Canada-Patent Protection of Pharmaceutical Products, Report of the Panel, WTO, WT/DS114/R (2000)

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Summary

A WTO dispute settlement panel ruled that:

(1) Regulatory review exception – that permits competitors to use a patented invention, without the authorization of the patent holder, for the purposes of obtaining marketing approval – is consistent with the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS);

(2) Stockpiling exception – that allows competitors to manufacture and stockpile patented pharmaceuticals for sale upon expiration of the patent – is inconsistent the TRIPS.

The Facts

The Food and Drug Regulations of Canada require marketing authorisation for the manufacture of drugs and active pharmaceutical ingredient (API) regardless of whether the drug is a patented or generic product. The regulatory review procedure is time consuming. It may take from 1 to 2½ years to complete. Apart from the time the Food and Drug Authority needs for processing marketing authorisation, generic manufacturers will have spent from 2-4 years on the development of their submissions. The delay is due to the fact that generic manufacturers first have to develop internally or by third parties the API, then develop the formulation and dosage forms of the medicine by mixing the API with excipients (inactive ingredients), produce the medicine in small batches for testing, undertake studies and compile the data to establish bioequivalence with the patented drug, and carry out a six-month stability test. Thus, the overall time required for a generic manufacturer to develop its submission and to complete the regulatory review process ranges from 3 to 6½ years. Where the generic manufacturers and API producers are prevented from working on the patented invention, their entry into the market will equally be delayed by 3 to 6 years after the expiry of the patent.

Canada reviewed its Patent Act in 1993, to allow any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada (Section 55.2(1) of the Patent Act– so-called "regulatory review exception"). It also provided for a provision that allows those that acquired regulatory approval to manufacture and store the products, beginning six months prior to the expiry of the patent, but for sale after the patent expires (Section 55.2(2) of the Patent Act – so-called "stockpiling exception"). Article 27.1 of TRIPS (1994) requires patents to be available and patent rights enjoyable without discrimination as to the field of technology. Under Article 28.1 of TRIPS patent owners have the right to exclude others from making, using, selling, offering for sale or importing the patented product during the term of the patent. The European Commission (EC), in 1999, initiated a WTO dispute challenging the consistency of Canada's Patent

Act with Articles 27.1 and 28.1 of TRIPS. Canada requested the dispute settlement panel to reject the complaints of the EC arguing that the two exceptions are permitted under Article 30 of the TRIPS Agreement, which allows countries to adopt limited exceptions to patent rights, and that the exceptions are available for all products that are subject to regulatory approval processes, and, hence, are consistent with Article 27.1 of the TRIPS Agreement.

The legal issues

For an exception to granted patent rights to be consistent with TRIPS, Article 30 of TRIPS establishes that three criteria that must be met, i.e. that the exception must (1) be "limited"; (2) not "unreasonably conflict with normal exploitation of the patent"; and (3) not "unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties". The three conditions are cumulative, each being a separate and independent requirement that must be satisfied.

The Panel held the view that the stockpiling exception removes the patent owner's rights to exclude the "making" and "using" the patented product entirely during the last six months of the patent term, and that such an exception cannot be considered a "limited exception", hence not consistent with Article 30. In the Panel's view, however, Canada's regulatory review exception is a "limited exception" within the meaning of TRIPS Article 30. It is "limited" because of the narrow scope of its curtailment of the patent rights provided under Article 28.1. As long as the exception is confined to conduct needed to comply with the requirements of the regulatory approval process, the extent of the acts unauthorized by the right holder that are permitted by the exception will be small and narrowly bounded.

The regulatory review exception should also satisfy the other conditions of Article 30:

1. Normal Exploitation: The normal practice of exploitation by patent owners is to exclude all forms of competition during the terms of the patent. The Panel considered that after the expiry of the patent, the patent holder may enjoy an additional period of *de facto* market exclusivity if third parties are prevented from working on the patent for submissions for regulatory authorization. Such a *de facto* market exclusivity is only the unintended consequence of enforcing a patent. Hence, the regulatory review exception does not conflict with a normal exploitation of patents;
2. Legitimate Interests: The issue was whether patent owners could claim a "legitimate interest" in the economic benefits that could be derived from an additional period of *de facto* market exclusivity and, if so, whether the regulatory review exception "unreasonably prejudiced" that interest. The Panel rejected the EC's interpretation of the term “legitimate interest” as referring to legal interests provided under the rights of patentees pursuant to Article 28.1 TRIPS. Instead, the term in the view of the Panel must be defined in the way that it is often used in legal discourse — as a normative claim calling for protection of interests that are ‘justifiable’ in the sense that they are supported by relevant public policies or other social norms. The Panel considered the fact that patent owners whose innovative products are subject to marketing approval requirements also suffer a loss of economic benefits for 8-12 years until they secure

marketing authorisation. Some countries' laws provide for an extension of the patent term to compensate for the delay in regulatory approval, with or without a regulatory review exception. Canada and several other countries have adopted, or are in the process of adopting, regulatory review exceptions removing the *de facto* extension of market exclusivity, but these countries have not enacted, and are not planning to enact, any *de jure* extensions of the patent term for producers adversely affected by delayed marketing approval. On balance, the Panel concluded that the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognized that it could be regarded as a "legitimate interest". The Panel observed that notwithstanding the number of governments that had responded positively to that claimed interest by granting compensatory patent term extensions, the community of governments was obviously still divided over the merits of such claims. The Panel believed that the "legitimate interests" concept under Article 30 TRIPS should not be used to decide, through adjudication, a normative policy issue that is still obviously a matter of unresolved political debate. Consequently, the Panel concluded that Canada had demonstrated to the Panel's satisfaction that its regulatory review exception did not prejudice "legitimate interests" of affected patent owners within the meaning of Article 30.

Finally, the Panel considered whether the regulatory review exception discriminates against pharmaceutical product patents, in a manner inconsistent with the requirement of Article 27.1 of TRIPS. Applied literally, the exceptions apply to any of a wide range of products that require regulatory approval for marketing. The EC itself mentioned agricultural chemicals, foodstuffs, cosmetics, automobiles, vessels and aircraft as products that often require regulatory approval. The Panel also accepted Canada's assurance that the exception was legally available to every product that was subject to marketing approval requirements. The Panel concluded that the EC had not demonstrated that the regulatory review exception had had a discriminatory effect limited to patented pharmaceutical products.

Points of Significance

1. The Panel commented *obiter dictum* on the so-called experimental use/research exception — that permits the use of the patented product for experimentation during the term of the patent – stating that:

> … this exception is based on the notion that a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public. To the contrary, the argument concludes, under the policy of the patent laws, both society and the scientist have a 'legitimate interest' in using the patent disclosure to support the advance of science and technology.[1]

[1] See paragraph 7.69 of the panel decision.

2. The regulatory review exception is sometimes referred to as 'Bolar exception' after a case in the United States (where it was held that the US experimental use exception does not include research for regulatory submission purposes). Following the ruling, the United States amended its domestic law to provide for a regulatory review (Bolar) exception.[2]
3. Canada did not request for the review of the Panel's findings by the Appellate Body of the WTO. It amended its law to remove the stockpiling exception. The application of the three criteria under Article 30 of TRIPS remains a contentious issue between developing and developed countries. The EC, on its part, equally refrained from appealing to the Appellate Body and adopted its own regulatory review exception under its pharmaceutical regulatory directive (Directive 2001/83/EC [2001] OJ EC L311/67) in 2004.
4. The express authorization by a WTO panel of the regulatory review exception provides important guidance for other countries on the design of comparable exceptions under their domestic laws.

Key words: "regulatory review exception", "exception to patent rights", "Bolar" exception

Available at:
https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/DS/114R.pdf&Open=True

and (overview):

https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm

[2] See the summary of the decision *Roche Products Inc. v. Bolar Pharmaceutical Co.* in this database.