REVERSE PAYMENT SETTLEMENTS IN PHARMACEUTICAL LITIGATION:

What Are They and Do They Occur in Canada?

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Comparison of Canadian and U.S. Pharmaceutical Approval Process Related to Patent Protection

U.S. — Hatch-Waxman Act

On September 24, 1984, President Reagan signed into law the *Drug Price Competition and Patent Term Restoration Act of 1984*,[1] which is more commonly known as the *Hatch-Waxman Act*. Title 1 of the *Hatch-Waxman Act* amended the Federal *Food, Drug, and Cosmetic Act*[2] to expand the universe of drugs for which the FDA would accept abbreviated new drug submissions (ANDAs).

The *Hatch-Waxman Act* also provided for New Drug Product Exclusivity—often referred to as Hatch-Waxman exclusivity due to the sponsorship for the amendments provided by Senator Hatch and Congressman Waxman in Congress to encourage research and development, as well as to increase the speed of the entry of generic drugs into the market. The purpose of the *Hatch-Waxman Act* was to balance rapid innovative drug development with market introduction of less expensive generic drugs.

Canada — Patented Medicines (Notice of Compliance) Regulations

The *Patented Medicines (Notice of Compliance) Regulations*[3] (the "*Regulations*") were enacted in 1993 under Section 55.2[4] of the *Patent Act*,[5] and modelled after the *Hatch-Waxman Act* in the U.S. The purpose of the *Regulations* was to balance innovation in the pharmaceutical industry with increased production of less expensive, more accessible generic drugs. The enactment of Section 55.2 of the *Patent Act* provided an exception to patent infringement in Canada whereby a person (such as a generic drug company) could make, construct, use or sell a patented product or process prior to expiration of the relevant patent provided it was "related to the development and submission of information required under any law of Canada."

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[1] Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b-68c, 70b (1994)
[2] Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended 21 U.S.C. §§ 301 et seq.)
[3] SOR/93-133
[4] S.C. 1993, c. 2, s. 4
[5] R.S.C. 1985, c. P-4

Process for Generic Entry under the *Hatch-Waxman Act* in the U.S.

In the U.S., drug products that are new or have been modified require approval of the FDA before market entry. Thus, a company seeking market entry with a new or modified drug must file an application to the Secretary of Health and Human Services of the FDA (the "Secretary"). There are two types of applications commonly filed:

> *New Drug Applications* ("NDAs"), which are generally filed by innovators or brands; and
>
> *Abbreviated New Drug Applications* (ANDAs), which are generally filed by generics.

The innovator or brand pharmaceutical company also files a list of relevant patents with the FDA to be listed in the Orange Book. The Orange Book is publicly available[6] and provides generic manufacturers with a tool to monitor drug patents covering brand-name drug products, while at the same time giving those companies that hold NDAs the opportunity to obtain an automatic suspension of FDA approval for any ANDA that the NDA-holder believes infringes on the Orange Book-listed patents. Patents are generally listable in the Orange Book if the patent relates to the medicine in the brand-name product, subject matter concerning the physical or chemical form of the medicine, or the drug delivery system (*eg.* formulation). The Orange Book is not meant to encompass patents directed to the preparation of the brand-name product.[7]

If an ANDA is sought, the applicant generic must premise its application on one of the following bases:

> (a) the required information for the patent was not filed,
>
> (b) the patent has expired,
>
> (c) the patent will expire on a particular date, or

[6] http://www.fda.gov/cder/ob/
[7] M.M. Rumore, "Patent Law, Trademarks, and Copyrights" in D.D. Konnor, Ed., *Pharmacy Law Desk Reference* (The Haworth Press: 2007) at 130

(d) the patents listed in the Orange Book relevant to that medicine are invalid or not infringed.

If the generic premises its application by stating that the patents are invalid or will not be infringed, the generic must also file a "notice of opinion," which must be given to the brand within 20 days of the notice's postmark date. The patent holder has 45 days after receipt of the notice of opinion within which to commence an action for infringement. If no action is commenced by the patent holder, the Secretary has 180 days within which to either approve the application so the generic can enter the market if the scientific requirements for the ANDA are satisfied, or inform the applicant of the opportunity for a hearing if the scientific requirements have not been met.

Thirty-month stay under the Hatch-Waxman Act

Once an action for infringement is commenced by the brand, a 30-month stay is imposed within which the approval of the ANDA will not be effective. The 30-month stay will be lifted if, prior to its expiration, a court determines that the patent is invalid or is not infringed.

Exclusivity under the Hatch-Waxman Act

In the U.S., New Drug Product Exclusivity is provided by the *Federal Food, Drug, and Cosmetic Act* under section 505(c)(3)(E) and 505(j)(5)(F). New Drug Exclusivity provides the holder of an approved NDA limited protection from new competition in the marketplace for the innovation represented by its approved drug product.

A 5 year period of exclusivity is granted to NDAs for products containing chemical entities never previously approved by FDA either alone or in combination. During this 5-year exclusivity period, no 505(b)(2) application or ANDA may be submitted. There is an exception—such applications may be submitted after 4 years if they contain a certification of patent invalidity or non-infringement.

Under *Hatch-Waxman Act*, certain ANDAs may also enjoy limited exclusivity. A 3-year period of exclusivity is granted for a drug product that contains an active moiety that has been previously approved, when the application contains reports of new clinical

investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. For example, changes related to the active ingredient(s), strength, dosage form, route of administration or conditions of use may be granted exclusivity if clinical investigations were essential to approval of the application containing those changes.

180-day generic exclusivity under the Hatch-Waxman Act

If the ANDA is approved by the FDA and was based on a paragraph IV certification (*i.e.* that the patent is invalid or not infringed), the generic receives 180 days of market exclusivity. This 180-day generic exclusivity is only granted to the first generic that applied for an ANDA and filed a paragraph IV certification. The first generic enjoys the benefit of the 180 day generic exclusivity if it is successful in the patent infringement action (*i.e.* the patent is shown to be not infringed), but also if the generic reaches an agreement with the patent owner or NDA holder.

This 180-day generic exclusivity is not part of the pharmaceutical patent regime in Canada under the *Regulations*.

Process for Generic Entry under the *Patent Medicines (Notice of Compliance) Regulations* in Canada

For an innovative pharmaceutical company (generally known as a "brand" name pharmaceutical company, or a "first person" under the *Regulations*) to obtain market approval in Canada, it must first file a New Drug Submission ("NDS") with the Minister of Health. Generally, the first person also files a Form IV patent list with Health Canada for addition of patents to the Patent Register in relation to its NDS or, if applicable, its Supplemental New Drug Submission ("SNDS") (see Section 4(1) of the *Regulations*). Those patents currently listed against medicinal ingredients are publicly available on the Patent Register website.[8]

A patent list in relation to a NDS is eligible to be added to the register if the patent contains:

> (a) a claim for the medicinal ingredient and the medicinal ingredient has been approved through the issuance of a notice of compliance in respect of the submission;
>
> (b) a claim for the formulation that contains the medicinal ingredient and the formulation has been approved through the issuance of a notice of compliance in respect of the submission;
>
> (c) a claim for the dosage form and the dosage form has been approved through the issuance of a notice of compliance in respect of the submission; or
>
> (d) a claim for the use of the medicinal ingredient, and the use has been approved through the issuance of a notice of compliance in respect of the submission.

If a generic (a "second person" under the *Regulations*) wishes to sell an equivalent product, it must file Abbreviated New Drug Submission ("ANDS") in order to obtain a Notice of Compliance ("NOC") from the Minister of Health, which is required before the

[8] http://www.patentregister.ca

generic can enter the Canadian market (Section 5(1) of the *Regulations*). The Minister of Health cannot grant an NOC to a generic until it addresses all the patents listed on the patent register against the specific drug in question.

Pursuant to Section 5(1) of the *Regulations*, to obtain an NOC, the generic has the following options, it can:

(a) state that it accepts that the NOC will not issue until the patent expires; or

(b) it can serve a Notice of Allegation ("NOA") alleging that:

(i) the first person is not the owner of the patent, or the exclusive licencee, or does not have the consent of the owner,

(ii) the patent has expired,

(iii) the patent is invalid, or

(iv) no claim for the medicinal ingredient, no claim for the formulation, no claim for the dosage form and no claim for the use of the medicinal ingredient would be infringed by the second person making, constructing, using or selling the drug for which the submission is filed.

An NOA sent by the second person (*i.e.* the generic) to the first person (*i.e.* the brand) must set out a detailed statement of the legal and factual basis for the allegations. Upon being served with the NOA, the first person has 45 days to apply to the court for an order prohibiting the Minister of Health from issuing an NOC until the expiry of the patent(s) to which the NOA relates. The order of prohibition is sought by the first person by way of judicial review application and the court must decide whether the allegations raised in the second person's NOA are justified or not.

The 45 day period available to the first person or the patent holder is the same in both the *Regulations* and the *Hatch-Waxman Act*—but under the *Regulations*, if the first person does not commence an application, the Minister may issue the NOC after the 45-day

period has expired. However, there is requirement for a specific time within which the NOC must be issued (this will depend on the approval process for the generic's ANDS).

Twenty-four-month stay under the Regulations

Upon commencing an application, the first person obtains a 24-month stay, which is similar to an interlocutory injunction. During that 24-month period, the Minister is prohibited from issuing an NOC unless either a court determines the allegations made in the second person's NOA are justified, or the patent(s) to which the NOA relates expire. The risk to the first person, however, is that if the first person commences a prohibition proceeding under the *Regulations* but is unsuccessful (*i.e.* the second person's allegations are found to be justified), the first person faces the risk of the second person's claim for damages under Section 8 of the *Regulations*.

Data Exclusivity under the Food and Drug Regulations

On October 18, 2006, the Federal Government amended the *Regulations* and the data protection provision of the *Food and Drug Regulations*[9] to create an 8-year exclusivity period of data protection for new drugs (previously a 5-year period) from the date the new drug received a NOC, unless the drug owner consents to a generic manufacturer's filing of an ANDS.

The data protection amendments to the *Food and Drug Regulations* clarified and implemented Canada's obligations under the *North American Free Trade Agreement* ("NAFTA") and the *Trade-Related Aspects of International Property Rights* ("TRIPS") to protect research data submitted to regulatory authorities by innovative companies. These amendments were intended to provide clarity, predictability and balance to laws affecting the pharmaceutical and biopharmaceutical industries in Canada.

Under the data protection amendments, the first 6 years are considered to be a no-filing period, within which a generic is prohibited from filing an ANDS for the reference product (*i.e.* the new drug). During the final 2 years, the generic may file an ANDS and directly or indirectly compare its generic version with the new drug based on the new

[9] C.R.C., c. 870

drug's safety and efficacy data; however, the Minister of Health will not issue the NOC until the expiry of the full 8 years of data exclusivity. The data protection period applies only to drugs marketed in Canada—it ceases to apply once a drug is no longer marketed in Canada.

Reverse Payment Settlements in Pharma Patent Litigation

Settlements in pharmaceutical litigation may raise competition law issues in situations where payments are to be going the wrong way—*i.e.* the brand (or patent owner) pays an undisclosed amount of money to a generic in exchange for settling the ongoing litigation and the generic refraining from entering the market with a competing product (at what would be a substantially lower price).

As discussed below, the FTC in the U.S. of the view that such settlements are the result of collusion to monopolize, and are anti-competitive act by preventing competition in the market.

Reverse Payment Settlements in the U.S.

In the U.S., the FTC has challenged reverse payment settlements between pharmaceutical companies as anticompetitive on a number of occasions.

In 2001, the FTC issued an administrative complaint against Schering-Plough Corp., Upsher-Smith Laboratories and American Home Products Corp. alleging violations of Section 1 of the *Sherman Act*[10] and Section 5 of the *FTC Act*.[11] The FTC's final order, finding the respondents liable for antitrust violations, was reversed on appeal to the Eleventh Circuit in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005), cert. denied, 548 US 919 (2006).

In *Schering-Plough*, the settlements related to patent infringement suits between Schering- Plough Corp. and Upsher-Smith Laboratories, Inc. and between Schering and an affiliate of American Home Products. The product at issue was an extended release formula of a potassium chloride supplement called K-Dur 20.

In late 1995, Schering sued Upsher for patent infringement after Upsher filed its ANDA for a generic version of the drug. Before trial, Schering and Upsher agreed to a settlement that set an "earliest" date of entry for the generic product in 2001. The settlement contained a separate agreement whereby Schering agreed to pay Upsher for a license to

[10] ch. 647, 26 Stat. 209, 15 U.S.C. § 1-7
[11] 15 U.S.C. §§ 41-51

market other Upsher products. The agreement reached to settle the litigation resulted in $60 million in initial royalties, $10 million in milestone royalty payments and 10% or 15% royalties on sales flowing from Schering to Upsher.

At generally the same time, Schering reached a settlement agreement with an affiliate of American Home Products with respect to its generic version of K-Dur 20. The agreement reached in this case was that the American Home Products generic version of K-Dur 20 would enter the market in 2004, three years before the patent expired. According to the settlement, $5 million for legal fees flowed from Schering to American Home Products, and an additional $10 million would be paid if American Home Products received FDA approval by a certain date (which was unlikely).

After the FTC filed a complaint against Schering, Upsher and American Home Products in March 2001, the Commission held that the settlements were anti-competitive.

On appeal, however, the Court of Appeals for the Eleventh Circuit overturned the Commission's decision, holding that the proper analysis of antitrust liability where patent infringement settlements are concerned is neither a per se or rule of reason analysis, but should include an examination of:

(a) the scope of the exclusionary potential of the patent;

(b) the extent to which the settlement agreement exceeds that scope; and

(c) the resulting anticompetitive effects.

The Court of Appeals found no evidence that the patents were invalid or that the infringement claims were a "sham". The Court found that policy favours the settlement of litigation, and in the context of complex pharmaceutical patent infringement actions, "the caustic environment of patent litigation may actually decrease product innovation by amplifying the period of uncertainty around the drug manufacturer's ability to research, develop, and market the patented product or allegedly infringing product."

Since the 2005 decision in *Schering-Plough Corp. v. FTC*, the Eleventh Circuit's approach has been followed by numerous federal circuit and district courts, including by

the Second Circuit in *In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187 (2d Cir. 2006), and by the Federal Circuit in *In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 544 F.3d 1323 (Fed. Cir. 2008).

In the *In re Ciprofloxacin Hydrochloride*, the court held that settlements of patent claims by agreement, even those that involve the exchange of substantial consideration, are not precluded by the *Sherman Act*, even if there is an adverse effect on competition. The court explained in that case that, "a sizable exclusion payment from the patent holder to the generic manufacturer is not unexpected under the *Hatch-Waxman Act*, where the relative risks of litigation are redistributed."[12]

No federal court has adopted the FTC's view of final pharmaceutical patent settlements.

A New Challenge – FTC v. Watson Pharmaceuticals et al.

On January 29, 2009, the FTC, in conjunction with California's Attorney General, launched a challenge to reverse payment settlements in *Fed. Trade Comm'n et al. v. Watson Pharm., Inc. et al.*, 09-cv-00598.

The FTC's complaint includes the brand company Solvay Pharmaceuticals, which produce a popular testosterone replacement drug called AndroGel. AndroGel, protected by a formulation patent, is Solvay's top-selling drug in the U.S., generating more than $400 million in sales in 2007. The complaint also names the generics Watson Pharmaceuticals, Par Pharmaceuticals and Paddock Laboratories.

The FTC's complaint is based on the fact that after Watson obtained final approval from the FDA to market its generic version of AndroGel in 2006, Watson and Solvay agreed to settle their patent dispute. According to the settlement, Watson agreed to refrain from marketing its generic version of AndroGel until 2015, or earlier if another generic company entered the market before that date. The FTC claims that Solvay and Watson entered into a co-promotion deal in which Solvay was to share a portion of AndroGel's profits with Watson. The FTC's position is that the substantial profits Solvay agreed to

[12] 544 F.3d 1323 at 1333, n. 11, citing *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 at 1074 (11th Cir. 2005)

share under the co-promotion agreement was designed to, and did in fact, induce Watson to refrain from competing with Solvay until 2015. Solvay and Watson voluntarily terminate the patent litigation on this basis, but didn't file their settlement or co-promotion agreements with the court.

On the same day that Solvay settled with Watson, Solvay also settled with Par Pharmaceuticals and Paddock Laboratories, which both agreed to refrain from marketing their generic until 2015, in exchange for a co-promotion deal wherein Solvay agreed to pay $10 million annually for six years. The patent litigation between Solvay, Par and Paddock was dismissed pursuant to a consent judgment. Again, the parties did not file their settlement and co-promotion agreements with the court.

The FTC's complaint alleges that the reverse payment settlements unlawfully eliminated competition between would-be competitors, denying consumers the opportunity to purchase lower-cost generic versions of AndroGel, at a cost of hundreds of millions of dollars a year to the consumers.

Competition Law in Canada as it relates to Patents

In Canada, the Commissioner in a section 45 proceeding or the plaintiffs in a section 36 claim[13] under the current *Competition Act*[14] would likely be required to show that the settlements resulted in an "undue" lessening of competition.

The federal *Competition Act* applies to all sectors of the Canadian economy (with a few specific exceptions) and all "products", which includes both articles and services.[15]

[13] Section 36(1) of the *Act* reads as follows:

36. (1) Any person who has suffered loss or damage as a result of
(a) conduct that is contrary to any provision of Part VI, or
(b) the failure of any person to comply with an order of the Tribunal or another court under this Act,
may, in any court of competent jurisdiction, sue for and recover from the person who engaged in the conduct or failed to comply with the order an amount equal to the loss or damage proved to have been suffered by him, together with any additional amount that the court may allow not exceeding the full cost to him of any investigation in connection with the matter and of proceedings under this section.

[14] R.S.C. 1985, c. C-34

[15] *Competition Act*, s. 2(1)

As set out in Section 1.1 of the *Act*, the purpose of the *Competition Act* is:

> [T]o maintain and encourage competition in Canada in order to promote the efficiency and adaptability of the Canadian economy, in order to expand opportunities for Canadian participation in world markets while at the same time recognizing the role of foreign competition in Canada, in order to ensure that small and medium-sized enterprises have an equitable opportunity to participate in the Canadian economy and in order to provide consumers with competitive prices and product choices.[16]

The underlying policy of the *Competition Act* is that competitive markets are socially desirable and lead to an efficient allocation of resources. Competition laws are targeted at the inappropriate creation or enhancement of market power, which is defined by the Competition Bureau as:

> [T]he ability of firms to profitably cause one or more facets of competition, such as price, output, quality, variety, service, advertising or innovation, to significantly deviate from competitive levels for a sustainable period of time.[17]

Section 45(1) of the *Competition Act* relates to conspiracy to lessen competition, and under the current version of the *Act* reads as follows:

> 45. (1) Every one who conspires, combines, agrees or arranges with another person
>
> > (a) to limit unduly the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any product,
> >
> > (b) to prevent, limit or lessen, unduly, the manufacture or production of a product or to enhance unreasonably the price thereof,
> >
> > (c) to prevent or lessen, unduly, competition in the production, manufacture, purchase, barter, sale, storage, rental, transportation

[16] *Competition Act*, s. 1.1
[17] The Competition Bureau, *Intellectual Property Enforcement Guidelines*, (Ottawa - Industry Canada, 2000) at 3.

or supply of a product, or in the price of insurance on persons or property, or

(d) to otherwise restrain or injure competition unduly,

is guilty of an indictable offence and liable to imprisonment for a term not exceeding five years or to a fine not exceeding ten million dollars or to both.

Section 45 of the *Act* has recently been amended[18] to remove the requirement that the act "unduly" prevent, limit or lessen competition.[19] Under the new subsection 45(1), it will be an offence to conspire, agree or arrange with a competitor (a) to fix, maintain, increase or control the price for the supply of the product; (b) to allocate sales, territories, customers or markets for the production or supply of the product; or (c) to fix, maintain, control, prevent, lessen or eliminate the production or supply of the product. An exception is provided by subsection 45(4), whereby the accused party must show that the *Act* is not contravened because the impugned agreement or arrangement was ancillary to a broader or separate agreement or arrangement between the same parties and directly related to, and reasonably necessary for giving effect to, the objective of the ancillary agreement or arrangement. It must also be shown that the ancillary agreement or arrangement, considered alone, does not contravene subsection 45(1).

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[18] On March 12, 2009, the *Budget Implementation Act* received Royal Assent and contained amendments intended to modernize the *Competition Act*. Provisions relating to collaborations between competitors do not come into force for one year (http://www.cb-bc.gc.ca/eic/site/cb-bc.nsf/eng/03023.html).

[19] Section 45(1), (2) and (4) of the amended *Act* are as follows:

45. (1) Every person commits an offence who, with a competitor of that person with respect to a product, conspires, agrees or arranges

(a) to fix, maintain, increase or control the price for the supply of the product;

(b) to allocate sales, territories, customers or markets for the production or supply of the product; or

(c) to fix, maintain, control, prevent, lessen or eliminate the production or supply of the product.

(2) Every person who commits an offence under subsection (1) is guilty of an indictable offence and liable on conviction to imprisonment for a term not exceeding 14 years or to a fine not exceeding $25 million, or to both.

(4) No person shall be convicted of an offence under subsection (1) in respect of a conspiracy, agreement or arrangement that would otherwise contravene that subsection if

(a) that person establishes, on a balance of probabilities, that

(i) it is ancillary to a broader or separate agreement or arrangement that includes the same parties, and

(ii) it is directly related to, and reasonably necessary for giving effect to, the objective of that broader or separate agreement or arrangement; and

(b) the broader or separate agreement or arrangement, considered alone, does not contravene that subsection.

The mere exercise of an IP right in Canada, such as enforcing an issued patent, does not in itself violate the provisions of the current *Competition Act*.[20] As stated above, for an act to be contrary to section 45 of the current *Act*, it must have an undue lessening of competition. A patent, by its nature, results in a lessening of competition by granting the patentee the right to exclude others, as part of the essential bargain between the patentee and the state. Thus, the exercise of this right does not constitute *undue* lessening of competition, although it is also not immune from the provisions of the *Competition Act*.[21]

Do Reverse Payment Settlements Occur in Canada?

As discussed above, there are a number of important distinctions between the U.S. regime under the *Hatch-Waxman Act* and the Canadian regime under the *Regulations*. The key differences can be summarized as follows:

U.S. Regime:	
Type of proceeding:	infringement action – trial on the merits
Length of stay:	30-months
Generic exclusivity:	180-days
Canadian Regime:	
Type of proceeding:	judicial review – whether allegation is justified or not
Length of stay:	24-months
Generic exclusivity:	n/a

Given these differences, there is a much greater incentive in the U.S. for the brand to bargain with the first generic—the brand can essentially buy an additional 180 days of exclusivity from the generic, while avoiding the risk of losing an infringement action, after which the patent may be declared invalid and unenforceable against other generics. A reverse payment settlement with the first generic means the brand can profit on its own sales during the 180-day exclusivity period and still pay the first generic a sum equivalent to the profits the generic would have made, plus a premium. The generic can postpone its operating costs to manufacture and sell its product, and still realize the profit it would have made had it entered the market.

[20] *Eli Lilly and Co. v. Apotex Inc.*, 2005 FCA 361 at para. 34
[21] *Eli Lilly and Co. v. Apotex Inc.*, 2005 FCA 361 at paras. 30-32

In Canada, a proceeding under the *Regulations* is a judicial review application with no final determination as to the validity of the patent(s) at issue—the only finding made is whether the allegations of the generic are justified or not. If the brand is unsuccessful in the prohibition proceeding, Health Canada is free to grant an NOC to the generic (provided its submission is acceptable) and the generic can enter the market. The brand will often then commence an action for infringement and *res judicata* does not apply. While a judicial review application under the *Regulations* is on a paper record (without live witnesses in court), a judge hearing an action for infringement has the benefit of live witnesses and expert testimony, so the brand may succeed in the infringement action despite having lost in the earlier proceeding.

Despite the differences above and the much greater bargaining incentive for a brand in the U.S., there is still an incentive in Canada for a brand to settle a proceeding under the *Regulations* with the first generic to reach a hearing on the merits. The Federal Court of Appeal has held that first persons will not be permitted to defend against allegations by subsequent generics after the same allegation made by an earlier generic has been found to be justified.[22] Consequently, if a brand unsuccessfully challenges a generic's invalidity allegation, not only will that generic be granted an NOC and likely enter the market, but any proceeding involving a subsequent generic in which the same allegation is raised can be dismissed[23] and an NOC can issue. The brand must then commence infringement actions against each generic to force them out of the market.

Thus, where a brand fears the first generic may succeed in the prohibition proceeding on its invalidity allegations, there is an incentive to settle *before* a decision is rendered to prevent a flood of generics from entering the market. For instance, the brand may strike a deal with the first generic whereby the generic will consent to the issuance of a prohibition order in exchange for an undisclosed sum and an agreement by the brand to consent to the issuance of an NOC at a date prior to the expiry of the relevant patents, or the same day as any subsequent generic is granted an NOC (if this occurs).

[22] *Sanofi-Aventis Canada Inc. v. Novopharm Ltd.*, 2007 FCA 163 at para. 50
[23] Pursuant to section 6(5) of the *Regulations*

According to the approach adopted by the courts in the U.S., unless a patent has been successfully challenged in a Canadian court, a reverse payment settlement may not be considered to be a lessening of competition in the Canadian marketplace. It is not surprising that a number of settlements reached in Canada between brands and generics with respect to proceedings under the *Regulations* occur before a decision is rendered on the validity of the patent(s) at issue. Where the patent may still be considered valid, a settlement based on that patent, even if it involves reverse payments from the brand to the generic, may not attract liability under Canada competition laws. Under the amended version of the *Act*, even if a reverse payment settlement is considered by a court to contravene subsection 45(1), the parties may be able to avail themselves of subsection 45(4) if they can prove that the reverse payment was ancillary to and reasonably necessary for the agreement to settle the proceeding, which on its own would likely not violate subsection 45(1).