March 31, 2023

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To Whom it May Concern:

RE: Competition Law Consultation Submission – Innovative Medicines Canada

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Innovative Medicines Canada ("IMC") provides these comments in response to the Government of Canada's consultation on the future of competition policy in Canada. We welcome the opportunity to comment on the Government of Canada's proposed changes to the *Competition Act* and Canada's competition regime.

IMC is an industry group representing 49 members of Canada's innovative pharmaceutical industry. We help our members discover, develop, and deliver innovative medicines and vaccines. Our industry supports nearly 108,000 high-quality, well-paying jobs in Canada and invests up to $2.4 billion in research and development every year. Collectively, the innovative pharmaceutical industry contributes over $15.9 billion per year to Canada's knowledge-based economy.[1] During the COVID-19 pandemic, IMC members developed treatments, test kits, and vaccines that were vital for Canada's fight against the spread of the virus. We are committed to being valued partners in Canada's healthcare system. IMC Members invest heavily to the benefit of the Canadian economy and the health of all Canadians and Canada's intellectual property laws recognize this investment by allowing pharmaceutical companies to benefit from their innovative medicines and vaccines.

The *Competition Act* and Canada's competition regime are cornerstones of Canada's economy, ensuring the efficient functioning of Canada's market-based economy and protecting industry members and consumers from inappropriate and predatory market activity. Equally important to a knowledge economy is recognition that the mere exercise of intellectual property rights is not an anti-competitive act.

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[1] Statistics Canada, "The Canadian Research and Development Pharmaceutical Sector, 2020" (January 30, 2023).

IMC is concerned that certain elements of the Discussion Paper's proposed reforms will lead to unintended consequences to the pharmaceutical and health sectors, specifically:

A. The Government of Canada is exploring whether to subject each patent litigation settlement (in the pharmaceuticals industry only) to notice or voluntary clearance (ex ante scrutiny). However, forced notification and review of each litigation settlement agreement not only singles out an already highly regulated industry, but also has the potential to stifle rather than promote competition in pharmaceutical manufacturing. Ex ante scrutiny is a departure from the ex post approach normally best suited to competition law which lays down general principles and leaves to companies how to comply, i.e. company self-assessment with complaint-based investigation by regulator.

B. The Government of Canada is considering relaxing the abuse of dominance provisions of the *Competition Act* so that joint dominance can be found on a *de facto* basis where there is parallel conduct. Further, the Government is considering loosening the need to demonstrate that the anti-competitive practice is resulting in or likely to cause a substantial lessening or prevention of competition. Instead, the Commissioner would merely need to show that alleged anti-competitive conduct is "capable of having anti-competitive effects." By relaxing these standards, there is the serious possibility that abuse of dominance provisions will be used to prevent persons from exercising legitimate economic rights.

C. The Government of Canada has indicated that the various provisions of the *Competition Act* covering civilly reviewable actions between sections 75 and 81 of the *Competition Act* should either be consolidated into a principles-based abuse of dominance or market power provision or supplemented with a provision or set of provisions that would focus on "fair competition" as opposed to anti-competitive effects. The Government of Canada must clarify what it means by "fair competition" and ensure that this standard focuses on the fairness of the competitive process rather than being used to favour certain competitors over others.

D. The Government of Canada is exploring whether individuals should be able to apply to provincial and federal courts for damages caused by alleged civilly reviewable conduct under the *Competition Act*. Unfortunately, this proposal is likely to result in delayed remedies, inconsistent or even contrary jurisprudence, and substantially increase the cost of competition law enforcement for both the public and industry participants.

E. The Government of Canada invites views on whether the collusion provisions of the *Competition Act* should continue to apply only to "agreements" between competitors or whether an agreement can also be inferred between parties even in the absence of a meeting of the minds. This proposal is highly concerning as it will prohibit cooperation

between manufacturers and service providers that are specifically meant to benefit consumers, such as patient support programs, rather than result in anti-competitive harm.

F. IMC recommends enhancing the intellectual property rights exception for abuse of dominance cases set out in Section 79(5) of the *Competition Act*. The exception has been construed so narrowly as to become meaningless and not to protect legitimate uses of intellectual property.

We expand on each of these concerns below and in doing so provide some potential alternatives that we believe better reflect the intended competition policy goals. We hope this submission helps the Government of Canada make the Canadian economy more competitive, effective, and efficient for all Canadians.[2]

A. The Government of Canada Should Not Subject Patent Settlements to Mandatory Notice

In the Discussion Paper, the Government of Canada points to the mandatory pharmaceuticals litigation settlement notice system in the United States as an example of a scheme that Canada may want to emulate.[3] Under this system, each time a pharmaceutical company settles patent litigation with a generic drug producer, the parties to the settlement must notify the U.S. Federal Trade Commission (the "FTC") and provide the settlement agreement to the FTC for review.[4]

Mandatory disclosure and review of all settlement agreements without discretion, and only as they pertain to a single industry will provide little benefit and instead distort the *Competition Act*'s purpose from rules of general application to specifically targeting one industry. Paradoxically, this may even prevent or lessen competition by injecting delay and uncertainty into otherwise normal course litigation practices.

First, it is clear from the U.S. experience, where a notice system for pharmaceutical litigation settlements exists, that this system imposes a substantial undertaking for both pharmaceutical companies and the competition authorities. In fact, the vast majority of these settlement agreements do not contain any type of compensation beyond legal fees. The FTC published reports in 2016 and 2017 on the total number of patent litigation settlements it reviewed in each respective year.[5] In its 2017 report on compensation in settlement agreements – which is the

[2] These are only a few of the issues arising from the decision paper that we have decided to address directly, and the fact that IMC has not directly addressed other portions of the Discussion Paper should not be construed as tacit acceptance or indifference to reform for such issues by IMC or our members.
[3] Discussion Paper at Section VI.2.
[4] **Attachment 1**, FTC, "Pharmaceutical Agreement Filings".
[5] **Attachment 2**, FTC, "Overview of Agreements Filed in FY 2017: A Report by the Bureau of Competition", (December 3, 2020); **Attachment 3**, FTC, "Overview of Agreements Filed in FY 2016: A Report by the Bureau of Competition" (May 24, 2019).

latest report of this kind published by the FTC – the FTC found that of the 226 patent settlements it reviewed in a twelve-month period, only three included compensation beyond legal fees.[6] In other words, 98.7 percent of all agreements contained no non-litigation compensation. Further, and importantly, according to its website, despite the hundreds of cases reviewed, the FTC has only identified four instances where it decided to pursue enforcement against "pay for delay" agreements.[7] That means, of the hundreds of cases that have been reviewed by the FTC each year for potential "pay for delay" arrangements, the FTC has found that only four of these agreements warranted enforcement action. Without empirical evidence that the pharmaceutical industry requires particular scrutiny over an activity that regularly occurs in the context of litigation negotiation, a specific notice requirement for this one industry will only serve to perpetuate a significant level of distrust and suspicion from both the public and the Competition Bureau which is otherwise unfounded.

Second, the *Competition Act* is intended to provide a general framework law for the economy as a whole rather than a repository of industry-specific rules. This is consistent with the formal name of the *Competition Act* as "An Act to provide for the general regulation of trade and commerce" and consistent with Parliament's power to legislate for the general "regulation of trade and commerce" under section 91 of the *Constitution Act, 1867*.[8] By introducing a requirement that is sector-specific, the Government of Canada will create an uneven playing field as between different sectors in Canada. In doing so, the *Competition Act's* objective of supporting general competition rules applicable to all economic actors will be undermined. This would prejudice the pharmaceutical industry in comparison to other industries in Canada that are free to negotiate similar settlement agreements in litigation dispute contexts without Competition Bureau scrutiny. As discussed in further detail below, the pharmaceutical industry is already heavily regulated and does not require additional provisions to be grafted onto a law of general application.

Third, imposing a mandatory review of all settlement agreements by the Competition Bureau would prejudicially impact both parties to the agreement by inserting a substantial amount of uncertainty to otherwise normal commercial practices. The Competition Bureau will be required to devote substantial resources to analyze every single settlement agreement between pharmaceutical companies.[9] Reviewing and reporting on these agreements will be a time-consuming undertaking, as demonstrated by the U.S. experience. For example, the latest FTC report on compensation in pharmaceutical settlements was published in 2020 and related to

[6] **Attachment 2**, FTC, "Overview of Agreements Filed in FY 2017: A Report by the Bureau of Competition", (December 3, 2020).
[7] **Attachment 4**, FTC, "Cases Tagged with pay for delay".
[8] *The Constitution Acts, 1867 to 1982* at s. 91.
[9] Note that in the Discussion Paper, the Government of Canada states that the Competition Bureau is already overburdened.

settlement agreements that took place in 2017 – a three-year delay.[10] A similar delay in Canada is likely to cause a chilling effect on settlements which are intended to allow both parties to move forward in a commercially efficient way and instead lead to protracted litigation in an attempt to achieve certainty and finality – a less desirable outcome for both parties. At a minimum, parties would be incentivized to wait until the Competition Bureau has finished its review of any proposed agreement before finalizing the settlement agreement. The Commissioner's review period would paradoxically result in a *de facto* 'waiting period' situation that would delay generic entry.

Finally, it is important to recognize that the pharmaceuticals industry is already one of the most heavily regulated industries in Canada and faces significant downward pricing pressures both through non-excessive pricing rules and through the consolidated buying power of public payors. Acts and regulations applicable to the pharmaceutical industry include the *Patent Act,* the *Patent Rules,* the *Food and Drugs Act*, the *Food and Drugs Regulations*, and the *PM(NOC) Regulations*.[11] Members of the pharmaceutical industry are also subject to additional requirements from multiple government agencies including:

- Health Canada
- Innovation, Science and Economic Development Canada
- The Canadian Intellectual Property Office
- The Patented Medicine Prices Review Board
- The Canadian Agency for Drugs and Technologies and Health
- Pan-Canadian Oncology Drug Review
- Institut national d'excellence en santé et en services sociaux (INESSS)
- The pan-Canadian Pharmaceutical Alliance
- Multiple provincial, territorial and federal drug plans[12]

The Government of Canada has published information showing that there are over 130 different federal guidance documents pertaining to the interpretation of Canada's various

[10] **Attachment 2**, FTC, "Overview of Agreements Filed in FY 2017: A Report by the Bureau of Competition", (December 3, 2020).
[11] *Patent Act,* RSC 1985, c P-4; *Patent Rules*, SOR/2019-251; *Food and Drugs Act*, RSC 1985, c F-27; Food and Drug Regulations, CRC, c. 870; *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133.
[12] *See for instance*: Health Canada, "Drugs and Health Products", August 12, 2022; Government of Canada, "Evaluation of Innovation, Science and Economic Development (ISED) Canada's funding to the Centre for Drug Research and Development (CDRD)", (July 6, 2022); Canadian Intellectual Property Office, "Patents", February 14, 2023; Government of Canada, "Patented Medicine Prices Review Board", (February 10, 2023); Canada's Drug and Health Technology Agency, "Health Technology Review", (March 13, 2023); Pan-Canadian Pharmaceutical Alliance, "About pCPA"; Ontario, "Check medication coverage", (December 20, 2022).

pharmaceuticals policies, statutes and regulates.[13] Further, unlike most products sold in Canada, pharmaceutical products are already controlled from production, to marketing, to sale. Not only will adding an additional layer of regulation to our members in the litigation context be burdensome and unnecessary, the potential risk of engaging in anti-competition conduct is already restricted by the complex web of regulation already targeted at the pharmaceuticals industry and could create unnecessary barriers to innovation.

B. The Government of Canada Must Not Relax the Abuse of Dominance Criteria to the Point Where Exercising Legitimate Economic Rights Becomes Illegal

The Government of Canada proposes to relax the abuse of dominance criteria under section 79 of the *Competition Act* in two important respects. First, the Government of Canada suggests that the *Competition Act* should explicitly provide that parallel conduct alone is sufficient for the Competition Bureau to prove firms hold a jointly dominant position in a market.[14] Second, the Government of Canada proposes to relax the "anti-competitive effects" requirement for finding abuse of dominance to capture behaviour that is "capable of" having anti-competitive effects rather than behaviour that actually has or is likely to have anti-competitive effects.[15] IMC is concerned that both of these proposals are so broad in scope that they will prevent legitimate market behaviour that is in the Canadian economic interest and, by doing so, defeat the purpose of the *Competition Act*'s abuse of dominance provisions.

As currently drafted, the abuse of dominance provisions in the *Competition Act* do not allow the Competition Bureau to find that multiple competitors in a market are jointly dominant based on parallel conduct alone. The Competition Bureau recognizes this explicitly in its Abuse of Dominance Enforcement Guidelines.[16] Instead, the Competition Bureau must provide evidence of *coordinated* conduct between these competitors. Without a coordinated conduct requirement to establish joint abuse of dominance, otherwise legitimate and parallel market behaviour would always be indicative of joint dominance and remove the point of the requirement altogether.

The overriding purpose of the *Competition Act* is to promote competition. However, it is often difficult to distinguish legitimate but aggressive competition from an "anticompetitive act" within the meaning of Section 79(1)(b). This difficulty is not normally visited on firms which are not dominant – they can compete vigorously without fear of investigations and remedial orders including monetary penalties that might be imposed under Section 79. On the other hand,

[13] **Attachment 5**, Government of Canada, "Guidance Documents – Applications and submissions – Drug products", (February 27, 2023).
[14] Discussion Paper at Sections V.1(a) and V.2.
[15] Discussion Paper at Sections V.1(b) and V.2.
[16] Competition Bureau, "Abuse of Dominance Enforcement Guidelines".

dominant firms must tread more cautiously. Accordingly, expanding the scope of joint dominance to cover more firms tends to chill competition.

For instance, multiple competitors supplying a particular product may, independently of each other, realize that they are able to profitably sell high volumes of their product at lower prices in a way that outcompetes other suppliers who are not able to do so. This is extremely common in any market economy and caused by regular supply and demand forces.[17] However, under the Government of Canada's proposal, this parallel conduct alone could be indicative of joint-dominance and could potentially lead to intervention in regular market activity that is, in effect, beneficial to consumers. In other words, under the Government of Canada's proposal, any regular market pricing or supplying behaviour that is responsive to market realities could make suppliers "jointly dominant." This would remove the purpose of current paragraph 79(1)(a) as members of virtually every industry would become jointly dominant simply for following market principles rather than actively coordinating to abuse their market power, which is what the abuse of dominance provisions seek to prevent.[18] A further difficulty is the broader concept that joint dominance injects uncertainty: firms may not be able to determine whether they are (jointly) dominant because they lack sufficient information about the conduct of their rivals to determine if they are engaging in parallel conduct.

Currently, paragraph 79(1)(c) of the *Competition Act* requires the Competition Bureau to demonstrate that an action is likely to have anti-competitive effects to prove abuse of dominance. In proposing to relax this requirement to demonstrate that the impugned behaviour is only "capable" of having anti-competitive effects, the Government of Canada purports to be inspired by a European approach. However, recent decisions of the European court, namely *re Intel* (Jan 2022) and *Qualcomm* (June 2022) appear to reverse such trend and annulled European Commission rulings which did not establish an anti-competitive effect. IMC is concerned that lowering the current standard would capture market behaviour that does not, and is not likely to, have anti-competitive effects. This is made all the more likely by the Competition Bureau's own submission on the immediate consultation, in which it states that it wants the Tribunal to remedy conduct under the *Competition Act's* abuse of dominance provisions even when the Competition Bureau is unable to prove competitive harm.[19] This threatens to defeat the entire purpose of the abuse of dominance provisions which are meant to prevent anti-competitive conduct, and not conduct caused by the exact competitive market forces that the *Competition Act* upholds. This may result in the Bureau intervening where not required and produce market outcomes with unintended consequences.

[17] *See for instance:* Akshay R. Rao, Mark E. Bergen, and Scott Davis, "How to Fight a Price War" (March-April 2000).
[18] Competition Bureau, "Abuse of Dominance Enforcement Guidelines" at para i.
[19] Competition Bureau, "The Future of Competition Policy in Canada", (March 15, 2023), at Section 2.3.

C. The Government of Canada Must Ensure that its Proposed "Fair Competition" Standard is Not Used for Political Intervention

The Government of Canada proposes to reposition several of the unilateral conduct provisions of the *Competition Act* under a single, broadened "fair competition" provision.[20] This would include section 75 on refusal to deal, section 76 on price maintenance, section 77 on exclusive dealing, section 79 on abuse of dominance, and section 81 on delivered pricing.[21] IMC does not find the notion of including a "fair competition" standard within the *Competition Act* problematic. However, the Discussion Paper provides virtually no guidance outlining what this new standard would entail. Without clear and defined criteria, IMC is concerned that an overly broad and amorphous concept of something being 'fair' can result in government intervention being motivated by politics as opposed to an agnostic goal of establishing market efficiency.

Importantly, the mere exercise of valid patent rights by the patent holder could be viewed as violating a standard of "fairness". Such a notion of fair competition would go far beyond the European standard which requires that an anti-competition effect to be established under art. 102 of the Treaty on the Functioning of the European Union (TFEU) or article 101 of the TFEU (anti-competitive agreements and concerted practices) where infringement "by object" kind of "*per se*" standard is available only for cartels (e.g. bid rigging, price fixing) whereas an anticompetitive effect must be proven in other cases (i.e. "by effect" standard). At a minimum, the *Competition Act* must include an exception, like that currently present in the abuse of dominance provisions, explicitly to permit the mere exercise of intellectual property rights.

The notions of "fair competition" or "fairness in the marketplace" are insufficiently defined in the Discussion Paper and, when taken together with the statement in the same section of the Discussion Paper that "not all civil provisions in the Act require proof of broader competitive harm"[22]are cause for concern. A provision focused on "fair competition" that does not require proof of competitive harm could be so broadly applied that it could be used to punish nearly any behaviour that the Commissioner deems is improper. At worst, this impact could lead to situations where companies are selectively punished by the Commissioner for simply being in a politically unpopular position rather than because their conduct is harmful to Canada's economy.

Providing the Competition Bureau with this extremely broad power absent definitional guidance would lead to the Competition Bureau taking up a position as a competition law "referee" as opposed to its current gatekeeping function as contemplated by the *Competition Act*. Indeed, according to the *Competition Act*, its purpose is:

[20] Discussion Paper at Section V.2.
[21] Discussion Paper at Section V.2.
[22] Discussion Paper at Section V.2.

> [T]o maintain and encourage competition in Canada in order to promote the efficiency and adaptability of the Canadian economy, in order to expand opportunities for Canadian participation in world markets while at the same time recognizing the role of foreign competition in Canada, in order to ensure that small and medium-sized enterprises have an equitable opportunity to participate in the Canadian economy and in order to provide consumers with competitive prices and product choices.[23]

This could create a situation where certain market participants are politically favoured over others through the application of an ambiguous "fair competition" standard, *regardless* of the relative effects on the Canadian economy. This would, in effect, transform Canada's competition law into focusing on politics rather than market efficiency and the provision of consumers with competitive prices and product choices. Criteria for what is "fair competition" should focus on ensuring that all sizes of enterprise have an equitable opportunity to participate in the Canadian economy and not on ensuring that every enterprise is artificially supported to succeed in this competition.

This is especially the case considering the Competition Bureau's request in its submission in this consultation for the civil enforcement regime to be amended to significantly reduce the Competition Bureau's evidentiary burden. The Competition Bureau states that the evidentiary burdens under several areas of the *Competition* Act's civil enforcement regime are too high for the Competition Bureau, and that it should not have to prove that a particular action will cause or has caused competitive harm on a balance of probabilities.[24] As mentioned by the Competition Bureau itself, the purpose of the civil enforcement provisions of the *Competition Act* are to remedy actual harm to competition in Canada. However, preventing a particular action before it has affected the market could in fact *harm* Canadian competition by preventing market behaviour that turns out to be beneficial. Therefore, allowing too wide a berth for the Competition Bureau to bring actions against certain behaviour regardless of whether it is actually harming Canadian competition, is likely to lead the Competition Bureau to pursue remedies against actions that do not have anti-competitive effects.

IMC is also concerned by the impact that the proposed "fair competition" provision may have on the exercise of intellectual property rights. Parliament has currently exempted the sole use of intellectual property rights from the application of the abuse of dominance provisions under section 79 of the *Competition Act*.[25] This exception ensures that the mere use of exclusive intellectual property rights does not place a party in a dominant position for the purpose of section 79. If not for this exception, a firm exercising intellectual property rights could be subject

[23] *Competition Act* s. 1.1.
[24] Competition Bureau, "The Future of Competition Policy in Canada", (March 15, 2023), at Section 2.3.
[25] *Competition Act* s. 79(5).

to an order by the Tribunal preventing it from using these rights. Currently, this exception, does not exist for other provisions in the *Competition Act* including the refusal to deal, price maintenance, and exclusive dealing provisions. If the unilateral conduct provisions are ultimately collapsed into a broader and undefined standard of "fair competition", then a similar exception allowing a party to exercise its intellectual property rights must be included to ensure that companies are not punished for exercising their legitimate economic rights. Otherwise firms and individuals will no longer see the grant of intellectual property rights as sufficient value to spur innovative investment as any subsequent exercise of their intellectual property rights could be held as anticompetitive.

IMC encourages the Government of Canada to either provide substantial guidance on the way that this new "fair competition" provision would function or provide distinct criteria in the law. Further, in the case that the Government of Canada repositions the *Competition Act*'s civil review provisions under a "fair competition" standard, it is just as essential that the Government of Canada include an exception to this provision allowing firms to exercise their intellectual property rights without being penalized by the *Competition Act*, similar to the exception in paragraph 79(5) of the *Competition Act*.

D. The Government of Canada Should Not Provide a Private Right of Action for Parties Under the Civil Provisions of the *Competition Act.*

The *Competition Act* does not contain a private cause of action for damages against behaviour captured by the civil provisions of the *Competition Act*. In the Discussion Paper, the Government of Canada suggests that providing individuals with a private cause of action for damages from civilly reviewable conduct would develop jurisprudence and lead to quicker case resolutions.[26] IMC disagrees. Including a private right of action for damages will instead substantially delay the final resolution of cases, will complicate jurisprudence, could be used by litigious groups to stifle competition, and will frustrate public enforcement.

In the leading case of *Canada v. Vavilov,* the Supreme Court of Canada noted that statutory tribunals such as the Competition Tribunal exist to be the experts of their own statute in accordance with the specialized functions designated to them by Parliament.[27] The issues that are litigated under the civil provisions of the *Competition Act* are complex and often misunderstood. This is why Parliament has empowered the Competition Tribunal, as expert decision-maker, to oversee Canada's competition regime. In the case the Government of Canada decides that a private right of action for damages against civilly reviewable conduct may proceed before a court regardless of whether the Competition Tribunal made a remedial order,

[26] Discussion Paper at Section VIII.1 and VIII.2.
[27] *Canada (Minister of Citizenship and Immigration) v. Vavilov,* 2019 SCC 65, [2019] 4 SCR 653 at paras 27-30.

this could lead to situations where less specialized courts are making decisions that fundamentally impact the *Competition Act*.

Allowing individuals to bring lawsuits under the *Competition Act*'s civil enforcement regime would lead to the courts and the Competition Tribunal developing jurisprudence independently of each other, which would substantially complicate the interpretation of the civil provisions of the *Competition Act*. This is especially true considering that appeals of trial-level court and the Competition Tribunal decisions lay before appellate-level courts,[28] meaning the decisions of a trial-level court would not be binding on the Competition Tribunal and vice-versa.[29] Additionally, in the case the amendments permit a claim to be heard by a provincial court, an appeal of a trial court decision may also not be binding on the Competition Tribunal.[30] Such a jurisprudential split is not currently a concern under section 36 of the *Competition Act*, as both section 36 and section 45 of the *Competition Act* are dealt with exclusively by courts, and the legal standards applied by courts under section 36 are different to those applied by courts under section 45.[31]

The Government of Canada could attempt to remedy this substantial complication of jurisprudence by requiring the Competition Tribunal to order a remedy under the civil enforcement regime of the *Competition Act* before a civil cause of action is available. This would be an imperfect solution, however, because it will significantly extend the length of civil cases under the *Competition Act*. Full resolution would not be achieved until after the Competition Tribunal made its finding on remedy and a court made its ruling on damages. This could extend competition law cases by years and would cut against the proposed amendment's goal of "quicker case resolutions" as stated in the Discussion Paper.[32]

Finally, a private right of action is a poor remedy for civilly reviewable conduct. Such a remedy conflicts with the Government of Canada's statement in the Discussion Paper that "the civil enforcement scheme within the Act is primarily geared toward correcting competitive harm for the good of the market; in contrast to criminal enforcement or tort law, assigning responsibility for its origins is secondary, and tied chiefly to being able to direct a remedial order

[28] *Competition Act* at s. 13.
[29] *Weber v. Ontario Hydro*, 1995 CanLII 108 (SCC), [1995] 2 SCR 929 at paras 14-15; See also Windsor Law, "CanLII Primer - "Legal Research Principles and CanLII Navigation for Self-Represented Litigants: The National Self-Represented Litigants Project", at 11 and 12.
[30] R. v Brown, 2014 BCPC 113 at para 12; Government of Canada, "The Judicial Structure: How the Courts are Organized", (September 1, 2021).
[31] As section 45 prescribes a criminal penalty, courts applying section 45 must determine guilt beyond a reasonable doubt. Contrarily as section 36 prescribes a civil law cause of action, courts hearing a case pursuant to section 36 must determinate liability based on a balance of probabilities. *See Sun-Rype Products Ltd. v. Archer Daniels Midland Company*, 2013 SCC 58, [2013] 3 SCR 545 at para 115. *Infineon Technologies AG v. Option consommateurs*, 2013 SCC 59, [2013] 3 SCR 600, 68, 89, 145.
[32] Discussion Paper at Section VIII.1.

appropriately."[33] The civil enforcement scheme of the *Competition Act* already has specific remedies, each of which is focused on reversing the situations that led to competitive harm. In contrast, damages litigation is inherently more expensive and punitive, and is less concerned with fixing conduct going forward compared with assigning blame for historical conduct. Firms who pursue damage claims are motivated not so much by whether the conduct is actually blameworthy but whether the litigation risk may compel a defendant to pay compensation in order to secure a release. Indeed, it is telling that none of the many class actions brought under Section 36(1) of the *Competition Act* based on an alleged violation of the criminal conspiracy provision (Section 45) has reached a trial decision on the merits. Most cases settle without any advancement of the substantive law. One can expect damages actions for abuse to have a similar outcome, with a real prospect of firms resiling from aggressive but proper competition for fear of the costs and risks of intractable private damages litigation.

E. The *Competition Act* Should Continue to Apply only Between Competitors

The Government of Canada proposes to make certain collaborations civilly reviewable even if they are not made between direct competitors. This proposal is concerning to IMC, as it inadvertently prohibits market behaviour that is not anti-competitive and is otherwise beneficial to Canadians.

Certain agreements between producers and down-stream suppliers benefit and may even be essential to consumers. A clear example in the pharmaceutical context is patient support programs. A patient support program is established by pharmaceutical manufacturers for patients who have been prescribed complex medical therapies.[34] To address these barriers, a patient support program will partner pharmaceutical manufacturers with a variety of different healthcare partners, including doctors and insurers, to ensure that patients are able to access their prescribed treatment. Until such time as our healthcare system is able to address these barriers to access, patient support programs continue to perform a vital role in addressing gaps in our healthcare systems. Without these programs, many Canadians will effectively be left without adequate medical care.

IMC understands that the types of agreements between producers and downstream suppliers that underpin patient support programs are not reviewable under the *Competition Act*. However, we are concerned that, by making agreements between non-competitors subject to civil review, such programs could needlessly be subject to scrutiny and discourage companies from entering into these essential arrangements. For example, patient support programs may include agreements between health teams and a pharmaceutical provider to ensure that healthcare professionals are properly trained in the administration of these therapies. They also ensure that these trained healthcare professionals are available to the patients who need them. Preventing

[33] Discussion Paper at Section V.1(a).
[34] **Attachment 6**, IMC, "Patient Support Programs and Medical Practice Activities", (2016).

healthcare professionals and pharmaceutical suppliers from entering into these types of agreements will only result in a disincentive for companies to continue to invest in essential patient support programs.

Finally, in the case that an agreement between non-competitors provides a particular supplier with market power, then any anti-competitive action taken by that supplier with the effect of harming competitors would already be covered by section 79 of the *Competition Act.* Therefore, IMC questions whether and in what circumstances the actions that the Government of Canada intends to catch under these proposed amendments would not already be adequately covered by the *Competition Act*.

F. Section 79(5) should be amended to better respect Intellectual Property Rights

Section 79(5) of the *Competition Act* creates an exception for abuse of dominance applications in respect of the exercise of intellectual property rights:

- **Exception**

  (5) For the purpose of this section, an act engaged in pursuant only to the exercise of any right or enjoyment of any interest derived under the *Copyright Act*, *Industrial Design Act*, *Integrated Circuit Topography Act*, *Patent Act*, *Trademarks Act* or any other Act of Parliament pertaining to intellectual or industrial property is not an anti-competitive act.

There is an inherent tension between the operation of intellectual property legislation and the definition of "anticompetitive act" under Section 78(1). Intellectual property rights include the right to exclude others, including competitors and potential competitors, from using the subject matter of the right. In so doing, intellectual property protects and rewards investments in research and development and fosters innovation. By contrast, Section 78(1) defines an anticompetitive act to include an act intended to have an exclusionary negative effect on a competitor or an adverse effect on competition.

While Section 79(5) was introduced to protect intellectual property interests in face of this tension, the scope of protection has been significantly read down in the jurisprudence. In the leading case of *Toronto Real Estate Board* decision,[35] the Federal Court of Appeal wrote the following with respect to the interpretation of Section 79(5):

> [176] In light of the determination that the VOW Policy was anti-competitive, subsection 79(5) of the *Competition Act* precludes reliance on copyright as a defence to an anti-competitive act.
>
> …
>
> [179] Subsection 79(5) seeks to protect the rights granted by Parliament to patent and copyright holders and, at the same time, ensure that the monopoly and exclusivity

[35] *Toronto Real Estate Board v. Canada (Commissioner of Competition)*, 2017 FCA 236

> rights created are not exercised in an anti-competitive manner. The language of subsection 79(5) is unequivocal. It does not state, as is contended, that any assertion of an intellectual property right shields what would otherwise be an anti-competitive act.
>
> [180] Parliament clearly signaled, through the use of the word "only", to insulate intellectual property rights from allegations of anti-competitive conduct in circumstances where the right granted by Parliament, in this case, copyright, is the sole purpose of exercise or use. Put otherwise, anti-competitive behaviour cannot shelter behind a claim of copyright unless the use or protection of the copyright is the sole justification for the practice.

With respect, the reasoning of the Court of Appeal is circular. Although the plain words of Section 79(5) provide an exception to conduct that otherwise would be an anticompetitive act, the Court holds that the exception cannot apply precisely because the conduct is anticompetitive. The Court goes on to suggest that Section 79(5) only operates where the intellectual property is the sole purpose or sole justification of the exercise or use. It is unclear what this means. Firms exercise the rights conferred by intellectual property to advance their commercial interests for any number of reasons. As written, Section 79(5) does not refer to the purpose or intention, but to objective conduct- the exercise of the right. That could include excluding others from using the rights, even if the motivation is to avoid competition that might ensue from such use.

However, in view of the jurisprudence, it is necessary to amend and expand Section 79(5) to reformulate what is deemed not to be an anticompetitive act, including by removal of the word "only".

G. Conclusion

In its discussion paper, the Government of Canada states that it "aims to ensure that the [competition] regime remains fit for purpose, able to stand up to the new challenges brought about by a changing and more digital economy." This aim is laudable and important, if not essential, to the future of Canada's economy. However, by amending the *Competition Act* to drastically widen the scope of behaviour that may be caught under its civil provisions and by proposing sector-specific competition rules, the Government of Canada introduces substantial risk that these provisions will prevent or discourage behaviour that is beneficial for the Canadian economy. IMC sincerely hopes that the Government of Canada will closely examine and strictly define the scope of behaviour that these proposed amendments to the *Competition Act* will capture to ensure that the *Competition Act* remains a law of general application that encourages rather than stifles competition and innovation in the Canadian market.

ATTACHMENT 1

FTC, “Pharmaceutical Agreement Filings”

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

Pharmaceutical Agreement Filings

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires that brand-name drug manufacturers and generic drug applicants file certain agreements with the FTC and the Department of Justice. This page presents information related to the filing process, as well as, fiscal year reports summarizing the number and types of agreements filed.

- Pharmaceutical Agreement Filings – Overview
- Frequently Asked Questions
- MMA Pharmaceutical Agreement Filing Cover Sheet (NDAs & ANDAs)
- MMA Pharmaceutical Agreement Filing Cover Sheet (BLAs)

Advisory Opinions and Guidance

MMA Guidance

For Release: May 10, 2011: FTC Staff Finds Sanofi-Aventis, Watson Pharmaceuticals, and Synthon Holding B.V. Failed to Report Drug Patent Agreements as Required by Law: The FTC Does Not Take Enforcement Action, but Urges Industry to Closely Consider Advisory

- Letter to Helene D. Jaffe, Counsel for Sanofi-Aventis
- Letter to Joseph J. Simons and E. Anthony Figg, Counsel for Synthon Holding B.V.
- Letter to Steven C. Sunshine, Counsel for Watson Pharmaceuticals/Watson Laboratories

Annual Filings Reports

- 2017
- 2016
- 2015

- 2014
- 2013
- 2012
- 2011
- 2010
- 2009
- 2008
- 2007
- 2006
- 2005
- 2004

ATTACHMENT 2

FTC, “Overview of Agreements Filed in FY 2017: A Report by the Bureau of Competition”, (December 3, 2020)

Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Overview of Agreements Filed in FY 2016
A Report by the Bureau of Competition

During fiscal year 2016 (October 1, 2015 to September 30, 2016), pharmaceutical companies filed 232 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers, significantly more than any other year since enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[1]

Overview of FY 2016 Final Settlements—In FY 2016, the FTC received 232 final settlements relating to 103 distinct branded products. For 40 of those products, the FTC received its first final settlement covering that product in FY 2016; for the other 63 products, the FTC had received a final settlement relating to the product in one or more previous fiscal years.

- 30 final settlements contain both explicit compensation from a brand manufacturer to a generic manufacturer and a restriction on the generic manufacturer's ability to market its product in competition with the branded product.
    - 29 of these 30 agreements contain payment in the form of litigation fees, with the brand manufacturer's payment to the generic manufacturer ranging from $250,000 to $7 million.
        - The average payment is $2.85 million, with 27 of the 29 agreements containing payments less than $7 million.
        - Three of these 29 agreements also involve a form of possible compensation (discussed below).
    - The single remaining final agreement involves compensation in the form of a brand manufacturer's promise not to market an authorized generic in competition with the generic manufacturer's product for some period of time.
- 14 additional final settlements are categorized as containing one or more forms of "possible compensation" because it is not clear from the face of each agreement whether certain provisions act as compensation to the generic patent challenger. Analysis of whether there is compensation requires inquiry into specific marketplace circumstances, which lies beyond the scope of this summary report. Each of these settlements also contains a restriction on generic entry.

[1] This report summarizes the types of final settlements filed in FY 2016. A table summarizing certain key figures regarding settlements filed since 2004 is attached as Exhibit 1.

- The most common form of possible compensation—appearing in 9 final settlements—is a commitment from the brand manufacturer not to use a third party to distribute an authorized generic for a period of time, such as during first-filer exclusivity. This type of commitment could have the same effect as an explicit no-AG commitment, for example, if the brand company does not market generics in the United States.

- Another common form of possible compensation is an agreement containing a declining royalty structure, in which the generic's obligation to pay royalties is reduced or eliminated if a brand launches an authorized generic product. This type of provision may achieve the same effect as an explicit no-AG commitment, and appear in 3 agreements in FY 2016.

- 151 of the 232 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

- 37 final settlements contain no restrictions on generic entry. None of these involve explicit or possible compensation to the generic manufacturer.

Final Settlements Involving First Filers

- Of the 232 final settlements filed under the MMA in FY 2016, 76 involve "first-filer" generics—*i.e.*, those generic manufacturers who were the first to file abbreviated new drug applications on the litigated product and, at the time of settlement, were potentially eligible for 180 days of generic exclusivity under the Hatch-Waxman Act. Of these 76 first-filer settlements:

    - 16 contain explicit compensation to the generic—all in the form of payment for litigation costs—and a restriction on generic sales;[2]

    - 9 contain possible compensation to the generic and a restriction on generic sales, but no explicit compensation;

    - 48 restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation; and

    - 3 do not restrict the generic manufacturer's ability to market its product.

Features of Final Settlements

- *Scope of Patent License*—215 of the 232 final settlements involve the generic manufacturer receiving rights to patents that were not the subject of any litigation between the brand manufacturer and that generic manufacturer.

    - In 191 of these final settlements, the generic manufacturer receives licenses or covenants not to sue covering all patents that the brand

[2] Two of these 16 agreements also include possible compensation.

manufacturer owns at settlement or at any time in the future that could be alleged to cover the generic product.

- In 24 other final settlements, the generic manufacturer receives licenses or covenants not to sue covering some, but not all, such additional patents.

- *Acceleration Clauses*—187 final settlements contain a restriction on the generic manufacturer selling its product for some period of time, but also provide the generic manufacturer a license or covenant not to sue to begin selling the generic product prior to the expiration of the relevant patent(s).

    - 177 of these 187 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events.

    - Some of the most common events that accelerate a licensed entry date are: (i) another company selling a generic version of the branded product, (ii) another company obtaining a final court decision of patent invalidity or unenforceability or of non-infringement, (iii) the brand manufacturer licensing a third party with an earlier entry date, (iv) sales of the branded product falling below specified thresholds, or (v) the brand manufacturer obtaining FDA approval for another product with the same active ingredient.

- *At-Risk Launch*—13 of the final settlements occurred after the generic company had launched its product at risk. Each of these settlements permitted the generic manufacturer to continue selling the generic product and required the generic company to pay the brand manufacturer damages for the at-risk sales, with approximately $12.5 million as the average amount of damages.[3]

- *PTAB Settlements*—At least two final settlements involve simultaneous resolution of federal court litigation and an *inter partes* review or a post-grant review initiated by the generic manufacturer. One of those settlements involves compensation to the generic manufacturer.

[3] This calculation likely overstates the amount of damages, because in most cases the dollar totals reflected damages for past at-risk sales and a lump-sum royalty for future sales of the generic product. Because the amount for future sales is not apportioned separately, the whole amount is included as damages for at-risk sales for purposes of this calculation.

EXHIBIT 1

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232
w/ Restriction on Generic Entry and Compensation	0	3	14	14	16	19	31	28	40	29	21	14	30
w/ Restriction on Generic Entry and Compensation (excluding Solely Litigation Fees $\leq$ $7 million)	0	3	13	14	15	11	17	25	33	15	11	5	1
w/ Restriction on Generic Entry and Compensation Involving First Filers	0	2	9	11	13	15	26	18	23	13	11	7	16

ATTACHMENT 3

FTC, "Overview of Agreements Filed in FY 2016: A Report by the Bureau of Competition" (May 24, 2019)

Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Overview of Agreements Filed in FY 2016
A Report by the Bureau of Competition

During fiscal year 2016 (October 1, 2015 to September 30, 2016), pharmaceutical companies filed 232 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers, significantly more than any other year since enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[1]

Overview of FY 2016 Final Settlements—In FY 2016, the FTC received 232 final settlements relating to 103 distinct branded products. For 40 of those products, the FTC received its first final settlement covering that product in FY 2016; for the other 63 products, the FTC had received a final settlement relating to the product in one or more previous fiscal years.

- 30 final settlements contain both explicit compensation from a brand manufacturer to a generic manufacturer and a restriction on the generic manufacturer's ability to market its product in competition with the branded product.
    - 29 of these 30 agreements contain payment in the form of litigation fees, with the brand manufacturer's payment to the generic manufacturer ranging from $250,000 to $7 million.
        - The average payment is $2.85 million, with 27 of the 29 agreements containing payments less than $7 million.
        - Three of these 29 agreements also involve a form of possible compensation (discussed below).
    - The single remaining final agreement involves compensation in the form of a brand manufacturer's promise not to market an authorized generic in competition with the generic manufacturer's product for some period of time.
- 14 additional final settlements are categorized as containing one or more forms of "possible compensation" because it is not clear from the face of each agreement whether certain provisions act as compensation to the generic patent challenger. Analysis of whether there is compensation requires inquiry into specific marketplace circumstances, which lies beyond the scope of this summary report. Each of these settlements also contains a restriction on generic entry.

[1] This report summarizes the types of final settlements filed in FY 2016. A table summarizing certain key figures regarding settlements filed since 2004 is attached as Exhibit 1.

- The most common form of possible compensation—appearing in 9 final settlements—is a commitment from the brand manufacturer not to use a third party to distribute an authorized generic for a period of time, such as during first-filer exclusivity. This type of commitment could have the same effect as an explicit no-AG commitment, for example, if the brand company does not market generics in the United States.

- Another common form of possible compensation is an agreement containing a declining royalty structure, in which the generic's obligation to pay royalties is reduced or eliminated if a brand launches an authorized generic product. This type of provision may achieve the same effect as an explicit no-AG commitment, and appear in 3 agreements in FY 2016.

- 151 of the 232 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

- 37 final settlements contain no restrictions on generic entry. None of these involve explicit or possible compensation to the generic manufacturer.

Final Settlements Involving First Filers

- Of the 232 final settlements filed under the MMA in FY 2016, 76 involve "first-filer" generics—*i.e.*, those generic manufacturers who were the first to file abbreviated new drug applications on the litigated product and, at the time of settlement, were potentially eligible for 180 days of generic exclusivity under the Hatch-Waxman Act. Of these 76 first-filer settlements:

    - 16 contain explicit compensation to the generic—all in the form of payment for litigation costs—and a restriction on generic sales;[2]

    - 9 contain possible compensation to the generic and a restriction on generic sales, but no explicit compensation;

    - 48 restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation; and

    - 3 do not restrict the generic manufacturer's ability to market its product.

Features of Final Settlements

- *Scope of Patent License*—215 of the 232 final settlements involve the generic manufacturer receiving rights to patents that were not the subject of any litigation between the brand manufacturer and that generic manufacturer.

    - In 191 of these final settlements, the generic manufacturer receives licenses or covenants not to sue covering all patents that the brand

[2] Two of these 16 agreements also include possible compensation.

manufacturer owns at settlement or at any time in the future that could be alleged to cover the generic product.

- In 24 other final settlements, the generic manufacturer receives licenses or covenants not to sue covering some, but not all, such additional patents.

- *Acceleration Clauses*—187 final settlements contain a restriction on the generic manufacturer selling its product for some period of time, but also provide the generic manufacturer a license or covenant not to sue to begin selling the generic product prior to the expiration of the relevant patent(s).

    - 177 of these 187 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events.

    - Some of the most common events that accelerate a licensed entry date are: (i) another company selling a generic version of the branded product, (ii) another company obtaining a final court decision of patent invalidity or unenforceability or of non-infringement, (iii) the brand manufacturer licensing a third party with an earlier entry date, (iv) sales of the branded product falling below specified thresholds, or (v) the brand manufacturer obtaining FDA approval for another product with the same active ingredient.

- *At-Risk Launch*—13 of the final settlements occurred after the generic company had launched its product at risk. Each of these settlements permitted the generic manufacturer to continue selling the generic product and required the generic company to pay the brand manufacturer damages for the at-risk sales, with approximately $12.5 million as the average amount of damages.[3]

- *PTAB Settlements*—At least two final settlements involve simultaneous resolution of federal court litigation and an *inter partes* review or a post-grant review initiated by the generic manufacturer. One of those settlements involves compensation to the generic manufacturer.

[3] This calculation likely overstates the amount of damages, because in most cases the dollar totals reflected damages for past at-risk sales and a lump-sum royalty for future sales of the generic product. Because the amount for future sales is not apportioned separately, the whole amount is included as damages for at-risk sales for purposes of this calculation.

EXHIBIT 1

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232
w/ Restriction on Generic Entry and Compensation	0	3	14	14	16	19	31	28	40	29	21	14	30
w/ Restriction on Generic Entry and Compensation (excluding Solely Litigation Fees $\leq$ $7 million)	0	3	13	14	15	11	17	25	33	15	11	5	1
w/ Restriction on Generic Entry and Compensation Involving First Filers	0	2	9	11	13	15	26	18	23	13	11	7	16

Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Overview of Agreements Filed in FY 2017
A Report by the Bureau of Competition

During fiscal year 2017 (October 1, 2016 to September 30, 2017), pharmaceutical companies filed 226 agreements constituting final resolution of patent disputes between brand and generic pharmaceutical manufacturers. This figure represents a slight decline from the 232 in FY 2016, which remains the most final settlements in any year since enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[1]

Overview of FY 2017 Final Settlements—In FY 2017, the FTC received 226 final settlements relating to 114 distinct branded products. For 46 of those products, the FTC received its first final settlement covering that product in FY 2017; for the other 68 products, the FTC had received a final settlement relating to the product in one or more previous fiscal years.

- 20 final settlements contain both explicit compensation from a brand manufacturer to a generic manufacturer and a restriction on the generic manufacturer's ability to market its product in competition with the branded product.
    - 17 of these 20 agreements include explicit compensation solely in the form of litigation fees.
        - The brand manufacturer's payment to the generic manufacturer ranges from $500,000 to $6.5 million. The average payment is $2.78 million.
        - 2 of these 17 agreements also involve a form of possible compensation (discussed below).
    - 3 of these 20 agreements include explicit compensation beyond solely litigation fees.
        - One involves a side deal in which the brand manufacturer assigned the generic manufacturer five patents unrelated to the litigated product at no cost.
        - One involves a side deal in which the generic sold intellectual property related to the litigated product to the brand manufacturer. This settlement also includes litigation fees and a form of possible compensation (discussed below).

[1] This report summarizes the types of final settlements filed in FY 2017. A table summarizing certain key figures regarding settlements filed since 2004 is attached as Exhibit 1.

- One involves the brand manufacturer acquiring the generic manufacturer's potentially competing 505(b)(2)[2] product that was the subject of the patent litigation.

- 8 final settlements (in addition to the 3 settlements referenced above that also contain explicit compensation, totaling 11 final settlements) are categorized as containing one or more forms of "possible compensation" because it is not clear from the face of each agreement whether certain provisions act as compensation to the generic patent challenger. Analysis of whether there is compensation requires inquiry into specific marketplace circumstances, which lies beyond the scope of this summary report. Each of these settlements also contains a restriction on generic entry. Common forms of possible compensation include:

    - A commitment from the brand manufacturer not to use a third party to distribute an authorized generic for a period of time, such as during first-filer exclusivity. This type of commitment could have the same effect as an explicit no-AG commitment, for example, if the brand company does not market generics in the United States; this provision appears in 5 agreements in FY 2017.

    - A declining royalty structure, in which the generic's obligation to pay royalties is reduced or eliminated if a brand launches an authorized generic product. This type of provision may achieve the same effect as an explicit no-AG commitment and appears in 4 agreements in FY 2017.

    - An agreement that provides AG supply to a non-first-filer ANDA holder during the first-filer's exclusivity period, thereby permitting the non-first-filer ANDA holder to sell an authorized generic during the exclusivity period. While such an arrangement may have competitive benefits under certain circumstances, the ability to earn profits during the 180-day period when the ANDA holder would not otherwise be approved to sell could also induce the ANDA holder to abandon patent litigation that might result in earlier generic entry. This type of provision appears in 4 agreements in FY 2017.

- 169 of the 226 final settlements restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

- 29 final settlements contain no restrictions on generic entry.

    - 2 of these agreements involve explicit compensation to the generic manufacturer.

[2] The 505(b)(2) NDA pathway is a streamlined drug approval process that allows applicants to rely on existing literature or clinical data. It can be used to seek approval of a brand product and may also be used to seek approval of a generic product in situations where the ANDA pathway is not appropriate. *See* 21 U.S.C. § 355(b)(2).

        - One provides compensation in the form of litigation fees.

        - One provides compensation in the form of a supply deal for a dosage strength of the litigated product that was not covered by the generic manufacturer's ANDA.

Final Settlements Involving First Filers

- Of the 226 final settlements filed in FY 2017, 72 involve "first-filer" generics—*i.e.*, generic manufacturers that were the first to file abbreviated new drug applications on the litigated product and, at the time of settlement, were potentially eligible for 180 days of generic exclusivity under the Hatch-Waxman Act. Of these 72 first-filer settlements:

    - 6 contain explicit compensation to the generic and a restriction on generic sales. All 6 of these agreements include compensation in the form of litigation fees.

        - 1 of these 6 agreements also includes explicit compensation in the form of a side deal in which the generic sold intellectual property related to the litigated product to the brand manufacturer and a form of possible compensation.

        - 2 of these 6 agreements (in addition to the agreement referenced in the bullet above, totaling 3 agreements) also include a form of possible compensation.

    - 5 contain possible compensation to the generic and a restriction on generic sales, but no explicit compensation.

    - 55 restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.

    - 6 do not restrict the generic manufacturer's ability to market its product.

        - 1 of these 6 agreements provides compensation in the form of litigation fees.

Features of Final Settlements

- *Scope of Patent License*—205 of the 226 final settlements involve the generic manufacturer receiving rights to patents that were not the subject of any litigation between the brand manufacturer and that generic manufacturer. None of the 226 final settlements involved a generic company receiving an exclusive license to any patent.

    - In 177 of these final settlements, the generic manufacturer receives licenses or covenants not to sue covering <u>all</u> patents that the brand

manufacturer owns at settlement or at any time in the future that could be alleged to cover the generic product.

- In 28 other final settlements, the generic manufacturer receives licenses or covenants not to sue covering some, but not all, such additional patents.
- In 10 final settlements the generic manufacturer only received a license to the litigated patents.
- In the remaining 11 final settlements, the generic manufacturer did not receive the right to any patents, including the litigated patents, because the agreements involved the withdrawal of the ANDA or a dismissal in which the generic did not obtain the right to enter until the patent expired.

- *Acceleration Clauses*—192 final settlements contain a restriction on the generic manufacturer selling its product for some period of time, but also provide the generic manufacturer a license or covenant not to sue that would allow the generic manufacturer to begin selling the generic product prior to the expiration of the relevant patent(s).
  - 181 of these 192 agreements contain provisions that accelerate the effective date of the licenses or covenants not to sue based on other events.
  - Some of the most common events that accelerate a licensed entry date are: (i) another company selling a generic version of the branded product, (ii) another company obtaining a final court decision of patent invalidity or unenforceability or of non-infringement, (iii) the brand manufacturer licensing a third party with an earlier entry date, (iv) sales of the branded product falling below specified thresholds, or (v) the brand manufacturer obtaining FDA approval for another product with the same active ingredient.
- *At-Risk Launch*—3 of the final settlements occurred after the generic company had launched its product at risk. Each of these settlements permitted the generic manufacturer to continue selling the generic product and require the generic company to pay the brand manufacturer damages up to $250,000 for the at-risk sales.
- *PTAB Settlements*—11 of the final settlements involve the resolution of an *inter partes* review or a post-grant review initiated by the generic manufacturer.
  - 5 of these final settlements involve simultaneous resolution of federal court litigation and an *inter partes* review or a post-grant review initiated by the generic manufacturer.
    - 2 of these settlements involve explicit compensation to the generic manufacturer in the form of litigation fees.

- 6 of these final settlements involve resolution of an *inter partes* review initiated by the generic manufacturer prior to its ANDA being filed, avoiding federal litigation entirely.
    - 4 of these 6 settlements involve explicit compensation to the generic manufacturer in the form of litigation fees.
    - 1 involves explicit compensation in the form of a side deal in which the brand manufacturer assigned the generic manufacturer five patents unrelated to the litigated product at no cost.

EXHIBIT 1

	FY2004	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	FY2012	FY2013	FY2014	FY2015	FY2016	FY2017
Final Settlements	14	11	28	33	66	68	113	156	140	145	160	170	232	226
w/ Restriction on Generic Entry and Compensation	0	3	14	14	16	19	31	28	40	29	21	14	30	20
w/ Restriction on Generic Entry and Compensation (excluding Solely Litigation Fees $\leq$ $7 million)	0	3	13	14	15	11	17	25	33	15	11	5	1	3
w/ Restriction on Generic Entry and Compensation Involving First Filers	0	2	9	11	13	15	26	18	23	13	11	7	16	6

ATTACHMENT 4

FTC, “Cases Tagged with pay for delay”

FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

Cases Tagged with pay for delay

- Impax Laboratories, Inc., In the Matter of (April 13, 2021)
- Endo Pharmaceuticals Inc./Amneal Pharmaceuticals, Inc. (January 25, 2021)
- Allergan, Watson and Endo (February 27, 2019)
- Cephalon, Inc. (February 20, 2019)

ATTACHMENT 5

Government of Canada, “Guidance Documents – Applications and submissions – Drug products”, (February 27, 2023)

Guidance Documents – Applications and submissions – Drug products

For industry information about COVID-19, visit our COVID-19 Drugs and vaccines section.

Guidance documents have been prepared to assist in the interpretation of policies and governing statutes and regulations. They are intended to assist in preparing drug submissions when seeking an approval to sell a pharmaceutical drug product in Canada.

A B C D E F G H I L M N O P Q

R S T U V

A

- Acetaminophen Labelling Standard

- Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs
- Adverse Reactions:
  - Reporting Adverse Reactions to Human Cells, Tissues and Organs
  - Mandatory reporting of serious adverse drug reactions and medical device incidents by hospitals
- Antiseptic Drugs for Human-Use
- Asthma: Data Requirements for Safety and Effectiveness of Subsequent Entry Inhaled Corticosteroid Products Used for the Treatment of Asthma

B

- Bioavailability and Bioequivalence
  - Comparative Pharmacokinetic Studies for Orally Inhaled Products: Guidance Document
  - Conduct and Analysis of Comparative Bioavailability Studies
  - Comparative Bioavailability Standards: Formulations use for System Effects
  - Data Requirements for Safety and Effectiveness of Subsequent Market Entry Steroid Nasal Products for Use in the Treatment of Allergic Rhinitis
  - Preparation of Comparative Bioavailability Information for Drug Submissions in the CTD Format (draft)
  - ICH M9: Guideline on Biopharmaceutics Classification System-based Biowaivers
  - ICH M9: Q&A on Biopharmaceutics Classification System-based Biowaivers

C

- Canadian Reference Product - Use of a Foreign-sourced Reference Product as a Canadian Reference Product
- Cannabis - Health products containing cannabis or for use with cannabis
- Certificate of Supplementary Protection Regulations (CSP)
- Chemical Entity Products/Quality
- Clinical Trials
    - Guidance on applications for COVID-19 drug clinical trials under the Regulations
    - Notice to Stakeholders - Clarification of Requirements under the Food and Drug Regulations when Conducting Clinical Research with Cannabis
    - Applications for drug clinical trials under the Interim Order: Guidance document
    - Clinical Trial Applications
    - Clinical Trials Manual
    - Clinical Trial Applications
    - Preparation of Clinical Trial Applications for use of Cell Therapy Products in Humans
    - Quality (Chemistry and Manufacturing) Guidance: Clinical Trial Applications for Pharmaceuticals
        - Template: Quality Overall Summary - Chemical Entities Clinical Trial Application - Phase I (QOS-CE (CTA - Phase I))
        - Template: Quality Overall Summary - Chemical Entities Clinical Trial Application - Phase II (QOS-CE (CTA - Phase II)) Template: Quality Overall Summary - Chemical Entities Clinical Trial Application - Phase II (QOS-CE (CTA - Phase II))

        - Template: Quality Overall Summary - Chemical Entities Clinical Trial Application - Phase III (QOS-CE (CTA - Phase III))
    - Update for Clinical Trial Sponsors: Requirements for Tuberculosis Screening of Healthy Volunteers in Phase I Clinical Trials involving Immunosuppressant Drugs or Drugs with Immunosuppressant Properties - Notice
    - Notice: Update to Clinical Trial Site Information Form
    - Standards for Clinical Trials in Type 2 Diabetes in Canada
    - Inclusion of Women in Clinical Trials
    - ICH M4: Common Technical Document
- Common Electronic Submissions Gateway (CESG)
- Confidential Business Information - Disclosure under Paragraph 21.1(3)(c) of the Food and Drugs Act
- Cost Recovery guidance documents for drug products and applications and submissions
- Notice: Guidance Document Updates to Reflect New Fees and Policies for April 1, 2020

D

- Data Protection under C.08.004.1 of the Food and Drug Regulations
- Databases - Drug and Medical Devices
- Diabetes: interim approach for evaluating cardiovascular risk for new antidiabetic therapies to treat Type 2 diabetes mellitus - Notice
- Disinfectants
    - Disinfectant Drugs
    - Management of Disinfectant Drug Applications **[in effect until March 31, 2020]**

    - Management of Disinfectant Drug Applications **[in effect April 1, 2020]**
    - Safety and Efficacy Requirements for Contact Lens Disinfectants
    - Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs
    - Safety and Efficacy Requirements for High-level Disinfectants and Sterilants for Use on Reusable Semi-critical and Critical Medical Devices
- Drug Facts Table for Non-prescription Drugs
- Drug Identification Number (DIN)
    - Preparation of DIN Submissions
    - Drug Identification Numbers for Schedule C Drugs (Radiopharmaceuticals and Kits) **[in effect until March 31, 2020]**
    - Drug Identification Numbers for Schedule C Drugs (Radiopharmaceuticals and Kits) **[in effect April 1, 2020]**
    - Regulatory Requirements for DINs
- Drug Submission Status Requests
- Drugs Currently Regulated as New Drugs

F

- Filing Submissions Electronically
- Food and Drugs Act
    - Amendments to the Food and Drugs Act Guide to New Authorities
    - Consultation on the Amendments to the Food and Drugs Act: Guide to New Authorities - What We Heard
- Notifying Health Canada of Foreign Actions
- Foreign Reviews

G

- Guidance Document on the Distribution of Drugs as Samples [2020-04-29]
- Good Guidance Practices
- Good Manufacturing Practices
    - Good manufacturing practices guide for drug products (GUI-0001) effective on 2018-10-01
    - Submission filing requirements - GMP/DEL

H

- Human-Use Antiseptic Drugs
- Haemodialysis Solutions
- Helicobacter pylori
- Hepatotoxicity - Pre-market Evaluation of Hepatotoxicity in Health Products
- Hormone Replacement Therapy
    - Product Monographs of Non-Contraceptive Estrogen/Progestin-Containing Products
    - Guidelines for Preparation of a New Drug Submission for Products Used for Estrogen-Progestin Replacement Therapy in Menopause (HRT)

I

- Inhalers
    - Guidance to Establish Equivalent or Relative Potency of Safety and Efficacy of a Second Entry Short-Acting Beta2-Agonist Metered Dose Inhaler

    - Guidance Document - Data Requirements for Safety and Effectiveness of Subsequent Market Entry Steroid Nasal Products for Use in the Treatment of Allergic Rhinitis
- International Council for Harmonisation (ICH)

L

- Labelling
    - Drug Facts Table for Non-prescription Drugs
    - Labelling of Pharmaceutical Drugs for Human Use
    - Labelling Requirements for Non-prescription Drugs
    - Non-prescription Drugs: Labelling Standards - Drug Product
- Look-alike Sound-alike (LA/SA) Health Product Names: Marketed Health Product Name Assessment

M

- Master Files (MFs) - Procedures and Administrative Requirements
    - Notice: Update to the Guidance Document: Master Files (MFs) – Procedures and Administrative Requirements Effective January 1, 2022
- Management of Drug Submissions **[in effect until March 31, 2020]**
- Management of Drug Submissions and Applications (formerly Management of Drug Submissions) **[in effect April 1, 2020]**

N

- New Drugs
    - Listing of Drugs Currently Regulated as New Drugs (New Drugs List)

- Non-Clinical Laboratory Study Data Supporting Drug Product Applications and Submissions: Adherence to Good Laboratory Practice
  - Questions and Answers
- Non-prescription Drugs: Category IV Monographs
- Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)
- Notice of Compliance with Conditions

O

- Official Methods
  - Conjugated Estrogens
  - Determination of the Disintegration Time of Tablets
  - Determination of Flame Projection
  - Determination of Net Contents
  - Thyroid
- Opioids
  - Opioid Warning Sticker and Patient Information Handout, and Risk Management Plans
  - Tamper-resistance Formulations of Opioid Drug Products
- Oral Contraceptives

P

- Patented Medicines
- Submission of Pharmacogenomic Information
- Questions and Answers: Plain Language Labelling Regulations for Prescription Drugs **[in effect April 1, 2020]**
- Pharmacometrics - Use in drug submissions and clinical trial applications: Policy statement

- Plain Language Labelling Regulations for Non-prescription Drugs and Contact Lens Disinfectants - Questions and Answers **[in effect until March 31, 2020]**
- Plain Language Labelling Regulations for Non-prescription Drugs - Questions and Answers **[in effect April 1, 2020]**
- Post-Drug Identification Number (DIN) Changes
- Post-Notice of Compliance Changes
    - Consultation: Release of draft revised guidance documents on Post-Notice of Compliance (NOC) Changes - Quality, for stakeholder consultation
    - Notice: Release of draft revised guidance documents on Post-Notice of Compliance (NOC) Changes - Quality, for stakeholder consultation
    - Post-Notice of Compliance (NOC) Changes: Safety and Efficacy Document **[in effect April 1, 2020]**
    - Post-Notice of Compliance (NOC) Changes: Framework Document **[in effect April 1, 2020]**
    - Post-Notice of Compliance Changes: Quality Document
    - Updated - Notice regarding the Post-Notice of Compliance (NOC) Changes: Notices of Change: Level III Form
        - Post-Notice of Compliance (NOC) Changes: Notices of Change (Level III) Form **[in effect April 1, 2020]**
- Pre-market Evaluation of Hepatotoxicity in Health Products
- Prescription status - Determining Prescription Status for Human and Veterinary Drugs
- Priority Review
- Product Monograph
    - Notice - Product Monograph Implementation Plans

    - Updated: Notice - Notification of Safety Labelling Changes to the Product Monographs of Pharmaceutical Drug Products
    - Health Canada changes filing requirements for product monographs: Notice
- Product Vigilance

Q

- QT/QTc Interval Prolongation
- Quality

R

- Reconsideration of Decisions Issued for Human Drug and Natural Health Product Submissions
- Reconsideration of Final Decisions
- Regulatory Enrolment Process
- Regulatory Requirements for DINs
- Review of Drug Brand Names
    - Frequently Asked Questions

S

- Schedule A and Section 3 to the Food and Drugs Act
- Source Establishment - Reporting Adverse Reactions to Human Cells, Tissues and Organs
- Submission Filing Requirements - Good Manufacturing Practices (GMP)/Drug Establishment Licences (DEL)
- Switches

    - Notice - Release of the draft revised Guidance Document: Switching a medicinal ingredient from prescription to non-prescription status
    - Draft revised Guidance document: Switching a medicinal ingredient from prescription to non-prescription status

T

- Tablet Scoring of Subsequent-entry Pharmaceutical Products
- Drug Submissions Relying on Third-Party Data (Literature and Market Experience)

U

- Use of a Foreign-sourced Reference Product as a Canadian Reference Product

V

- Product Vigilance
- Veterinary Drugs Application and Submission Guidance Documents

Date modified:
2023-03-10

ATTACHMENT 6

IMC, “Patient Support Programs and Medical Practice Activities”

PATIENT SUPPORT PROGRAMS AND MEDICAL PRACTICE ACTIVITIES

14.1 Definitions

14.1.1 Patient Support Programs

Patient Support Programs are programs offered by Member companies for the benefit of patients. The programs aim at increasing or facilitating patient understanding of a disease and / or treatment, better patient outcomes as well as possibly improving patient adherence to treatment. Such programs may also serve to ensure or assist with access and/or reimbursement of a product. The programs must have a primary objective of bettering patient health outcomes. Any benefit experienced by the prescribing or dispensing Health Care Professional must be incidental to the primary objective. 1

14.1.2 Medical Practice Activities

Medical Practice Activities are programs / services offered by Members to contribute to the Medical Practice's ultimate goal of bettering patient health outcomes via a comprehensive/holistic approach to medicine. The objective of these activities may be related to patient management practices and clinical outcomes management practices but must not be solely intended to improve or manage day-to-day administrative or operational responsibilities. Any benefit experienced by the prescribing or dispensing Health Care Professional must be also be incidental to the primary objective. 2

14.2 General Principals

14.2.1 Intent

The Code recognizes that industry plays a vital role in supporting patients and medical practices for the purpose of enhanced patient outcomes and to benefit health care obtained by patients. However, these programs / services must not serve solely to cover day to day activities or resources considered part of the practice's operational expenses nor should they replace or compete with services or resources provided and funded by the existing healthcare system. Effort should be made for the healthcare system to absorb the cost of long term initiatives.

1 Patient Support Programs do not include Health Canada Special Access Programs or any other similar programs which are mandated by Health Canada (e.g. a program which is a condition of the notice of compliance (NOC)).

Examples of Patient Support Programs are diagnostic testing, education of patients on disease state, training by a Health Care Professional of patients on the use of a device or administration of a product, adherence programs and support provided to patients in the form of counselling by a non-prescribing Health Care Professional or a related health service provider.

Programs related to the access and/or reimbursement of a product can include, but are not limited to, financial co-pay programs, provision of product when formulary reimbursement is not available via bridging / payment assistance programs, provision of product via vouchers or via compassionate use programs, financial assistance based on the patient's inability to pay for a prescribed Member product or assistance with the reimbursement process associated to said product and the patient's insurance provider.

2 For example, activities or services offered by the Member related to how a group medical practice manages a certain patient type with a specific disease therefore allowing the practice to close patient care gaps would be considered Medical Practice Activities.

The provision of resources for the sole purpose of improving the practice's efficiencies and therefore resulting in greater billing opportunities, for example, would not be considered an appropriate Medical Practice Activity.

14.2.2 Ensure integrity of the industry

When providing Patient Support Programs or support for Medical Practice Activities, the overarching principle is that the activity, whether provided by the Member directly or through a third party acting on the Member's behalf, should not bring the industry into disrepute. Member company staff / third party vendors must have the requisite training and expertise so as to proceed in an ethical and professional manner. In addition, all elements of these programs / services should be appropriate, reasonable, and in accordance with treatment protocol / guidelines, clinical standards and relevant Code sections.

14.2.3 Conflict of Interest

These programs / services / activities should never be offered nor provided to Health Care Professionals, Medical Practices, patients, their agents or healthcare facilities:

- As an incentive to gain access to a medical practice or hospital formulary listing;
- As an obligation or undue inducement to prescribe particular Prescription Medicines;
- In exchange for recommending for use; or
- In a manner that could be construed as a gift.

Any payment made to a Health Care Professional must be for appropriate services as described in a written agreement. Such payments must not be intended to cover acts or tasks that are part of the Health Care Professional's standard of care or which are covered as part of the healthcare system's reimbursement process.

Under no circumstances can the Health Care Professional acting as intermediary between Member company and patient be paid solely for offering the Patient Support Program to their patients.

All clinical decisions, which may include the selection of appropriate Prescription Medicines or the development of management plans, are the responsibility of the relevant Health Care Professional. Product specific activities can be initiated only after the prescribing Health Care Professional has made the treatment decision and/or prescribed the product.

Such services / programs must never be sold, distributed or included on a claim for reimbursement or other submission for payment. [3]

14.2.4 Design and Oversight

These programs / services / activities must be designed and approved by the Canadian Member's head office so as to ensure proper design according to this and any other related section of this Code as well as the appropriate oversight. [4]

[3] For example, it would be inappropriate to have a set amount provided to the Health Care Professional on a per-patient-enrolled basis. Health Care Professionals are not to be remunerated for simply offering the patient the Member program.

If a Member provides a Patient Support Program to the Health Care Professional free of charge, the Health Care Professional must not subsequently sell it to patients.

[4] For example, a Patient Support Program or Medical Practice Activity designed and executed by a sales representative for his/her specific territory would not be an acceptable program or activity.

14.3 Standards

14.3.1 Objective, Timelines and Scope

Patient Support Programs or Medical Practice Activities must have clear objectives, timelines and scope:

- The objective should be to achieve better patient health outcomes and/or facilitate access to a Member product.
- The timelines should be predetermined and justified by the clinical purpose.
- Consideration must be given to the appropriate use of the prescribed product (should the program involve a specific product) and the scope of the availability of the programs / services / activities. Members are to design and offer programs/services to be intended for all eligible patients. If the program/services are to be limited in distribution, Members are to consider the criteria for eligibility to ensure a fair and appropriate dissemination.

14.3.2 Confidentiality, Transparency and Privacy

Members must be clear regarding information and communication with patients or medical practices whether it be done directly by the Member or through a third party acting on behalf of the Member:

- Patient confidentiality must be maintained at all times. In addition, proper privacy practices must be exercised in all such programs /services related to any potential data collected and the purpose of the collected data.
- Transparency regarding the Member Company or any third party acting on behalf of a Member is to be maintained in all programs / services / activities provided to patients or medical practices.
- In the case of the Patient Support Programs, the patient must subscribe or consent to a program and have the ability to opt out of the program at any given time and is to be provided clear instructions on how to do so.

Member companies should make all reasonable efforts to encourage the transparency by Health Care Professionals towards their patients regarding any financial or other material relationships with Members.

14.3.3 Data and Outcomes

Data collected, analysed, disseminated and/or published must be done according to current scientific standards and must be unbiased and accurate.

Key learnings or best practices collected from these programs / services can be used to illustrate the impact on health outcomes, in scientific exchanges and promotional activities. Such findings may also be the subject of reports or other communications provided that appropriate permissions and approvals are obtained. [5]

[5] Members must make a distinction between Section 14 and Section 18 of the Code. Programs / services described in Section 14 are not intended to demonstrate the clinical use of a Prescription Medicine.

14.4 Request for Support by Stakeholders

In some instances Members may be invited or solicited by Health Care Professionals or Medical Practices to contribute or participate in an initiative they are leading related to patient management or clinical outcomes management. In such cases, Members are to evaluate the appropriateness of the request and their ability to contribute, whether it be by means of a financial contribution (see Section 12) or by offering a Patient Support Program or Medical Practice Activity as described in this section. 6

6 It may not be appropriate for Members to collaborate with Health Care Professionals or Medical Practices on their efforts due to a potential conflict of interest or the perception of undue influence by the Member company. In such cases, Members may consider the provisions under Section 12 which allow Members to provide an arm's length type of funding instead.