

USE IT OR..... ELSE: PATENT NON-USE AS ABUSE OF DOMINANT MARKET POSITION

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In a matter of a first impression under the Canadian Competition Act, on May 13, 2014 the Competition Bureau released a [Position Statement](#)^[1] regarding what it refers to as "product hopping" or "product switching". That is conduct designed to switch demand from one of a firm's patent protected products to another, with the goal of making generic entry more difficult. This is the first time that the Bureau has conducted a formal inquiry into product hopping, although the conduct has been subject to US and European competition scrutiny.^[2] In the particular Canadian case, however, the Bureau closed its inquiry under the abuse of dominant market position provisions of the Act without taking action, because it found that the product had only been withdrawn from the market for a limited period of time, such that no injury occurred. Alcon Canada Inc. ("Alcon") was a supplier of the patented anti-allergy drug Patanol. One of the two patents protecting Patanol was set to expire in the Fall of 2012 and generic entry appeared likely to occur shortly thereafter. As a result, the Bureau alleged that Alcon began restricting the stock of Patanol available in the marketplace from July 2012. A short time before that it had introduced a new drug with much longer patent protection, Pataday. Pataday is indicated to address the same allergy concerns as Patanol, although it is a longer lasting formulation. Pataday's sales were increasing but were much smaller than those of Patanol until September 2012, when Patanol was no longer available in the marketplace. Sales of Pataday then replaced the vast majority of the sales of Patanol.

The Bureau's concern was that withdrawal of Patanol was designed to achieve product switching or product hopping. To become established in the marketplace, generic drugs generally depend on substitution of the generic drug for the prescribed brand name drugs by pharmacists. That is, if two drugs – one brand name and one generic – are chemically equivalent, pharmacists can (and under many drug plans are required to) substitute the less expensive generic for the more expensive brand name drug. However, insofar as prescriptions are no longer written for the original brand name drug because it has been withdrawn from the marketplace by the manufacturer, and are instead written for a chemically different replacement drug, for which – because of extended patent protection – there is no generic substitute, the pharmacist cannot substitute generic version of the withdrawn brand name drug on prescriptions written for the newly introduced and chemically different brand name drug. This will deprive the generic drug of significant sales, and may discourage generic manufacturers from introducing the drug into the marketplace at all.

In the case in question, as noted the Bureau closed its inquiry in March 2014. It found that while Patanol had been withdrawn in the Summer of 2012 it was reintroduced into the marketplace relatively soon after the Bureau launched its inquiry. By May of 2013, which was the beginning of the allergy season during which demand was high for the drug, Patanol's sales were back where they had been prior to the withdrawal. Further, the Bureau noted that competitors subsequently entered the marketplace with generic versions of Patanol and captured a significant market share.

This is the first instance – at least first publicly known instance – of the Bureau pursuing product hopping as an anti-competitive act under the abuse of dominance provisions of the *Competition Act*. The Bureau notes in its Position Statement that life cycle management strategies in the pharmaceutical sector are not inherently anti-competitive, and may bring significant advancements in health care. Nevertheless, there is clearly a concern that product hopping may be anti-competitive. The question is, however, whether the Bureau's approach to enforcement with respect to product hopping is consistent with intellectual property laws, with the *Competition Act*, and with existing jurisprudence related to the interface between competition and intellectual property laws.

Pursuant to the Bureau's existing *Intellectual Property Enforcement Guidelines*^[3] the "mere exercise" of intellectual property rights – including refusing to supply someone with intellectual property rights – will not, in the Bureau's view, constitute an infringement of the *Competition Act* – except possibly under the special remedies provisions in Section 32 which have been employed only very very rarely.

The mere exercise of an IP right is not cause for concern under the general provisions of the *Competition Act*. The Bureau defines the mere exercise of an IP right as the exercise of the owner's right to unilaterally exclude others from using the IP. The Bureau views an IP owner's use or non-use (emphasis added) of the IP also as being the mere exercise.^[4]

However, in April 2014 the Bureau published revised *Draft update of Intellectual Property Enforcement Guidelines*^[5] – essentially updating the existing Guidelines given statutory changes in the interim. Virtually the only substantive change to those Guidelines was with respect to non-use of intellectual property. Under the new Draft Guidelines, refusal to use intellectual property could be challenged under the abuse of dominance provision. In the above quoted provisions the words "or non-use" were struck from the paragraph of the revised Draft Guidelines.^[6]

Whether the Bureau's view in its new Draft Guidelines – that non-use of intellectual property, in particular by product hopping, can be challenged under the abuse of dominance provision of the *Competition Act* – is an open question. Section 79(5) of the *Competition Act* provides:

79(5). For the purpose of this section, an act engaged in pursuant only to the exercise of any right or

enjoyment of any interest derived under the *Copyright Act*, *Industrial Design Act*, *Integrated Circuit Topography Act*, *Patent Act*, *Trade-marks Act* or any other Act of Parliament pertaining to intellectual or industrial property is not an anti-competitive act.

In the *Tele-Direct*^[7] case, dealing with refusal to allow use of trade-marks, the Tribunal stated:

The respondents' refusal to license their trade-marks falls squarely within their prerogative. Inherent in the very nature of the right to license a trade-mark is the right for the owner of the trade-mark to determine whether or not, and to whom, to grant a licence; selectivity in licensing is fundamental to the rationale behind protecting trade-marks. The respondents' trade-marks are valuable assets and represent considerable goodwill in the marketplace. The decision to license a trade-mark -- essentially, to share the goodwill vesting in the asset -- is a right which rests entirely with the owner of the mark. The refusal to license a trade-mark is distinguishable from a situation where anti-competitive provisions are attached to a trade-mark licence.^[8]

In the *Warner Music*^[9] case dealing with refusal to supply copyright materials, the Tribunal stated:

The *Copyright Act* is similar to the *Trade-marks Act*, in that it allows the trade-mark owner to refuse to license and it places no limit on the sole and exclusive right to license.^[10]

Further, it is worth noting that, prior to 1993 the *Patent Act* contained a provision allowing the invalidation of a product for "non-working".^[11]

65(2). The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances: (a) if the patented invention (being one capable of being worked within Canada) is not being worked within Canada on a commercial scale, and no satisfactory reason can be given.

In 1993 that provision was repealed.^[12]

Given all of the foregoing, it is difficult to understand how the mere refusal to supply a patent protected product could constitute an abuse of dominant market position. The case against Alcon did not proceed, but if a similar case is pursued in the future these issues will, no doubt, be tested.

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[1][ps2id id='1' target=''] Competition Bureau, *Competition Bureau Statement Regarding the Inquiry into Alleged Anti-Competitive Conduct by Alcon Canada Inc.* (May 13, 2014), available [online](#).

[2][ps2id id='2' target=''] *Mylan Pharmaceuticals, Inc., et al. v. Warner Chilcott Public Limited Company, et al.*, Civ. No. 12-3824 (E.D.Pa.); *Commission fines AstraZeneca €60 million for misusing patent system to delay*

market entry of competing generic drugs (June 15, 2005), available [online](#).

[3][ps2id id='3' target=''] Competition Bureau, *Intellectual Property Enforcement Guidelines* (September 2000).

[4][ps2id id='4' target=''] *Ibid.*, para. 4.2.1.

[5][ps2id id='5' target=''] Competition Bureau, Draft update of Intellectual Property Enforcement Guidelines (April 2, 2014).

[6][ps2id id='6' target=''] *Ibid.*, para 4.2.1.

[7][ps2id id='7' target=''] *Director of Investigation and Research v. Tele-Direct (Publications) Inc.*, CT-1994-003 (Comp. Trib.).

[8][ps2id id='8' target=''] *Ibid.*, page 40.

[9][ps2id id='9' target=''] *Director of Investigation and Research v. Warner Music Canada Ltd.*, CT-1997-003 (Comp. Trib.).

[10][ps2id id='10' target=''] *Ibid.*, page 17. See also *Harris v. Glaxosmithkline Inc.* 106 O.R. (3d) 661.

[11][ps2id id='11' target=''] *Patent Act*, RSC 1985, c P-4, s. 65(2)(a).

[12][ps2id id='12' target=''] *Patent Act Amendment Act*, S.C. 1993, c.2, s. 5.

A Cautionary Note

The foregoing provides only an overview and does not constitute legal advice. Readers are cautioned against making any decisions based on this material alone. Rather, specific legal advice should be obtained.

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