PRIVATE RIGHTS VS PUBLIC INTERESTS IN THE TRIPS AGREEMENT: THE ACCESS TO MEDICINES DISPUTE

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The conflict over the impact of the TRIPS agreement's global minimum standards for protection of intellectual property (IP) rights on access by poor people to essential medicines starkly dramatises key issues at the heart of the emerging constitution of the international economic order.

The aim of the WTO is to establish a `rule of law' for the global economy, but law is in many ways the pursuit of politics by other means. It does not embody inherent standards of fairness, and indeed the WTO's rules have been accused in an Oxfam report last year of being `rigged' against the poor. The WTO can't claim legitimacy merely because it acts through law, if the processes for making and applying those laws lack transparency, responsibility, and accountability to the public. The WTO's complex system of agreements and regulations are made and administered by unelected technocrats, whose activities are occasionally given political approval by semi-informed trade ministers. Further, when law is used to define and enforce economic rights, it can reinforce the rights of the economically strong, the haves against the have-nots. In particular, the protection of private IP rights will produce gains for those with the power to appropriate the results of innovation and creativity, and reduce the diffusion of knowledge and cultural products by increasing the costs of access to those without such power.

The most visible aspect of the WTO's legalization is its powerful Dispute Settlement (DS) mechanism, which may offer weaker states some protection against arbitrary acts and economic pressures from the powerful. However, use of the DS has been dominated by strong states, especially the US and the EU, who have the resources to make selective use of complaints in accordance with their broader trade strategies. Ruth Okediji[1] has suggested that this strategic use of DS will mean less certainty and uniformity in IP law, while for developing countries the uncertainties and cost may make it harder to make adequate use of the degree of flexibility or `wiggle room' afforded by TRIPS. While the access to medicines campaign resulted in withdrawal of the US complaint against Brazil's law permitting compulsory licensing on grounds of failure to work patents locally, the US can still challenge such measures, although of long standing in many countries and compatible with the Paris Convention, as contrary to TRIPS article 27 despite the exceptions allowed in articles 30 and

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[1] Ruth Okediji, *TRIPS Dispute Settlement and the Sources of (International) Copyright Law* , J. Copyright Soc'y U.S. 585 (2001).

31, which have certainly been interpreted narrowly by the WTO Panel report in *Canada Pharmaceuticals*.[2]

Perhaps more importantly, the WTO is at the centre of a complex system to manage the process of deregulation and reregulation of international markets. Neo-liberalism claims that WTO obligations do not restrict a state's right to regulate, provided it does not discriminate in favour of domestic firms. However, the experience under GATT was that any regulatory differences are seen as an obstacle by foreign firms seeking access to a market, so national regulations must be justified by stringent criteria, in particular the `least-trade-restrictive' test.

The WTO agreements therefore entailed a shift towards international harmonization of regulation, by requiring states to adopt internal regulations based on international standards. Unsurprisingly this has made the WTO the focus of debates and conflicts about globalization. This raises three main issues for the WTO as an institution: (i) the `linkages' between the WTO and related regulatory regimes (especially standard-setting bodies); (ii) the tension between uniformity and appropriate diversity inherent in the slippery concept of harmonization; and (iii) the accountability, transparency and responsibility of the WTO as a public institution.

The `linkages' issue has been mainly associated with the debate about the `social clause', in which it has been widely asserted that the ILO, not the WTO, is the appropriate body for labour standards; equally, WIPO should be the relevant body for IPRs, and the WHO for health. For good global governance, these bodies should work together harmoniously and in the public interest. A particular problem is that WIPO's aim is to promote IP protection, which it pursues by enhancing harmonization and effective enforcement of IPRs, and it has been dominated by those favouring stronger protection. This tends to neglect the important balance between private rights and the public interest in the definition of IPRs, especially for developing countries. Hence, the Commission on Intellectual Property Rights set up by the UK's Department for International Development, last year recommended that it might be necessary to amend WIPO's articles to ensure it addresses this crucial question of balance. In the meantime, developing countries must continue to press that the TRIPS agreement should allow states to decide for themselves the appropriate balance between appropriation and diffusion inherent in the definition of IPRs.

This will pose problems, however, as long as the WTO, in this instance the Council for TRIPS, continues to see its role as imposing `disciplines' on states, to ensure that their IP laws meet high minimum standards of protection. Developing countries also face double jeopardy, in that TRIPS is treated as a minimum standard, and has not so far protected them against bilateral pressures from the US and the EU, egged on by the industry lobbies, for TRIPS-plus standards of IP protection.

Developing countries won a valuable partial respite in the Declaration on TRIPS and Public Health agreed at Doha in November 2001. This reaffirmed the right of countries to make use of the flexibility offered by the TRIPS, in particular to interpret and implement it in ways which would support public health, and for each state to decide for itself what constitutes a national emergency justifying the granting of compulsory licences under article 31; as well as

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[2] Canada – Patent Protection of Pharmaceutical Products, Report of the Panel, WTO Doc. WT/DS114/R (Mar. 17, 2000), *available at* http://www.wto.org.

an extension to 2016 of the transition period for implementation of TRIPS for the least-developed countries, with respect to pharmaceutical products. However the TRIPS Council failed to agree as requested in paragraph 6 of the Declaration on resolving the problem posed by the restriction in article 31(f) of TRIPS limiting compulsory licensing to the domestic market, which creates severe inequalities and difficulties for the many developing countries with insufficient drugs manufacturing capacity. The chair's draft of December 2002 has been rejected by the US government (many allege at the behest of the big pharmaceutical companies), but conversely it has been criticised as inadequate by NGOs such as Oxfam and Médecins Sans Frontières (MSF), although accepted as a compromise by developing countries.

Commentators remain divided as to whether this conflict can best be resolved by amendment of TRIPS article 31(f), or by resort to article 30, which would not require consensus but may be challenged. The alternative is a conditional moratorium on enforcement of TRIPS (also referred to as non-justiciability), as put forward by the US government. While this is unfavourable to developing countries, as long as there is no consensus on amending article 31, and the scope of article 30 exceptions is uncertain and likely to be interpreted restrictively by WTO Panels (though perhaps not the Appellate Body), it may be the only available outcome.

More generally, we can reflect on what can be learned from this episode about proposals to enhance the role of the WTO in global economic governance, debated among commentators under the rubric of the `constitutionalization' of international economic law, originating with Jackson's broad concept of the `trade constitution'. A radical vision has been put forward by Ernst-Ulrich Petersmann, from an ordo-liberal perspective, which would enshrine the `freedom to trade' as a fundamental right, legally entrenched in national constitutions and enforceable through national courts.[3] The anti-democratic implications of this view are justified by its roots in a particular concept of liberal democracy, in which state power must be confined, in order to safeguard individual rights and liberties, especially private property and market freedoms. This was strongly challenged by others, leading to a vehement debate in the *European Journal of International Law*.[4]

However, the application of WTO rules in the light of international human rights norms has other supporters, who see it as a means to counterbalance neo-liberal globalization, and this has been put forward in several reports by the UN High Commissioner on Human Rights, focusing especially on trade and the WTO.[5] Clearly, these initiatives come from a very different institutional and ideological perspectives than Petersmann's.

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[3] E.-U. Petersmann, *How to Constitutionalize International Law and Foreign Policy for the Benefit of Civil Society* 20 **Michigan Journal of International Law** 1 (1998); E.-U. Petersmann, *The WTO Constitution and Human Rights* 3 **Journal of International Economic Law** 19-25 (2000).

[4] E.-U. Petersmann, *Time for a United Nations `Global Compact' for Integrating Human Rights Law into the Law of Worldwide Organizations: Lessons from European Integration,* 13 Eur. J. Int'l L. 621 (2002); Philip Alston, *Resisting the Merger and Acquisition of Human Rights by Trade Law: A Reply to Petersmann,* 13 Eur. J. Int'l L. 815 (2002); E.-U. Petersmann, *Taking Human Rights, Poverty and Empowerment of Individuals More Seriously: Rejoinder to Alston,* 13 Eur. J. Int'l L. 845 (2002).

[5] UN Comm'n on Human Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights,* Report of the High Commissioner, UN Doc. E/CN.4/Sub.2/2001/13 (2001); UN Comm'n on Human Rights, *Globalization and Its Impact on the Full Enjoyment of Human Rights,* Report of

This demonstrates that human rights are contestable, not immutable concepts. Typically, also, they entail striking a balance between various rights and prioritizing them. Historically, human rights have been most strongly articulated in the `first generation' civil and political rights, while the `second generation' economic, social and cultural rights are often considered to be aspirations at best; and `third generation' collective rights including sustainable development are not easily made legally enforceable. It is significant that the right to property has been considered a civil rather than an economic right, and that this is the only positive economic right usually recognized, the remainder seem to articulate rather broader social or public interests. Thus, the key needs for access to land and natural resources, shelter, food, work, and health, let alone cultural rights are generally aspirational and not enforceable rights.

Certainly, IPRs may be evaluated in relation to the balance they strike between the more `public' interests in the enjoyment of cultural life and the benefits of science, and private legally enforceable rights in property. All too often, however, private rights tend to prevail over public interests, especially when claims take a legal form. The key issue is how to define the scope of IP rights according to public welfare criteria, as recognized in all IP regimes, and indeed in article 7 of the TRIPS agreement itself. The problem is that the TRIPS emphasizes the property rights which states must grant and protect, and it defines rather narrowly the exceptions which states may provide to safeguard the public interest.

Thus, a recourse to human rights does not resolve issues about the substantive content of international economic rules, it merely shifts the debate to a different ground. Indeed, if human rights norms are limited to liberal concepts of protection of private property and individual liberty, they may inhibit important public concerns such as the alleviation of poverty, disease and hunger. This is well illustrated by the constitutional challenge brought by pharmaceutical firms against South Africa's new medicines laws.[6] Strikingly, this was a claim of human rights violations, especially the deprivation of property without compensation. This case raised echoes of the successful constitutional challenge brought by pharmaceutical companies in Italy in 1978, on the grounds that the exclusion of medicines from patent protection was unfairly discriminatory, which dealt a mortal blow to the once-flourishing Italian generic drug manufacturing industry.[7] Certainly, counter-arguments could be made, especially since the South African constitution recognizes rights *inter alia* to health care, and places an obligation on the government to take `reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights'. Few other constitutions provide such a basis to balance vested property rights against the rights of the dispossessed. However, the collapse of the case was due to the global attention attracted by the access to medicines campaign, which was able to build international support around the issue of HIV-AIDS, and gave a new impetus to the political debates

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the High Commissioner, UN Doc. E/CN.4/2002/54 (2002); UN Comm'n on Human Rights, *Liberalization of Trade in Services and Human Rights*, Report of the High Commissioner, UN Doc. E/CN.4/Sub.2/2002/9 (2002).

[6] Pharmaceutical Manufacturers' Association a.o. v. Pres. of the Rep. of S. Africa, Case no. 4183/98, High Court of South Africa (Transvaal Provincial Division) (2001); for an account and analysis of the case in its political context see Mark Heywood, *Debunking `Conglomo-Talk': A Case Study of the Amicus Curiae as an Instrument for Advocacy, Investigation and Mobilization*, available at http://www.tac.za/ last visited Aug. 6, 2003.

[7] See F. M. Scherer an& Sandy Weisburst, *Economic Effects of Strengthening Pharmaceutical Patents Protection in Italy*, 26 I.I.C. 1009 (1995).

around the TRIPS agreement. Without this political debate, the South African courts might easily have upheld the pharmaceutical companies' rights to their patents.

Ultimately, how the balance is struck between different conflicting rights-claims must be decided by democratic deliberation. For a supra-national adjudicative body to evaluate the validity of regulations adopted by national democratic states, on the basis of its perception of the proper balance of private rights of individuals, gives insufficient emphasis to democratic decision-making. An important proposal has been made in this respect by Laurence Helfer, for the adoption of the principle of the `margin of appreciation' in WTO practice and jurisprudence, especially in relation to the TRIPS.[8] This aims to restore a better balance between the local/national and global/international levels of governance. It is notable that although some of the WTO's trade-remedy rules articulate a standard of review which does provide leeway for national state judgements, this is not present in the TRIPS.

Indeed, neither Panels nor the AB have explicitly addressed the development of a standard of review against which to evaluate regulations adopted by states, except those of the trade regime itself (notably, the `least trade restrictive' standard). This is an important reason why trade considerations tend to dominate their decisions, so that they act virtually as a court of appeal in adjudicating the public interest limits on IPRs enacted at national level. This can be seen in the restrictive approach they have adopted to the TRIPS provisions on exceptions to IPRs in both *Canada-Pharmaceuticals* and *US-Copyright*,[9] although in practice, they did offer a pragmatic compromise, in permitting some and invalidating other exceptions.

The main problem with the TRIPS is its strong emphasis on IPRs as private rights, subject only to some limited exceptions to protect the public interest. This obscures the reality that IPRs entail an artificial creation of scarcity (and monopoly rights) by the state, so that the initial definition of the scope of the rights should be determined by public interest criteria. This is particularly important for patents, where the basic provisions on patentability in article 27 largely derive from WIPO's draft Patent Harmonization Treaty. However, the TRIPS drafters essentially selected those provisions favouring patent-owners, many of which were actually strengthened compared to the 1991 WIPO draft (the 20-year minimum term, the requirement of product patents, and the reversal of the burden of proof for process patents). In contrast, the power for states to limit patentability was drawn more narrowly, in particular by specifying that it does not extend to micro-organisms or to non-biological or micro-biological processes.

On the other hand, although TRIPS specifies the three basic conditions of patentability (novelty, inventive step, and industrial applicability/utility), neither these nor the all-important distinction between a discovery and an invention are defined. It is this laxity that has allowed patent offices in some countries, notably the USA, to grant `patents on life', and to encourage bio-piracy and the privatization and commodification of community knowledge and techniques. In this respect, there is a need for greater specificity and less flexibility in the TRIPS. As presently worded, the TRIPS would permit a complaint against failure by a state to allow patenting of micro-organisms and microbiological processes, but not against over-

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[8] Lawrence R. Helfer, *Adjudicating Copyright Claims under the TRIPs Agreement. The Case for a European Human Rights Analogy* 39 **Harvard International Law Journal** 357 (1998).

[9] United States – Section 110(5) of the U.S. Copyright Act, Report of the Panel, WTO Doc. WT/DS160/R (June 15 2000) available at http://www.wto.org.

broad protection due to lax interpretation of patentability requirements. Here again, the structure of the TRIPS agreement favours private rights over public interests.

Nevertheless, developing countries could and should take advantage of the lack of specificity as to patentability standards in the TRIPS.[10] There are strong arguments that they should adopt more stringent standards for novelty, inventive step and utility, limit the scope of patentability (e.g. to exclude therapeutic techniques), and use various other means for ensuring IPR monopolies do not unreasonably restrict competition.

Indeed, a cogent argument can be made, which is not limited to developing countries, for more competition-friendly IPRs, based on a principle of fair remuneration for innovation and creativity, rather than the exclusive rights which derive from the private property model. This recognises that IPRs are not inherent private rights, but created and protected by the state, and hence that their scope and form should be defined in the public interest. We may hope that the debate over the relationship of IPRs and public health will help open up this broader set of issues, rather than remaining confined to the narrower perspective which simply counterposes strong protections of private rights against generally weak limitations and exceptions to safeguard public interests.

[10] Sol Picciotto & David Campbell, *Whose Molecule Is It Anyway? Private and Social Perspectives on Intellectual Property*, in **New perspectives on property law, obligations and restitution**. (Alistair Hudson ed. 2003)