Forum

Canada v European Union — competition and patents at the WTO

This article by Dr Charles Lawson of the Commission's Brisbane office examines a decision made by the World Trade Organisation in a case between Canada and the European Union. The upholding of Canadian patent laws that reduce a patent holder's minimum rights has implications for the effects of patenting on competition law in Australia.

Introduction

Patenting has been variously justified to encourage innovation, reward inventors, disclose the details of the invention to assist further innovation and protect an inventor's natural rights. In competitive markets patenting is rationalised as overcoming failure of the market to prevent loss of innovation incentives through competitors taking a 'free ride'. However, for countries like Australia, which is a net importer of high technology, the interface between patenting and competition laws promises to be a key determinant in ensuring reasonably priced access to new patented technology, and particularly biotechnology.

The Uruguay Round of the General Agreement on Tariffs and Trade (GATT) created the World Trade Organisation (WTO) and finalised the Agreement on Trade Related Aspects of Intellectual Property (TRIPs). TRIPs set binding minimum patenting standards among member states (including Australia) and allows for their enforcement through compensation and trade retaliation under the WTO. TRIPs also included specific measures to address the abuse of intellectual property rights by right holders and practices that unreasonably restrain trade. However, the balance between recognising the rights of patent holders and the potential for domestic laws to overcome anti-competitive practices imposed by the patent have been unclear. The recent WTO decision in *Canada v European Union* WT/DS114 (17 March 2000) provides some insight into the relevant considerations in assessing this balance.

The dispute between Canada and the European Union was referred to a panel according to the 'Understanding on rules and procedures governing the settlement of disputes' negotiated as part of GATT. In this case the disputed Canadian laws proposed a scheme to reduce the high costs of patented pharmaceuticals paid by taxpayers by limiting the patent holder's rights and ensuring competition in the market as soon as possible after the end of the patent term. In effect the domestic law measures were enacted to reduce price distortions in the market and allow generic pharmaceuticals to effectively compete on price at the end of the patent term.

The decision is significant because it reduces some of the patent holder's exclusive rights in favour of speeding up effective market competition at patent term expiry. However, the decision stopped short of valuing principles over and above a patent holder's minimum rights.

The decision

The panel upheld the Canadian law which allowed persons other than the patent holder '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 ... that regulates the manufacture, construction, use or sale of any product'. This decision means the patent holder's exclusive rights may be limited to the

extent that allows the unauthorised use of a patented pharmaceutical by another person as part of the regulatory review necessary to market the pharmaceutical at the time the patent expires (the regulatory review exception). In these circumstances the unauthorised use during the term of the patent was a valid exception.

In contrast the panel rejected the Canadian law allowing stockpiling of patented products during the term of a patent if a person was to 'make, construct or use the invention ... for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires' (the stockpiling exception). Therefore, unauthorised use for regulatory review purposes during the patent term is acceptable while stockpiling during the patent term is unacceptable.

The reasons

In effect the panel was required to interpret articles 27 and 28 of TRIPs. Article 28.1 provides an exclusive right 'to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes' the patented product and process. Article 27.1 provides 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application'. According to article 33 the exclusive rights of the patent must last a minimum of 20 years from the patent filing date.

In interpreting TRIPs the panel accepted a need to consider its extended context. Canada argued its object and purpose was broader than just protecting patent holders. In particular Canada argued other parts of TRIPs were relevant in interpreting the extent of rights under it. This included:

- Article 7 which provides the 'protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation ... 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';
- Article 8.1 which provides member states can formulate or amend their laws to 'adopt measures' including measures 'to promote the public interest in sectors of vital importance to their socio-economic and technological development'; and
- Article 8.2 which provides 'appropriate measures' may include measures 'needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade'.

Canada relied on articles 7 and 8 as demonstrating considerations beyond the patent holder's rights could be relevant in complying with TRIPs and so exceptions to a patent holder's rights should be interpreted flexibly to allow patent rights to be adjusted to meet other policy objectives. In this instance Canada introduced the domestic law exceptions as a way to promote competition in the drug market, to overcome the price distortions in the market caused by the patents and reduce the cost of drugs for the publicly funded health system. This general argument was supported by various third party submissions.

In opposition, the European Union argued the phrase in article 8.2, 'provided that such measures are consistent with the provisions of this Agreement' meant that any other considerations beyond the patent holder's rights were subordinate to the protection of the minimum intellectual property rights guaranteed by TRIPs.

The panel rejected the European Union argument and accepted adjustments to a patent holder's rights were contemplated, but limited by the three conditions set out in article 30 (and presumably article 31), taking into account the object and purpose of articles 7 and 8 and other relevant provisions of TRIPs. Articles 30 and 31 provide for limited exceptions to the patent holder's exclusive rights set out in articles 27 and 28. Article 30 provides a three-limbed and cumulative exception: (a) there must be a 'limited exception' (b) the exception must not 'unreasonably conflict with normal exploitation of the patent', and (c) the exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking

account of the legitimate interests of third parties'. Article 31 provides, where article 30 has no application, a patent holder's exclusive rights may be diminished by an authorising law after judicial or administrative processes have determined the patent to be anti-competitive, although each authorisation must be considered on its individual merits.

The panel did not go as far as to accept that competition laws were paramount to patent laws. However, it seems that TRIPs does recognise the deleterious effects of patents and will allow some exceptions from the patent holder's exclusive rights to restrain anti-competitive conduct and promote the public interest in important socio-economic development, subject to the limits imposed by article 30 (and presumably article 31).

In dealing with article 30 in the context of regulatory review and stockpiling exceptions the panel provided some insight into relevant arguments in interpreting this provision. The panel accepted that the 'limited exceptions' should be narrowly defined so that it 'does not undercut the body of rules from which it is made' and 'one which makes only a small diminution of the rights in question'. Significantly the panel concluded that in the absence of other indicators 'it would be justified in reading the text [of article 30] literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact'.

So, in the present dispute the panel found the Canadian law allowing stockpiling before the patent term expired was without limits on the quantity that could be stockpiled and was therefore a 'substantial curtailment' rather than a 'limited exception'. Thus it was contrary to article 30. Given this finding it was not necessary for the panel to consider the other elements of article 30 for stockpiling. However, the panel expressly left open the question of how much curtailment of the patent holder's right was sufficient to constitute a 'substantial curtailment'. In reaching this conclusion the panel noted that each possible limitation needed to be considered independently and the commercial detriment to the patent holder's rights was relevant in assessing curtailment.

In contrast, the panel accepted that the Canadian law allowing an exception for regulatory review was a 'limited exception' because '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 it will be small and narrowly bounded'. Perhaps reading into the panel's decision, the presence of regulatory review provisions in a number of WTO member states' laws (including Australia) seemed to be significant in persuading the panel such exceptions were in fact limited.

The panel considered the 'normal practice' of exploitation by patent owners was 'to exclude all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity'. In the present matter the panel considered market exclusivity beyond the patent term as a result of delayed regulatory approval (de facto exclusive rights) was not a 'normal practice' and therefore the further element of 'unreasonableness' was not considered. The panel therefore accepted the regulatory review provisions were within the scope of this limb.

In assessing the final limb of article 30 the panel expressed some sympathy for including the policy justifying national patent laws as determining the scope of a 'legitimate interest' and this was broader than just legal interests. This finding is consistent with the broader policy aims of patent laws and in particular the competition objectives set out in article 7 that intellectual property should contribute 'in a manner conducive to social and economic welfare, and to a balance of rights and obligations'. This is significant for Australia as the Patent Act was expressly intended to balance economic and community interests. In this case market exclusivity beyond the patent term was not a 'legitimate interest' for the purposes of article 30 and so could not be 'unreasonably prejudiced'.

The panel concluded that because Canada's regulatory review provision complied with each limb of article 30 the domestic law did not conflict with TRIPs. Further, no discrimination as to the field of technology was found (a requirement of article 27) as Canada asserted the regulatory review provision was available

wherever regulatory approval was required. The European Union was unable to rebut this contention even though the Canadian laws had been enacted with pharmaceuticals in mind.

Commentary

The significance of this decision is a recognition by the WTO that competition can be affected by the rights of patent holders and that those rights can be diminished by domestic law to promote effective competition objectives. This is a welcome recognition of the monopoly pricing derived by patented products and the de facto patent extensions granted to patent holders by regulatory reviews. It is also significant that the panel very carefully left open its interpretation of the limits of a 'limited exception' in article 30 and arguably requires only some form of identifiable boundary to the domestic law effects on the patent holder's rights.

Applying the principles of this decision to competition laws in Australia, and in particular the Trade Practices Act, it would seem there is considerable scope to argue any laws which prohibit an abuse of a patent holder's exclusive rights may be justified by articles 7 and 8 and satisfy the allowable exception set out in article 30 (and possibly article 31). For example, a law that prohibits a patent holder with substantial market power from misusing that power for the patent would seem to have some merit. Prohibitions against such anti-competitive conduct are likely to be a 'limited exception' because the conduct is readily identifiable and the extent of the unauthorised acts are likely to be limited, identifiable and narrowly bounded. Further, anti-competitive conduct in breach of the Trade Practices Act is unlikely to be 'normal conduct' as abusing market power is clearly contrary to the generally accepted norms of a pro-competitive market in most WTO member states. There is unlikely to be a need to further establish this conduct is unreasonable. Finally, it would seem a patent owner would have difficulty establishing a 'legitimate interest' in the benefits of abusing market power or that such abuse 'unreasonably prejudiced' that interest. Similar arguments might also justify a domestic law against conduct that substantially lessens competition (with some exceptions for licences and assignments).

Unfortunately the panel did not consider the scope of article 31. It is significant that article 31 will only have application for a use other than that contemplated by article 30 and includes government and third party uses. This article effectively allows compulsory licensing as set out in the Patent Act. However, article 31 would appear to have a broader application. On its face it is conceivable an action might be brought against a patent holder under the Trade Practices Act as a judicial or administrative process examining anti-competitive conduct on the basis of individual conduct which might limit a competitive market.

Based on this brief analysis the Trade Practices Act's prohibitions against anti-competitive conduct may have some application. However, the scope of article 8.2 probably limits these actions to the 'abuse' of the patent holder's rights or practices which 'unreasonably restrain trade' (or adversely affect technology transfer). This view is reinforced by article 40 which expressly recognises that national laws may be applied to some intellectual property practices that can restrain competition and adversely affect trade (and technology transfer).

The decision is also important in providing alternatives to prevent anti-competitive conduct by patent holders outside the scope of the Patent Act. The recent Federal Court decision in *Bristol-Myers Squibb Co v F H Faulding & Co Ltd* [2000] FCA 316 (22 March 2000) reduced the scope of part of section 6 of the Statute of Monopolies and this most probably extends to all the elements of that provision including the measures against 'mischievous to the state by raising prices of commodities at home' and 'hurt trade'. These are parts of section 6 that would arguably have limited anti-competitive practices by a patent holder. With the loss of these provisions the importance of the Trade Practices Act is enhanced as an effective alternative and the *Canada v European Union* decision adds credibility to these alternatives.

While the application of the Trade Practices Act to patenting in Australia has been limited in recent times, the rapid developments in

biotechnology and its commercialisation are likely to provide some interesting domestic challenges. This technology relies heavily on patenting, is dominated by a small number of large corporations (predominantly pharmaceutical and agricultural) which are accumulating key technology in the form of genetic materials, processes and organisms, and the stock of biological materials are a distinctly finite resource. In these circumstances the potential for substantial market power and the lessening of competition are enhanced by large numbers of broad patents that effectively limit access to the raw materials (principally gene and gene sequences, biological processes and organisms). The *Canada v European Union* decision gives some hope that the ideology of patenting will not entirely overrule the benefits of competition and that anti-competitive conduct can be curtailed.

Dr Lawson can be contacted by email at: charles.lawson@accc.gov.au