Goodmans LLP Update

Canadian Pharmaceutical Antitrust Litigation – Lessons Learned From Recent U.S. Decisions

Overview

There is, of course, a close link between intellectual property ("**IP**") rights and competition law. IP laws provide incentives for innovation and technological diffusion by establishing enforceable property rights for the creators of new and useful products, technologies and original works of expression. Competition law seeks a fair functioning of the market and seeks to ensure that market entry is not unduly prevented by anti-competitive behavior.

In Canada, the Competition Bureau (the "**Bureau**") is tasked with investigating allegedly anti-competitive practices and promoting compliance with the laws under its jurisdiction, most importantly the *Competition Act* (the "**Act**"). In today's knowledge-based economy, IP rights are increasingly important and there is keen interest in Canada on how the Bureau will deal with competition issues involving IP.

IPEG Guidelines and Bureau Investigations of Competition Law Breaches

Published in 2016, the *Intellectual Property Enforcement Guidelines* (the "**IPEG Guidelines**") articulate how the Bureau approaches the interface between competition policy and IP. More particularly, the IPEG Guidelines describe how the Bureau will determine whether conduct involving a party's IP raises an issue under the Act, and outline circumstances where the Bureau may commence an investigation to determine whether such conduct warrants sanction.

The IPEG Guidelines illustrate conduct the Bureau indicated may warrant intervention, including the commencement of frivolous litigation (where an action is commenced with a *mala fide* purpose of only excluding market entry by others), product switching or pay for delay settlements (where, for example, a patent holder enters into an agreement with a competitor to maintain market exclusivity for a defined period in exchange for monetary consideration). However, importantly, the IPEG Guidelines also set out behavior which will *not* warrant Bureau investigation, *i.e.*, those circumstances where an IP holder is validly exercising its right to exclusivity.

U.S. Antitrust Litigation

Unfortunately, there is no Canadian jurisprudence, yet, which provides IP holders with clarification as to the enforceability of the IPEG Guidelines, or provides any additional direction as to the manner in which the Bureau may enforce provisions of the Act. However, guidance may be taken from U.S. experience in this respect, particularly in the field of pharmaceuticals where IP holders face near constant litigation commenced by government actors (both at the federal level by the Federal Trade Commission (FTC) and at the state level) and by private drug insurers and public payors.

In this regard, two recent U.S. antitrust decisions illustrate the very different outcomes that can arise where actions are commenced.

Notably, these decisions highlight the importance of establishing a proper litigation strategy at the outset (whether addressing a Bureau complaint or a private action brought against an IP holder) which can have the effect of negating a claim in its infancy, or permitting one to proceed.

i. Novartis Succeeds in Antitrust Appeal in Gleevec Proceeding

After a series of lengthy courtroom battles, U.S.-based Novartis' successful legal strategy dealt a knockout blow to a pair of class action lawsuits brought against it in relation to its leukemia drug, imatinib (Gleevec). At its peak, sales of Gleevec approached almost $5 billion per year.

The actions, brought by health plans and a direct purchaser, alleged that Novartis illegally sought to extend Gleevec's monopoly by way of sham patent litigation, fraudulently obtaining a follow-up patent over one of the original compound's corresponding salts (the "mesylate" salt of imatinib) and had improperly engaged in exclusionary and anticompetitive behavior by entering into an agreement with Sun Pharma, a generic manufacturer, for a predefined entry date for its competitive generic imatinib medication.

The First Circuit of Appeals Court affirmed an earlier ruling that the plaintiffs failed to establish that Novartis had pursued litigation it never expected to win and that it knowingly misrepresented facts to the United States Patent and Trademark Office. In addition, the Court accepted Novartis' argument that the plaintiffs lacked standing to bring class actions challenging presumptively valid patents, a precondition to an antitrust claim.

Accordingly, the class actions were dismissed *in their entirety*.

ii. Pfizer Fails to Dismiss Lipitor Antitrust Lawsuit

The result in the Novartis decision can be contrasted with Pfizer's experience with respect to its blockbuster drug, atorvastatin (at one date, the highest selling medicine in the world).

Pfizer sought to dismiss an antitrust claim brought against it by end-payor purchasers of Lipitor who alleged it conspired with Ranbaxy to delay sales of generic versions of its product, causing them to pay inflated costs for the brand-name drug. Specifically, it was alleged Pfizer entered into a pay for delay settlement with Ranbaxy, to have engaged in sham litigation and to have fraudulently obtained a second, duplicative U.S. patent.

In the action, U.S. District Judge Sheridan rejected Pfizer's argument that the state law antitrust claims were pre-empted by federal patent law, noting the goals of patent law and antitrust and consumer protection law are "wholly different". The Court did, however, dismiss a significant number of antitrust and consumer protection claims in some states because the plaintiffs did not follow proper notice requirements, lacked standing and/or the state legislation barred consumer protection class actions. The plaintiffs' claims were allowed to move forward in the other states.

Interestingly, while the Court in both the Novartis and Pfizer cases considered the issue of standing, the Court in the Novartis case did not appear to consider the interplay between federal patent law and antitrust state law which was deliberated upon in the Pfizer proceeding (and appears to have been a key consideration). It also appears that counsel emphasized the evidence in the Novartis case, whereas the Pfizer proceeding appears to have been dealt with more on legal arguments.

Conclusion

In Canada, IP holders, particularly those in the pharmaceutical market, have been, and can expect to face, Bureau investigations seeking to implement the IPEG Guidelines and class action proceedings mirroring those commenced in the U.S. To effectively respond to any such claims (or Bureau investigation), it is essential to have appropriate legal counsel consider, at first instance, the appropriate legal strategy to be employed in responding to, or defending against, these type of allegations.

Goodmans LLP

The Goodmans Intellectual Property team is a recognized leader in Canadian IP law and has been described as having the country's premier practice in this area. Our IP Group provides wide-ranging services, including strategic and general advice on the development, acquisition, sale and protection of IP and technology assets including patents, trade-marks, trade dress, copyright, industrial designs, rights of personality, confidential information and trade secrets. When disputes arise, our IP litigators – who are known nationally for their expertise – provide effective advisory and litigation services.

Similarly, the Goodmans Competition team, in addition to complex merger review, regularly advises clients in contentious matters that raise competition issues relating to the criminal and civil provisions of the Act, including conspiracy, abuse of dominance, resale price maintenance, refusal to deal and deceptive marketing practices.

For further information, please contact any member of our Competition Law or Intellectual Property Groups.

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