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I. INTRODUCTION

The Canadian Competition Bureau, pharmaceutical companies operating in Canada, and Canadian lawyers have been following the U.S. Supreme Court proceedings in *FTC v. Actavis, Inc. et al.* with some interest.[2] In its June 2013 decision, the Court ruled on how so-called "reverse payments" by originator pharmaceutical companies to generic pharmaceutical companies in settlement of patent infringement litigation will be assessed under U.S. antitrust law. This note considers how reverse payments might be analyzed under the *Canadian Competition Act* in light of Canada's regulatory and statutory framework and enforcement approach towards intellectual property rights and competition law. While the *Actavis* case is interesting in a number of respects, it does not account for the unique Canadian statutory and regulatory environment, thus limiting its applicability to the Canadian context.

Among the notable implications are the following:

- *Actavis* holds that U.S. antitrust law can apply to reverse payments. However, since most reverse payments do not provide the patent holder with any market power that exceeds that conferred by the grant of the patent, under existing Canadian jurisprudence Canadian competition law ought not to apply to such agreements.
- To the extent scrutiny of reverse payments under the *Competition Act* is allowed, such scrutiny should only occur under Section 90.1 of the Act (the civil competitor collaboration provision).
- The requirements under Section 90.1 of the Act may very well require proof of the invalidity or non-infringement of a patent to establish that a reverse payment violates the statutory provision.

II. U.S. SUPREME COURT DECISION IN ACTAVIS

In *Actavis*, the five-justice majority held that courts could accommodate both patent and antitrust law policies. The majority took note of the fact that there is "a general legal policy favoring the settlement of disputes," and that the settlement of patent disputes avoided the need to litigate the validity of a patent, which is expensive and time-consuming. However, the majority also noted that there were important considerations why reverse payments could be subject to

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[2] *FTC v. Actavis, Inc. et al.*, 526 U. S. 756 (2013) ("Actavis").

antitrust scrutiny, including their potential to have adverse effects on competition.[3] Given the significance of the antitrust considerations, the majority held that reverse payments in settlement of patent litigation were not immune from scrutiny under U.S. antitrust law.

The dissent would have held that antitrust law does not apply to the exercise of rights within the scope the monopoly powers conferred by patent (actions beyond that scope can be subject to antitrust scrutiny, the dissent acknowledged). According to the dissent, assessments of a patent's validity are best left to patent laws, which provide a legislated mechanism for challenge.

The majority in *Actavis* also considered whether reverse payments ought to be treated as presumptively illegal under U.S. antitrust law or instead subject to a "rule of reason" analysis, where the pro- and anti-competitive effects of the settlement are weighed against each other. The majority held that a "rule of reason" approach was appropriate:

> because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries.

According to the decision in *Actavis*, in the United States, "where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services," there will be no antitrust violation. Where, however, a "patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement," greater scrutiny is likely to arise.

The majority has instructed courts that "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness, all without forcing a court to conduct a detailed exploration of the validity of the patent itself." Among other things, the actual validity of the underlying patent and the patent holder's reason for settling (including its own risk aversion) do not appear to be relevant considerations in the antitrust assessment prescribed by the majority.

III. INTERFACE OF PATENT LAW AND COMPETITION LAW IN CANADA

The Canadian statutory framework, the enforcement policies of the Canadian Competition Bureau, and the decisions of Canadian courts concerning the relationship between intellectual property law (including patent law) and competition law are clear that respect for intellectual property rights is consistent with the goals of competition policy.

A. Canadian Bureau's Current Approach Towards Intellectual Property

In 2000, the Canadian Competition Bureau issued its *Intellectual Property Enforcement Guidelines* ("IPEGs"). The IPEGs provide general guidance about how conduct concerning patents will be treated for the purposes of the *Competition Act*; there is no express policy about

[3] These considerations were as follows: (1) reverse payments have the "potential for genuine adverse effects on competition"; (2) the adverse effects on competition will "sometimes prove unjustified"; (3) where a reverse payment might produce an anticompetitive effect, patent holders have market power sufficient "to bring that harm about in practices"; (4) it is feasible to determine the competition law question without litigating the validity of the patent; and (5) there are other means by which parties can settle patent litigation without resorting to reverse payments.

how the Bureau will apply the *Competition Act* to reverse payments, however.[4] The IPEGs provide that "[t]he mere exercise of an IP right is not cause for concern under the general provisions of the Competition Act" and that "[t]he unilateral exercise of the IP right to exclude does not violate the general provisions of the Competition Act no matter to what degree competition is affected." This is consistent with the view articulated by the dissent in *Actavis*, as well as certain provisions in the *Competition Act*. For instance, section 79(5) of the *Competition Act* provides that for the purposes of the abuse of dominance section, "… an act engaged in pursuant only to the exercise of any right or enjoyment of any interested derived under [the intellectual property statutes] is not an anti-competitive act."

The IPEGs provide that where conduct involves "something more than the mere exercise of an IP right," the Bureau will scrutinize such conduct under the "general provisions" of the *Competition Act* (that is, the abuse of dominance, cartel, and other general antitrust provisions). However, where the conduct "involv[es] the mere exercise of the IP right and nothing else," then the Bureau will only consider whether action under Section 32 of the Competition Act is appropriate.[5] Section 32 of the Act has not been judicially considered in more than 20 years,[6] and the IPEGs indicate that the Bureau would attempt to seek an order under its terms "only in very rare circumstances."

B. Canadian Case Law

In the cases that have considered how the *Competition Act* might apply to the conduct of a patent holder in respect of its patent, Canadian courts have also found that the mere exercise of rights conferred by patent law alone is not capable of scrutiny under the general provisions of the *Competition Act*.[7] "Where, however, there is evidence of something more than the mere exercise of patent rights that may affect competition in the relevant market," the general provisions of the *Competition Act* can apply.[8] Similarly, the Competition Tribunal in *Tele-Direct*[9] stated: "The Tribunal is in agreement with the Director that there may be instances where a trade-mark may be misused. However in the Tribunal's view, something more than the mere exercise of statutory rights, even if exclusionary in effect, must be present before there can be a finding of misuse of a trade-mark."[10]

[4] Canada, Competition Bureau, *Intellectual Property Enforcement Guidelines* (September 2000) at Section 3.4. *See also* Canada, Competition Bureau, *"Regulated" Conduct Bulletin* (September 27, 2010) at Section 3.

[5] Section 32 of the *Competition Act* permits a court to order, among other things, a license on terms the court deems proper or the revoking of a patent. The Bureau does not have jurisdiction to bring an application under Section 32; instead, it must request that the Attorney General do so on its behalf. Further, the court cannot make an order unless it finds that the respondent's conduct has lessened or prevented competition unduly.

[6] *Society of Composers, Authors & Music Publishers of Canada v. Landmark Cinemas of Canada Ltd.* (1992), 45 C.P.R. (3d) 346 (TD).

[7] *Molnlycke AB v. Kimberly-Clark of Canada Ltd* (1991), 36 C.P.R. (3d) 493 (F.C.A.) ["*Molnlycke*"].

[8] *Apotex Inc. v. Eli Lilly and Company et al*, 2004 FCA 232 at ¶15, citing *Molnlycke*, *ibid*.

[9] *Canada (Director of Investigation & Research) v. Tele-Direct (Publications) Inc.* (1997), 73 C.P.R. (3d) 1 (Competition Tribunal).

[10] See also *Canada (Director of Investigation and Research)* v. Warner Music Canada Ltd. (1997), 78 C.P.R. (3d) 321.

IV. REVERSE PAYMENTS UNDER CANADIAN LAW

Absent any Canadian case law specifically considering the application of the *Competition Act* to reverse payments, set out below are considerations that we believe should be assessed in formulating Bureau policy or by Canadian courts when adjudicating such matters.

A. IP/Antitrust Interface in Canada

Based on the current approach in Canada towards intellectual property rights and competition law, it is doubtful whether reverse payments should even be subject to the "general provisions" of the *Competition Act*. Under existing Canadian case law and the IPEGs, it is unlikely that a court would find that reverse payments (which provide the originator with no greater market power than that which was originally provided in the grant of the patent) would count as "something more." No Canadian court has yet recognized that the mere exercise of rights within the scope of a patent that was lawfully granted is capable of scrutiny under the general provisions of the *Competition Act*.

If the general provisions of the *Competition Act* are to apply to reverse payments, the policy reasons why such settlements are not the exclusive domain of the *Patent Act* and the scheme for drug regulation in Canada should be clearly articulated. This was a key argument of the dissent in *Actavis*. Such an explanation is necessary given that these schemes, established by Parliament, anticipate that generics will (and the scheme encourages generics to) attempt to prove the invalidity or non-infringement of originators' patents, and that such litigation will be decided in favor of generics or originators on a case-by-case basis. By anticipating litigation, the schemes must also have necessarily anticipated the possibility of settlement (even where compensation flows from "plaintiff" to "defendant").

The legislation does not contain prohibitions on such settlement or on the terms of such settlements, nor does it require that settlements be reported to the Bureau (which requirement exists in the United States). Indeed, the dissent in *Actavis* recognized that restrictions on the ability of originators and generics to settle a patent dispute could have the unintended effect of discouraging generics from challenging patents in the first place, which would be contrary to the purpose of the legislation.

B. Unique Canadian Regulatory Considerations in Canada

If the *Competition Act* can apply to reverse payments because of the "potential for genuine adverse effects on competition" from such payments (per the majority in *Actavis*), any policy (or a Canadian court) should also take into account the regulatory landscape for the pricing of patented drugs in Canada, which differs in important respects from the United States. While *Actavis* effectively took judicial notice of the potential for adverse effects on competition based on the possibility of the existence of the originator earning supra-competitive profits during the term of an invalid patent, consideration is required in Canada as to whether supra-competitive profits are available to an originator whose drug is already subject to pricing restrictions under the Canadian patented medicines regulatory scheme and provincial government formularies.

C. Only the Civil Collaboration Provisions of the Competition Act Could Apply

If one were to apply the *Competition Act* to reverse payments, one would likely have to characterize the conduct as a competitor collaboration, as it may not fit within other defined types of conduct that are reviewable under the *Competition Act* (*e.g.*, abuse of dominance).[11] The *Competition Act* has two provisions that concern competitor collaborations: (1) Section 45, which criminalizes agreements between competitors to fix, maintain, or control prices or output, or allocate sales or markets, and (2) Section 90.1, which subjects to civil prohibition agreements between persons, two or more of which are competitors, where the agreement is likely to substantially lessen or prevent competition in a market.[12] In our view, *if* such settlement agreements are properly subject to antitrust scrutiny in Canada, Section 90.1 is the only section of the *Competition Act* under which reverse payments might potentially be analyzed.[13]

- ***Bureau Guidelines.*** The Bureau's Competitor Collaboration Guidelines provide that Section 45 will only be used to prosecute so-called "naked restraints," which include agreements between competitors to limit the quantity of products supplied. These agreements are treated as presumptively, or *per se*, illegal under Section 45 because they "are so likely to harm competition and to have no pro-competitive benefits that they are deserving of prosecution without a detailed inquiry into their actual competitive effects."[14]

  The U.S. Supreme Court confirmed in *Actavis* that reverse payments do not meet the analogous U.S. standard of *per se* violations (*per se* violations of Section 1 of the *Sherman Act* are reserved only for situations where "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets"). The uncertainty of whether competitive harm results from reverse payments (and the degree of harm, if any), together with the recognized benefits of the settlement of litigation, militate strongly against any attempt to treat reverse payments as a naked restraint and presumptively criminal under Section 45 of the *Competition Act*.

D. Section 90.1 May Very Well Require an Assessment of a Patent's Validity

Section 90.1 requires, among other things, that the Bureau prove that (1) two parties to the agreement are competitors or likely competitors, and (2) competition in a market has been or is likely to be lessened or prevented substantially by the agreement. Section 90.1 therefore presents an immediate difficulty, since proving the parties to the reverse payment are competitors would require proof of the patent's invalidity or non-infringement.

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[11] See *The Commissioner of Competition v. The Toronto Real Estate Board*, 2013 Comp. Trib. 9.

[12] The separate criminal and civil provisions for investigating horizontal agreements had not yet been passed into law at the time that *Apotex v. Eli Lilly* was decided. If they had been, another issue for the court might have been whether an allegation under Section 45 concerning conduct that is not a "naked restraint" could survive a motion for summary judgment.

[13] Applications under Section 90.1 are made exclusively to the Competition Tribunal, a specialized tribunal for the adjudication of certain matters under the *Competition Act.*

[14] Canada, Competition Bureau, *Competitor Collaboration Guidelines* (December 23, 2009), Section 2.1.

Though Section 90.1 has yet to be judicially interpreted, courts have interpreted other civil sections of the *Competition Act* as requiring that a "but for" test be conducted—but for the operation of the agreement, would the market be (or would the market likely be) substantially more competitive?[15] If a "but for" test were applied under Section 90.1, it would necessitate an assessment of the degree of competition that would prevail had the litigation not been settled.

This seems to encompass two questions: (1) would the patent have been invalidated or been declared non-infringed, and (2) if the answer to the first question is "yes," would the relevant market have been substantially more competitive (following entry by the generic).

In respect of the first question, as of yet there is no authority in Canada for a court to examine the size of the reverse payment as a "surrogate" for a patent's weakness, as permitted in *Actavis*. Instead, it appears that the Tribunal would have to overcome the same conceptual problem that arose in *Actavis* (which would require, among other things, that the Tribunal – a specialized competition law court—consider its expertise relative to the expertise of the Federal Courts, which typically adjudicate patent disputes). This conceptual problem appears particularly difficult in light of guidance provided by the current IPEGs, which shields conduct involving the mere exercise of patent rights from scrutiny of the "general provisions" of the Act, including Section 90.1. Additionally, the adjudication of a prohibition proceeding usually requires the consideration of expert evidence on infringement and/or validity as well as other technical evidence, and so it would not be a simple matter for the Tribunal to determine whether a patent would have been declared invalid or not infringed had the matter proceeded to a hearing before the Federal Court.

In respect of the second question, the Tribunal would have to consider the applicable dynamics (including Canadian pricing regulation) in the markets at issue. The relative complexity of this question may differ from case-to-case.

E. Remedial Considerations

If the Bureau established that a reverse payment lessened or prevented competition substantially, under Section 90.1 the Tribunal could only prohibit the agreement that provides that the generic will not enter the market. Such an order would not give the generic (or other generics) the right to market a generic version of the originator's drug—the generic would still face the risk of a prohibition proceeding and subsequent infringement suit, where it would be put to the cost, difficulty and uncertainty of proving the invalidity or non-infringement of the patent in the Federal Court.[16]

Thus, the effectiveness of any order by the Tribunal under Section 90.1—measured by the degree of competition that the order produces as compared with the level of competition that

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[15] *Canada (Commissioner of Competition) v. Canada Pipe Company Ltd.*, 2006 FCA 233 at ¶37.

[16] Chief Justice Roberts' dissent in *Watson* alluded to the changing position generics would be forced to adopt. "The majority's rule will discourage settlement of patent litigation. Simply put, there would be no incentive to settle if, immediately after settling, the parties would have to litigate the same issue—the question of patent validity—as part of a defense against an antitrust suit. In that suit, the alleged infringer would be in the especially awkward position of being for the patent after being against it." The position would be further complicated in Canada, where if the Bureau prevailed against the reverse payment, the generic would have to reverse its position and assert for a second time that the patent is invalid or not infringed.

prevailed during the operation of the agreement—may depend upon the outcome of the subsequent prohibition proceedings. It is not within the power of the Tribunal to declare that a patent is invalid or not infringed, or to prohibit the originator from bringing further prohibition proceedings or patent infringement litigation. Even if the *Competition Act* can apply to reverse payments, the Tribunal has no authority under Section 90.1 to undo or overcome the exclusionary scope of the patent.

V. CONCLUSION

Interested observers in Canada followed the proceedings in *Actavis* carefully. The decision is interesting, in particular for its discussion of the ambiguous competitive effects that might arise from reverse payments. Naturally, however, *Actavis* does not address a number of unique Canadian statutory and regulatory issues that any Canadian court or policymaker would have to consider. As a result, parties in Canada must continue to resolve their disputes and assess such issues in light of the Canadian-specific regulatory and statutory requirements.