Competition Bureau reiterates its position against anti-competitive generic drug delay tactic

APRIL 15, 2020 6 MIN READ

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For decades, pharmaceutical intellectual property and competition policy have been directed towards striking a balance between stimulating new drug innovation and enabling affordable access to medicines. Brand and generic drug companies have evolved their strategies over the years to respond to changes in the marketplace. Occasionally, however, a tactic emerges that does not serve either of these goals of pharmaceutical policy – innovation or access – and requires government intervention.

One such tactic is the unjustified denial or delay by branded pharmaceutical companies to provide samples of their product to generic companies so that they can conduct testing to establish bioequivalence. In order for a generic company to market a drug without conducting duplicative clinical trials, it must demonstrate that its version of the drug is bioequivalent with the brand product. To do so, it needs samples. If the generic company cannot get samples, it cannot do the required testing and cannot obtain regulatory approval for the marketing of its generic lower- priced version of the product, which would result in substantial savings to publicly and privately funded health plans.

On April 2, 2020, the Competition Bureau (Bureau) issued a press release expressing concern about the denial by one brand company, Otsuka Canada Pharmaceutical Inc. (Otsuka), of samples of its kidney disease drug, Jinarc, to a generic company for purposes of bioequivalence testing, despite the fact that the Bureau had provided in December 2018 prior guidance warning branded companies about engaging in such conduct. The Bureau stated that further obstruction to the manufacture of generic alternatives will not be tolerated.

In an accompanying position statement, the Bureau indicated that on the basis of a credible and specific complaint, it swiftly opened an investigation against Otsuka under the abuse of dominance provisions of the *Competition Act* and, within two months, resolved the matter by requiring Otsuka to provide the requested samples.

The three elements to be established before an order can be made under the abuse of dominance provision are (1) a person or group of persons substantially or completely controls a market (i.e., dominance); (2) that person or group of persons has engaged in a practice of anti-competitive acts; and (3) the practice has had or is likely to have a substantial prevention or lessening of competition in a market.[1]

As this investigation was resolved "at an early stage of the investigation" the Bureau's views on key elements of the legal analysis, summarized below, are characterized as "preliminary."

- **Dominance:** The relevant market is the national supply of drugs that contain tolvaptan for the treatment of autosomal dominant polycystic kidney disease. As Jinarc is the only drug that is approved for the treatment of this disease in Canada and Otsuka is the only marketer of such drug in Canada, this element is satisfied.
- **Anti-competitive acts and intent:** The exclusionary impact of the denial of samples is obvious as, without samples, the generic firm cannot undertake the bioequivalence testing and, consequently, cannot take steps to enter the market and compete with the brand. Accordingly, the critical question was whether Otsuka had a legitimate business justification for engaging in such exclusionary conduct. The Bureau's comment on this aspect of the analysis is particularly helpful to the generic industry as the Bureau rejected Otsuka's purported legitimate business justification. Otsuka indicated that its denial of samples was a direct result of the fact that its Health Canada approval was conditional upon the implementation of a risk management plan (RMP) that imposed strict limits on its distribution of Jinarc due to safety risks associated with the drug. Otsuka took the position that providing samples might put it in breach of its RMP. The Bureau pointed out that the legitimacy of such a position is undermined by Health Canada's July 4, 2019 direction to the industry that generic drug development cannot be hindered or delayed (for example, by denying access to samples) in the name of RMP, including controlled distribution programs. Further, if Otsuka had concerns about whether the provision of samples may breach its RMP, it could have simply asked Health Canada for guidance. Instead Otsuka waited until the Bureau investigation was well under way to do so.
- **Substantial prevention of competition:** The Bureau stated that generic entry of the product was delayed by approximately 11 months by Otsuka's actions and would have been delayed longer had adequate supply not been provided soon after the Bureau commenced its investigation. As typically the first generic drug introduced to the market is priced at 85% (or less) of the cost of the branded pharmaceutical, the Bureau indicated that it had no information to suggest that the first generic tolvaptan product on the market would not also have a similar substantial price reduction from the cost of Jinarc.

The Bureau discontinued its investigation after Otsuka provided the requested samples. The Bureau stated in the press release that it "remain[ed] very concerned that this type of conduct persists" and that the Bureau "will keep a very close eye on this sector and use all the tools at [its] disposal to take action against companies [that] would harm competition in this industry…." Furthermore, in correspondence to the Canadian Generic Pharmaceutical Association (CGPA) enclosing the Bureau's position statement, the Deputy Commissioner of the Mergers and Monopolistic Practices Branch re-emphasized to the CGPA's membership the Bureau's commitment to enforcement with respect to these issues and specifically stated:

> Should Generics face similar issues in the future, the Commissioner encourages them to bring any concerns to the Commissioner's attention at an early stage. As illustrated in this case, specific and credible information substantiating allegations is of significant assistance in demonstrating the appropriateness of, and facilitating, early and effective intervention by the Commissioner. If another situation arises where evidence establishes competitive harm resulting from a failure to provide access to samples of branded products, or any other conduct that excludes competitors, the Commissioner will not hesitate to take appropriate action.

The Bureau is not the only enforcement agency to speak out against the practice of denying

access to samples for the purposes of comparative testing. In May 2018, the Commissioner of the United States Food and Drug Administration (FDA) issued a statement calling out this practice, stating that it had received more than 150 inquiries about being denied access to drug samples on the basis of RMP. The FDA published a list of companies appearing to engage in this practice as a measure to enhance transparency. The United States Federal Trade Commission issued its own statement soon afterward outlining measures to combat this practice.

The dual objectives of enhancing drug innovation and enabling affordable access to medicines have never been more important. At the time of publication of this article, the entire world is looking to the capabilities of the pharmaceutical industry to innovate and manufacture new medicines to combat COVID-19. For public goods of such pressing importance, the Bureau's investigation into Otsuka's conduct is a reminder that monopolistic tactics that have no legitimate business justification will not be tolerated.

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[1] For further information on whether an organization may be found to have engaged in a practice of anti-competitive acts, please read our Osler Update, "Competition Tribunal confirms business justification is the paramount consideration in an abuse of dominance case."