Innovative pharmaceutical companies need to be aware of the Competition Act

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The Competition Bureau closely monitors business matters in Canada

The Competition Bureau (the Bureau) in Canada has a long history of investigating business matters relating to innovative pharmaceutical companies in the country. Most of the time this involvement relates to the settlement of patent infringement cases. However, it can also relate to pricing issues, and other decisions made by innovative pharma.

Indeed, over the last six months, the Bureau has issued three news releases relating to pharmaceuticals, and produced an advocacy piece with a request for more power.

News releases

Most recently, on June 27, the Bureau announced that it had completed its preliminary investigation of relabelled biologic drugs, which it described as drugs identical to originator biologic drugs but marketed under a secondary brand name. The news release indicated that "the drugs in question have not been marketed in Canada." No mention is made of the drugs that were in question, nor of the manufacturers involved. However, the Bureau promises to monitor developments in this area.

In May, the Bureau announced that it had closed two investigations into pharmaceutical patent litigation settlements. Again, no drugs nor manufacturers were named, and no anti-competitive behaviour was identified in the course of these two settlements. However, the Bureau also released a Position Statement the same day, summarizing its general approach to reviewing pharmaceutical patent litigation settlement agreements. The Position Statement generally accords with the most recent Intellectual Property Enforcement Guidelines, serving as an important reminder that the Bureau has stated that settlement agreements that include a payment from an innovator to a generic manufacturer will prompt further review by the Bureau. Once a payment is involved, the Bureau no longer assumes the settlement reflects a compromise based on the expectations of success in litigation.

In January, the Bureau and Health Canada announced a collaboration "to support Canadians' access to safe and effective pharmaceuticals and biologics." Notably, this

notice refers to the period of market exclusivity granted to innovative medicines by the *Food and Drugs Act*, but does not mention the importance of the patent system to companies making innovative medicines. The Bureau indicates that it will provide support "designing laws, regulations, and policies in a way that balances policy objectives, including access to safe and effective therapies, with competition considerations". This statement needs to be taken in conjunction with the Bureau's February advocacy piece, discussed below, asking for a mechanism to be made aware of pharmaceutical patent litigation settlements. The Bureau also reiterated that companies must cooperate in requests for samples of reference products.

The Bureau and its advocacy

It is also important to remember that the Bureau regularly advocates to regulators and policy makers. In February 8, 2022, it provided a submission titled "Examining the Canadian *Competition Act* in the Digital Era" to Senator Wetston's invitation to comment on Canada's competition policy framework. The submission referenced pharmaceutical settlements a number of times, despite such settlements not changing in the context of the so-called digital era. In the context of civilly reviewable competitor collaborations, the Bureau's position is that s. 90.1 of the *Competition Act* has significant gaps in coverage, including that pharmaceutical patent litigation settlements can be difficult to detect. The Bureau advocates for legislative reform to address the noted gaps. The Bureau also advocates for a specific mechanism to make the Bureau aware of pharmaceutical patent litigation settlements.

Key takeaways

The Bureau is making clear that it will be closely monitoring the business dealings of pharmaceutical companies in Canada. Therefore, innovative pharmaceutical companies need to remain vigilant that they do not run afoul of the provisions of the *Competition Act* in bringing pharmaceuticals to market in Canada. Experienced competition and patent counsel work together when advising these companies on market strategies and patent (and other intellectual property) infringement cases.

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