

COMPETITION BUREAU'S DRAFT INTELLECTUAL PROPERTY ENFORCEMENT GUIDELINES PROVIDE WELCOME CLARITY ON BUREAU TREATMENT OF INTELLECTUAL PROPERTY

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In the second phase of a planned two-phase revision process, the Canadian Competition Bureau released its draft [Intellectual Property Enforcement Guidelines](#) ("**Draft IPEGs**") for comment by the legal and business communities on June 9, 2015. The Draft IPEGs are the first major revision to the Bureau's 2000 *Intellectual Property Enforcement Guidelines* and follow the Bureau's more modest September 2014 revision that updated the 2000 guidelines chiefly to reflect changes in the *Competition Act* since 2000. Going beyond the 2014 update, the Draft IPEGs are a thorough-going update to the Bureau's analytical framework concerning intellectual property issues in light of the last decade and a half of developments, with particular emphasis on issues of reverse payments in patented medicines disputes, product-switching, patent assertion entities, and standard-essential patents.

Confirmation of Existing Approach – Mostly

1) "Mere Use" and "Non-Use"

As with the 2000 and 2014 IPEGs, the Draft IPEGs confirm the Bureau's recognition that intellectual property and competition laws are complementary. Again, as with the earlier IPEGs, the Draft IPEGs confirm that "something more" than the "mere exercise" of an intellectual property right is necessary to warrant the scrutiny of the Competition Bureau under the *Competition Act*'s general provisions. In this context, "mere exercise" means either the owner's own use or the owner's unilateral exclusion of others from using the intellectual property. This much is consistent with the 2000 IPEGs. However, the Draft IPEGs also contain an important change to the "mere exercise" approach of the 2000 IPEGs. Like last year's updated IPEGs, the Draft IPEGs indicate that an owner's *non-use* of an IP right could be more than the "mere exercise" of that IP right. Thus, the Draft IPEGs assert that such non-use of an IP right could be the basis of a Bureau enforcement action, particularly in the context of alleged "products switching". (We discuss this issue detail in our [Use It Or..... Else: Patent Non-Use as Abuse of Dominant Market Position](#).)

2) Criteria for special remedies under the Competition Act

Just as with the earlier IPEGs, the Draft IPEGs state that where the conduct under scrutiny constitutes the "mere exercise" of intellectual property rights (that is, without "something more"), the Bureau will generally not concern itself except in certain exceptional circumstances, as noted below.

Like the earlier IPEGs, the Draft IPEGs note that the Bureau may consider recommending enforcement pursuant to the special intellectual property-related remedy provision under the Competition Act in respect of a "mere exercise" of an IP right only if the Bureau is satisfied on two fronts.

- First, that an IP owner's refusal to license its IP (usually a perfectly legitimate exercise of an owner's IP right) has adversely affected competition in a relevant market to a substantial degree.
- Second, that invoking the Act's special remedy against the IP owner is unlikely to stifle future innovation. If both of these criteria are met, the Draft IPEGs confirm that the Bureau may recommend to the Attorney General of Canada that he seek such special remedy from the Federal Court of Canada. The Attorney General can, among other things, ask the court to void an existing license, restrain some or all aspects of the exercise of an existing license or mandate a compulsory license.

Analysis Under Standard Provisions of *Competition Act*

As noted, the Draft IPEGs are consistent with the 2000 and 2014 IPEGs in stating that the Bureau will examine conduct involving "something more" than the "mere exercise" of an IP right under the *Competition Act's* general provisions — that is, the same provisions that apply in respect of any commercial activity and any type of property over which the Bureau normally has jurisdiction — and not look to the Act's special remedy provision.

Like both the 2000 IPEGs and their 2014 update, the draft IPEGs contain many examples of how the Bureau will go about analyzing intellectual property rights and their exercise under the *Competition Act*. In general, the analytic approach illustrated by those examples is consistent with the Bureau's approach under its earlier IPEGs and contain useful illustrations of the Bureau's analysis, pertaining in particular to exclusive licensing and supply agreements, patent-pooling arrangements and refusal to license IP rights. However, the Draft IPEGs also touch on four new areas, some that have engendered much scrutiny and debate over the last 15 years, namely: (1) arrangements between innovative drug manufacturers and generic manufacturers (including settlements) in the context of Canada's Patented Medicines Notice of Compliance ("**PMNOC**") regulations under the *Patent Act*; (2) product-switching; (3) patent assertion entities; and (4) patents that are essential to an industry standard.

1) *PMNOC Arrangements*

The first of these new issues involve the settlement of patent disputes. There has been considerable debate

about the issue, particularly in the United States. The key question has been whether a payment to a party seeking to enter into the generic production of a patented drug by the holder of that patent may be challenged as anticompetitive. The Draft IPEGs indicate that "in the vast majority of cases" the Bureau will consider the implications of settlement of disputes with respect to PMNOC issues under the Competition Act's civil competitor collaboration provision or, in certain circumstances, under the Act's abuse of dominance provision. In those circumstances, the Bureau will determine whether the PMNOC settlement under scrutiny is likely to lead to a substantial lessening or prevention of competition before it would consider enforcement action in respect of such a settlement. Moreover, the Draft IPEGs confirm that a PMNOC settlement will be reviewed under the Act's criminal conspiracy provision "only where the intent of the payment was to fix prices, allocate markets or restrict output" and adds that "[t]he Bureau anticipates that such circumstances would occur on a limited basis." The examples in the Draft IPEGs concerning the analysis of PMNOC settlements suggest that the Bureau will only review such settlements under the Act's criminal conspiracy provision where, for example, the "Bureau found convincing documentary evidence that both parties [that is, both the innovative and generic manufacturers] recognize that the patent was not valid."

The examples of the Bureau's analytic approach to PMNOC settlements also suggest a "safe harbour" of sorts for settlements that both

- permit the generic manufacturer to enter the market with its generic product at the expiry of the innovative manufacturer's patent (or earlier) and
- do not involve any additional consideration paid by one party to the other.

Where a PMNOC settlement involves additional consideration paid to the generic manufacturer by the innovative manufacturer, the Bureau will look at the magnitude of such consideration to determine whether the intent was to settle the PMNOC litigation or to delay the generic manufacturers entry into the market. If the Bureau determines that the magnitude of the payment was so large that:

- it was probably for the purpose of delaying entry;
- the competitive effects from the generic manufacturer's delay were significant; and
- timely entry from other generic suppliers was not likely to occur on a scale and magnitude sufficiently to constrain the ability of the parties to the arrangement to exercise market power in the relevant market,

then the Bureau would conclude that the settlement substantially prevented or lessened competition. In such circumstances, say the examples, the Bureau would likely seek enforcement action under the Competition Act's competitor collaboration provision. As noted, only in extraordinary cases would challenge be brought under the Act's criminal provisions.

2) Product Switching

The process of developing and patenting new processes and products is generally a continuing one. An innovator will generally look at ways of improving its process or product and seek to obtain patent protection for that improvement. In the pharmaceutical field, these improvements may include different forms of an existing, patent-protected drug that has improved properties or new method of delivery, e.g. timed release. However, the Bureau has noted that this conduct can give rise to adverse effects on competition. In particular, since generic drugs are often dispensed automatically to fill prescriptions for the typically more expensive original brand name product, the substitution of a new version of the original drug, coupled with the withdrawal of the prior version facing generic competition, may deprive the generic of its ability to be substituted and thereby stifle competition.

Recently, the Bureau investigated a case in which an innovator, Alcon Canada Inc., introduced a new version of its drug ("**Pataday**"), but withdrew from the marketplace the older version ("**Patanol**") prior to the expiration of the patent on Patanol. This is sometimes referred to as "product hopping" or "product switching". Following the Bureau's investigation, Alcon re-introduced Patanol into the market place and the Bureau issued a [position statement](#) in May 2014 addressing the case and indicating its general approach to analyzing such "life-cycle management" strategies and asserted a right to address such conduct under the general provisions of the *Competition Act*, even though the conduct simply involved refusing to supply a patented product, and supplying a patented product.

The Draft IPEGs include an analogous example to the *Alcon* case. The analysis accompanying the Draft IPEG's product switching example is consistent with the Bureau's position statement on the *Alcon* case. The example suggests that the Bureau would seek, based on expert medical opinion, to determine whether the newly-introduced product provided a "substantive medical benefit" compared to the old product. As there is no indication in the Bureau's position statement on the *Alcon* case that it relied on expert medical advice to determine whether there was a valid business justification for Alcon's withdrawal of Patanol from the marketplace in favour of Pataday, this is arguably a novel element in the Bureau's analytic approach to such questions.

This raises the issue of how an innovative drug manufacturer is to know *ex ante* whether the Bureau's panel of medical experts will determine whether the manufacturer's new product will lead to a "substantive medical benefit". Since medical opinions can differ even in respect of long-standing medical controversies, how medical experts can reach a consensus on the "substantive medical benefit" of a drug which, by definition, is novel is not at all clear.

3) Patent Assertion Entities

There has been considerable debate recently on the desirability from a policy perspective of certain types of conduct of patent assertion entities (often disparagingly called "patent trolls") and their aggressive assertion of their acquired patent rights. The Draft IPEGs do not address these broad policy considerations. Rather, they approach such entities only in the rather narrow context of whether such an entity's assertion of its patent rights in an indiscriminate manner might comprise the reviewable or criminal practice of making a false or misleading representation to the public. The IPEGs example contemplates a patent assertion entity sending out thousands of notices to businesses stating that it had proof that the recipient was infringing one or more of the patents owned by that entity, and demanding that each recipient pay a licensing fee to avoid litigation. The Bureau's analysis of these hypothetical facts suggest that if the patent assertion entity did indeed have proof of the alleged infringement, no Competition act provision would be engaged. Likewise, if the evidence showed that the patent assertion entity was sending such infringement notices to businesses indiscriminately, or was indifferent to whether the representations were misleading, then the misrepresentations might be seen to have been made knowingly or recklessly and could raise concerns under both the reviewable matters and criminal provisions the Act.

While helpful in making clear one way in which the Bureau will look at the conduct of patent assertion entities, few familiar with those provisions of the Act would find much new in this example and its related analysis.

4) Standard Essential Patents

Technological standards arise through developments under the auspices of formal standard development organizations ("**SDOs**") or through other means such as government action or the rise of a de facto standard through operation of market forces. In the context of standard essential patents, the Draft IPEGs recognize that such technical standards can be pro-competitive and lead to such benefits as the lowering of production costs, increases in efficiency and consumer choice, and the fostering of innovation. However, the Draft IPEGs also recognize that standards development can raise competition concerns. These could include reducing price competition, foreclosing innovative technologies and restricting the ability of firms to compete by denying access to the standard or providing access on discriminatory terms. The examples set out in the draft IPEGs provide the Bureau's analytic approach to so-called "patent hold up" and "patent ambush" scenarios; scenarios where patent holders reneged on so-called FRAND/RAND (that is, "fair, reasonable and non-discriminatory") licensing commitments in the context of an SDO, where a patent that was the subject of such commitments was subsequently transferred from the patent holder to a third party; and where a patent holder sought an injunction against a prospective licensee in such a context. The Draft IPEGs make clear that, in general, the Bureau will analyze most conduct related to standard essential patents pursuant to the Act's abuse of dominance provisions, since "patent hold ups" and "patent ambushes" necessarily involve "something more" than the "mere exercise" of the patent rights of those engaging in such conduct and are aimed at enhancing

their market power through their dishonest dealings with SDOs.

The Draft IPEGs also note that competitors collaborating to set a technical standard in the context of an SDO risk criminal price-fixing allegations if their collaboration extends to the joint discussion of licensing terms and conditions and, even absent such discussion, risks investigation under the Act's civil competitor collaboration provision. In short, the Draft IPEGs make clear that while SDOs can serve pro-competitive functions, competitors must exercise caution when coming together in such a manner.

Conclusion

In general, the Draft IPEGs are a welcome clarification on the Bureau's analytic approach to questions that have come much more to the fore in recent years. That said, and as noted above, the Draft IPEGs raise some genuine and potentially controversial issues. Parties interested in making submissions to the Competition Bureau are invited to do so before August 10, 2015.

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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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