Doha contemplated, or beyond what it was actually effective to authorise?

To revert to the scenario contemplated at the start of this article, suppose, if only for the sake of argument, that the Doha Declaration (if and insofar as it purports to authorise the expropriation of private property) constitutes or contemplates a breach of international law; or, rather more plausibly, that individual member states of the WTO may have purported to apply it in a manner which is non-compliant with international law, whether the law in question is to be found in the Paris Convention, TRIPs, customary international law or a relevant Bilateral Investment Treaty.

What then are the options for any aggrieved intellectual property right-holders? Many of these issues might be litigated under the WTO dispute settlement system as it applies to TRIPs. Taken as a whole, they seem to raise issues of TRIPs compliance which are at

⁵⁰ Nos 2,311,988; 2,070,230; 2,068,790; 2,286,126; 2,216,634; 2,105,487; 2,059,263; 2,009,637 and 2,030,056. It may be noted that Rwanda does not appear to have issued any compulsory licences itself, presumably because there were no corresponding patents in its territory.

⁵¹ See www.wto.org/english/tratop_e/trips_e/public_health_e.htm (where notifications are recorded); as well as Andemariam, S (2007) 'The Cleft-Stick between Anti Retroviral Drug Patents and HIV/AIDS Victims: an In-depth Analysis of the WTO's TRIPs Article 31 bis Amendment Proposal of 6 December 2005' *Intellectual Property Quarterly* 414; Paas, K (2009) 'Compulsory Licensing under the TRIPs Agreement — a Cruel Taunt for Developing Countries?' 31 *European Intellectual Property Review* 69.

⁵² See Rott 'The Doha Declaration' *supra* n 46; Gathii, J (2002) 'The Legal Status of the Doha Declaration on TRIPs and Public Health under the Vienna Convention on the Law of Treaties' 15 *Harvard Journal of Law & Technology* 291.

least arguable, and the global pharmaceutical industry is not noted for sleeping on what it claims as its rights, or for lacking influence to bring to bear on governments when only they can act on its behalf.

This would be necessary, because so far as injured private parties are concerned, TRIPs does not even attempt to deliver direct access to the WTO dispute settlement system. Parties are still dependent on 'diplomatic protection', and in particular on persuading a friendly government to take up their case. States, however, think in different terms from private litigants. They quite naturally rank national interest above purely private interests, and industries above individual firms. They tend to look to the future for improvement, rather than redressing the wrongs of the past. States, even within the WTO, tend to favour negotiation over litigation, and this is consistent with the philosophy of the WTO itself. The pharmaceutical industry as a whole can probably live with this state of affairs, and there is every indication that it pursues a similar long-term agenda. But what about individual complainants?

What a private party wants is simply stated: a tribunal with all the usual virtues of simplicity, speed, low cost and suitable expertise; direct access to that tribunal without time-consuming or discretionary preliminaries such as the need to request 'diplomatic protection'; compulsory jurisdiction over states, with the tribunal having competence to determine its own jurisdiction and little or no opportunity for states to delay or challenge; no sovereign immunity; and, finally, readily enforceable money judgments to compensate for past state misconduct. Oh, and (with the South African experience very much in mind) secrecy of proceedings would be nice, too.

Is all this possible, or even any of it?⁵³ The underlying problem is that international law exists on an entirely separate plane from private law, and the two planes are never supposed to meet. Treaties such as Paris, Berne and TRIPs exist on the plane of public international law, so that the rights and obligations they create arise between states, and only between states. Private parties have no locus on this plane. Their rights and obligations are typically created by the transposition of treaties like these into domestic law (whether by legislation, executive action or under a doctrine of direct effect); but TRIPs (at least) is uniformly considered to lack direct effect, and in any event the paradigmatic situation with which this article is concerned is that of a state failing to observe relevant international norms in its domestic law and practice.

In the literature of fantasy, if one wants to travel instantaneously from one world to another one looks for what is called a 'portal': a magical gateway between worlds, like the wardrobe in CS Lewis's *Narnia* stories. In cosmology the equivalent is a 'wormhole'. In the legal world there is indeed a portal or wormhole between the public international law of states and the private law of persons, and it is fast becoming almost as well trodden as H Street, Washington DC, which (as it happens) is precisely where the traveller through this particular space-time anomaly will emerge. One need only say the magic word: 'ICSID'.

ICSID is the International Centre for the Settlement of Investment Disputes. It was established by treaty in 1965,⁵⁴ has over 140 members⁵⁵ and is attached to the World Bank,

⁵³ Though all these desiderata (and more) are precisely what is offered at ICSID, there is the proviso that ICSID deals only with 'investment' disputes and not with intellectual property in general.

⁵⁴ *Supra* n 11.

⁵⁵ <http://icsid.worldbank.org/ICSID/Index.jsp>, and follow link to 'About ICSID'.

hence the Washington address. There is an enormous body of learning on ICSID, and what immediately follows can barely scratch the surface, since it is confined to what is strictly necessary to understand the role which might be found for it in translational intellectual property disputes between a state as respondent and a private party who can invoke its jurisdiction.

This jurisdictional 'wormhole' is the principal attraction of ICSID to private litigants, insofar as they can sue defaulting states directly, in a neutral and investor-friendly forum, without having to invoke the assistance of their home state, and without the defendant state having much wriggle-room to evade jurisdiction or escape liability. However, there is a second 'wormhole effect' which relates to the substantive law applicable to the claim. Normally, the separation between private and international law would mean that a private party could not invoke treaty provisions (or other favourable provisions of public international law) owed by the defendant state to the private party's home state, except to the extent that they had been transposed into private (municipal) law, whether by legislation or by a doctrine of direct effect. However BITs frequently contain provisions for national treatment and most-favoured-nation treatment, as well as what is called an 'umbrella clause', under which a mixture of public law and private law obligations owed by the host state to the investor may be justiciable at ICSID.

So at both the procedural and substantive levels, ICSID is unique (or very nearly so) insofar as it provides a permanent institution and standing procedures for adjudicating complaints by private parties against member states. In complete contrast to the normal Westphalian system of laws, ICSID permits travel between the world of public international law and state actors, and the separate world of private law, private rights and private actors. So far, so good, at least as far as potential claimants are concerned. However, the 'I' (whether in BIT or ICSID) stands for 'investment', not for 'intellectual property', and it remains to be seen whether, or to what extent, any given BIT, or the ICSID Convention itself, applies to intellectual property rights.

The ICSID Convention is deliberately open-ended as to what may constitute an 'investment',⁵⁶ and although there does not appear to be any (published) case law directly in point, there seems no reason to exclude intellectual property from the category of investments, in limine. Each individual BIT must, of course, be interpreted separately, according to its own terms and context, though certain generalisations can usefully be made. Definitions of 'investment' in BITs are typically open-ended, and may (in many cases) expressly include intellectual property, either generically or by a seriatim recital of nominate intellectual property rights. For example, the model UK IPPA⁵⁷ reads:

Article 1 (Definitions)

- (a) 'investment' means every kind of asset and in particular, though not exclusively, includes: ...
- (iv) intellectual property rights, goodwill, technical processes and know-how; ...

This is not to say that all intellectual property rights are to be regarded as 'investments' in all circumstances and for all purposes, but rather that intellectual property rights may be

⁵⁶ ICSID Convention, *supra* n 11, art 25.

⁵⁷ *Supra* n 33.

a kind of 'asset'; and that where they have the necessary characteristics of an 'investment' then they are to be protected as such, in the same way as more familiar kinds of asset (in this context) such as shares, securities, debentures, concessions and so on.

Continuing with the standard UK IPPA, article 2 provides for 'fair and equitable treatment' and 'protection and security' of investments made by nationals or companies of the opposite party; while article 3 provides for national and most-favoured-nation treatment. The provisions of article 4 relating to compensation in the event of war, insurrection, riots etc are not immediately relevant, but article 5 (expropriation) is significant, in providing that investments of nationals (or a company) of a contracting party are not to be nationalised or expropriated, or subjected to measures having equivalent effect, except for a public purpose related to the internal needs of the expropriating party, on a non-discriminatory basis, and against prompt, adequate and effective compensation. The person affected is to have a right under the internal law of the expropriating state to an independent (but not necessarily judicial) review of its case and of the valuation of the investment.

Finally (for present purposes) article 8 of the UK model IPPA provides for reference of disputes to ICSID (as the preferred option), or to international arbitration.

A CASE OF 'WORK IN PROGRESS'

This article has tentatively suggested that intellectual property is capable of being an 'investment' for the purpose of a particular Bilateral Investment Treaty (depending on both the proper interpretation of the relevant BIT, and the investment-like character of the intellectual property in question or the absence thereof); that as such, the intellectual property investments of nationals of one contracting party are to be protected against illegal nationalisation or expropriation by the other party, as well as measures having equivalent effect; that expropriation is prohibited unless it is non-discriminatory, and for a public purpose related to the internal needs of the appropriating state; that the former owner is entitled to prompt, adequate and effective compensation, with a right of judicial review; and finally (again depending on the terms of the precise BIT in question) that an aggrieved or dissatisfied private party may pursue a claim for compensation before ICSID or another appropriate tribunal.

I appreciate that these are propositions which have merely been asserted rather than proven with academic rigour, and that even if they are to be taken as read, then many questions still remain. Under what circumstances does intellectual property count as an 'investment' in a particular host state? What constitutes 'nationalisation or expropriation', and what are 'measures having equivalent effect'? In particular, does the issue of compulsory licence(s) amount to some kind of expropriation (or its equivalent), either in general or in certain circumstances (such as the imposition of a nominal royalty)? More generally, how does one value the patent or invention, and ascertain the appropriate level of compensation? To add to these complexities, one may have to look well beyond the terms of any individual BIT, because provisions for national and most-favoured-nation treatment and any 'umbrella clause' can potentially have the effect of incorporating relevant obligations from other sources of law, perhaps quite unexpected ones.

A CAUTIONARY NOTE

After delivering the oral version of this paper, I became aware of an article by Tsai-Yu Lin of the Department of International Business, Soochow University, Taiwan.⁵⁸ Professor Lin identifies three particular reasons why state-state dispute settlement should be preferred to investor-state arbitration in the present context. First, compulsory licences and access to medicines involve wide-ranging public policy issues which are inappropriate for highly specialised tribunals such as ICSID, or even for the WTO DSB itself, with its predisposition to decide cases according to rather narrow considerations of trade and intellectual property policy. Secondly, ICSID (and other investment-oriented tribunals) have no institutional experience in intellectual property law.⁵⁹ Finally, the law of investor-state arbitration typically places the (private) rights of the foreign investor above the public interests of the host state, and has no adequate mechanisms for taking those public interest factors into account. Overall, Professor Lin concludes⁶⁰:

With the proliferation of BIAs [Bilateral Investment Agreements], the legal risks associated with the expropriation rules and investor-state arbitration are collaterally rising, and expose developing countries to more potential litigation by pharmaceutical corporations grounded on the reason for the grant of compulsory licenses for access to medicines. It has been shown that entering into BIAs with developed countries in pursuit of foreign investment would not be without cost to developing countries; sometimes it will be at the cost of public health in certain emergencies.

Compulsory licenses might potentially amount to indirect expropriation provided that their effects constitute a severe curtailment of the patent rights. Inasmuch as the expropriation standards in BIAs differ from those articulated under the TRIPS Agreement, particularly in the focus of due process and compensation requirements, the ability of developing countries to make use of compulsory licenses at the WTO level might be reduced, which is an area that needs to be constantly observed. Also, regarding the arbitral procedure, it is of much value from the public health perspective that an investor-state arbitration structure could pursue a balanced reform between private investment and public policy, notwithstanding some difficulties that might arise. In view of wider public implications and the very nature of health-related compulsory licenses, it is a matter for deliberation whether an ultimate return to state-state dispute settlement, rather than investor-state arbitration, would be more feasible to settle disputes under BIAs in the future.

⁵⁸ Lin 'Compulsory Licenses' supra n 37.

⁵⁹ Although this could be addressed by the appointment of suitably qualified arbitrators, as could the previous objection.

⁶⁰ Lin 'Compulsory Licenses' supra n 37.

BACK TO THE BEGINNING

As for the issue of TRIPs compliance in South Africa, with which we began, according to the chief executive of one pharmaceutical company⁶¹:

Under the terms of the settlement the South African government has confirmed that its new law will be implemented in a way compliant with the international Trade-Related Intellectual Property Rights Agreement (Trips). In doing so, it has affirmed the need for strong intellectual property protection consistent with international agreements and the underlying importance of intellectual property protection as an incentive to innovation. Put simply, intellectual property is not an obstacle to access.

At the time, this may have seemed like nothing more than a particularly barefaced attempt at presenting a brave face to adversity, but the historical record suggests otherwise. Since 2001, South Africa has consistently failed to utilise even the original inbuilt flexibilities of TRIPs, let alone those of the Doha Declaration, and it in fact operates a de facto TRIPs-plus patent regime.⁶² Rather than having a once-and-for-all determination of the rights and wrongs of the pharmaceutical manufacturers' case in open court, which might have set the scene for the Doha Declaration, we have instead a situation in which the pharmaceutical industry has successfully withdrawn from public and global negotiating fora such as the WTO and WIPO, only to pursue the same agenda behind the scenes, and on a country-by-country basis, through so-called Free Trade Agreements and Bilateral Investment Treaties.

⁶¹ Press release: 'GlaxoSmithKline welcomes the settlement of industry association litigation against the South African Government' 19 April 2001, www.gsk.com/press_archive/press_04192001.htm.

⁶² See Roumet, R (2010) 'Access to Patented anti-HIV/AIDS Medicine: the South African Experience', 32 *European Intellectual Property Review* 137.