

The Canadian Generic Medicines Panel A Dangerous Precedent in Dangerous Times

By Robert Howse

Among the most important criticisms of the WTO that echoed loudly in the protests in Seattle last November, was that the World Trade Organization unduly constrains the regulatory autonomy of Member states, defeating or frustrating democratic choices in important areas of social, economic, environmental and cultural policy. When properly interpreted and applied, many WTO rules do, however, permit a considerable amount of regulatory diversity, provided the domestic policies in question do not discriminate against foreigners.

The area where the WTO interferes most explicitly with the ability of governments to strike a balance in their policies between diverse public values, is that of intellectual property. The TRIPs Agreement

prescribes substantive standards of intellectual property protection, limiting the ability of democratic polities to strike their own balance between the provision of incentives for innovation on the one hand, and consumer welfare on the other; nor are these the only public values at stake, as debates surrounding biodiversity and intellectual property clearly illustrate. Moreover, on a conventional economic analysis, unlike the removal of tariffs, quotas and other overtly discriminatory trade barriers, raising intellectual property protection may actually reduce total domestic and even global economic welfare. For example in the case of increased patent protection, the additional monopoly rents to producers may generate little additional (efficient) innovation, while creating substantial welfare losses to consumers, who are deprived of cheaper imitations of patented products.¹

Nevertheless, thanks particularly to the persistent resistance of developing countries to the annihilation of regulatory diversity in TRIPs, the agreement does contain a balance of rights and obligations that provides some scope for Members to circumscribe intellectual property rights in the name of competing public values. For instance, Article 7 of the TRIPs Agreement provides that the protection and enforcement of intellectual property rights should contribute not only to the promotion of technological innovation but also the “transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.

The recent decision of a WTO panel in the Canadian generic medicines² case, however, ignores these words about balance and mutual advantage, interpreting the patent provisions of the TRIPs Agreement primarily from the perspective of intellectual property rights holders, largely dismissing competing social interests, and reducing considerably the range of regulatory diversity permitted under TRIPs.

At the first glance, the decision may appear a victory for those concerned about limiting intellectual property rights for compelling reasons of public policy; one of the measures at issue in this dispute, a Canadian provision that allowed competing generic manufacturers to test patented products before the required period of protection expired, was upheld as consistent with the TRIPs

Agreement. The companion measure, however, that permitted manufacture and storage (“stockpiling”) of patented products before the expiration of the patent, so they can be available for sale immediately upon expiration of the patent, was struck down. Most importantly – even if Canada’s generic medicine industry is largely satisfied by the *result* of the ruling – the *legal interpretations* of the TRIPs Agreement constructed by the panel in this case, if followed in future cases, will have very harmful impacts, particularly on developing countries.

Both Canadian measures were aimed at achieving Canada’s longstanding policy goal of providing relatively low cost medications to consumers as soon as possible, consistent with its



basic legal obligation under the WTO Agreement to provide 20 years of patent protection. The TRIPs Agreement provides that patent rights extend to the ability to prohibit the non-authorized manufacture and use of a patented product (Art. 28(1)(a)), and on the other hand reflects the decision of Members to limit the required period of “protection” from a patent to 20 years (Art. 33). The “protection” that a patent holder receives from a patent is, fundamentally, the protection against competition, i.e. a right to monopoly rents. If it

were necessary to prohibit manufacture and use of a patented product by a competitor for the full 20 year term, the result would be that the stream of monopoly rents to the patent holder extend beyond the 20 year period to the time after the patent had expired that it took the competitor to engage in testing for regulatory approval and manufacture for the market.

In defending its measures, Canada relied on the Article 30 exception in the TRIPs Agreement. This provision states that: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the rights holder, taking account of the legitimate interests of third parties.”

In applying this provision to the Canadian experimental testing measure, the panel found that the testing exception was “limited”. However, it considered the meaning of the expression “limited” solely from the perspective of the rights holder, and without regard to the policy goals or purposes of the exception.³ It never asked what scope the exception might require to achieve the social purposes at issue. It thus failed to interpret Art. 30 in light of the context, purpose and object of the TRIPs Agreement, as reflected in Art. 7, referring to the mutual advantage of producers and users, and a balance of rights and obligations. Moreover, the panel concluded that the stockpiling exception was not “limited”, even though there was a time limit on the exception, that allowed it to be used only in the final six months before expiration of the patent, and only by those availing themselves of the testing exception. While the panel had to admit that the six month cap constituted some kind of limitation (para. 7.37), it adopted the complainant’s view that a narrower rather than broader meaning of “limited” should be applied: for “limited” read “small”.

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In justifying its choice of the narrower interpretation, the panel relied on the character of Art. 30 as an “exception”, and appears to have let assumptions about “exceptions” being by their nature grudging or confined influence its reading of the modifying adjective “limited”. However, in the *Hormones* case, the Appellate Body held: “merely characterizing a treaty provision as an ‘exception’ does not by itself justify a ‘stricter’ or ‘narrower’ interpretation of the provisions than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in light of the treaty’s object and purpose [...]”⁴

As is suggested in this passage, the presumption that exceptions must be read narrowly may be connected to a failure to consider the words of the treaty in light of its object and purpose. This is precisely the case with the panel here, which assumed that the “basic” purpose of the TRIPs Agreement “was to lay down minimum requirements for the protection and enforcement of intellectual property rights” (panel ruling, para. 7.25). However, as indicated by Art. 7 of the TRIPs Agreement the basic purpose is *not* protection and enforcement of these private rights as such, but rather in a manner so as to achieve the *mutual* advantage of both producers and users and a *balance* of obligations and rights.

To do justice to this purpose, the panel would, at a minimum, have had to consider the scope implied in the word “limited” from the perspective not only of how much rights holders’ interests were being curtailed but also from the perspective of consumer interests.

This said, it is something of a mystery how the panel could find the testing exception sufficiently narrow but not the stockpiling exception. In fact the testing exception could actually curtail much more substantially rents that the patent holder might receive after the end of the 20 year period than the stockpiling exception; the period of testing required as a preliminary for regulatory approval of pharmaceuticals in Canada was three years, much longer than the six month period for stockpiling. But for the testing exception, the patent holder might have three additional years past the 20 year period of protection because the competing generic manufacturer would have to wait until the end of the 20 years to begin testing for regulatory approval, thus delaying by three years or so the moment the generic product would be competing in the actual marketplace.

This mystery is partly resolved when we move on to consider another criterion in Art. 30 – that the exception not “unreasonably conflict with a normal exploitation of the patent”. In explaining why the testing exception could meet this criterion, while the stockpiling exception did not, the panel made the following observation: “Some of the basic rights granted to all patent owners, and routinely exercised by all patent holders, will typically produce a certain period of market exclusivity after the expiration of a patent. For example, the separate right to prevent ‘making’ the patented product during the term of the patent often prevents competitors from building an inventory needed to enter the market immediately upon expiration of a patent. There is nothing abnormal about the more or less brief period of market exclusivity after the patent has expired” (panel ruling, para. 7.56).

“The Panel considered that Canada was on firmer ground, however, in arguing that the additional period of de facto market exclusivity created by suing patent rights to preclude submissions for regulatory authorization should not be considered ‘normal’. The

additional period of market exclusivity in this situation is not a natural or normal consequence of enforcing patent rights. It is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights” (panel ruling, para. 7.57).

This distinction is artificial, if not tendentious. The time required to build an inventory for sale subsequent to the expiry of the patent may well reflect the need to use production methods that respond to requirements for safety and quality in production, the *same* regulatory concerns that, ultimately, underlie a lengthy period of testing prior to regulatory approval. Moreover, the ability of producers to build inventory rapidly, *while ensuring quality and safety*, may well differ depending upon levels of economic development. In the Canadian case, the time needed was apparently around three weeks but one could not assume the same for generic producers in developing countries, where (ironically) – given the weak purchasing power of the vast majority of consumers – any delay in the marketing of generic products at lower cost might have significant health consequences, if not in certain cases deadly ones.

The panel’s interpretation of the legal implications of the TRIPs Agreement could have harmful impacts on developing countries, where any delays in the marketing of generic drugs might cause serious health effects.

It is significant in this respect that while most of the developed countries who intervened as third parties in the litigation, most notably the US and Japan, viewed the stockpiling provision as different from the testing provision, and not justifiable under Art. 30, the developing country intervenors (including Brazil, Ecuador, Cuba, and Thailand) generally saw the two provisions as linked, and viewed *both* as acceptable under Art. 30. Finally, by limiting early working exceptions to those for regulatory approval purposes, the panel’s reasoning excludes exceptions for basic research, including research that may improve on the patented product – in fact, in some instances, the only way to understand the possibilities of such improvement may be to reproduce or manufacture the product. There may be important social gains from allowing such research activity during the period in which the rights holder is enjoying monopoly rents from the patent.⁵

Perhaps most damaging of all to the legitimate balance of rights and obligations in the TRIPs Agreement is the panel’s finding (despite textual silence on the matter) that the non-discrimination provisions in Art. 27.1 of the TRIPs Agreement apply to any exception granted under Art. 30. These non-discrimination provisions are very different from those found typically in other WTO treaties, which prohibit discrimination between domestic and foreign products and services. Art. 27.1 of the TRIPs Agreement prohibits discrimination, *inter alia*, with respect to “field of technology.” However, based on legitimate social and economic objectives, a Member may well wish to limit intellectual property rights in one particular industrial sector – generic medicines is, of course, a classic example. The importance of health concerns in this sector, might well argue in favor of limits that it would be inappropriate to impose across the board on all sectors. Such imposition might create unnecessary costs for both domestic and foreign industries in those sectors – unnecessary in terms of the policy purposes of the exception in question. The panel entirely missed the implications of its treatment of manufacturing under Art. 30 for research and development, because of its general indifference to the purposes that underlie the taking of exceptions under that Article.

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the case of artisanal fisheries: children work at an early age alongside their relatives and earn a share of the gross earnings, and collective bargaining is not relevant because artisanal fisheries have a stipulated sharing system.

Conclusion

The export of fish and fish products is very important for many maritime developing countries. When about 40 percent of global fish production enters international trade, only about six to eight percent of forest products enter international trade (FAO, 2000. *Globalisation and Implications for International Fish Trade and Food Security*)³. The net foreign exchange earnings of developing countries in 1997 from fish and fish products stood at about US\$16 billion, which, according to FAO, is more significant than the combined net export earnings from coffee, tea, rice and rubber.

It is still unclear or too early to say how the market will respond to both eco-labelled and fairly-traded fish. In the light of growing interest in linking environment and labour standards to international trade, these developments could be seen as an opportunity as well as a matter of concern. Environmental and labour standards could complement the standards for food safety, which are strictly adhered to in the US, EU and the Japanese markets. (In fact, the greatest denial of market access for fish and fish products from developing countries is under the mantle of food safety standards).

Environment and labour standards and those concerning food safety could complete the triangle of external concerns about fish production and consumption. One can actually speculate a situation where a fish product imported from a developing country, sold in an EU supermarket, will carry three logos: one for food safety, the second for its origin from a sustainable fishery and the third, for being exported by an association of fishworkers that complies with the core labour standards of the ILO!

Many fishers in developing countries could benefit from these developments, including those using environmentally selective fishing methods and practices, as well as those belonging to genuine fishworker cooperatives or associations. While making all efforts to profit from such developments, fishworker organisations and national governments should exercise sufficient caution to prevent such standards from acting as technical barriers to trade. National or provincial fisheries authorities, together with fishworker organisations and the scientific community, could develop realistic and practical sustainability criteria and a management mechanism, and implement them effectively.

Well-managed and well-organized fisheries are becoming important marketing opportunities in international trade. Unlike many other developing country exports, fish is not a commodity easily substitutable with fish from the North. This realisation, coupled with a proactive engagement with the concerns of consumers, could very well promise a better future for both fish and the fishworker.

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ENDNOTES

¹ *Samudra Report* No. 9 February, 1994

² *Fish Stakes*, ICSF, 1998

³ Agenda item 6. Sub-Committee on Fish Trade, Seventh Session, Bremen, 22-25 March 2000.

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The panel's reasoning on this issue is totally perverse – it claims that Art. 27.1 limits the Art. 30 exception, because there is nothing in Art. 30 that says otherwise. Where there is no explicit qualification to an exception, one should assume that the exception applies generally to its explicit subject matter, which is, in this case, patent rights. Throughout the TRIPs Agreement, where the parties wished to qualify a right or obligation in a particular provision by making it conditional on some *other* provision of the agreement, they employed the formula that the right or obligation is “subject to” that other provision.⁶ The approach used in the generic drugs case leaves it up to the panel to determine on a case-by-case basis when a general non-sector specific exception applied in practice to only one sector constitutes a sham in respect of the non-discrimination obligation in Art. 27.1. This reduces the legal security of both rights holders and those social interests seeking to limit intellectual property protection, and increases the scope for panels to make intuitive, sniff-test type judgments about when inappropriate discrimination is occurring.

By failing to interpret the TRIPs Agreement in a manner that does justice to the delicate balance of social and economic interests reflected in the stated purposes of that agreement, the panel has crafted a set of readings that unduly curbs the regulatory autonomy of Members, and tends to undermine the legitimacy of the WTO in the eyes of its critics, at a difficult point in the Organization's history.

Despite the far-reaching implications of this decision, particularly for the systemic concerns of developing countries about TRIPs, critics should not allow this ruling to obscure other developments in WTO jurisprudence favorable to a balanced and sensitive reading of TRIPs. For instance, the recent panel on Section 301 of the US trade legislation took a sensitive view of the extent to which WTO panels should micro-manage the choices of Members in reflecting WTO obligations in their domestic law, suggesting that one could not consider whether a statute adequately implemented WTO obligations, without looking at other elements in a Member's domestic legal and administrative landscape, such as constitutional rules, and declarations of the authorities as to how the statute might be read or applied. That panel's analytical optic was much less intrusive of domestic sovereignty than the one through which the panel in the Indian Patents case viewed the evidence of compliance with WTO law. Thus, not all the recent news from Geneva is bad.

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ENDNOTES

¹ A.V. Deardorff, “Should Patent Protection be Extended to all Developing Countries?”, reprinted in R. Howse, ed., *The World Trading System: Critical Perspectives on the World Economy, Vol. IV* (London and New York: Routledge, 1998), pp. 37-48.

² *Canada-Patent Protection of Pharmaceutical Products*, Report of the Panel, WT/DS114/R, 17 March 2000. Adopted on 7 April.

³ “... ‘limited’ is to be measured by the extent to which the exclusive rights of the patent holder have been curtailed”, para. 7.31.

⁴ *EC Measures Concerning Meat and Meat Products (Hormones)*, Report of the Appellate Body, WT/DS26/AB/R, WT/DS48/AB/R, 16 January 1998, para. 104.

⁵ R. Eisenberg, “Patents and the Progress of Science: Exclusive Rights and Experimental Use”, (1989), 56 *University of Chicago Law Review* 1017.

⁶ This formula is employed in Arts. 6, 27.1, 36, and 65.1.