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Pharma in Brief

Competition Bureau publishes Final IP Enforcement Guidelines



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On March 13, the Competition Bureau published a revised version of its IP Enforcement Guidelines (**IPEGs**). The IPEGs clarify the Bureau's approach to conducting investigations of alleged anti-competitive activities that involve IP, including settlement of pharmaceutical patent litigation under the ***Patented Medicines (Notice of Compliance) Regulations*** (***Regulations***).

The revised IPEGs replace the earlier 2016 version. Sections 7.2 and 7.3 include a detailed explanation of the Bureau's approach to litigation settlements under the ***Regulations***, which can be summarized as follows:

1. **Entry-split agreements.** An entry-split settlement pursuant to which the generic firm enters the market on or before patent expiry will not pose an issue under the ***Competition Act*** where no other consideration is provided to the generic.
2. **Agreements with a payment to a generic.** A settlement with a payment to the generic firm pursuant to which the generic firm enters the market on or before patent expiry, may be reviewed under section 90.1 of the ***Competition Act*** (anti-competitive agreements or arrangements between competitors), or possibly section 79 (abuse of a dominant position). The Bureau takes a broad view of what constitutes a "payment" which includes for example, the provision of services (e.g., marketing or manufacturing). Any payment would be evaluated to ensure that it is not compensation to the generic firm in return for delaying its own entry into the market, having regard to the fair market value of any goods or services provided by the generic, the magnitude of brand's section 8 damages exposure under the ***Regulations***, and the brand's expected remaining litigation costs absent settlement. Notably, "expected remaining litigation costs" may include costs of a subsequent appeal, and potential adverse cost awards.
3. **Potentially criminal agreements.** The Bureau will not review a settlement under section 45 (criminal conspiracy) unless (a) the settlement extends beyond the exclusionary potential of the patent by delaying generic entry past the date of patent expiry, (b) the settlement extends beyond the exclusionary potential of the patent by restricting competition for products unrelated to the patent subject to the PMNOC proceeding, or (c) the settlement is a "sham" (***e.g.***, where both parties know the patent is invalid or not infringed). The Bureau expects such circumstances to be rare.

The above suggests that the key considerations in structuring settlement agreements under the ***Regulations*** include limiting them to the term of the patent and tying any consideration paid under the agreement to the product and the litigation. However, the IPEGs do not cover all possible settlement scenarios or their potential competition implications. Further, the IPEGs are not a binding expression of the law or how the Commissioner of Competition would exercise discretion in any given case.

In addition to the specific content relating to pharmaceutical patent litigation, the revised IPEGs also address the interface between IP and competition law (including the incentivizing role of property rights and the promotion of a competitive marketplace), the application of the ***Competition Act*** to conduct involving IP, and the analytical framework that will be used by the Bureau in the context of IP. In this regard, the IPEGs also include examples on infringement of IP rights, price-fixing, exclusive licensing, exclusive contracts, output royalties, patent-pooling, agreements to foreclose complementary products, refusal to license IP, product switching, conduct involving patent assertion entities (a.k.a. "trolls"), and collaborative standard-setting and standard-essential patents.

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