PHARMACEUTICALS AND COMPETITION LAW, REGULATORY CONTEXT, SETTLEMENT AGREEMENTS, AND MORE

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Pharmaceuticals play a key role in our health system and society, and therefore are of interest from many different perspectives, including competition law. Intellectual property rights are an essential element of the pharmaceutical industry. Over the past decade, there has been increased interest in the interface between intellectual property and competition law, and therefore one would expect those interface issues to play prominently in the pharmaceutical sector. There are several significant areas of tension and controversy between competition law and IP rights related to pharmaceuticals. This paper is one of four on this panel to consider the pharmaceutical industry and competition law. This paper will look at the pharmaceutical regulatory regime as a necessary backdrop to understanding some of the issues, and will then look at intellectual property settlements between innovator and generic companies, and briefly touch upon authorized generics and the so called "evergreening" issue.

It has become fashionable to say that intellectual property law and competition law are complementary. They both have as their ultimate objective the fostering of innovation, development of markets and competitiveness. They may have similarities, but there are also serious differences. From the perspective of an economist, intellectual property protection has long-term goals and requires long-term assessment, whereas competition law has far shorter term goals. However, at a more fundamental level, competition law seeks to break down barriers and exclusions, whereas intellectual property, by its very nature, provides exclusivity to the protected property. There will be situations where the clash between patent rights and competition law cannot be resolved with general comments that they are complementary. There will be situations where, in the end, one body of law or the other must be paramount.

Pharmaceuticals raise even greater challenges for the application of competition law because, in addition to the intellectual property interface, pharmaceuticals are subject to a web of regulatory regimes dealing with marketing approval, patent challenges and reimbursement. Therefore, a regulatory overview is provided below.

As noted above, a clash between IP and competition law respecting pharmaceuticals is not unexpected given the importance of pharmaceuticals and the
complex regulatory regimes that prevail. Accordingly, there has been an increased interest in the pharmaceutical industry by competition authorities. There have been recent developments in the EU and the U.S.A., but less so in Canada.

In the U.S.A., the FTC has a history of challenging settlements of patent litigation between the innovator (patent holder) and generics, especially those involving payments from the innovator to the generic, resulting in the generic remaining off the market. The Department of Justice under the new administration has reversed its position and now sides with the FTC on this issue. The FTC has also released a recent study with respect to authorized generics.

In the EU, the Commissioner launched an inquiry into the pharmaceutical industry in 2008, which was initiated by a series of "dawn raids" at pharmaceutical headquarters across Europe. In July, 2009, the EU released its report on its inquiry indicating increased enforcement against tactics used by the innovator companies to allegedly delay generic entry.

In Canada, there has been less extensive study or enforcement activity. The Bureau did intervene before the Federal Court of Appeal in the case of Eli Lilly v. Apotex, respecting the application of section 45 to the acquisition of multiple patents by an innovator pharmaceutical company which was alleged to have anti-competitive effects by excluding a generic. The Bureau had also done an inquiry in 2004 in response to a 6-resident application under section 9 into alleged misuse of drug patent rules (i.e. evergreening). In March, 2007, it hosted a symposium concerning IP issues which included papers and discussion on authorized generics. It also released a study on the generic drug industry. However, the Bureau has not provided specific public guidance with respect to drug patent settlements with generics, and has provided little public discussion or guidance respecting other pharmaceutical industry issues. The Bureau has indicated interest in the pharmaceutical industry, but does not appear to have engaged in the same level of study or enforcement as in the U.S.A. or the EU. It may well be that differences in the regulatory regimes respecting pharmaceuticals results in the competition issues not being as acute here as elsewhere.
REGULATORY CONTEXT

- Pharmaceuticals have unique market characteristics due to the combination of drug regulatory and patent regimes, the role of pharmacies and of third party payers and provincial formularies, as well as the doctor/patient relationship.

- Drugs take years to develop and get approved, and bringing a product to market costs in the billions of dollars. Only a tiny percentage of projects result in a drug being marketed. Therefore, patent and data protection and the consequent exclusivity is essential to the pharmaceutical industry and its benefits to patients.

- Pharmaceuticals can only be sold with approval of Health Canada, which determines efficacy and safety. Innovator companies must pursue patent protection and marketing approval, both of which are long and involved processes. The Patent Office grants patents, but that is not an authorization to sell a drug which can only come from Health Canada.

- Once a patent is granted and marketing approval is issued by Health Canada, innovator companies will seek listing on the Provincial Formularies, which creates yet another regulatory hurdle. Provinces reimburse the drug costs of patients qualifying for various social assistance programs, and therefore the province decides whether to approve a drug for reimbursement (i.e. listed on the Provincial Formulary). The province also determines the price at which it will reimburse.

- Provincial Formulary price tends to determine the price in the general market.

- The Provincial Formularies also set the price for generic versions once they enter the market. Generic drugs are at a substantial discount from the original patented version (example: 50% in Ontario), although generic prices in Canada tend to be higher than those elsewhere, and significantly higher than in the U.S.A.
Provincial reimbursement creates a situation where the province is the payer but is not the purchaser and not the decision maker on what drug will be used. However, once a generic version is approved, provincial laws tend to require that the pharmacy substitute the generic version for the original version, unless doctors specifically provide otherwise (automatic substitution).

Generics are bio-equivalent copies of a pharmaceutical and can enter the market, once all relevant patents expire, or potentially sooner, under the PMNOC regulations of the Patent Act (see below).

Physicians make the prescribing decisions in consultation with the patients, and therefore doctors essentially make the choice between possible alternative drugs within the same therapeutic class, or make the decision whether or not to require use of the innovator version as opposed to a generic. Although physicians are essentially the decision-makers, they are not the purchasers. Therefore, unlike normal product markets, pharmaceuticals operate in a context where the decision-maker often is not the party making the payment, and the consumer may be reimbursed by either a government or a private insurer.

A patent provides exclusive rights to the owner for the period between the grant of the patent and the 20th anniversary of the filing date of the application. Applications may take several years to process, and therefore patents typically provide exclusivity for a period far less than 20 years.

If all generics respect the patents of the innovator, there will be no generic copy of that particular drug on the market until expiry of all relevant patents. However, the innovator drug may well be in competition with other innovator drugs of a different compound but within the same therapeutic class, and which might be used in substitution for it.

Theoretically, a generic might choose to ignore the innovator patents and enter the market in competition, or may do so in the belief that a patent is invalid or would not be infringed by its product. That would leave the innovator to sue the
generic for infringement, and would essentially limit the claim to damages because it is virtually impossible to obtain an injunction in that context to keep the generic off the market pending resolution of the patent issues.

- In a compromise between patent protection for innovators and generic entry, the Patent Act creates a "linkage" between Health Canada approval of generic drugs and the potentially applicable patents of the innovators through application of the Patented Medicine Notice of Compliance (PMNOC) regulations of the Patent Act. Generics can either wait for patent expiry before entering the market, or they can potentially enter sooner under the PMNOC regulations.

- When innovator companies seek Health Canada market approval, they file a New Drug Submission or, occasionally, a Supplemental New Drug Submission, and in conjunction, they provide Health Canada with a list of patents listed against the ingredients. If certain requirements are met, the patents are listed on the Patent Register.

- If a generic seeks marketing approval, which is a Notice of Compliance (NOC), the Minister of Health cannot grant an NOC unless the generic addresses all patents listed on the Patent Register related to the drug in question.

- A generic can either accept that NOC will not issue until patent expiry, or it can serve upon the innovator a Notice of Allegation (NOA) alleging that the innovator is not the owner of the patent and does not have owner consent, or the patent has expired, or the patent is invalid, or the generic version will not infringe the patent.

- Generic sends NOA to innovator, along with a detailed statement of legal and factual bases, and innovator has 45 days to apply to Federal Court for an Order of Prohibition against issuance of an NOC until patent expiry.

- Requests for prohibition is by way of judicial review, and therefore it is based on affidavits and transcripts and not a full trial with witnesses examined in court.
Also significant that court does not decide whether or not the patent is valid or infringed, but only whether the allegations raised by the generic in its NOA are justified or not.

If innovator loses the application and generic enters the market, innovator can still subsequently sue for infringement damages, in which case it will be a full trial with witnesses, and will determine the actual issue of validity or infringement.

Given the different test between a prohibition application and an actual patent trial and the difference in evidence presentation, an innovator may lose the judicial review application to prevent generic market entry, but may succeed on a subsequent infringement trial, and this has occurred.

If the innovator does not launch proceedings within 45 days, the NOC may be issued to the generic but if the innovator does commence proceedings, there is an automatic 24 month stay during which an NOC may not be issued unless the Court rules against the innovator on the application or the patents expire.

If innovator succeeds, generic cannot enter market until patent expiry.

If generic succeeds, generic can appeal the decision but if generic succeeds on the application, courts have ruled the innovator companies cannot appeal.

There is risk to innovator because if it launches proceedings and is unsuccessful, a generic may claim section 8 damages for its losses for the period it was excluded from the market under the 24 month stay.

Patent settlements between innovators and generics take place in the context of PMNOC, and therefore this context is important in assessing the settlement issue (see below).

In using and assessing U.S.A jurisprudence on patent settlements, it is important to understand differences between our PMNOC regime and the U.S.A. equivalent.
In the U.S.A., the *Hatch-Waxman Act* governs generic entry and innovator challenge.

As in Canada, innovator companies seeking approval for drugs in U.S.A. also file a list of relevant patents which are listed in the Orange Book. If a generic seeks approval, it must address the Orange Book and allege that required information was not filed, the patent has expired, or the patents are invalid or not infringed.

As in Canada, the generic must give notice to the patent holder who then has 45 days to commence an action for infringement. One distinction here is that it is an action for infringement, as opposed to a judicial review, on the more limited evidence and issue scope provided in Canada.

If innovator commences infringement action, there is an automatic 30 month stay unless prior to its expiry, a court determines the patent is invalid or not infringed.

In the U.S.A., the first generic to obtain approval will be given a 180 day generic exclusivity if it is successful in the patent infringement action or if a generic reaches an agreement with the patent owner. This creates incentive for generics to challenge patents or reach agreements with owners, because they will be able to exclude all other generics for 180 days (except for authorized generics which are the identical drug licensed by the innovator).

Main differences between U.S.A. and Canada regimes are that U.S.A. litigation is an action and not just an application, first generic has 180 day exclusivity in U.S.A., and U.S.A. does not provide for section 8 damages.

As noted, if generic succeeds in PMNOC litigation or if the litigation does not occur, and the generic enters the market, the patent holder can still sue for infringement. However, even if successful, the market tends to be ruined after generic entry and damages may be difficult to assess. There is, therefore, an incentive to keep generics off the market, rather than sue for infringement after the fact.
PATENT LITIGATION SETTLEMENTS

A. What Are They?

- Issue arises in context of patent litigation where patent holder settles litigation with patent challenger, which results in challenger not entering the market or delaying market entry.

- Could arise in litigation between two innovator companies but, typically and most critically, arises in context of PMNOC or Hatch-Waxman litigation between innovator and generic.

- Regulators are most concerned about delay or exclusion of generics because they are a lower priced alternative.

- Although typically arises in PMNOC or Hatch-Waxman context, could also arise in Canada in post-market infringement action in which innovator and generic settle suit by generic market exit.

- In the context of infringement or PMNOC litigation, the innovator and generic may decide to settle lawsuit with the result that the generic delays its entry for all or some of the remaining patent period.

- The settlement agreements may include a variety of terms:
  - Splitting the remaining patents terms of the generic can enter prior to a patent expiry, but later than it would had it succeeded in the litigation.
  - Paying generic legal and other costs.
  - Making substantial payments to generic.
  - Agreeing generic will have earlier entry than any other generic.
  - Agreeing that there will be no authorized (innovator) generic launched once a generic is allowed on market after delay.
- Entering related concurrent agreements to provide other benefits to generic, such as licensing other products or entering production and supply agreements.

**B. Conflicting Policies**

- Conflict between competition law and patent rights most acute in this context.

- At core, patents give right to exclude, including launching PMNOC applications or infringement actions.

- Also, public policy favours settlement of litigation and parties are ordinarily entitled to settle suits.

- However, some regulators allege that settlement agreements delay generic entry are thereby denying competition and offending competition policy.

- It is alleged that the settlements are merely disguised anti-competitive agreements, in which innovators keep generic competition off the market, and generics may achieve acceptable commercial results without having to compete.

- Greatest concern is for settlement involving large cash payments from the innovator to the generic, which opponents stigmatize as "pay for delay" settlements or otherwise known as reverse payment settlements.

**C. U.S.A Settlements**

- FTC and U.S.A. courts accept that patent settlements can result in delayed generic entry. FTC views the splitting of the remaining patent period between the innovator and the generic as the litigation parties' approximation and allocation of litigation risk.

- However, FTC strenuously opposes reverse payment settlements. It views these as simply payments to the generic to keep them off the market, and not a legitimate approximation and allocation of litigation risk. Theory is that if
innovator is making a large cash payment to the generic, it indicates innovator’s assessment that it would likely lose and if it would likely lose, it indicates that the public is being denied earlier generic competition simply because of the cash payment.

- DOJ has previously opposed the FTC position on reverse cash payments, but with the new U.S.A. administration, the DOJ has changed its position and now fully supports the FTC, and has recently submitted to the courts that cash payments should be seen as presumptively illegal under U.S.A. anti-trust law.

- FTC will accept innovator payment of generic legal costs and what is referred to as a modest payment to bridge the gap between parties’ assessment of risk. However, no indication of what this means or how it is to be assessed.

- FTC position is that it would accept parties dividing the remaining patent period or the generic remaining off the market for the entire remaining patent period without a cash payment, but it would oppose the same result if a cash payment were involved. Presumably, without the cash payment, the FTC is comfortable that it is a true approximation of the parties’ assessment of risk, whereas it does not accept that is the case when cash in involved. Arguably, the result is the same from a market perspective and the differentiation invalid.

- Main two criteria for acceptable settlement according to cases is that
  
  (a) the patent litigation that is being settled is not a sham and there has been no fraud on the Patent Office;

  (b) there is no bottleneck or anti-competitive exclusion beyond the zone of exclusion created by the patent itself (i.e. no overreaching).

- See for example:

  - *Schering-Plough Corp. v. Fed. Trade Comm’n*, 402 F. 3d 1056 (11th Cir. 2005);
Important to keep in mind differences between U.S.A. and Canadian context. In U.S.A. under Hatch-Waxman, there is a full trial on the merits in an infringement action, no risk of section 8 type damages, and the first generic has 180 day exclusivity. In Canada, there is only judicial review under PMNOC, and not a determination of infringement, the innovator faces potential section 8 damages, and no generic has exclusivity by virtue of being a first mover.

In the U.S.A., there is a greater incentive for the innovator to bargain with the first generic, as the innovator can essentially buy an additional 180 days of exclusivity and avoid the risk of losing an infringement action after which the patent could be held invalid and unenforceable against all generics. In Canada, loss of a PMNOC proceeding against one generic is not binding with respect to other generics, and there is no final determination of the validity of the patent or infringement. Although there may not be a presumption of validity of the patent within the PMNOC litigation, there is also not a determination with respect to infringement and the patent itself, for all other purposes, would be presumed valid until proven otherwise.

FTC takes the position that validity of the patent is not at issue in anti-trust suit challenging a settlement. FTC position is that cash settlements are presumptively illegal and the underlying validity of the patent is not at issue. However, courts have disagreed and have stated that as long as there is no evidence that the parties clearly know that the patent is invalid and that the litigation is simply a sham, then the patent should be accepted as valid.

D. **Canadian Position**

- There is no Canadian jurisprudence respecting these types of settlements, and the Bureau has not taken a public position or provided specific public guidance.
Arguably should apply approach of U.S.A. courts, but that may be in flux.

If cash payments are acceptable in U.S.A. jurisprudence, they should also be acceptable here, especially given the differences between the two patent litigation regimes as noted. The case against them may be stronger in the U.S.A.

It is public record that PMNOC cases have been settled although the terms of the settlement are not public, and it is expected that the Bureau has looked at some of them but it has not taken any enforcement action.

As with the U.S.A., it is assumed that cash payments would raise the greatest concern, although it is not clear why in principle that should be so.

It is assumed that enforcement action in Canada would be conducted under section 45 or abuse of dominance.

Fundamental criteria will be no fraud or sham or extension of the patent period or other over-reaching of patent rights. However, unclear what result would be for settlements within the zone of exclusion provided by the patent.

Crucial issue will be status of presumption of patent validity. Contrary to FTC position, it is arguable that Bureau or prosecution must establish that the patent litigation that was settled would have been determined against the patent holder. Even so, arguably would have to prove party knew that would be the case. Raises spectre of litigating the validity and infringement of the patent within the context of a criminal prosecution, which is a challenging scenario for the Bureau.

Under current section 45, issue would not likely be determined based on undue lessening, but rather on whether patent rights and the right to settle litigation trumps the *Competition Act* and whether the prosecution would have to prove that the patent holder would have lost the patent litigation.

If that is the case, the change to a new section 45 should not affect the outcome or the analysis.
In *Eli Lilly v. Apotex*, FCA determined that section 45 may apply to exercise of patent rights if the conduct at issue involved "something more" than the mere exercise of the patent right. At heart of patent right is the right to exclude others, and therefore litigating against a generic could not satisfy "something more". Also, given public policy favouring settlements, it is hard to see that settling a patent lawsuit could amount to "something more" unless it was a complete sham. If there is presumption of validity and the Bureau has to establish the innovator enforcing an invalid or non-infringed patent, then successful prosecution is unlikely.

No directly applicable Canadian jurisprudence, but Federal Court decision, July, 2008, in *Servier v. Apotex* is of interest.

In this case, ADIR and two other pharma companies were applying for patents related to a particular drug. There were conflicting claims among the three patent applications, which were therefore in dispute in the formal conflict claims processed before the Commissioner of Patents. None of the patents had yet issued. The overlapping claims were resolved in a settlement which was embodied in Minutes of Settlement which were attached to a court order. Thereafter, the patents issued and ADIR obtained the patent at issue in the litigation with Apotex. Apotex alleged that the agreement among the three brand companies was a section 45 conspiracy, because the actions of ADIR and the other parties to the settlement agreement ensured that those parties would gain effective control over the manufacture and supply of a number of drugs, including those within the scope of the patent at issue in the litigation. In other words, Apotex alleged that the settlement permitted all of the patents to issue, and alleged that the three parties had divided up the various claims among them so as to gain effective control over a number of drugs. It was alleged that they entered into the settlement agreement for the purpose of unduly lessening competition contrary to section 45.

The patent at issue had been found valid in the patent litigation.
Absent court determination to the contrary, the other patents resulting from the settlement agreement are also valid (presumed valid?).

No evidence that the parties did anything contrary to the *Patent Act* in order to obtain the patents (i.e. no fraud on the Patent Office etc.).

The parties acted within their rights under the *Patent Act* in obtaining the patents.

Court held that the very existence of a patent lessens competition but, in this case, obtaining the patent did not offend the *Competition Act*. There was no "something more" beyond obtaining the patents through the settlement. Unlike the *Lilly* case, there was no existing ownership by ADIR of any patent rights that would result in more market power than that inherent in the patents that were obtained.

Although *Servier* was not an IP settlement case in the sense of settling a disputed patent, it was a settlement among brand companies of conflicting patent claims, and the court's comment that the parties were simply pursuing their legitimate rights under the *Patent Act* would also be applicable to patent infringement settlements.

It is also interesting to note that in *Servier*, the Court stated that the other patents that were not the subject of the litigation were valid "absent any court determination to the contrary", which indicates the Court was relying on the presumption of patent validity.

There would be good arguments excluding *Competition Act* application, whether under section 45 or abuse of dominance.

As of next year, if the Bureau were to pursue settlements as anti-competitive agreements, it is more likely that it would proceed under the new section 90.1, civil track. This is especially so given the likely difficulties of establishing criminal liability and addressing the validity of patent issue. Also, according to its
guidelines, these settlements should not be viewed as naked cartel agreements, and therefore more appropriately considered under the civil track.

- If the new section 45 were applied, consideration would also have to be given to the ancillary restraints defence.
- Some argue for application of the regulated conduct doctrine, but it may be too narrow and not appropriate.

E. Other Approaches

- In the U.S.A., it is quite likely that there will be a legislated response to patent settlements with a possible prohibition of reverse payments.
- In the U.S.A., there is a requirement that settlements be provided to the FTC for review by the FTC in advance of implementation, but there is no such requirement here.
- Parties could seek Bureau review under the advisory opinion process, but that is voluntary. It is expected that has occurred but is not public.
- In the U.S.A., there has been extensive study and publication by the FTC and extensive jurisprudence from the courts, all of which is lacking in Canada. Any policy positions or enforcement actions should await more fulsome debate and dialogue in Canada. It must also be remembered that the litigation and regulatory context is different in Canada from that in the U.S.A.

AUTHORIZED GENERICS

- Authorized generics are drugs made by the innovator drug companies and are the identical drug to the original patented brand name drug, but they are sold by generic companies at the lower generic price through a licensing agreement.
• An innovator may decide to license an authorized generic, just before or contemporaneous with patent expiry, in order to enter the market and compete with other generics.

• Generic companies sometimes complain about authorized generics as somehow presenting unfair competition and, in Canada, Apotex had commenced litigation several years ago against a number of innovator companies claiming damages on the basis of *Competition Act* breaches caused by authorized generics. (The author is defence counsel in those cases and hereby declares his bias.) Apotex has not pursued the litigation and the cases remain dormant, and therefore there has been no determination.

• The generics also complained to the Bureau raising many of the same issues and the Bureau did not take any action (presumably seeing no basis).

• The theory has been presented that authorized generics deter other generics and are thereby anti-competitive.

• Both the EU and the FTC in the U.S.A. have raised concerns about authorized generics and have studied them, but have not taken action against them.

• In Canada, there has been no enforcement action by the Bureau.

• In March, 2007, there was a symposium hosted by the Bureau addressing the interface between IP rights and competition law, and one of the studies addressed the effects of authorized generics on Canadian drug prices. The author concluded that authorized generics were mildly pro-competitive in drug markets facing some generic competition. There was no conclusion of anti-competitive effects (Competition Policy and Intellectual Property, 2009, Irwin Law, Grootendorst, Chapter 3).

• The generics complain that authorized generics create a disincentive for generic companies to challenge patents during the patent period because if they succeed in the patent challenge, they may lose the fruits of their challenge by facing
immediate competition from an authorized generic. However, any company entering a market faces several risks, including the risk of competition from others, and it is hard to see why generics should be insulated from authorized generics which will provide competition.

- Studies to date do not provide any convincing case against authorized generics, and it is unlikely that the Bureau will pursue this.

**ADDITIONAL PATENTS DELAYING GENERIC ENTRY ("EVERGREENING")**

- After patenting the original medication, innovator companies may obtain new patents for improvements or variations on the original medicine, such as changes to dosage, strength, delivery method or new uses for the drug. Innovators may then have these further patents added to the Patent Register with the result that a generic seeking to enter the market must also address these additional patents under the PMNOC regulations, with the result that the new patents may extend the patent exclusivity of the original medication.

- The position of innovator companies is that these are legitimate enhancements to the medication for which patents are appropriately granted, and that the patents would not be granted if there were not an appropriate innovation.

- The generics claim that these are illegitimate attempts to keep extending patent monopolies by adding patents to the Patent Register to exclude generics, a process that generics call "evergreening".

- Following a 6-resident application under section 9 in June, 2003, the Bureau commenced an inquiry into the alleged evergreening practice.

- On February 27, 2004, the Bureau published a backgrounder setting out its conclusions. It concluded that the *Competition Act* was not the appropriate vehicle to address this issue given that it was subject to the PMNOC regulations and the jurisdiction of the Federal Court. The Court had the jurisdiction to dismiss claims that were based on inappropriate patent extensions and could
give damages to generic manufacturers. Given that the Regulations provided specific provisions to address and balance the competing interests, the Bureau concluded that the Competition Act did not have a role.

- It is unlikely that there would be any Competition Act implications for alleged evergreening in the current regulatory climate, nor is it likely that these allegations could form the basis of any civil litigation beyond normal patent litigation, which is the appropriate vehicle for determining the issues. Either the patents that were granted for the new modifications to existing medications were valid or not, and if they are, there is no reason patent holders cannot enforce them.