ARTICLES

ANTITRUST CONVERGENCE IN A DIVERGENT REGULATORY ENVIRONMENT: THE IPEGS' TREATMENT OF REVERSE PAYMENT SETTLEMENTS OF PHARMACEUTICAL LITIGATION[1]

Paul-Erik Veel[2]

Much effort has been spent promoting the convergence of antitrust law globally. While there has been a degree of convergence over time, such convergence in antitrust law often takes places in the presence of significant differences in other regulatory schemes. The legal framework applicable to reverse payment settlement of pharmaceutical litigation shows how antitrust convergence can lead to significant problems in the presence of divergent regulatory schemes that overlap with the scope of antitrust law. In 2016, the Competition Bureau promulgated its Intellectual Property Enforcement Guidelines. A significant component of the IPEGs was the Competition Bureau's indication that it would review reverse payment settlements of litigation under the PM(NOC) Regulations for antitrust concerns, generally under s. 90.1 of the Competition Act. While some reverse payment settlements undoubtedly can have anti-competitive effects, unique institutional features of Canadian pharmaceutical litigation mean that reverse payment settlements are and should be less of a cause for concern here than they are in the United States. At a result, policy-makers should be cautious before transporting American antitrust principles north of the border in the name of promoting convergence in antitrust law. In at least some cases, the effect of the IPEGs may be to deter parties from entering into settlement agreements which have significant social value. Moreover, even if reverse payment settlements are a cause for antitrust concern, the approach set out in the IPEGs is likely not an effective means of addressing those concerns. This article suggests that reform of the IPEGs is required, and it proposes both wholesale and narrow changes that would improve their operation.

Bien des efforts ont été consacrés à la promotion de l'harmonisation du droit antitrust à l'échelle mondiale. Alors qu'au fil du temps on constate une certaine harmonisation, ce rapprochement de législation antitrust a fréquemment lieu en présence de différences considérables dans d'autres régimes de réglementation. Le cadre juridique applicable aux paiements renversés au titre du règlement de litiges dans le secteur pharmaceutique illustre la mesure dans laquelle l'harmonisation de la législation antitrust peut susciter de graves problèmes en présence de mécanismes de réglementation divergents dont la

portée chevauche celle de la législation antitrust. En 2016, le Bureau de la concurrence a publié des Lignes directrices sur la propriété intellectuelle (LDPI), dont l'un des éléments importants était que le Bureau indiquait vouloir examiner les paiements renversés au titre du règlement de litiges en vertu du Règlement sur les médicaments brevetés (avis de conformité) à l'égard d'enjeux liés à l'antitrust qui tombent généralement sous le coup de l'article 90.1 de la Loi sur la concurrence. Alors que certains paiements renversés au titre du règlement de litiges peuvent sans aucun doute avoir des effets anticoncurrentiels, les caractéristiques institutionnelles uniques en leur genre du contentieux pharmaceutique canadien signifient que les paiements renversés au titre du règlement sont et devraient être moins préoccupants dans ce pays qu'ils ne le sont aux États-Unis. Par conséquent, les décideurs au Canada devraient être prudents avant de s'approprier les principes américains de l'antitrust au nom de la promotion de l'harmonisation du droit antitrust. Dans au moins certains cas, les LDPI pourraient avoir pour effet de décourager les parties de passer des accords de règlement qui possèdent une considérable valeur sociale. Qui plus est, même si les paiements renversés au titre du règlement suscitent des préoccupations dans le domaine de l'antitrust, l'approche énoncée dans les LDPI n'est probablement pas un moyen efficace pour y répondre. Cet article suggère qu'il faut modifier les LDPI et propose des changements, tant généraux que plus particuliers, qui en amélioreraient le fonctionnement.

Introduction

Pharmaceutical patent litigation is expensive and time-consuming, and the outcome of such litigation can have significant consequences, both for the litigants and for society more broadly. For both innovators and generics, the impact of such cases can range from millions to billions of dollars, depending on the product. More broadly, a win for an innovator that successfully protects a patent yields returns that incentivize research, yet those returns flow from monopoly pricing that increases costs to consumers and creates economic inefficiencies. Given those stakes, settlements ought to be desirable, in order to eliminate cost and risk and find appropriate trade-offs between competing objectives. Yet settlements of litigation between competitors can also lead to competition law concerns. This gives rise to the question as to whether such settlements should be regulated and, if so, how.

In 2016, the Competition Bureau promulgated its Intellectual Property Enforcement Guidelines (the "IPEGs"). In that document, the Bureau set out for the first time some basic rules as to when it considers settlements of certain types of patent litigation between innovator and generic

pharmaceutical manufacturers to fall offside Canada's federal *Competition Act*. The upshot of the IPEGs is clear: the settlement of a pharmaceutical litigation under the *Patented Medicine (Notice of Compliance Regulations)* that involves a payment of money by an innovator to a generic—often referred to as a reverse payment settlement or, more pejoratively, a "pay-for-delay" agreement—is potentially subject to challenge under the *Competition Act*. The Bureau justifies this intervention into such settlements as being necessary to avoid anticompetitive agreements between innovators and generics.

The fact of intervention by the Competition Bureau is not itself surprising. Such agreements are subject to antitrust scrutiny in the United States, and in many respects, the IPEGs mirror certain principles recently set out under U.S. federal law. To that end, the IPEGs' approach to reverse payment settlements could be lauded as a case of desirable antitrust convergence.

This article rejects that view and instead provides a critical analysis of the rules in the IPEGs relating to settlements of *PM(NOC)* proceedings. This article does not seek to comprehensively address the economic or antitrust issues relating to reverse payments generally; this ground has been well-covered elsewhere.[3] Rather, this article contends that the approach set out in the IPEGs to the regulation of such settlement agreements is not an appropriate policy response in the Canadian context. Put simply, the application of the *Competition Act* to an intellectual property regime that is itself already calibrated to balance the inherent trade-offs in intellectual property rights is at best unnecessary and at worst counterproductive.

As discussed below, the framework set out in the IPEGs—which attempts to place the square peg of the *Competition Act* in the round hole of the *PM(NOC) Regulations*—is conceptually strained. In the Canadian context in particular, attempts to dissuade parties from entering into reverse payment settlements are likely to be less effective than in the United States. Even if they were effective, they are likely to have more ambiguous welfare effects than in the United States. A recurrent theme in this article will be that whatever the merits of the approach to reverse payment settlements in the United States, the approach set out in the IPEGs represents an unfortunate attempt to borrow particular rules from American antitrust law and apply them in Canada, without sufficient regard for the very different legal context that prevails in Canada. This article argues that the approach to settlement agreements in the IPEGs should be substantially overhauled.

This article proceeds as follows. Part II provides an overview of the competing legal frameworks that apply in this area, namely, the relevant

provisions of and case law under the *Competition Act* and the *PM(NOC) Regulations*. Part III summarizes the pertinent provisions of the IPEGs. Part IV sets out the principal problems with the current approach in the IPEGs to settlement of *PM(NOC)* proceedings. Part V then sets out potential reforms, both fundamental and incremental, that address the concerns identified in the previous section. Part VI provides a brief conclusion.

I. The Legal Frameworks: Competition Law and PM(NOC) Regulations

The IPEGs reflect the Competition Bureau's attempt to set out its approach to problems at the intersection of competition law and intellectual property law. As a result, in order to situate the IPEGs, it is necessary to provide some background as to how each of those separate regimes operates in Canada. The following sections provide an overview of the relevant portions of both the *Competition Act* and the *PM(NOC) Regulations*, including the most relevant case law.

1. The Competition Act

Given the broad range of anti-competitive conduct governed by the *Competition Act*, and the gamut of institutional tools used to address such anti-competitive conduct, this article will not canvass the entirety of the Act. Rather, this article will focus on those portions of the *Competition Act* that are relevant to the regulation of settlements of disputes under the *PM(NOC) Regulations*.

At its highest level, the purpose of the *Competition Act* is to encourage competition between competitors.[4] A primary means of fostering competition is ensuring that competitors do not band together to act, jointly, like monopolists.[5] Virtually all competition and antitrust regimes around the world give great scrutiny to agreements between competitors with respect to the sale of products, on the theory that such agreements may allow competitors to act more like monopolists. Cartel behaviour is almost universally condemned by economists and regulators alike.[6] In this respect, the *Competition Act* is no different.

The *Competition Act* contains a number of different legal tools for regulating potentially anticompetitive agreements between competitors. An agreement between two competitors that relates in some way to an intellectual property right is potentially affected by two distinct portions of the *Competition Act*: the criminal prohibition against "hard-core" cartels in s.

45 of the Act; and the civil prohibition against agreements that prevent or lessen competition substantially in s. 90.1 of the Act.

Section 45(1) of the *Competition Act* creates a criminal prohibition against what are often referred to as "hard-core" cartels: that is, agreements between competitors relating to a number of subjects, including to "fix, maintain, increase or control the price for the supply of the product" or to "fix, maintain, control, prevent, lessen or eliminate the production or supply of the product".[7] That prohibition is a *per se* offence that is established without the need for any analysis as to whether the agreement actually has a deleterious impact on the market or is justified by business considerations. The hard edges of that prohibition are only slightly softened by certain statutory defences, such as the ancillary restraints defence. Under that defence, an agreement that would otherwise be an unlawful conspiracy avoids liability if: 1) the impugned agreement is ancillary to a broader or separate agreement or arrangement that includes the same parties; 2) the impugned agreement is directly related to, and reasonably necessary for giving effect to, the objective of that broader or separate agreement or arrangement; and 3) the broader or separate agreement or arrangement, considered alone, does not contravene s. 45(1).[8]

Contravention of s. 45(1) of the Act carries with it heavy potential penalties. Criminal penalties can be as high as a 14-year jail term or a fine of up to $25 million.[9] A criminal conviction can also give rise to a host of ancillary consequences.[10] The *Competition Act* also creates a private civil right of action for anyone who suffers loss or damage as a result of criminal conduct under the Act.[11] Class actions are all but guaranteed in any case where parties are alleged to have engaged in criminal conduct under the Act.[12]

The second potentially applicable provision is s. 90.1 of the Act. That provision allows the Commissioner of Competition to challenge certain forms of agreements before the Competition Tribunal. Namely, where two or more competitors with respect to a product have entered into an agreement that "prevents or lessens, or is likely to prevent or lessen, competition substantially in a market", the Tribunal may, on application by the Commissioner, make an Order prohibiting any person from doing anything under the agreement.[13]

Section 90.1 applies to a far broader scope of arrangements than does s. 45. However, it also requires an analysis as to whether the agreement in question actually has an anti-competitive effect. Unlike under s. 45 of the Act, it is a defence to a proceeding under s. 90.1 that the efficiency gains

from the impugned agreement outweighed the anti-competitive effects of the agreement.[14]

Section 90.1 carries with it a far lesser threat to businesses than does a prosecution under s. 45. Neither jail time nor a fine or other monetary penalty is a potential consequence of a finding under s. 90.1, and no private actions (including class actions) can be brought in respect of agreements in respect of which an order is made under s. 90.1 (unless those agreements are actionable under s. 45 of the Act). Absent the consent of the party whose agreement is being reviewed, the only remedy that can be imposed under s. 90.1 is an order that the person not engage in conduct under the agreement.[15]

Separate and apart from the provisions of the *Competition Act* regulating agreements between competitors, the Act also contains provisions that constrain the unilateral exercise of market power. While a settlement of litigation under the *PM(NOC) Regulations* is most easily characterized as an agreement, it could also, depending on the circumstances, represent a unilateral exercise of market power by a monopolist. After all, the purpose of intellectual property rights is to create time-limited monopolies in order to incentivize the creation of socially useful products. As such, one can conceptualize a range of conduct by an innovator—including whether to enter or not enter into a settlement agreement, and the terms of such settlement agreements—as a unilateral exercise of market power by that innovator in respect of its monopoly over that product.

Two sets of rules under the *Competition Act* are potentially applicable to such conduct. The first are the unilateral conduct provisions in Part VIII of the Act. These include provisions relating to a refusal by a company with market power to deal with a competitor (under s. 75 of the *Act*), those relating to exclusive dealing (under s. 77 of the *Act*), and those prohibiting anticompetitive acts that would allow a party with a dominant position in a market to abuse that dominance (under s. 79 of the *Act*).[16] On the face of them, each of these provisions applies to anticompetitive uses of intellectual property rights, though s. 79(5) of the Act specifically provides a carve-out for abuse of dominance, clarifying that an intellectual property right holder's mere exercise of rights is not an anticompetitive act that gives rise to an abuse of dominance.[17] The orders that can be made to remedy reviewable conduct under Part VIII of the Act consist of remedial orders requiring the party to stop engaging in the anti-competitive behaviour and, in the cases of findings of abuse of dominance, administrative monetary penalties. These provisions cannot give rise to criminal liability, nor can penalties be levied against individuals within the organization. In addition, while is the

possibility of private rights of action under certain provisions of Part VIII of the Act before the Competition Tribunal, such litigation is limited by the fact that no damages are available to successful litigants, and no class actions can be brought in respect of such conduct.

Second, the *Competition Act* contains special provisions relating to intellectual property rights. Section 32 of the Act permits the Federal Court to make a series of orders in relation to the exercise of intellectual property rights—including invalidating agreements with respect to such rights or compelling the licensing of such rights, among other things—in order to remedy abuses of such intellectual property rights.[18]

There is little Canadian case law interpreting any of these provisions in the context of intellectual property rights. As of the publication of this article, there have been almost no Canadian cases that have touched on the intersection of sections 45 and 90.1 of the *Competition Act* with intellectual property rights. In its 2005 decision in *Apotex Inc v Eli Lilly and Company*, the Federal Court of Appeal held that the assignment of a patent could, in appropriate circumstances, constitute an offence under previous version of s. 45 of the *Competition Act*, prior to substantial amendments made in 2009.[19] However, the Federal Court later disposed of that issue on other grounds,[20] so courts have provided little analysis to when such an agreement could constitute an offence under s. 45. Moreover, there have been no cases since the 2009 amendments that have seriously considered the application of s. 45 of the *Competition Act* to intellectual property rights.

Most of the few cases addressing intellectual property rights in the competition law context have done so under the unilateral conduct provisions of the *Competition Act*. The first case to consider the intersection of intellectual property rights and the *Competition Act* was *Director of Investigation and Research v Tele-Direct Inc.*[21] In that case, the Director of Investigation and Research (as the Commissioner of Competition was then known) alleged that Tele-Direct's failure to licence its trade-marks, including the words "Yellow Pages" and the walking fingers logo, constituted a practice of anti-competitive acts that gave rise to an abuse of dominance. Although s. 79(5) of the *Competition Act* specifically provided that acts engaged in pursuant to various intellectual property statutes were not anticompetitive acts for the purpose of the abuse of dominance provision of the Act, the Director alleged that Tele-Direct's failure to licence its trade-marks nonetheless constituted an anti-competitive act. The Tribunal rejected this reasoning, holding as follows:

> 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. Subsection 79(5) explicitly recognizes this.
>
> The respondents' refusal to license their trade-marks falls squarely within their prerogative. Inherent in the very nature of the right to license a trade-mark is the right for the owner of the trade-mark to determine whether or not, and to whom, to grant a licence; selectivity in licensing is fundamental to the rationale behind protecting trade-marks. The respondents' trade-marks are valuable assets and represent considerable goodwill in the marketplace. The decision to license a trade-mark—essentially, to share the goodwill vesting in the asset—is a right which rests entirely with the owner of the mark. The refusal to license a trade-mark is distinguishable from a situation where anti-competitive provisions are attached to a trade-mark licence.

The second decision on the intersection of competition law and intellectual property rights, *Canada (Director of Investigation and Research) v Warner Music Canada Ltd*, was to much the same effect as the *Tele-Direct* case.[22] At issue in *Warner Music* was the failure of Warner Music to grant copyright licences to BMG (Canada), which needed such licences to compete in the mail order record club market. The Director alleged that such a failure to licence was an unlawful refusal to deal pursuant to s. 75 of the *Competition Act*.

Warner Music brought a motion to strike the Director's application, contending that the Tribunal did not have jurisdiction to compel it to issue licences for the manufacture, distribution and sale of sound recordings. The Tribunal agreed, holding that licences were not "products" within the meaning of s. 75 which could be the subject of a refusal to deal application. The Tribunal held as follows:

> … the Tribunal has concluded that on the facts of this case the licences are not a product as that term is used in section 75 of the Act, because on a sensible reading section 75 does not apply to the facts of this case. Although a copyright licence can be a product under the Act, it is clear that the word "product" is not used in isolation in section 75, but must be read in context. The requirements in section 75 that there be an "ample supply" of a "product" and usual trade terms for a product show that the exclusive legal rights over intellectual property cannot be a "product"—there cannot be an "ample supply" of legal rights over intellectual property which are exclusive by their very nature and there cannot be usual trade terms when licences may be withheld. The right granted by Parliament to exclude others is fundamental to intellectual property rights and cannot be considered to be anti-competitive, and there is nothing in the legislative history of section 75

> of the Act which would reveal an intention to have section 75 operate as a compulsory licensing provision for intellectual property.

The core of the *Warner* decision was confirmed more recently by the Competition Tribunal in its 2015 decision in *Stargrove Entertainment Inc v Universal Music Publishing Group Canada*.[23]

These decisions show the caution with which the Competition Tribunal approaches claims relating to failures to licence intellectual property rights. Pursuant to *Tele-Direct*, the mere decision of a trade-mark holder to licence or not licence its trade-mark is not, without more, an anticompetitive act. Under *Warner* and *Stargrove*, the failure to licence a copyright cannot be the subject of a refusal to deal application under s. 75 of the Act. While none of these decisions specifically addresses agreements between competitors relating to intellectual property rights, they do manifest a recognition that intellectual property rights cannot be treated identically to other products under the *Competition Act*.

2. The PM(NOC) Regulations

In contrast to the wide-ranging provisions of the *Competition Act*, the federal *PM(NOC) Regulations* deal with a narrow issue unique to a single-industry: the approval of generic pharmaceutical products in circumstances where an innovator is already marketing an equivalent product that is patent-protected. In so doing, the *PM(NOC) Regulations* represent a self-contained and carefully calibrated regime that attempts to balance the competing interests of innovators and generics, which are themselves proxies for the competing normative goals of dynamic and static inefficiency that underpin intellectual property law.[24] The *PM(NOC) Regulations* do so by regulating the circumstances in which government will give regulatory approval in the form of a Notice of Compliance to a generic entrant for a pharmaceutical product. While the *PM(NOC) Regulations* share some similarities with the Hatch-Waxman regime in the United States, they have some significant differences, as set out below.

Broadly speaking, the *PM(NOC) Regulations* allow innovator pharmaceutical companies to list, for each of their pharmaceutical products, any patents that are associated with those pharmaceutical products on the patent register.[25] Once such patents are listed on the patent register, a generic pharmaceutical company that wishes to obtain an NOC for its product must take steps to address those patents before an NOC can be issued. The generic pharmaceutical manufacturer can address those patents in one of two ways: it can either stipulate that it will not market its product until the patents

listed on the patent register expire; or it can assert its right to market the product notwithstanding those listed patents, by alleging either that the patents are invalid or that the generic's product would not infringe those patents.[26]

If the generic wishes to assert its right to market the product notwithstanding the listed patents, it must serve a Notice of Allegations on the patent holder.[27] Upon so doing, the innovator has 45 days in which commence a proceeding in the Federal Court to prohibit the Minister of Health from issuing a NOC to the generic pharmaceutical company.[28]

If the innovator is successful in that proceeding, the generic will be prohibited from receiving its NOC until the patents in question expire. By contrast, is the generic is successful, the Minister of Health is compelled to issue an NOC to generic, which provides the generic with regulatory permission to begin marketing its product. Historically, a loss in those circumstances did not technically invalidate the innovator's patent, and the innovator could still sue the generic pharmaceutical manufacturer for patent infringement. However, 2017 amendments to the *PM(NOC) Regulations* meant that the validity of a patent can now be determined in the context of a *PM(NOC)* proceeding.[29] In any event, even prior to the amendments, the fact that the patent was not invalidated often provided little comfort for the innovator that faced the reality of a generic competitor in the marketplace: the loss of a proceeding under the *PM(NOC) Regulations* often meant in the practice the end of an innovator's exclusivity for that product.

Under the *PM(NOC) Regulations*, the mere commencement of a prohibition action has significant implications. The *PM(NOC) Regulations* provide that once a prohibition action is commenced, there is an automatic stay of 24 months (or until a decision is rendered, which is typically shortly before the 24 months expire) on the Minister of Health issuing a NOC to the generic pharmaceutical company.[30] The innovator need not take any affirmative steps to show that its prohibition action has merit or that a stay is warranted; rather, the stay is automatic.

The *quid pro quo* of the automatic stay under the *PM(NOC) Regulations* is unique to Canada: if the innovator's action is ultimately dismissed or discontinued, the generic pharmaceutical company is granted a statutory cause of action for damages under s. 8 of the *PM(NOC) Regulations* against the innovator for the generic's losses due to having been kept off the market.[31] The generic need not establish that the innovator's prohibition action was tactical or ill-conceived; rather, the mere fact of the action being dismissed

or discontinued automatically gives rise to a right for the generic to sue to recover its losses. The quantum of such claims—depending on the product, the time period, and the claimant—can be significant; claims can total hundreds of millions or even billions of dollars.

Prior to 2017, the generic's right to recover lost profits was limited to lost profits during the period between the date the generic would have otherwise been given regulatory approval and the date the action was dismissed or discontinued. The implication of this was that claims for diminished sales after the relevant period, permanent loss of market share, or loss of business value were not available under s. 8.[32] However, amendments to the *PM(NOC) Regulations* that came into force in September 2017 removed that limitation, thus allowing claims for lost profits in respect of the period after the action was dismissed or discontinued.

The jurisprudence interpreting section 8 of the *PM(NOC) Regulations* exposes innovators to the risk of competing claims from multiple generics. In a series of cases dealing with Ramipril decided in 2013, the Federal Court of Appeal held that the hypothetical but-for world constructed in section 8 cases to determine the generic's lost profits must be constructed under the basis that only the plaintiff generic would have automatically been entitled to be on the market, while other generics in that but-for world would still have had to comply with the usual provisions of the *PM(NOC) Regulations*.[33] The effect of this ruling is that, in each case, the plaintiff generic in that case has a leg up in arguing that it would have been the sole generic on the market. As in the Ramipril cases, this can give rise to inconsistent findings between cases. Because a sole-source market invariably yields greater profits for a generic than a multi-source market, an innovator can be faced with large damages claims from several generics that can each plausibly claim that they would have been alone on the market, when in fact there was no possibility in the real world that more than one (and in many cases any of them) would have ever been alone on the market.

Given these considerations, the risks on both sides in prohibition proceedings are significant. If the innovator loses the proceeding, it risks losing its exclusivity for its product, potentially several years in advance of the expiry of its patent. It also faces the risk of significant exposure in a s. 8 claim. This exposure is particularly significant following the 2017 amendments to the *PM(NOC) Regulations*. Under the previous version of the *PM(NOC) Regulations*, an innovator at least knew that its exposure was limited to lost sales during the period that the generic was kept off the market, which put a natural and ascertainable cap on the innovator's potential liability. Under

the new amendments, however, even a brief delay in market entry for the generic can give rise to significant section 8 damages, particularly if that short delay causes that generic to lose the position of being the first generic entrant into the market. In theory, a delay of even a few months, representing relatively modest lost sales to the generic during that time, could give rise to massive future damages if the generic loses a first mover advantage and instead is forced to enter the market at the same time as a raft of other generics.[34] Combining such claims with the possibility of multiple claims by different generics, each able to assert its own but-for world that is most favourable to that generic, gives rise to the very real possibility that innovators will face section 8 claims well in excess of any amounts that they would earn as a result of delaying generic entry for a product.

By contrast, a loss for the generic is significant as well: the generic faces the prospect of being kept out of a lucrative market for potentially several more years. Moreover, the generic also risks missing out on the advantage that exists for being a first entrant in the market; when the patent ultimately expires, the generic who brought the initial challenge under the *PM(NOC) Regulations* will seldom be the sole generic to enter the market.

In those circumstances, with significant risks on either side, there are clear incentives for litigants to settle prohibition proceedings. Such settlements could result in a compromise as to the date of entry: where a successful prohibition proceeding might keep the generic out of the market for 10 years (when the patent expires), and an unsuccessful proceeding would result in immediate entry, the parties might agree to settle the proceedings for the generic being allowed to enter the market in five years.

Such settlements have several beneficial effects. First, they can result in generic entry earlier than would be the case if the innovator is successful in its prohibition action, which would result in lower costs to consumers and the public purse for those medications. Second, settlements provide certainty to both the innovator and the generic, allowing for more effective planning and the avoidance of unnecessary costs. They avoid, for example, the possibility that a generic will produce product in anticipation of a successful opposition to a prohibition action, only to then have to destroy that product if they are unsuccessful. Finally, they end litigation, resulting in the reduction of the parties' litigation costs and Court resources.

II. An Overview of the Intellectual Property Enforcement Guidelines

Competition law and intellectual property law seemingly do not make easy bedfellows: the latter seeks to create a temporary monopoly, while the former seeks to eliminate them.[35] Yet there is no doubt that each fosters a socially important goal, and the two must work together harmoniously. The Competition Bureau's Intellectual Property Enforcement Guidelines seek to create rules that govern the intersection of the two.

The Bureau promulgated the first version of the IPEGs in 2000. Those initial IPEGs largely articulated broad principles, without much guidance regarding the application of the *Competition Act* in particular circumstances. Ultimately, this led the Bureau to conduct a significant update between 2013 and 2016. After an extended process, the final version of the new IPEGs was released on March 31, 2016. The IPEGs were subsequently updated in a new version dated March 13, 2019, though those updates did not substantially modify the Bureau's approach to reverse payment settlements. As set out below, the current IPEGs set out the rules at the intersection of competition law and intellectual property law, both by the articulation of broad principles and through the creation of detailed rules that provide guidance.

1. The Need for IPEGs

The need for IPEGs is indisputable. The reality of competition law in Canada—due to the combination of the fact that most of competition law is enforced by the resource-constrained Commissioner of Competition and the fact that private litigation is restricted in scope and usually settles prior to hearings on the merits— is that there is relatively little case law interpreting the *Competition Act*. Indeed, in contrast to the situation in both the United States and in the European Union, there is almost no case law that squarely addresses the interface between competition law and intellectual property law. There is undoubtedly a need for the Competition Bureau to publish guidelines that set out its enforcement approach to matters involving intellectual property.

But the fact that the Competition Bureau should set out its regulatory approach to an area does not in turn imply that it should actively regulate that area. As I have argued previously in the context of copyright law, intellectual property law regimes often contain tools internal to those regimes that have the effect of addressing the very same concerns that competition law purports to address.[36] Put differently, expansive antitrust law and internal limiting principles in intellectual property law can be substitutes in

reaching the same objective. As such, the wholesale application of competition law principles to a regime that is already internally calibrated to balance the trade-off between innovation and broad dissemination of low cost products can be at best unnecessary, and at worst counterproductive.

2. The General Framework

The IPEGs recognize that competition law and intellectual property law both further important values which are not inherently incompatible. The IPEGs describe the interface between the two as follows:

> IP and competition laws are both necessary for the efficient operation of the marketplace. IP laws provide property rights comparable to those for other kinds of private property, thereby providing incentives for owners to invest in creating and developing IP and encouraging the efficient use and dissemination of the property within the marketplace. Applying the Act to conduct associated with IP may prevent anti-competitive conduct that impedes the efficient production and diffusion of goods and technologies and the creation of new products. The promotion of a competitive marketplace through the application of competition laws is consistent with the objectives underlying IP laws.[37]

Consistent with that normative framework, the general enforcement approach set out in the IPEGs is that, except in particular circumstances that fall within the scope of s. 32 of the Act, the "mere exercise" of an intellectual property right is not a cause for concern under the Act.[38] The "mere exercise" of an intellectual property right includes both the "exercise of the owner's right to unilaterally exclude others from using the IP" and the "IP owner's use or non-use of the IP".[39] Where conduct involves the "mere exercise" of an intellectual property right, the Bureau will not enforce the *Competition Act* in respect of such conduct, irrespective of the competitive consequences. The IPEGs describe this as follows:

> Unilaterally exercising the IP right to exclude does not violate the general provisions of the Act no matter to what degree competition is affected. To hold otherwise could effectively nullify IP rights, impair or remove the economic, cultural, social and educational benefits created by them, and be inconsistent with the Bureau's underlying view that IP and competition law are generally complementary. [40]

However, what first appears to be a broad exclusionary zone from the application of competition law is quickly narrowed. The IPEGs clarify that once a party begins exercising its intellectual property rights in a variety of ways, the Bureau conducts its normal analysis to determine if such conduct

contravenes the Act. For example, the IPEGs provide that where the intellectual property rights form the basis of an agreement between competitors, the Bureau will apply its usual analysis to determining if those agreements contravene the *Competition Act*.

3. The IPEGs' Approach to Settlements of PM(NOC) Cases

The IPEGs set out particular principles that the Bureau will apply in analyzing settlements of prohibition proceedings under the *PM(NOC) Regulations*. In so doing, the IPEGs imply a conclusion that is worth making explicit: settlement agreements of cases under the *PM(NOC) Regulations* are subject to the *Competition Act* and scrutiny by the Competition Bureau. That fact is in and of itself noteworthy. As described further below, that such settlement agreements should be subject to scrutiny under the *Competition Act* is not necessarily self-evident as a matter of either law or policy.

Having accepted the implicit conclusion that such settlement agreements are subject to competition law principles, the IPEGs attempt to define certain "safe harbours" for particular types of conduct that will not attract scrutiny under the Act, or which will only attract more limited scrutiny.

First, the IPEGs make clear that it is only in rare and narrowly defined circumstances that settlement agreements will be subject to review under the s. 45 criminal prohibition. The Bureau will only review them under s. 45 where the settlement agreement: 1) extends the exclusionary period for the product in question beyond the life of the patent by delaying generic entry past the point of patent expiry; 2) restricts competition in the markets for products unrelated to the subject of the litigation; or 3) is a sham.[41] Moreover, even in those cases, the Bureau will consider whether the ancillary restraints defence could apply.[42] As such, criminal liability will rarely be a realistic prospect for parties that enter into such settlement agreements.

Second, the IPEGs provide that an "entry-split settlement", which the IPEGs define as an agreement whereby the innovator and the generic agree on a particular date before the expiry of the patent on which the generic will be allowed to enter the market, will not contravene any provision of the Act.[43] As such, settlement agreements of that form will always be permissible.

Third, the IPEGs stipulate that a settlement agreement pursuant to which a generic is permitted to enter on or before patent expiry but which includes a cash payment to the generic may be reviewed and challenged under s. 90.1 of the Act.[44]

The IPEGs recognize that such settlement agreements could cause the innovator to pay the generic to delay its entry into the market. While recognizing that not all such settlement agreements are problematic, the IPEGs define such settlement agreements as a potentially risky zone that is subject to challenge. As the IPEGs recognize, whether such agreements are anticompetitive and warrant proceedings under s. 90.1 is a complicated question that depends on numerous factors, including: the amount of the payment; the potential exposure of the innovator to section 8 damages; the innovator firm's expected remaining litigation costs absent settlement; and any efficiencies achieved as a result of the settlement.[45]

In promulgating the IPEGs, the Competition Bureau has in large measure adopted the approach taken in the United States to the regulation of such settlement agreements. In its 2013 decision in *Federal Trade Commission v Actavis*, the United States Supreme Court held, in a 5-3 decision, that the Federal Trade Commission could challenge settlements between innovators and generics that involved a payment by the innovator to the generic to stay out of the market.[46] The majority held that such agreements were not *per se* illegal (which would be equivalent to the standard for liability under s. 45 of the Competition Act), but rather that they should be considered under the rule of reason (which is roughly equivalent to the standard of liability under s. 90.1 of the *Competition Act*).

The majority decision was not a preordained conclusion. Prior to that decision, there had been a split among the Circuit Courts of Appeal as to whether such agreements attracted antitrust scrutiny and, if so, the appropriate framework to be applied.[47] Many Courts had previously applied the "scope of the patent" test, which asked whether the settlement was an action that fell within the scope of the patent. This test was relatively permissive in permitting reverse payment settlements. There was also significant disagreement in the academic commentary as to whether antitrust liability should attach to such settlements.[48] Moreover, in the *Actavis* decision itself, a three-judge dissent, authored by Chief Justice Roberts, rejected the applicability of antitrust laws to such settlement agreements. Chief Justice Roberts summarized the rationale for doing so as follows:

> The majority today departs from the settled approach separating patent and antitrust law, weakens the protections afforded to innovators by patents, frustrates the public policy in favor of settling, and likely undermines the very policy it seeks to promote by forcing generics who step into the litigation ring to do so without the prospect of cash settlements. I would keep things as they were and not subject basic questions of patent law to an unbounded

inquiry under antitrust law, with its treble damages and famously burdensome discovery.

Tempting through it might be to view the IPEGs as an example of coherent policy convergence, the institutional and regulatory landscape in Canada is very different from what it is in the United States. For example, the United States has no equivalent to s. 8 damages. Instead, the Hatch-Waxman Act provides that the first generic filer in the United States that successfully challenges a patent gains a 180-day exclusivity period during which they are the only generic permitted to sell that product, thereby providing that first generic filer with higher profits than would be possible if they faced generic competition. The United States also has a provision requiring that settlement agreements between innovators and generics be reported to the Federal Trade Commission, while there is no such mandatory reporting in Canada. Consequently, while the IPEGs have created some convergence as to the particular approach taken to scrutiny of settlement agreements, there remain significant differences between other aspects of both intellectual property and competition laws in the two jurisdictions. As described below, these differences are significant.

III. Problems In the IPEGs' Approach to Settlements of PM(NOC) Cases

Having outlined the Bureau's approach to settlement agreements as set out in the IPEGs, this article now turns to its core question: do they IPEGs reflect an appropriate approach to the regulation of settlement agreements in the Canadian context? Put differently, does the policy convergence in antitrust law reflected in the IPEGs actually make sense, given the rest of the applicable legal landscape in Canada. The answer is no. As described below, the approach set out in the IPEGs suffers from three problems. First, by layering inflexible statutory competition law rules on top of the carefully calibrated intellectual property law regime of the *Patent Act* and the *PM(NOC) Regulations*, the IPEGs are conceptually incoherent. Whatever the arguments for applying the Sherman Act to settlements of pharmaceutical litigation in the United States, those arguments are much weaker in the Canadian context. Second, even assuming the IPEGs set out a coherent set of principles that improve welfare, the tools chosen by the Bureau are ineffective in meeting their goals. Again, the approach set out by the Bureau in the IPEGs is decidedly less effective than the prevailing enforcement regime in the United States. Third, assuming that the IPEGs have the effect of preventing some reverse payment settlements, their welfare effects are ambiguous and may in some cases prevent settlement agreements that increase overall welfare. Each of these problems is described below in turn.

1. The Conceptual Problem

The IPEGs represent an approach that sees the provisions of the *Competition Act* layered on top of the regulatory structure created by the *Patent Act* and the *PM(NOC) Regulations*. As noted above, the normative underpinnings of competition law and intellectual property law pull in opposite directions. While they can be reconciled, such reconciliation must be done deliberately, not simply by reflexively applying one set of legal principles over top of another. The effect of simply layering one set of rules over another—without considering how such statutes interact—creates a regime that appears incoherent from the perspectives of its constituent components.

This layering is not necessarily a problem in all legal regimes, as discussed in greater detail below. However, in Canada, given the structures of the *Patent Act* and the *Competition Act*, there is an unavoidable tension that comes from attempting to layer one regime over another. From the perspective of the *Patent Act*, the IPEGs go too far in undermining the legal protections granted by patents. By contrast, from the *Competition Act* perspective, the IPEGs are too restrained. While these two conceptual problems pull in opposite directions, together they highlight the incoherence of the current IPEGs' approach to addressing this problem.

Taking first the perspective of Canadian intellectual property law, as a matter of law under the *Patent Act*, while prohibition proceedings are ongoing, the innovator continues to hold a valid and enforceable patent.[49] As such, the innovator has the legal right under the *Patent Act* to exploit that patent, including by taking steps to try to exclude other competitors from entering the market.[50] It is only once that patent has been held to be invalid that the innovator no longer has that right.

Consequently, where the settlement agreements that the IPEGs purport to govern relate to a period when the patent continues to be presumptively valid, those settlement agreements are entered into between one party that presumptively has the right to exclude the other party from the market. In that context, the generic has no legal right to market the product in question. In other words, while a settlement agreement may have the effect of keeping the generic out of the market for a period of time, the market was one that the generic presumptively had no right to enter into in the first place. The situation is not one where one company is simply conspiring with a potential competitor to keep it off the market. Rather, the situation is one where the *Patent Act* has granted the innovator a legal monopoly in order to provide the innovator with a return for its efforts to innovate. This

is, in effect, a mere exercise of the innovator's monopoly right that it lawfully holds.

Viewed from that perspective, it seems nonsensical that s. 45 or s. 90.1 of the *Competition Act* would apply to such settlement agreements. An innovator pharmaceutical company could understandably view the IPEGs as an attempt by one federal enforcement agency to take away by policy the very rights that are explicitly granted under different federal legislation. From this perspective, the IPEGs are an unjustified intrusion on the exclusive rights granted to the holder of the patent under the *Patent Act*. Put more neutrally, to apply the usual rules of competition law, which are designed to prevent competitors from acting in concert like monopolists, to a situation where the state has granted a legal monopoly to one company is incoherent.

From the standpoint of the *Competition Act*, the IPEGs are equally incoherent, though for the opposite reason. If an innovator and a generic are viewed in law as potential competitors, such that agreements between them relating to output presumptively fall within the scope of s. 45 of the Act, then every settlement agreement that has any impact on the timing of the generic's entry onto the market ought to run afoul of s. 45. Section 45 of the Act is deliberately designed to create a *per se* offence that requires no analysis of anti-competitive effects (in contrast to s. 90.1 of the Act, which is meant to provide for greater nuance and flexibility).[51] In that context, the limitations set out in the IPEGs on the application of s. 45 to settlement agreements seem arbitrary and bear no relationship to the provision of the *Competition Act*. There is no language in s. 45 that would limit its application only to settlement agreements that are shams or that extend beyond the life of the patent.

Moreover, if s. 45 does in fact apply to agreements to settle *PM(NOC)* proceedings, the fact that the Bureau has stated that it will not bring proceedings under s. 45 in respect of settlement agreements ought not give significant comfort to pharmaceutical companies. That is because if s. 45 does in fact apply to such agreements, then pharmaceutical companies entering into those agreements could face the risk of consumer class actions brought in respect of such settlements under the private right of action created by s. 36 of the *Competition Act*.[52] In other words, if s. 45 of the *Competition Act* applies at all to settlement agreements, there is nothing in the text of the Act that would limit private actions, including class actions, to only those circumstances where settlement agreements are shams or extend the life of the patent in question. This would expose pharmaceutical companies to a much broader scope of liability than the IPEGs seem to contemplate.

Pharmaceutical companies could try to rely on the ancillary restraints defence to defend against such class actions, though the almost complete absence of case law relating to the ancillary restraints defence makes it difficult to predict whether such a defence would be successful.

If that is the case, the apparently finely calibrated rules set out in the IPEGs become significantly more blunt. If the intention of the IPEGs in confining s. 45 to a narrow role in the domain of settlement agreements is to not overly dissuade parties from entering into settlement agreements, the IPEGs miss that mark. Rather, by suggesting that s. 45 applies at all to settlement agreements, the IPEGs seem to give broader scope to consumers to bring class proceedings against both innovator and generic pharmaceutical companies in respect of all such settlement agreements—even for settlement agreements that the Bureau has determined are clearly unobjectionable, such as entry split agreements. Again, while this may be reasonable from a competition law perspective, it seems ludicrous from the perspective of patent law.

Each of these conceptual problems is simply the realization in this context of the long-recognized tension between competition law and intellectual property law. Importantly, neither of these problems is meant to suggest that competition law either has or ought to have no application whatsoever to the domain of intellectual property. However, what is important to recognize is that existing competition law tools that are appropriate for one domain ought not be automatically transposed to a different domain to which they are ill-suited. That is precisely what the Bureau's IPEGs try to do. Rather, where competition law and intellectual property interface, it is crucial that such regimes be coherent and fully integrated in order to appropriately balance the goals of each regime.

Indeed, in many regimes, they co-exist relatively easily. As described above, there is no blanket immunity from antitrust law for patent holders in the United States, and the Federal Courts there are at least trying to strike an appropriate balance between the competing goals of intellectual property and antitrust law. However, the American legal context is quite different. While the differences in the regimes for generic pharmaceutical entry have already been described above, it is important to note that American antitrust law is also very different from Canadian competition law.

Contrary to the detailed provisions of the *Competition Act*, the federal Sherman Act in the United States is sparse in text and open-ended in meaning.[53] Much of U.S. federal antitrust law is derived from only two general provisions of the Sherman Act that have been in place for over a

century.[54] Those provisions have been given a rich and nuanced meaning by Courts, and that meaning has evolved over time. Indeed, the Sherman Act has been described as a common law statute.[55]

For those reasons, the Sherman Act provides Courts with a nuanced and flexible set of principles that can be used to tailor a set of rules that is appropriate for the context in particular. Unique doctrines can be developed by the Courts to deal with antitrust issues in intellectual property, and indeed Courts have done so. The *Actavis* decision and its progeny represent an attempt by Courts to craft antitrust rules that still facilitate the goals of intellectual property law.

The Canadian context is different. As noted above, the *PM(NOC)* regime already contains an internal mechanism that mitigates concerns regarding anti-competitive agreements in the form of section 8 damages. And on the competition law side, the current *Competition Act* is radically different from the Sherman Act. In contrast to open-ended and flexible provisions of the Sherman Act, the *Competition Act* contains detailed provisions governing a broad range of situations. It does not easily admit of new common law defences, nor does it contain limiting language that allows Courts to naturally limit the ambit of key provisions of the Act. For example, as described above, section 45 of the Act creates a *per se* rule that criminalizes a horizontal agreement between competitors to limit the supply of a product, without any consideration of the competitive effects or business objectives furthered by that agreement, except in limited, statutorily-defined circumstances.[56] If section 45 of *Competition Act* applies to a particular agreement, Courts seemingly have no discretion under the Act to tailor particular rules with which to evaluate such agreements. Contrary to the context-specific tailoring that is possible under the Sherman Act, the application of the *Competition Act* to settlement agreements in patent litigation necessarily involves the application of a blunt tool. While the IPEGs try to shape that tool into a somewhat more refined instrument, they remain limited by the structure of the Act.

2. The Enforcement Problem

Even if the approach set out in the IPEGs were conceptually sound, the IPEGs are unlikely to provide the Bureau with a meaningful ability to take action against any reverse-payment settlements that do have anticompetitive effects. More precisely, the Bureau is limited by the *Competition Act* in the tools it has available to it to take action against potentially anti-competitive reverse-payment settlement agreements. These tools are much more limited than the tools available to enforce antitrust law in the United States.

As described above, the circumstances to which the Bureau intends to apply s. 45 of the Act are extremely limited in scope, so the criminal prohibition that creates penalties for past conduct are unlikely to apply to very many cases. Consequently, the vast majority of settlement agreements will be scrutinized, if at all, under s. 90.1 of the *Competition Act*. However, section 90.1 of the Act is an unsuitable tool for effectively addressing these circumstances.

First, in order for the Bureau to potentially take any action in respect of a potentially anticompetitive settlement, the Bureau has to first know about that settlement. Unlike in the United States, there is no requirement in Canada that settlements of pharmaceutical litigation be reported.

Second, even if the Bureau learns of a settlement and forms the view that the settlement is anticompetitive, it will often be difficult for the Bureau to successfully establish that a settlement agreement is anti-competitive under s. 90.1, simply due to the complexity of the analysis. As noted above, the factors that the Bureau will consider in deciding whether to commence proceedings under s. 90.1 include such factors as the amount of the payment, the potential exposure of the innovator to section 8 damages, the innovator firm's expected remaining litigation costs absent settlement, efficiency as a result of the settlement, and presumably also the innovator's likelihood of prevailing in its prohibition proceeding.[57] Assuming that these are the same factors that the Tribunal would ultimately consider in deciding whether to make an Order under s. 90.1, the complexity of these factors means that it will be extremely difficult for the Commissioner to establish reviewable conduct under s. 90.1.[58]

Taking first the question of whether the innovator will be successful in the prohibition proceeding, the Bureau and the Tribunal will effectively have to adjudicate the decision that the Federal Court would have made on the prohibition proceeding, had the settlement not been made. This will require the Bureau to engage expertise in patent law as well as subject matter expertise in the relevant fields, so that the Bureau can assess the likelihood of success in prohibition proceedings. Given the complexity in contemporary Canadian patent law as well as the underlying subject matter of most pharmaceutical patent disputes, it is difficult to imagine that, in most cases, the Bureau or the Tribunal will be able to come to particularly strong conclusions as to the likelihood of success.

The Bureau and the Tribunal will also have to consider the potential exposure of the innovator to section 8 damages. This too is fraught with

challenges, as section 8 proceedings raise a host of issues. In virtually every section 8 case, the Court will have to consider a laundry list of factors to determine the appropriate quantum of damages, including the length of the relevant period, the ability of the plaintiff generic to supply the market in the but-for world, the total size of market for the product, the generics' share of the total market, the plaintiff generic's share of the generic market, the price of the product in the but-for world, the plaintiff's trade spend rates, and the plaintiff generic's manufacturing and other costs. In a typical section 8 case, most of these issues are hotly contested, and the sheer number of variables makes it difficult to predict the outcome.

Moreover, the nature of section 8 proceedings is that, in the vast majority of cases, there are not multiple heads of damages, but rather one overall head of damages—the generic's lost profits—which is a function of both revenues and expenses. Changes in each of the variables that go into calculating each are multiplicative rather than additive in their effect on the overall damages. As a result, even relatively small disagreements on a number of issues can have very significant effect. As an example, a 30% increase in each of the variables descried in the previous paragraph does not lead to a 30% increase in section 8 damages; rather, it leads to a 715% increase in damages. Put differently, with a disagreement of only 30% on each of the above issues, a defendant could value the case at $30 million, while a plaintiff could value the case at $245 million. Accurately predicting the quantum of damages in a section 8 proceeding is therefore extremely difficult.

At best, what the Bureau and Tribunal might be able to determine is what the likelihood is for each of a range of possible outcomes for each of the factors they are considering. In that universe, where both the innovator and the generic face significant risks, the range of appropriate settlement to be struck will depend on the relative degree of risk-seeking or risk-aversion of the parties to the negotiation. Different players may be motivated to reach very different agreements, depending on what their degree of risk tolerance is.

The difficulty the Bureau will face in establishing that a reverse payment settlement is anticompetitive was amplified substantially by the 2017 amendments to the *PM(NOC) Regulations*. As noted above, following those amendments, innovators can be held liable for lost profits, calculated on the basis of a hypothetical but-for world, even after the date of generic entry in the real world. This means that even short periods of exclusion could give rise to plausible claims for large damages and expands drastically the range of potential reasonable settlements of any section 8 claims. This in turn makes an assessment of whether a reverse payment settlement is anti-competitive even more challenging.

Compounding all of these considerations will be the evidentiary problems that the Bureau will face in bringing any proceedings under s. 90.1. In general, the Bureau has a very powerful tool in s. 11 of the *Competition Act* to compel the production of documents, to compel the provision of written returns, and to require individuals to submit to examinations under oath.[59] The difficulty for the Bureau in examining settlement agreements of *PM(NOC)* proceedings is that because the agreements in question settle litigation, one would expect that much of the documentation and analysis relating to those agreements would have been prepared by legal counsel. As such, much of the evidence that the Bureau would often be able to obtain will, in these cases, be protected by solicitor-client privilege. In the face of those considerations, it will often be difficult for the Bureau to establish, except in the clearest cases, that any particular agreement is beyond the pale.

Finally, even if the Bureau were able to obtain sufficient information and conduct a fulsome analysis that would allow it to bring proceedings under s. 90.1, it will be even rarer that it would be able to move quickly enough to be able to challenge an agreement. One of the most significant enforcement problems that the Bureau faces in using s. 90.1 is that it only applies to "existing or proposed" agreements; this is mirrored by the Bureau's remedies under s. 90.1, which are largely limited to prohibiting parties from carrying out the agreement. Consequently, if an agreement has lapsed on its terms, the Bureau has no ability to bring proceedings to challenge a past agreement.

If settlement agreements were in effect for extremely long periods, then the Bureau might effectively be able to use s. 90.1. However, the structure of the *Patent Act* and the *PM(NOC) Regulations* means that the terms of any reverse payment settlement agreements are likely to be quite short. The reason for this is as follows.

Under the *Patent Act*, the term of a patent is 20 years from the date on which the patent is filed.[60] However, an innovator is never ready to launch a product on the date on which it files its patent. Rather, for genuinely new products, patents are typically filed many years before an innovator receives regulatory approval in the form of a Notice of Compliance. In order to obtain that Notice of Compliance, they are required to comply with the extensive requirements set out in the *Food and Drug Regulations*.

It is only once the innovator obtains its Notice of Compliance that it faces the risk of generic competition on the basis of the generic filing an abbreviated new drug submission. However, that process itself is time consuming: even if the generic starts working on an abbreviated new drug submission the day that the innovator receives its Notice of Compliance, it may not be

prepared to file its abbreviated new drug submission for several years. Even after it has filed its Notice of Compliance, Health Canada may take another year to review and approve the abbreviated new drug submission.[61]

Once Health Canada approves the abbreviated new drug submission and provides the generic with a patent hold letter, there is an automatic two year stay on the generic being issued a Notice of Compliance when the innovator invariably commences prohibition proceedings. Assuming that, as is often the case, settlements are reached relatively near the date of the hearing, another nearly two years may have passed. By that point, depending on how long each of the earlier steps has taken, there may very well be only a few years of duration left on the patent. Indeed, much of the litigation under the *PM(NOC) Regulations* takes place only a few years before the relevant patents are set to expire.

The time period has become even shorter by virtue of the data protection provisions of the *Food and Drug Regulations*.[62] Under those provisions, for a large set of innovative drugs that obtained notices of compliance from 2006 onward, generic pharmaceutical manufacturers are prohibited from obtaining approval for products that are based on comparisons to an innovator's reference products for a period of eight years from the date on which the innovator obtains its Notice of Compliance. Those provisions further truncate the period during which there will be any potential litigation under the *PM(NOC) Regulations*.

In light of all of those factors, assuming that the parties do not try to extend the term of the settlement agreement beyond the life of the patent (which would in turn trigger the Bureau's consideration of s. 45 of the Act, according to the IPEGs), the duration of the agreement from the date it is entered into until its expiry might often be just a few years. Even if the Bureau immediately learned about the settlement agreement when it was entered into, which is unlikely, it would typically be difficult, if not impossible, for the Bureau to complete its investigation, bring an application before the Tribunal, and obtain an Order from the Tribunal within just a few years. Given the difficulties described above, as well as the significant resource constraints that the Bureau faces,[63] the Bureau seems unlikely to focus much of its resources in this area. Indeed, while not determinative, it is telling that no applications relating to settlements of pharmaceutical litigation have been brought by the Commissioner, nor have any consent agreements been entered into, since the IPEGs were enacted.

It is worth noting that such enforcement problems have not been proven insurmountable in the United States. In the wake of *Actavis*, a number of

Courts have grappled with the analyzing particular reverse payment settlement agreements under the guidelines set out by the Supreme Court.[64] But again, differences in the enforcement regimes between Canada and the United States demonstrate why antitrust law may play a suitable role in deterring anti-competitive reverse payment settlements in the United States while being entirely unsuitable in Canada. First, in the United States, private parties have a right of action in respect of anticompetitive reverse payment settlements. The possibility of consumer class actions along with government enforcement leads to more robust enforcement than is possible by a government enforcer acting alone. Second, a successful showing of liability allows a plaintiff to recover damages. This means that antitrust claims remain viable even after the term of the settlement agreement has expired, in contrast to the comparative lack of utility of s. 90.1 after the end of the agreement. Third, courts in the United States do not need to grapple with the additional complexities posed by generics' presumptive right to section 8 damages. Fourth, the mandatory notification provisions in respect of settlement agreements mean that such agreements are more likely to come to the attention of regulators than they are in Canada.

3. The Welfare Problem

Even if the IPEGs are successful at dissuading parties from entering into reverse-payment settlements, it is not obvious that, particularly in the Canadian context, this is positive from a welfare perspective. Indeed, dissuading parties from entering into reverse-payment settlement agreements may have adverse effects on welfare from both a static perspective, by dissuading parties from entering into welfare-enhancing agreements, and from a dynamic perspective, by disincentivizing entry and patent challenges by generics. While the welfare effects of reverse-payment settlements are ultimately an empirical matter and difficult to quantify *a priori*, the welfare considerations set out below provide grounds for concern about over-deterring such agreements.

Turning first to the static adverse welfare effects, the IPEGs have the effect of subjecting to s. 90.1 scrutiny certain agreements that are likely welfare-enhancing for consumers. To analyse this, first assume that subjecting reverse-payment settlements to scrutiny under the IPEGs will lead companies to enter into fewer such agreements. In absence of a mutually-agreeable settlement, the innovator and the generic will litigate the prohibition action to its conclusion. That will result in a binary outcome: either the innovator will win and the generic will be kept off the market until patent expiry; or the generic will win and be permitted to enter the market.

In a scenario where the innovator wins the action, the generic will be kept off the market until patent expiry. Any agreement that allows the generic to enter to the market before patent expiry—including those with reverse payments—will result in lower prices for consumers earlier than would have occurred had the innovator been successful in the litigation. If such lower prices are the goal of competition law, then a settlement that allows generic entry before patent expiry, including one that contains a reverse payment, is preferable to a successful action by the innovator.

By contrast, in a scenario where the generic wins the action, the generic will be permitted to enter the marketplace before patent expiry. That will immediately result in lower prices for consumers. Three points are worth noting.

First, at the time a settlement agreement is reached, it will not be known whether an innovator or a generic will win the action. While the parties may be able to make educated guesses, there is always significant uncertainty in litigation. A settlement agreement removes that uncertainty and, assuming that the agreement allows for generic entry at some point prior to patent expiry, at the very least allows for lower prices earlier than if the innovator succeeds in the litigation.

Second, under the *PM(NOC) Regulations*, the innovator has the ability to keep a generic pharmaceutical manufacturer off the market for a period of 24 months. As such, any settlement that would allow the generic to enter by the end of that 24 month period—irrespective of the amount of other consideration provided by one side to the other—would necessarily not be welfare-reducing.

Third, because settlements reduce costs and uncertainty, even settlements that delay generic entry by more than 24 months may maximize total surplus. Reaching a settlement can significantly reduce legal costs for both the innovator and the generic. Settlements can also eliminate costs to businesses of preparing for contingent scenarios that do not materialize. In those circumstances, total surplus may be greater under a settlement, even if the generic entry is delayed beyond the automatic 24 month stay provided for in the *PM(NOC) Regulations*. As such, even if a generic has a good case that a patent is invalid, settlement agreements that go beyond the automatic 24 month stay may be welfare-enhancing.

All of those arguments speak to the benefits of settlement of litigation under the *PM(NOC) Regulations*. However, they do not specifically address the benefits of reverse payment settlements. If reverse payments were

prohibited, and all parties that would have entered into reverse payment settlements simply entered into settlements that did not include reverse payments, then these arguments would have no merit. Rather, in order for reverse payment settlements to have the benefits outlined above, it must be the case that parties will enter into more settlements if reverse payments are an option than they would if it were not.

While the magnitude of this increase (if any) is difficult to predict without a body of empirical evidence, it seems likely that the availability of reverse payment settlements does increase the number of settlements. In general, any time parties lose the ability to include a term that is mutually beneficial in an agreement, reaching a settlement becomes more difficult.[65] Moreover, given the availability of section 8 damages in Canada, it seems especially likely that some settlements that might otherwise occur might not be entered into if reverse-payment settlements were prohibited. The reason for this is because the innovator and the generic will be unable to reach a mutually-beneficial agreement that splits the entry while also compensating the generic for its accrued section 8 damages.

As a stylized example of this problem, consider a drug product that generates profits of $100 million per year for an innovator.[66] Assume that for simplicity that there is only one potential generic challenger who, upon entering the market for that product, will earn profits of $50 million per year, while the innovator will earn no profits once the generic enters. Assume that at the time of the settlement the patent has 10 years remaining, and the innovator and generic each believe that each has a 50/50 chance of succeeding in the action. Assume that at the time the settlement is being negotiated, the action has been going on for one year, meaning that the generic would have a right to $50 million in s. 8 damages if it were successful in opposing the innovator's prohibition action—or, put differently, expected section 8 damages to the generic of $25 million (a 50% chance of winning multiplied by $50 million).

If both the innovator and the generic are risk-neutral, then leaving aside the accrued section 8 damages, the innovator and the generic would be willing to resolve the challenge on the basis of splitting the remaining life of the patent, i.e. allowing the generic to enter after five years. However, once the generic's expected right to $25 million in section 8 damages is introduced, no mutually beneficial resolution is possible without a reverse payment. For its part, in the absence of a reverse payment, the generic would insist on being permitted to enter six months earlier to compensate it for its $25 million in foregone section 8 damages. Yet that further six months

would cost $50 million to the innovator. Consequently, without a reverse payment settlement of $25 million for the accrued section 8 damages, there will be no entry date that would be agreeable to both parties.

The IPEGs attempt to address this problem by specifying that the Bureau will consider the potential exposure of the innovator to section 8 damages in deciding whether to bring proceedings to challenge a settlement agreement under s. 90.1 of the *Competition Act*. Yet the IPEGs do not go so far as to provide that compensation solely for accrued section 8 damages to the date of the settlement would not be the subject of proceedings by the Bureau. Given the desire of companies to avoid scrutiny by the Bureau, it seems likely that companies will tend to avoid even potentially questionable reverse payment settlements. If so, this could result in companies declining to enter into reverse payment settlements that would be welfare enhancing.

Even more difficult to quantify are the dynamic effects that could arise from prohibiting reverse payment settlements. There are a number of potential effects that must be considered.

First, and most obviously, to the extent that reverse payment settlements result in longer patent exclusivity for innovators (as is generally assumed),[67] a rule that discourages reverse payment settlements diminishes the value of the patent. To the extent that prohibiting reverse payment settlements diminishes the returns to patents, prohibiting such settlements could diminish incentives to innovate.[68]

Second, to the extent that reverse payment settlements are profitable for generic pharmaceutical manufacturers (or at least more profitable than an entry-split without a payment),[69] dissuading reverse payment settlements may result in fewer generic pharmaceutical manufacturers taking steps to challenge patents.[70] Assuming that an increase in the number of generic challenges increases the probability that the innovator will not reach a successful settlement with at least one of the generics, disincentivizing reverse payment settlements could, under certain circumstances, paradoxically result in delaying generic entry beyond what would occur if reverse payment settlements were permitted. Whether this would occur depends on the relative impacts of, on the one hand, the marginal incentives to challenge patents due to the possibility of a reverse payment settlement with, on the other hand, the higher likelihood of all settlements when reverse payment settlements are permitted. Yet the possibility of this effect shows the ambiguity inherent in rules that characterize reverse-payment settlements as potentially anti-competitive.

As noted at the beginning of this section, this article does not suggest that the welfare effects of reverse payments settlements are necessarily positive. These questions have been addressed elsewhere in both the economic and legal literature. Whether the welfare effects are positive or negative depends on complex static and dynamic effects, each of which depends very much on the circumstances. Rather, the purpose of this section is simply to note two points. First, the overall efficiency implications of prohibiting reverse payment settlements are ambiguous, rather than clearly positive (as is generally taken to be the case with prohibiting cartels). Second, whatever the efficiency implications of dissuading parties from entering such agreements might be in the US legal context, the welfare effects of dissuading parties from entering into such agreements are likely to be more negative in a system that allows for section 8 damages than in a system without section 8 damages. This too gives a reason for pause before importing American analysis and rules directly into the Canadian context.

IV. Towards a Better approach: Wholesale reform or Incremental Change?

The considerations above suggest that the current IPEGs are suboptimal, particularly given the particular structures of both the *Competition Act* and the *PM(NOC) Regulations*. They represent an approach that is legally incoherent, that can be welfare-reducing, and that is not practical as an enforcement mechanism. Then what alternative would be better? This article does not suggest that policy-makers should ignore competition considerations in intellectual property litigation. To the contrary, the welfare considerations at the core of economic analysis should be on the minds of policy-makers designing an optimal intellectual property rights scheme. Rather, what this article instead suggests is that there are preferable means for resolving such issues, either in the wholesale reform of the IPEG scheme or in incremental changes to address some of the most significant problems. In either case, an important motivating principle must be that there is little merit in convergence for convergence's sake; rather, there must be sensitivity to the overall context.

Option One: Wholesale Reform

A wholesale reform that would be an improvement over the current IPEGs would be to address any competition law concerns through the *PM(NOC) Regulations* themselves. As described above, the *PM(NOC) Regulations* contain a carefully calibrated regime that is meant to address the competing interests of innovators, generics, and consumers. Recent reforms

to the *PM(NOC) Regulations* indicate that Parliament's continuing preference is to address these concerns internally within the scheme created by the Regulations. In particular, the expansion of the scope for section 8 damages provides a strong check against innovators engaging in exclusionary conduct based on clearly untenable patents. The layering of the *Competition Act* on top of the carefully calibrated Regulations necessarily disrupts that balance.

If even the amended *PM(NOC) Regulations* were judged to be insufficient to deter anticompetitive conduct, the preferable approach would be to re-calibrate that regime internally to improve competition. If deemed appropriate, the federal Parliament could, for example, increase the damages available to the generic under s. 8, such as by allowing disgorgement of the innovator's profits, or by allowing awards of punitive damages where an innovator acts in bad faith. Alternatively, one could specifically enshrine a right of consumers to bring proceedings against an innovator if it brought prohibition proceedings unreasonably and was ultimately unsuccessful. From my perspective, neither of those would be optimal, as they would improperly dampen the incentives of innovators to try to enforce their patents, which is in turn critical to providing an incentive to innovate in the first place. Yet each of those options would at least involve a discussion about the proper calibration of an integrated regime that seeks to balance a number of competing social interests, rather than trying to bolt the *Competition Act* onto a different and internally calibrated regime.

Conceptually, this is a coherent approach that recognizes that the *PM(NOC) Regulations* are a carefully calibrated and self-contained scheme and that other legal regimes ought not to try to be grafted on top. This approach finds support in decisions of Canadian Courts of Appeal that have held that the *PM(NOC) Regulations* constitute a complete code for claims against innovators that ousts any further claims at common law.

This approach was most recently articulated by the British Columbia Court of Appeal in *Low v Pfizer Canada Inc.*[71] At issue in that case was a proposed class proceeding against Pfizer in connection with Viagra. The representative plaintiff alleged that Pfizer had unlawfully abused the patent system by exercising its rights under the *PM(NOC) Regulations* to keep generic competitors off the market, thereby leading to higher prices for Viagra for consumers. While the case was originally certified as a class action by the motions judge, the British Columbia Court of Appeal set that decision aside, holding that it was plain and obvious that class members had no cause of action against Pfizer. The British Columbia Court of Appeal articulated this as follows:

> However, I am of the view that the completeness of the Patent Regulatory Regime forecloses parallel civil actions by consumers that are rooted in a breach of the Patent Act. In my opinion, there is nothing in the legislation comprising the Patent Regulatory Regime (and in the Patent Act particularly) that evinces an intention to allow consumers to make such claims … .
>
> Courts have determined that the *Patent Act* constitutes a complete code as between brand name and generic manufacturers. Courts have also concluded that the completeness of the Patent Regulatory Regime prevents generic drug manufacturers from claiming disgorgement of profits based on unjust enrichment. It would make no sense logically or from a policy perspective to allow consumers to claim disgorgement of profits from brand names when generics are precluded from claiming the same based on identical wrongful acts.
>
> As Pfizer has noted in its factum, there is evidence that Parliament considered the interests of consumers when legislating the Patent Regulatory Regime. Under the *Patent Act*, drug innovators must submit proposed drug prices to the Patented Medicines Review Board (continued under s. 91), which has the power to reduce the price of medicine deemed to be excessive (see ss. 79-103) … .
>
> The Patent Regulatory Regime involves a balancing of interests through the implementation of legislative policy choices….In *Apotex Inc v Eli Lilly Canada Inc.*, the Federal Court of Appeal described the *PM(NOC) Regulations* (and s. 8 in particular) as "an attempt to strike a balance between the need for patent protection on the one hand and the timely entry of lower priced drugs on the market, on the other" (at para. 18). In my view, it is not for this Court to upset the balance that Parliament has struck by expanding the scope of available remedies.[72]

Canadian courts have also applied this complete code theory to exclude any application of common law causes of action, such as unjust enrichment, by generic pharmaceutical manufacturers against innovators in this context.[73]

This same theory should also oust application of the provisions of the *Competition Act*. The right of an innovator to begin or discontinue prohibition proceedings is granted under the *PM(NOC) Regulations* and is immune from challenge under other legal theories. By the same token, the ability to settle such proceedings represents a necessary corollary to the ability to commence or discontinue such proceedings, and it too should be immune from challenge under other legal theories, including provisions of the *Competition Act*. This approach is most consistent with the complete code theory that Canadian Courts of Appeal have routinely accepted.

This approach is by no means foreign to the *Competition Act* jurisprudence. As noted above, in the context of intellectual property rights, the Competition Tribunal has repeatedly recognized that the mere exercise of intellectual property rights is not reviewable conduct under the *Competition Act*. More generally, courts have long recognized that, in circumstances where a particular regulatory regime governs the relations between parties, the general provisions of the *Competition Act* may be ousted. This has given rise to the regulated conduct defence, which provides that parties to *Competition Act* proceedings may avoid prosecution on the basis that the conduct they are engaging in is regulated by another body.[74] Normatively, the regulated conduct defence reflects a very basic idea: the general provisions of the *Competition Act* should not apply where a particular market, because of its differing structure and characteristics, calls for a different policy approach.

It is again worth emphasizing that whatever arguments there may have been for subjecting settlement agreements between innovators and generics to antitrust scrutiny in the United States, the force of such arguments is substantially diminished in Canada. Four differences are paramount.

First, and most simply, the United States has no analog to section 8 damages. This means that there is no similar financial penalty to an innovator for keeping a generic off the market. Moreover, as noted above, the absence of such damages simplifies the analysis for American Courts considering whether a particular agreement is anticompetitive.

Second, in the United States, the Hatch-Waxman Act provides a unique incentive to the innovator to reach anticompetitive settlement with the first-filer or filers. Because the 180-day exclusivity period only attaches to the first filer, subsequent generic filers do not face the prospect of receiving such exclusivity, which diminishes their incentive to try to challenge the patent in the first place. Consequently, a successful reverse payment settlement agreement with the first filer can significantly blunt the financial risks it faces of further generic competition.

By contrast, in Canada, section 8 damages are available to each potential generic entrant that is kept off the market, and not only the first filer. That means that even if the first generic challenger is kept off the market through a settlement that includes a payment, subsequent generic challengers continue to have incentives—in the form of section 8 damages—to try to challenge patents. That means that an innovator cannot be assured of maintaining a monopoly position through a single settlement agreement with a payment; rather, the innovator, over time, would have to enter into

a series of such agreements with generic challengers in order to continue to maintain its exclusivity. These differences mean that, holding everything else equal, it is relatively more costly for innovators to try to effect an anti-competitive pay-for-delay strategy in Canada than it is the United States.

Third, in the United States, parties who enter into a settlement agreement to resolve pharmaceutical litigation are obligated to notify the Federal Trade Commission that such a settlement has been entered into.[75] This mandatory notification provision provides the government with greater ability to scrutinize those agreements than is available in Canada. While some type of mandatory notification system was suggested by the Bureau in its 2014 white paper,[76] no such system has been created.

Fourth, the structure of antitrust law in the United States allows for more efficient deterrence of undesirable anticompetitive agreements than does the *Competition Act* in Canada. In the United States, an agreement can be either *per se* illegal, which means that the agreement is automatically deemed to violate antitrust law, or subject to a rule of reason, a much more permissive standard that requires consideration of both pro-competitive and anti-competitive effects of the agreement. However, in either case, if the agreement is established to violate antitrust law, the offending parties can be made liable for damages. This possibility of damages deters parties from entering into anticompetitive reverse payment settlements.

By contrast, Canadian law does not allow for a settlement agreement to both be subject to rule of reason analysis *and* damages. Damages can be awarded under s. 45 of the *Competition Act*, but that provision makes certain arrangements *per se* illegal. The Bureau has set out in the IPEGs that it will not prosecute cases under s. 45 of the Act, in recognition of the fact that such agreements are not so clearly categorically impermissible as to be deemed *per se* illegal.[77] By contrast, if the Bureau wishes for such agreements to be scrutinized under a rule of reason analysis, its only option is s. 90.1. However, as noted above, the remedial powers open to the Tribunal under s. 90.1 do not include damages. As a result, the possibility of proceedings under s. 90.1 does not provide the same degree of deterrence that pharmaceutical companies might face in the United States.

These differences mean that it would be faulty reasoning to conclude that the policy decision made by the U.S. Supreme Court to apply antitrust scrutiny to such settlement agreements should be applied to Canada. Even accepting the rationale of such application in the United States—which is not free from controversy itself—the different context means that one

should be very careful before concluding that a similar rule ought to be applied in Canada.

Option Two: Incremental Changes

Even if the IPEGs are to remain in substantially their current form, another option would be to make incremental changes that could improve them. This article proposes two changes that could improve the IPEGs by providing parties with additional clarity.

The first incremental reform would be to create a new safe harbour for any settlements that result in a generic entering the market within 24 months following the commencement of a prohibition proceeding, regardless of any monetary payments or other consideration associated with such settlements. The reality is that the prohibition of settlements that result in entry during that period are almost necessarily welfare enhancing, since the innovator's alternative would to run out the course of the prohibition proceedings and keep the generic off the market for the entirety of the 24-month period. Consequently, settlements that result in generic entry within the 24-month period promote certainty for both parties, reduce costs for both parties, and result in lower prices for consumers.

Moreover, even if such settlements were welfare-reducing in some circumstances, it seems particularly unrealistic that the Bureau could meaningfully take any action against such settlements within that period of time. By definition, the generic will enter the market in a period of no longer than two years. It seems almost impossible that the Bureau would learn of the settlement, investigate the circumstances, come to a determination it was anti-competitive, and obtain relief from the Tribunal within two years.

Second, the Bureau should establish more concrete guidelines as to the metrics by which it will evaluate whether particular monetary settlements will attract scrutiny under s. 90.1 of the Act. One way to provide such clarity would be to provide certain formulas that set out either safe harbours or likely contraventions. For example, it seems unlikely that an entry split that allows generic at any point prior to patent expiry, coupled with a payment only for section 8 damages for the 24 month period of continued exclusivity allowed following the commencement of a prohibition proceeding under s. 6 of the *PM(NOC) Regulations*, could possibly be objectionable. Under such a settlement agreement, the innovator would already be liable for section 8 damages to that date if it maintained its prohibition proceeding through the entire stay period, while the entry split would reflect a compromise between the innovator and generic as to the success on the prohibition

proceeding. Such a resolution could hardly be seen as objectionable, as it would not involve compensating the generic for any subsequent delay after the 24-month period for which the innovator is entitled to delay generic entry. Such settlements could be considered as presumptively falling into a safe harbour. While this option would still raise difficult questions as to whether the payment in question was based on a genuine and reasonable estimate of section 8 damages to the date of the settlement, the parties would still have greater clarity than they do under the current regime.

Conversely, there could also be rough guidelines as to payments that will presumptively attract scrutiny under s. 90.1. For example, a payment to a generic in an amount that is substantially more than the generic could reasonably have earned during whatever period it is excluded from the market under the agreement seems *prima facie* to be questionable. That level of payment arguably necessarily reflects an innovator paying a generic for delaying its entry onto the market.

Between the safe harbours and presumptive rocky shoals, there will necessarily be a gray area of settlements involving monetary payments that will not admit of a clear formula and that will require further analysis. But the smaller that gray area becomes, the better it will be for all parties involved.

While it is difficult to develop a formula *a priori* that will govern all cases, even more basic guidance would still be preferable. For example, while the Bureau's current approach sets out a laundry list of factors that are to be considered in determining whether a particular settlement agreement including a monetary payment would be reviewable under s. 90.1, the IPEGs provide no normative framework for evaluating how those factors are to be assessed to determine whether a particular settlement is acceptable. In other words, they provide no basis on which parties can determine whether a particular settlement is either fair or foul.

V. Conclusion

One might have reached this point in the article and have concluded that I see no competition law concerns present in pharmaceutical litigation settlement. That would be far from the truth. The intersection of intellectual property law and competition law gives rise to a complex set of problems without simple solutions, and without proper care or consideration of both sets of principles, policy responses can create more problems than they solve. Pharmaceutical litigation must absolutely be assessed from a competition law perspective to avoid obvious problems.

The call in this article is not to avoid considering competition law entirely. Rather, the point is that difficult problems call for scalpels, not sledgehammers. The provisions of the *Competition Act* provide a blunt set of tools for addressing complex problems. They do not necessarily calibrate easily to particular and idiosyncratic institutional contexts. Even more, the conclusions of American antitrust law as applied to the American pharmaceutical litigation regime are even more difficult to transport north of the border, given the institutional differences in the Canadian analogues of each.

The *PM(NOC)* settlement rules in the IPEGs may provide some consistency with the corresponding US regime, and they may even represent a reasoned application of the provisions of the *Competition Act* in that context. Yet that assumes that the broad and general provisions of the *Competition Act*—designed for hard-core cartels (s. 45) and potentially anti-competitive competitor collaborations (s. 90.1)—must necessarily find some application in the unique world of *PM(NOC)* litigation. When that regime is itself internally calibrated to address competing policy goals, it is by no means clear that the application of the *Competition Act* leads to better outcomes.

ENDNOTES

[1] The views and opinions contained in this article are those of the author alone, and do not represent the views of Lenczner Slaght or its clients. Any errors are those of the author alone.

[2] Paul-Erik Veel is a partner at Lenczner Slaght and a lecturer in law and economics at the University of Toronto. Paul-Erik's litigation practice includes competition law, class actions, and complex commercial litigation.

[3] For the articles on both sides of the debate on the economic efficiency of reverse payment settlements, see the articles cited in C. Scott Hemphill, "Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem" 81 New York University Law Review (2006) 1553 at fn 15. See also Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent Settlements in the Pharmaceutical Industry" (2010) 19 Annals of Health Law 367. For articles in legal journals engaging in the debate on the merits of antitrust regulation of reverse payment settlements, see the articles cited below.

[4] *Competition Act*, RSC, 1985, c C-34, s. 1.1.

[5] Paul Belleflamme and Martin Peitz, *Industrial Organization: Markets and Strategies*, 2nd ed. (2017), p. 351.

[6] Paul Belleflamme and Martin Peitz, *Industrial Organization: Markets and Strategies*, 2nd ed. (2017), p. 349.

[7] *Competition Act*, RSC, 1985, c C-34, s. 45(1).

[8] *Competition Act*, RSC, 1985, c C-34, s. 45(4).

[9] *Competition Act*, RSC, 1985, c C-34, s. 45(2).

[10] For example, companies convicted of *Competition Act* offences may be barred

from bidding on government contracts for a period of time. Under the federal debarment policy, companies convicted under s. 45 of the *Competition Act* can be prohibited from bidding on federal contracts for up to 10 years. See the *Ineligibility and Suspension Policy* that forms part of the federal government's Integrity Regime.

[11] *Competition Act*, RSC, 1985, c C-34, s. 36.

[12] Competition class actions are now incredibly common in Canada, and it is reasonable expect that they will continue to proliferate in light of the favourable legal landscape that the Supreme Court of Canada has crafted in recent years for competition class actions, particularly in its decisions in *Pro-Sys Consultants Ltd v Microsoft Corporation*, 2013 SCC 57 and *Pioneer Corp v Godfrey*, 2019 SCC 42.

[13] *Competition Act*, RSC, 1985, c C-34, s. 90.1.

[14] *Competition Act*, RSC, 1985, c C-34, s. 90.1(4).

[15] *Competition Act*, RSC, 1985, c C-34, s. 90.1.

[16] *Competition Act*, RSC, 1985, c C-34, ss. 75, 77, 79.

[17] *Competition Act*, RSC, 1985, c C-34, s. 79(5).

[18] *Competition Act*, RSC, 1985, c C-34, s. 32.

[19] *Apotex Inc v Eli Lilly and Company*, 2005 FCA 361.

[20] *Eli Lilly and Company v Apotex Inc*, 2009 FC 991.

[21] *Canada (Director of Investigation and Research) v Tele-Direct (Publications) Inc and Tele-Direct (Services) Inc.* (1997), 73 CPR (3d) 1 (Comp Trib).

[22] *Canada (Director of Investigation and Research) v Warner Music Canada Ltd.* (1997), 78 CPR (3d) 321 (Comp Trib).

[23] *Stargrove Entertainment Inc v Universal Music Publishing Group Canada*, 2015 CACT 26.

[24] This trade-off is recognized in the economics of intellectual property rights. Increased protection of intellectual property rights requires a trade-off between static and dynamic efficiency. Increased protection of intellectual property rights decreases static efficiency by allowing for sales of products at a price above marginal cost, while decreased protect of intellectual property rights decreases dynamic efficiency by lessening the incentives to innovate. See Paul Belleflamme and Martin Peitz, *Industrial Organization: Markets and Strategies*, 2nd ed. (2017), pp. 540-541.

[25] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 4.

[26] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 5(2.1).

[27] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 5(3).

[28] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 6(1).

[29] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 6(3), 6.01.

[30] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 7(1)(d).

[31] *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133, s. 8.

[32] See eg *Apotex Inc v Merck & Co Inc*, 2009 FCA 187 at paras 92-102.

[33] *Apotex Inc v Sanofi-Aventis*, 2014 FCA 68 at paras 155-165; *Teva Canada Limited v Sanofi-Aventis Canada Inc*, 2014 FCA 67 at paras 144-145.

[34] Some authors have found a significant first mover advantage in the generic

pharmaceutical industry: see eg Aidan Hollis, "The importance of being first: evidence from Canadian generic pharmaceuticals", (2002) 11 Health Economics 723; Ali Shajarizadeh, Paul Grootendorst & Aidan Hollis, "Newton's First Law as Applied to Pharmacies: Why Entry Order Matters for Generics" (2015) 22 International Journal of the Economics of Business 201.

[35] This trade-off is recognized in the economics of intellectual property rights. See Paul Belleflamme and Martin Peitz, *Industrial Organization: Markets and Strategies*, 2nd ed. (2017), pp. 540-541.

[36] Ariel Katz and Paul-Erik Veel, "Beyond Refusal to Deal: A Cross-Atlantic View of Copyright, Competition and Innovation Policies" (2013) 79(1) Antitrust Law Journal 139.

[37] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 13, 2019, s. 3.4.

[38] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 13, 2019, s. 4.2.1.

[39] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 13, 2019, s. 4.2.1.

[40] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 13, 2019, s. 4.2.1.

[41] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 13, 2019, s. 7.3.

[42] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 13, 2019, s. 7.3.3.

[43] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 13, 2019, s. 7.3.

[44] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 13, 2019, s. 7.3.2.

[45] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 13, 2019, s. 7.3.2.

[46] *Federal Trade Commission v Actavis*, 570 U.S. 136.

[47] For an overview of the legality of reverse payment settlements prior to the Actavis decision, see David W. Opderback, "Rational Antitrust Policy and Reverse payment Settlements in Hatch-Waxman Patent Litigation" 98 Georgetown Law Journal 1304 at 1308-1317. The Second and Federal Circuits had held that such settlements were per se legal, provided that the litigation leading to the settlement was not a sham and that the settlement did not provide exclusivity beyond the scope of the patent. See eg T*amoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 212-213 (2d Cir. 2006); *Arkansas Carpenters' Health and Welfare Fund v Bayer AG*, 604 F.3d 98 (2d Cir. 2010); *Ciprofloxacin Hydrochlide Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008). The Third and Sixth Circuit Court of Appeal concluded that they were presumptively unlawful: see eg *Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003); *In re K-Dur Antitrust Litigation*, 686 F. 3D 197 (3rd Cir. 2012). The Eleventh Circuit had adopted an intermediate position, holding that such agreements were subject to antitrust scrutiny under the rule of reason: *Schering Plough Corp.*, 402 F.3d 1056 (11th Cir. 2005)

[48] See eg Herbert Hovenkamp, Mark Janis, and Mark A. Lemley, "Anticompetitive Settlement of Intellectual Property Disputes" (2002-2003) 87 Minn. L. Rev. 1719; Christopher M.Holman, "Do Reverse Payment Settlements Violate the Antitrust Laws?" (2006-2007) 23 Santa Clara Computer & High Tech. L.J. 489; David W. Opderbeck, "Rational Antitrust Policy and Reverse Payment Settlements in Hatch-Waxman Patent Litigation" (2009-2010) 98 Geo. L.J. 1303; Alex E. Korona, "Stuck in Neutral: The Future of Reverse Payments Agreements in Hatch-Waxman Litigation", 7 Seton Hall Cor. Rev. 201; Tania Khatibifar, "The Need for a Patent-Centric Standard of Antitrust Review to Evaluate Reverse Payment Settlements" (2012-2013) 23 Fordham Intell. Prop. Media & Ent. L.J. 1351. The Actavis decision has also drawn significant subsequent academic commentary: see eg Murat C. Mungan, "Reverse Payments, Perverse Incentives" (2013-2014) 27 Harvard J.L. Tech. 1; Zhengui Wang, "Reanalyzing Reverse-Payment Settlements: A Solution to the Patentee's Dilemma" 99 (2013-2014) Cornell L. Rev 1227; Peter Picht, "New Law on Reverse Payment Settlements—The Agenda for Courts and the Legislature After the Supreme Court's *Actavis* Ruling" (2013) 16 Tul. J. Tech. & Intell. Prop. 105; A.L. Knuckles, "Reverse Payment Settlements: The Ongoing Dilemma After FTC v. Actavis", (2013-2014) 8 Brook. J. Corp. Fin. & Com. L. 516; Herbert Hovenkamp, "Anticompetitive Patent Settlements and the Supreme Court's *Actavis* Decision" (2014) 15 Minn. J.L. Sci. & Tech. 3.

[49] *Patent Act*, RSC, 1985, c. P-4, s. 43(2) ("After the patent is issued, it shall, in the absence of any evidence to the contrary, be valid and avail the patentee and the legal representatives of the patentee for the term mentioned in section 44 or 45, whichever is applicable.).

[50] *Patent Act*, RSC, 1985, c. P-4, s. 42.

[51] *Competition Act*, RSC, 1985, c C-34, s. 45, 90.1.

[52] *Competition Act*, RSC, 1985, c C-34, s. 36.

[53] Sherman Act, 26 Stat. 209, 15 U.S.C. §§ 1-7.

[54] Those two provisions are s 1 of the Sherman Act, which prohibits conspiracies in restraint of trade, and s 2 of the Sherman Act, which prohibits monopolization. See Sherman Act, 26 Stat. 209, 15 U.S.C. §§ 1–2. (§ 1: "Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court."; § 2: "Every person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding $100,000,000 if a corporation, or, if any other person, $1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.")

[55] See eg *Leegin Creative Leather Products, Inc v PSKS, Inc*, 551 U.S. 877 (2007) ("From the beginning the Court has treated the Sherman Act as a common-law statute").

[56] *Competition Act*, RSC, 1985, c C-34, s. 45. Section 45 does contain certain defences, including the regulated conduct defence (discussed elsewhere in this article) and the ancillary restraints defence, which exempts parties from liability where an otherwise unlawful agreement is ancillary to a broader agreement with a lawful objective. There is limited case law interpreting most of these defences. In any case, the defences on their face are narrow in scope that do not allow for a broad consideration of the particular context.

[57] Competition Bureau, Intellectual Property Enforcement Guidelines, dated March 24, 2016, s. 7.3.2.

[58] Given the difficulties in distinguishing between pro-competitive and anti-competitive settlement agreements, some authors have proposed that unexplained changes in stock prices following reverse payment settlements should be taken as evidence that particular reverse payment settlements are anti-competitive: see Thomas G. McGuire, Keith Drake, Einer Elhauge, Raymond S. Hartman, and Martha Starr, "Resolving Reverse-Payment Settlements with the Smoking Gun of Stock Price Movements" 81 Iowa Law Review (2016) 1581.

[59] *Competition Act*, RSC, 1985, c C-34, s. 11.

[60] *Patent Act*, RSC, 1985, c P-4, s. 44.

[61] See Health Canada, "Guidance for Industry: Management of Drug Submissions", Appendix 3: Target Performance Standings for Drug Submission Review, available online at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/management-drug-submissions/industry.html>

[62] *Food and Drug Regulations*, CRC, c. 870, C.08.004.1.

[63] See eg the Competition Bureau's "Competition and Compliance Framework".

[64] See eg *King Drug Co of Florence, Inc. v SmithKline Beecham Corp.*, 791 F.3d 388 (3d Cir. 2015); *Rochester Drug Co-Operative, Inc v Warner Chilcott Co (In re Loestrin 24 FE Antirust Litig.)*, 2016 U.S. App. LEXIS 3049 (1st Cir. Feb. 22, 2016); *In re Nexium Antitrust Litigation*, No. 15-2005 (1st Cir. 2016*); In re: Wellbutrin XL Antitrust Litigation*, No. 15-2875 (3d Cir. 2017).

[65] The economic literature has described certain conditions under which settlements which would otherwise be beneficial for consumer welfare would not be reached without the availability of reverse payments. See eg Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent Settlements in the Pharmaceutical Industry" (2010) 19 Annals of Health Law 367 at 391-397. For another analysis of various reasons why reverse payments might be necessary to resolve complex disputes, see Henry N. Butler, "Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation" 96 Iowa Law Review (2010) 101 at 138-144.

[66] This stylized example is similar to the example described in Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent

Settlements in the Pharmaceutical Industry" (2010) 19 Annals of Health Law 367 at 377-381, except that the assumptions are modified to include the possibility of section 8 damages.

[67] A 2010 FTC study found that Agreements with compensation from the innovator to the generic on average prohibit generic entry for nearly 17 months longer than agreements without payments: see FTC, Pay-for- Delay: How Drug Company Pay-Offs Cost Consumers Billions at p. 4 (2010), <http://www.ftc.gov/os/2010/01/ 100112payfordelayrpt.pdf>.

[68] See eg Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent Settlements in the Pharmaceutical Industry" (2010) 19 Annals of Health Law 367 at 398.

[69] Some authors have found evidence that reverse payment settlements increase innovator's stock prices, which they interpret as supporting the hypothesis that reverse payment settlements are profitable and therefore anticompetitive: Keith M. Drake, Martha A. Starr, and Thomas McGuire, "Do 'Reverse Payment' Settlements of Brand-Generic Patent Disputes in the Pharmaceutical Industry Constitute an Anticompetitive Pay for Delay" NBER Working Paper No. 20292, July 2014.

[70] See eg Bret Dickey, Jonathan Orszag, and Laura Tyson, "An Economic Assessment of Patent Settlements in the Pharmaceutical Industry" (2010) 19 Annals of Health Law 367 at 398.

[71] *Low v Pfizer Canada Inc*, 2015 BCCA 506.

[72] *Low v Pfizer Canada Inc*, 2015 BCCA 506 at paras 68-71.

[73] See eg *Apotex Inc v Eil Lilly and Company*, 2015 ONCA 305; *Apotex v Merck & Co, Inc*, 2009 FCA 187; *Apotex v Eli Lilly*, 2011 FCA 358.

[74] See most recently the discussion of the regulated conduct defence in *Hughes v Liquor Control Board of Ontario*, 2018 ONSC 1723 at paras 195-247 and the cases referred to therein. The common law regulated conduct defence was expressly preserved in s. 45(7) of the current *Competition Act*.

[75] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1112(a)(1), § 1112(c), 117 Stat. 2066.

[76] Competition Bureau, Patent Litigation Settlement Agreements: A Canadian Perspective, September 23, 2014.

[77] This is consistent with the American approach. No member of the Supreme Court in *Actavis* went so far as to suggest that reverse payment settlements should be presumptively illegal, as the FTC had argued.