INTRODUCTION

The Sections are pleased to submit the following comments concerning the Canadian Competition Bureau’s (Bureau) September 23, 2014 paper entitled “Patent Litigation Settlement Agreements: A Canadian Perspective” (the White Paper). Given the ongoing and evolving discussion about the application of competition law to patent litigation settlements taking place around the world, and the importance of this discussion to pharmaceutical companies actively engaged in ongoing patent litigation, the Sections welcome the Bureau’s willingness to provide guidance in this important area of competition law.

The Sections acknowledge the substantial effort the Bureau is devoting in seeking to provide meaningful guidance for pharmaceutical companies. In many respects, the White Paper offers helpful insight into the Bureau’s enforcement policy. Such guidance is particularly valuable with respect to the application of provisions of the Competition Act that have not yet been interpreted by Canadian courts, either generally or in the specific context of patent litigation settlements in the pharmaceutical industry.

These comments reflect the Sections’ broad concern with the Bureau’s apparent emphasis on potential criminal prosecution of patent litigation settlements as part of the Bureau’s enforcement policy.

These comments also offer thoughts on the Bureau’s consideration of the regulatory framework, assumptions regarding patent validity and economic effect, and the Bureau’s request for a notification system in Canada.

BACKGROUND

Patent litigation settlements generally raise a number of complex competition policy issues. These include the interface between antitrust and other areas of law—namely intellectual property and pharmaceutical regulations regarding product approval and market entry. Antitrust

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2 The White Paper focuses on settlements involving pharmaceutical products, so our comments will focus on these settlements. The comments made here should not be taken to necessarily extend to settlements in other market contexts.
policy in this complex area must permit parties to efficiently settle patent disputes within the applicable regulatory framework while articulating a principled basis for challenging settlements in those instances where they would be deemed anticompetitive. The Sections recognize that each jurisdiction must evaluate its own approach to these complex issues, within the constructs of the applicable legal and economic factors.

The following is a brief summary of the current treatment of patent litigation settlements in the United States, which the Bureau may find informative. As this discussion demonstrates, U.S. courts and policy makers are still at the very early stages of developing the analytical framework to evaluate patent litigation settlements post-Actavis, as even basic, threshold issues remain unsettled and the subject of intense debate.

In June 2013, the U.S. Supreme Court ruled in FTC v. Actavis that pharmaceutical patent litigation settlements which include a “reverse payment” from the patent holder to the alleged infringer and an agreement by the infringer to stay off the market for some period of time are subject to rule of reason analysis under the U.S. antitrust laws. The majority opinion undertook a careful analysis of the applicable regulatory framework in the U.S. for the purposes of identifying whether antitrust harm might result from patent litigation settlements, including the key aspects of the Drug Price Competition and Patent Term Restoration Act of 1984 (more commonly referred to as the “Hatch-Waxman” Act). The majority opinion held that “a reverse payment, when large and unjustified, can bring with it the risk of significant anticompetitive effect,” namely that such a settlement can be used by a patentee “to avoid the risk of patent invalidation or a finding of noninfringement.” According to the majority opinion, the likelihood of a payment having such effects “depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.”

The majority opinion explained that under this rule of reason analysis it will not typically be necessary “to litigate the patent’s validity” because “[a]n unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about the patent’s survival.” The Court also provided a non-exhaustive list of examples of potential justifications for patent litigation settlements where value transfers from the innovator to the generic—(1) where the payment “amount[s] to no more than a rough approximation of the litigation expenses saved through the settlement” and (2) where a payment “reflect[s] compensation for other services that the generic has promised to perform.”

In applying a rule of reason analysis, the Court specifically declined to follow either of the standards proposed by the parties—the “presumptively unlawful” rule advocated by the Federal Trade Commission (FTC) and the “scope of the patent” test advanced by the defendants.

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4 *Id.* at 2236-37.
5 *Id.* at 2237.
6 *Id.* at 2244.
7 *Id.* at 2238.
In Actavis, the FTC asserted that “reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements” should apply a “quick look” analysis.\(^8\) The defendants on the other hand urged the Court to hold that patent litigation settlements are immune from antitrust liability so long as the anticompetitive effects of the settlement fall “within the scope of the exclusionary potential of the patent,”\(^9\) the patent was not obtained by fraud, and suits enforcing the patent were not objectively baseless. Known as the “scope of the patent” test, this approach was adopted by the majority of district and appeals courts that considered the issue of patent litigation settlements prior to Actavis.\(^10\)

In charting its own third course, the Court offered five “considerations” that underpin its conclusion that a rule of reason analysis, which weighs an agreement’s procompetitive and anticompetitive effects, is instead the appropriate means by which to evaluate patent litigation settlements. First, “the specific restraint at issue has the potential for genuine adverse effects on competition.”\(^11\) Second, “these anticompetitive consequences will at least sometimes prove unjustified.”\(^12\) Third, “where a reverse payment threatens to work unjustified anticompetitive harm, the patentee likely possesses the power to bring about that harm in practice.”\(^13\) Fourth, “an antitrust action is likely to prove … feasible administratively.”\(^14\) Fifth, and finally, “the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit.”\(^15\)

Aside from these broad guiding principles, the Court otherwise left it up to the lower courts to develop the exact rule of reason framework, and many derivative issues remain the subject of intense debate among policymakers, economists, lawyers, and academics. Examples of these issues include (but are not limited to):

- What constitutes a “payment” for Actavis purposes?
- How should different types of payments be valued and should pleading standards differ according to the type of payment being alleged?
- How big does a payment need to be in order to be considered “large”?
- What inferences can be drawn from the size of a payment? What is the relationship between the size of the payment and the dynamics of bargaining and risk aversion?

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\(^8\) Id. at 2237. So-called “quick look” analysis effectively shifts the burden of proof to the defendant to offer proof of procompetitive effects. See California Dental, 526 U.S. 756, 775 at n.12 (1999).


\(^10\) See e.g., FTC v. Watson Pharm., Inc., 677 F.3d 1298, 1306-15 (11th Cir.2012); Ark. Carpenters H. & Welfare Fund v. Bayer AG, 604 F.3d 98, 106 (2d Cir.2010); In re Tamoxifen Citrate Antitrust Litig., 466 F.3d 187, 213-15 (2d Cir.2006); Schering-Plough Corp. v. FTC, 402 F.3d 1056, 1066 (11th Cir.2005).

\(^11\) Id. (citing FTC v. Indiana Federation of Dentists, 476 U.S. 447, 460–461 (1986)).

\(^12\) Id. at 2235-36.

\(^13\) Id. at 2236.

\(^14\) Id.

\(^15\) Id. at 2237.
• How should the procompetitive benefits that may arise from a given agreement be evaluated and when does the burden of proof for establishing such benefits shift?

Lower courts in the U.S. have already begun to issue rulings on some of these issues, but the decisions issued to date reflect a split among the courts on key fundamental questions. The first post-Actavis issue to garner significant attention from a number of courts is whether agreements involving only non-cash forms of payment are also subject to the Actavis rule of reason framework. To date, seven U.S. district courts across four districts and two circuits have issued inconsistent rulings on the issue.  

Separately, three courts have ruled that although Actavis does apply to non-cash forms of payment, in order to survive a motion to dismiss, the monetary value of such a payment must be pled with specificity and a reasonable basis so that it may be analyzed against the Actavis factors.

Some courts have also suggested that different types of payments may require different valuation methods, and that some forms of payment may be far more difficult to value than others. In In re Loestrin 24 Fe, a federal court in Rhode Island ruled that Actavis does not apply to non-cash forms of payment because certain types of non-cash payments—namely, licenses, co-promotion agreements for other drugs, and no-authorized generic (“No-AG”) agreements—are likely to be particularly difficult to value. However, another federal court in In re Effexor concluded that it would not be prohibitively difficult to value non-cash forms of payment like No-AG agreements. That court held that “[a] rough approximation of the value of [a] no-authorized generic agreement could be based upon the difference in market expectations with and without an authorized generic.” The court explained further that this would need to include consideration of a number of issues including: (1) “the share of the market that converts from the brand to the generic;” (2) “the retail price of the generic during the 180-day exclusivity period, with and without an authorized generic;” and (3) “the share of the generic market that would have been retained by the authorized generic if there had been one.”

There is also extensive debate among leading voices in the antitrust community about the central holding by the U.S. Supreme Court in Actavis, namely that the antitrust laws should apply to patent litigation settlements only if there are payments that are “large and unjustified.” The

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18 Id. at *11.

19 Id. at *22.

20 Id.

attempts to identify when payments are “large and unjustified” are only just beginning, and the issue has yet to be litigated.

COMMENTS

I. The Bureau’s Intention to Apply Criminal Law to Patent Litigation Settlements

The Sections respectfully suggest that the Bureau’s focus on criminal enforcement could deter companies from entering into potentially efficient and procompetitive. While the Sections recognize that there may be rare circumstances where criminal enforcement in the context of pharmaceutical patent litigation settlements could be warranted, the Sections respectfully suggest that Bureau policy should both reflect the exceptional nature of the applicability of criminal standards in this area and clearly articulate (based on that premise) those limited circumstances that would justify criminal, rather than civil, enforcement.

A. Relationship to Existing Bureau Policy

The Bureau’s Competitor Collaboration Guidelines (the “Guidelines”) articulate the general standards the Bureau applies in determining when it will elect to pursue enforcement under section 45 (i.e., the criminal provision) as opposed to section 90.1 (i.e., the civil provision). According to the Guidelines, criminal enforcement under section 45 is reserved for types of conduct that constitute “naked restraints” on competition. The Sections respectfully observe that, by contrast, the White Paper states that the Bureau’s analysis begins by assessing whether a settlement should be subject to section 45, but does not explain (i) why the Bureau views patent litigation settlements as potentially constituting a “naked restraint”, or alternatively, (ii) why the Bureau is expanding the class of cases that it will treat under section 45 beyond just “naked restraints” to include at least some patent litigation settlements.

B. U.S. Experience and Enforcement Discretion

The U.S. Department of Justice (DOJ) has the authority to pursue criminal enforcement of the antitrust laws (while the FTC traditionally is responsible for antitrust enforcement in the pharmaceutical sector, only the DOJ has criminal enforcement authority). As a matter of longstanding policy, DOJ criminally prosecutes only “hard core” unlawful agreements that are by law presumed to be per se unlawful. It does not initiate criminal prosecutions in rule of reason cases, where the state of the law is unclear, or where there are novel issues of law or fact. The DOJ has never pursued criminal enforcement action based upon a pharmaceutical patent settlement agreement.22 This suggests that the DOJ has yet to identify any situation where a patent

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22 The DOJ has prosecuted pharmaceutical companies for violations of the antitrust laws, but not on the basis of an allegedly anticompetitive patent litigation settlement. As Assistant Attorney General Thomas Barnett has explained, “the Division focuses its criminal enforcement only on hard core violations. By focusing narrowly on price fixing, bid-rigging, and market allocations, as opposed to the "rule of reason” or monopolization analyses used in civil antitrust law, we have established clear, predictable boundaries for businesses.” (emphasis added) See speech by AAG Thomas O. Barnett, Criminal Enforcement of Antitrust Laws: The U.S. Model, FORDHAM COMPETITION LAW
settlement was used to conceal true hard core conduct. It is also notable that the FTC, which has been at the forefront in aggressively challenging allegedly anticompetitive patent settlements, has never suggested that criminal enforcement would be appropriate.

Finally, the Sections note that in any criminal prosecution, the prosecution must establish beyond a reasonable doubt all the constituent elements of the alleged offense, including intent. As to the intent element, when a per se violation of section 1 is properly charged, once DOJ has proved the existence of the anticompetitive agreement, courts have permitted it to satisfy the intent requirement by proving intent to enter the agreement. Given the ruling in Actavis that reverse payment settlements are not presumptively unlawful, however, in the very unlikely event that DOJ were to seek to prosecute such a settlement criminally, it would need to prove not only an intent to enter into the agreement charged but also a specific intent to unreasonably restrain trade. Establishing this "mental element" of the offense could be particularly challenging to prove in the context of a pharmaceutical patent settlement, where the minds of the accused will in almost all cases be focused on the resolution of ongoing litigation. Moreover, as a practical matter, many of the documents that evidence the parties' motivation and rationale for settlement will contain or reflect legal advice, and accordingly be subject to the applicable privileges.

C. Appropriateness of Per Se Treatment for Settlements with Uncertain Competitive Effects

As explained above, the Supreme Court in Actavis explicitly held that patent litigation settlements do not warrant per se treatment (even as a civil violation). In the view of the Court, patent litigation settlements are not such that "an observer with even a rudimentary understanding of economics could conclude that the arrangements in question would have an anticompetitive effect on customers and markets." The Court explained further that:

[this is because the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor’s anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification. The existence and degree of any anticompetitive consequence may also vary as among industries. These complexities lead us to conclude that the FTC must prove its case as in other rule-of-reason cases.]

The Sections respectfully suggest that further detailed study is required if the Bureau is to adopt an enforcement policy that holds patent litigation settlements to be presumptively unlawful, and which therefore might be subject to criminal sanction.

As a separate matter, the Sections note that the White Paper outlines two scenarios where the Bureau would be inclined to commence criminal enforcement.

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23 Actavis, at 2237 (quoting California Dental, 526 U.S. at 770).
24 Id.
The first of these scenarios concerns settlements with respect to markets or products that are not the focus of the patent litigation. Settlements that would fit this description include agreements that permit early entry in a market other than the market into which the challenged patent is sold or co-promotion agreements. Such agreements are currently the subject of extensive debate in the U.S., including discussion of how the procompetitive benefits that can arise from such settlements should be measured and balanced against other effects from the agreement. For example, if a settlement agreement includes a co-promotion agreement whereby the generic will promote a different drug of the branded manufacturer (or will promote the same drug as is at issue in the litigation, but in a different market) and the compensation for that co-promotion work reflects fair value for services, it is not clear that this arrangement would necessarily bring about anticompetitive effects at all, let alone that characterization as a criminal offence would be appropriate. As observed in Actavis, “[w]here a reverse payment reflects…fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.”

The second scenario involves “a settlement [that] is a vehicle for a ‘naked restraint’ on competition that is not implemented in furtherance of a legitimate collaboration or was motivated by factors beyond the issues associated with the litigation…” The Sections respectfully submit that this scenario is lacking in sufficient particularity to provide real guidance regarding the conduct that could possibly warrant criminal sanction. For example, it is not explained what facts or settlement terms might constitute a “naked restraint” on competition in the context of a patent litigation settlement, or what distinguishes a “legitimate” collaboration from other collaborations in this context. It is also difficult to conceive of any factual situation where the parties, in settling genuine litigation, were not motivated, at least in some part, by issues associated with the litigation. The Sections recognize the theoretical possibility of a sham patent litigation settlement deserving of criminal treatment (e.g., a situation where there is evidence that both the innovator and generic knew that the patent that was the subject of the litigation was invalid or not infringed). Such settlements, however, are so inherently unlikely as to be exceedingly rare. The Sections respectfully submit that fact situations that are inherently unlikely are an inappropriate lens through which to establish competition law enforcement policy and would not appear to warrant the heavy focus on criminal enforcement reflected in the White Paper.

Given that important questions remain open regarding the merits and net effect of these types of arrangements, and the risk of deterring procompetitive effects through over-enforcement, the Sections respectfully submit that the Bureau ought not to categorically seek to pursue criminal and per se enforcement in respect of this type of settlement.

D. Risks Associated with Criminal Prosecution

Patent litigation takes place on an ongoing basis in Canada. Litigating parties must continuously reassess the benefits and risks associated with continuing their litigation or settling their dispute. Settlement of litigation produces benefits for the litigating parties, for the justice system and for the general public. Settlement can provide certainty to litigating parties more quickly than litigating to a final conclusion, and result in the savings of money and time. Settlement relieves

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25 Id. at 2236.
courts from the burdens associated with fully litigated matters. And settlement of pharmaceutical patent litigation can lead to compromise outcomes that may be more equitable and efficient than litigating outcomes (e.g., settlements may result in the public obtaining access to competing pharmaceutical products earlier than they otherwise might have).

The threat of possible criminal prosecution for the settlement of pharmaceutical patent litigation in an undefined set of circumstances creates additional risks and uncertainties that litigating parties must weigh when continuously reassessing their litigation and settlement strategy. Potentially deterring settlements that create efficiencies and are potentially procompetitive on account of uncertainties associated with the Bureau’s enforcement policy will be of no benefit to the general public, and may in fact result in harm.

II. The Bureau’s Consideration of the Regulatory Framework

The White Paper acknowledges that there are important differences between Hatch-Waxman and the Patented Medicines (Notice of Compliance) Regulations (the PM(NOC)), but asserts that these differences do not “diminish the role of competition analysis in reviewing potentially anticompetitive settlements.” Although the Sections agree that these differences may not necessarily exclude antitrust scrutiny of settlements of patent litigation, the Sections’ view is that the White Paper does not fully capture the implications of these differences. At a minimum, the Bureau’s guidance should articulate a cogent explanation of how the regulatory regime in Canada under PM(NOC) informs the Bureau’s enforcement approach toward patent litigation settlements.

The Sections respectfully recommend that the Bureau’s analytical framework should more fully take account of the unique aspects of the Canadian regulatory framework, including the different risks and incentives that arise under PM(NOC), and how these risks and incentives affect bargaining by branded and generic pharmaceutical firms. This must necessarily take into account the ways Canadian courts have interpreted various sections of PM(NOC), which interpretations continue to evolve.

For example, a generic may have a greater incentive to settle in Canada than in the United States due to the following:

- The risk of having to pay costs if PM(NOC) proceedings fail. In the U.S. under Hatch-Waxman, assuming the generic does not opt to launch at-risk, it will generally only bear its own litigation costs;
- The risk of a finding of infringement outside PM(NOC) proceedings and the obligation to pay damages (i.e., double jeopardy); and
- The risk that incurring costs to litigate PM(NOC) proceedings will not yield sufficient return because the generic may immediately be subject to competition

26 Bureau White Paper, at 5.
from other generics (on account of there being no 180-day exclusivity period in Canada).  

Each of these differences may affect the context in which the patent litigation is settled (and therefore the ultimate terms of settlement) and in such instances should be relevant to how the Bureau exercises its enforcement discretion.

III. The Bureau’s Assumptions Regarding Patent Validity and Economic Effect

The Sections respectfully submit that the White Paper contains several assertions that should be the subject of further study before being assumed by the Bureau in the exercise of its enforcement discretion.

In his speech introducing the White Paper, Commissioner Pecman asserted that “the very existence of litigation casts the [validity and infringement of the] patent in doubt.” The Sections respectfully suggest that this assertion be carefully studied and analyzed in the specific context of the Canadian regulatory system. For example, the Sections note the following:

- The Sections are not aware of any study on innovator-generic pharmaceutical patent litigation in Canada. Such an exercise could provide important data regarding how often generics successfully challenge a branded patent when cases proceed through a hearing. Although studies like these have been done in the U.S., their applicability to the Canadian system is uncertain without careful evaluation of the similarities and differences between the U.S. and Canadian patent systems, and specifically with respect to pharmaceutical patents.

- The impact of the incentives put in place under the PM(NOC) to encourage generics to file suit to challenge branded patents with limited risk (i.e., not face liability for infringement damages) should be carefully evaluated to determine what, if any, effect these incentives may have on the filing or outcome of litigation in Canada (and whether this differs from situations in the U.S.).

- The likelihood of any particular patent being found to be invalid or not infringed is highly situation-specific, and so generalizations like these are likely to have limited utility in the course of analyzing the likely competitive effects of any particular agreement to settle litigation related to that patent.

Likewise, the Sections respectfully submit that the basis for the White Paper’s assertion that “the form of settlement makes a significant difference in determining its competitive effects” is not

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29 See e.g., RBC Capital Markets Equity Research, Pharmaceuticals: Analyzing Litigation Success Rates (January 15, 2010).
obvious. In the U.S., significant emphasis has been placed on the “reverse” nature of the payments in these agreements—i.e., the fact that the party paying is one who generally does not face the risk of damages liability in the litigation. However, whatever probative value that characteristic of these agreements has for purposes of analyzing competitive effects for U.S. purposes, its value in the context of the PM(NOC) system seems likely to be far less in light of the fact that branded manufacturers do in fact face the risk of potentially significant section 8 damages in Canada. Thus, the transfer of value from branded to generic manufacturers in these suits is built into the Canadian system itself by design. While competitive harm may potentially arise in the context of certain settlements, the mere form of settlement is not uniquely indicative of whether or not the patent litigation settlement has a competitive effect—it is instead, at most, in the Canadian regulatory context one of many factors that can be considered.

Similarly, the White Paper also asserts that “[w]hen a brand pays more than the generic could have obtained from PM(NOC) Regulation proceedings, such payments are less likely to be justified.” The Sections respectfully suggest that this assertion should be explicitly qualified to take into account, among other things, (i) the value of any services or other consideration that the generic might provide to the brand in return (whether within or outside the product market of the drug that is subject to PM(NOC) proceedings), and (ii) the uncertainty in calculating section 8 damages (which depends, at least in part, upon predictions about behavior by independent generics that are not party to the litigation, among other things).

The White Paper further states that “[i]n contrast, more nuanced analysis is called for when the payment falls within the realm of what could be expected in PM(NOC) Regulation litigation, such as where the brand faces section 8 damages liability and makes a modest payment that is less than the expected damages the brand would owe the generic.” What is not explained, however, is why the Bureau would subject such settlements to antitrust scrutiny at all, and, further, how the Bureau proposes to distinguish within this category of agreements those agreements that are actually anticompetitive, from the others that will have no competitive impact at all. These types of settlements seem to reflect the very model of what the Supreme Court in Actavis referred to as a “traditional” form of settlement in that they involve a situation where “a party with a claim (or counterclaim) for damages receives a sum equal to or less than the value of its claim.”

Such settlements in the “traditional” form are worthy of an antitrust safe-harbor as a matter of principle (consistent with Actavis), and this would also provide clarity to litigants who wish to settle cases within a verifiable range of potential section 8 damages. If the Bureau is not willing to confirm a safe harbor for such settlements, then the Bureau should clearly articulate the circumstances in which it would pursue antitrust enforcement in cases of this kind and the basis for such.

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30 Indeed, describing this very characteristic is how Justice Breyer opened his majority opinion in Actavis, “[b]ecause the settlement requires the patentee to pay the alleged infringer, rather than the other way around, this kind of settlement agreement is often called a ‘reverse payment’ settlement agreement.” Actavis, at 2227. Later in the opinion, he wrote that reverse payment settlements are something “quite different” than “traditional” forms of settlement because “a party with no claim for damages (and something that is usually true of a paragraph IV litigation defendant) walks away with money…” Id. at 2233.


32 Actavis, at 2233.
IV. The Bureau’s Request for a Notification System in Canada

Lastly, the Sections would like to address the Bureau’s call for a notification system for patent settlement agreements. As the Bureau notes in its White Paper, the U.S. Congress instituted a notification system under the Medicare Modernization Amendments Act of 2003 whereby certain pharmaceutical patent settlement agreements must be filed with the Assistant Attorney General of the U.S. Department of Justice Antitrust Division and the FTC. Although the burden of this system on the parties to settlement agreements has been relatively limited to date, the appropriateness of implementing such a system in Canada should be evaluated in the context of the other elements of the Bureau’s proposed approach articulated in the White Paper.

In particular, if a notification system is established in Canada, applying the criminal law to notified patent litigation settlements would be even more inappropriate. A notification system would require that companies self-report conduct that is not covert and potentially criminal. Such a system would stand in stark contrast to the immunity and leniency programs operated by the Bureau for true “naked constraints”, which merely incent companies to voluntarily self-report conduct that is covert and potentially criminal.

Second, substantial competitive harm is unlikely to result from settlements that are reported to the Bureau since the Bureau could take quick action to object to settlements that it considered to be inconsistent with the Competition Act. Given the absence (or at least greatly reduced risk) of substantial competitive harm and the openness of the parties about their agreements, use of criminal enforcement, with its significant penalties and reputational effects, is arguably unwarranted and disproportionate.