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It ended before it began: first private party sought leave to bring an 'abuse of dominance' application under the Competition Act

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On September 29, 2023, Apotex Inc. (Apotex) applied for leave to the Competition Tribunal (Tribunal) to file an application seeking a remedial order under the "abuse of dominance" provisions of section 79 of the *Competition Act* (the Act). Apotex's application for leave was the first such application. The June 2022 amendments to the Act created a private right of access to the Tribunal for conduct alleged to be contrary to section 79; prior to June 2022, enforcement under this provision was the exclusive jurisdiction of the Commissioner of Competition (Commissioner).

Notably, only two weeks after filing the application for leave, Apotex filed a notice of discontinuance. The sequence of events — and particularly the timeline — suggest that the June 2022 amendments may be having the intended effect of compelling efficient and effective private enforcement of section 79.

Context

For a generic pharmaceutical company to market a generic version of a branded drug without conducting duplicative clinical trials, the generic company must demonstrate that its version of the drug is a bioequivalent to the branded product. To do so, the generic company requires samples of the branded product. Without such samples, it cannot do the required testing and cannot obtain regulatory approval for the marketing of its generic, materially lower-priced version of the branded product.

Occasionally, a branded pharmaceutical company will deny or delay access to drug samples by the generic company as a tactic to delay generic entry. The Competition Bureau (Bureau) has on numerous occasions expressed concerns that these tactics raise issues under section 79, which is a civil provision that prohibits dominant firms from engaging in anti-competitive acts that result or are likely to result in a substantial lessening or prevention of competition in a market. Most recently, in April 2020 the Bureau announced the discontinuation of an inquiry into practices of Otsuka Canada Pharmaceuticals Inc. after the company took action to address the Bureau's concerns. In January 2022, the Bureau and Health Canada issued a joint notice to stakeholders highlighting the importance of their continued collaboration, including with respect to enforcement actions related to refusals to supply samples of branded drugs to generic manufacturers.

Apotex's application for remedies under the 'abuse of dominance' provisions

Apotex is a manufacturer of generic and branded drugs in Canada. Apotex plans to manufacture and supply ponatinib, a leukemia treatment produced by Takeda Pharmaceuticals U.S.A. Inc. (Takeda) and imported to and distributed in Canada by Paladin Labs Inc. (Paladin) (Takeda and Paladin, together with their respective affiliates Takeda Canada Inc. and Endo Pharmaceuticals Inc., the Respondents).

To do so, Apotex required the Respondents to provide samples of ponatinib so that Apotex could conduct the required testing to obtain Health Canada approval. Apotex claimed that it had attempted to obtain samples from the Respondents since June 2023 but had repeatedly been denied, with the Respondents stating that the samples could not be supplied because the drug was in short supply and that Apotex would need to apply to Paladin for a line of credit. Apotex claimed that these tactics were intended to exclude, prevent and delay Apotex from launching a lower-priced generic product that would compete with Takeda's branded version of ponatinib, ICLUSIG.

If granted leave to bring an application under section 79, Apotex intended to seek an expedited hearing and a remedial order requiring (1) the supply of the ponatinib samples; (2) an administrative monetary penalty (AMP) representing three times the amount earned by Paladin from the sale of ICLUSIG in Canada between September 22, 2023, and the date of the Tribunal order, or such other amount as determined by the Tribunal; (3) a ten-year prohibition on the Respondents engaging in practices that hinder or delay the supply to Apotex of ICLUSIG or any other branded drug supplied by the Respondents; and (4) an award for costs associated with the application. Notably, the AMP would be payable to the federal government as private parties cannot seek monetary damages for violation of the civil provisions of the Act.

Apotex's application for leave

Section 103.1 of the Act provides that the Tribunal may grant leave to commence an application under section 79 if the Tribunal has reason to believe that the applicant would be "directly and substantially affected" in its business by the conduct at issue. To date, the Tribunal has consistently ruled that a "substantial affect" on a business is measured in the context of the applicant's entire business rather than a sub-segment, such as a product line or market.

As Apotex's application noted, private access under section 79 was only established in June 2022; the prior leave decisions, therefore, were not made with reference to section 79. Apotex argued that applications for leave under section 79 should be read in a manner that is harmonious with the language of section 79, such that the section 103.1 analysis should focus on the effect of the practice on the applicant's business in the relevant product market at issue, rather than the applicant's entire business.

As part of the leave application process, section 103.1(3) provides that the Commissioner must certify to the Tribunal whether the matter in respect of which leave is being sought is the subject of an inquiry or was the subject of an inquiry that has been discontinued because of a settlement between the Commissioner and the party against whom the order is sought. For purposes of Apotex's application, the Commissioner certified that an inquiry had not been commenced nor had a settlement been reached with the Respondents. Notably, section 103.1(11) states that in deciding the application, the Tribunal cannot draw any inference from the fact that the Commissioner has or has not taken any action.

Notice of discontinuance

Within two weeks of applying for leave, Apotex filed a notice of discontinuance. Presumably this means that Apotex has secured supply from one or more of the Respondents. The events that have transpired and the condensed timeline — supply secured with a mere three months between the time Apotex first requested the samples and filed the application for leave — suggest that the June 2022 amendments to the Act may be having the intended effect of compelling effective private party enforcement on an expedited timeline as compared to what a Bureau investigation and enforcement alone might achieve.

For further information, please contact the members of Osler's Competition and Foreign Investment Group.