December 21, 2018

Competition Promotion Branch
Competition Bureau
50 Victoria Street
Gatineau, Quebec
K1A 0C9
**Submitted via online feedback form*

Re: Competition Bureau of Canada Consultations on Proposed Revisions to the Intellectual Property Enforcement Guidelines (IPEGs)

Dear Sir or Madam:

On November 1, 2018, the Competition Bureau of Canada released draft revisions to the Intellectual Property Enforcement Guidelines and invited interested parties to submit their views on the revised guidelines. These are the views of the Canadian Generic Pharmaceutical Association (CGPA).

The CGPA is an industry association that represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry.[1]

Prescription drugs are the fastest rising component of health care spending in Canada. To help control these mounting costs, Canadian payors depend on a steady supply of safe, cost effective, generic medicines.

In 2017, generic prescription medicines were used to fill 70.6% of all prescriptions, yet they accounted for only 21.8% of dollar value of the total Canadian prescription drug market, which totalled about $27.5 billion. According to 2017 IMS Health data, the average cost of a brand-name prescription was $100.43, while the average cost of a generic prescription was $20.51.

The availability of generic drugs in Canada has a very significant effect on drug expenditures in Canada by public provincial drug plans, private drug insurance plans and the Canadian public not covered by either public or private drug plans. In 2017, the availability and use of generic prescription medicines saved Canada's health-care system nearly $22 billion; for every additional 1% increase in the use of generic medicine Canadians would save an additional $527 million per year.

[1] A current list of CGPA's members is available at http://canadiangenerics.ca/about-us/our-member-companies/

Given the central role of its member companies in the Canadian pharmaceutical sector, the CGPA maintains a keen interest in regulatory developments in the field and how those regulatory developments may intersect with dynamic market forces.

In March 2016, the Bureau substantially revised its IPEGs, following an in-depth two-year consultation process. A considerable number of revisions offered guidance on transactions in the pharmaceutical space particularly in connection with the *Patented Medicines (Notice of Compliance) Regulations* (PMNOC Regulations).

The currently proposed revisions to the IPEGs also affect the pharmaceutical space, particularly section 7.3. The CGPA offers the following comments and proposals.

1. Proposed Removal of the "Dual Litigation" Discriminator

Under section 7.3, at paragraph 160, the current IPEGs recognize that there are significant differences in the regulatory regimes governing pharmaceuticals in Canada relative to other jurisdictions. Three examples are particularized. The last of these is the "dual litigation" nature of proceedings under the PMNOC Regulations. In the most recent proposal for the IPEGs, it is being suggested that the "dual litigation" discriminator at paragraph 160 be removed.

Prior to regulatory changes which occurred in 2017, the PMNOC Regulations contemplated court proceedings that inquired into the validity and/or non-infringement of patents pursuant to section 6 of the regulations. However, the proceedings were not technically private law actions for the enforcement of patent rights under the Patent Act. Rather, they were styled as judicial review applications whose ultimate outcome, if allowed, was to prohibit the federal Minister of Health from issuing a marketing authorization (i.e. a notice of compliance or "NOC") to a drug manufacturer.

Because these proceedings were in the nature of public law, judicial review, early on in the jurisprudence under the PMNOC Regulations, the courts determined that the results of these proceedings were not finally dispositive of private law disputes concerning patents. As acknowledged in the current IPEGs:

> Even after having succeeded in defending a prohibition proceeding brought under the PMNOC proceeding [sic], a generic firm faces the possibility of an infringement action by the brand firm if the generic chooses to launch prior to patent expiry. Similarly, a branded firm whose prohibition application was successful still faces the possibility of proceedings for impeachment of its patent(s).

In 2017, the PMNOC Regulations were substantially amended. Included amongst the amendments were changes to sections 6 and 6.1 which now require proceedings under the PMNOC Regulations to proceed by way of an action for infringement (as opposed to an application for judicial review).

Subject to the comments below, to be sure, these amendments will, in the future, put an end to dual litigation as existed under the prior PMNOC Regulations. However, the CGPA submits that it is premature to remove the "dual-litigation" commentary in paragraph 160 of the IPEGs because such removal does not take into account the continued applicability of the pre-2017 PMNOC Regulations as well as other considerations.

In this regard, the enacting regulations which ushered in the current PMNOC Regulations provisions in 2017 (i.e. SOR/2017-166, s.9) state as follows:

> "**9(1)** *The Patented Medicines (Notice of Compliance) Regulations*, as they read immediately before the day on which these Regulations come into force, continue to apply in respect of any matter that relates to a notice of allegation served on a first person before that day."

In other words, the new, single-track litigation regime under the present PMNOC Regulations does not have retroactive effect.

There are many instances of section 6 judicial review applications that have been decided or that are still being litigated under the old regime as a result of notices of allegation that were served before September 21, 2017 (the date on which the new Regulations took effect). For any case that fits this criterion, whether presently decided or still to be decided, the underlying patent dispute between the brand name company and the generic company remains subject to a second round of litigation involving actions for infringement and/or invalidity. As such, dual litigation is still a feature of the Canadian regulatory regime and will continue to be so for the foreseeable future. Accordingly, the CGPA believes this contingency should remain accounted for in the IPEGs.

The CGPA proposes that the "dual litigation" consideration in paragraph 160 not be removed as proposed. Instead, the CGPA recommends that the current "dual litigation" be replaced with the following:

> *Dual Litigation:* Although amendments to the PMNOC Regulations were made effective on September 21, 2017 to introduce a single-track procedure for the determination of patent rights in connection patents and certificates of supplementary protection listed on the Patent Register, the new regulations only apply with respect to notices of allegation served after the new regulations came into effect. For cases involving notices of allegation served before that date, the old regime under the PMNOC Regulations still applies. This means that brand and generic firms in Canada must continue to cope with the system of legal double jeopardy created by the previous iteration of the PMNOC ~~r~~Regulations. Even after having succeeded in defending a prohibition proceeding brought under the PMNOC ~~proceedings~~ Regulations, a generic firm faces the possibility of an infringement action by the brand firm if the generic chooses to launch prior to patent expiry. Similarly, a brand firm whose prohibition application was successful still faces the possibility of proceedings for impeachment of its patent(s). The potential follow-on litigation is a relevant consideration when evaluating the magnitude of a brand firm's payment to the generic firm in a settlement agreement.

2. Proposed Additional Consideration Re: Generic At-Risk Launches

Closely associated with the uncertainties arising out dual-litigation under the PMNOC Regulations are the uncertainties associated with a generic company launching at risk in any event of the PMNOC Regulations litigation. This can manifest itself in a number of ways including the following:

- Under the prior iteration of section 6 of the PMNOC Regulations, it was possible that the court could dismiss a prohibition proceeding and the Minister could consequently issue a NOC to the generic sponsor. In such circumstances, jurisprudence had developed to the effect that any appeal by a brand name firm became moot. Because the current iteration of section 6 requires proceeding by trial, the possibility of mootness in these circumstances has been eliminated. However, this has not eliminated the risk faced by

generic in terms of launching at risk.

- A generic manufacturer who prevails at trial in a section 6 proceeding could receive its NOC from the Minister and come onto the market only to be enjoined and face monetary liability in the event that the Federal Court of Appeal reverses a decision of the Federal Court.

- The problem of generic at risk launch also remains in connection with cases to which the prior iteration of section 6 applies – because a successful generic manufacturer in a prohibition proceeding could receive its NOC only to be successfully sued for infringement in a subsequent action.

- The problem of generic at-risk launch also remains in connection with possibility that there may other patents that relate to the medicine that are not eligible for listing under the PMNOC Regulations. As such, once again, the generic manufacturer may succeed under section 6 of the PMNOC Regulations only to be sued for infringement in connection with another patent otherwise related to the same pharmaceutical product.

- Finally, the problem of generic at-risk launch also remains in connection with section 6.01 of the new PMNOC Regulations:

  > **6.01** No action, other than one brought under subsection 6(1), may be brought against the second person for infringement of a patent or a certificate of supplementary protection that is the subject of a notice of allegation served under paragraph 5(3)(a) in relation to the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) unless the first person or the owner of the patent did not, within the 45-day period referred to in subsection 6(1), have a reasonable basis for bringing an action under that subsection.

  This provision leaves open the possibility that: a generic manufacturer serves a notice of allegation; the originator does not commence a section 6 action within 45 days; as a result, the Minister subsequently issues a NOC to the generic manufacturer; and, once the generic comes to market, the originator brings an action for infringement on the patent(s) that were the subject of the notice of allegation, maintaining (for some reason) that it did not have a reasonable basis for bringing the action within the 45 day period.

The foregoing represents a major deficiency in the September 21, 2017 amendments to the PMNOC Regulations that the CGPA believes should be addressed by Innovation, Science and Economic Development at the earliest opportunity. That said, as the foregoing represents the reality of the present system the CGPA proposes that the following additional consideration be noted in the IPEGs until such time that regulatory amendments are adopted:

> 160A. The Bureau also recognizes that, even under the new, single-track litigation procedure under the PMNOC Regulations, significant risks remain for generic manufacturers entering the market, even after receiving notices of compliance consequent upon being successful under section 6 litigation. These risks involve the possibility of a section 6 determination being reversed on appeal, a section 6 determination being made under the previous regime of the PMNOC Regulations such that further infringement litigation is still possible, a proceeding being commenced and maintained pursuant to section 6.01 and/or there being other patents, not eligible for listing on the Patent Register, that a brand name company may assert against the generic company after market entry.

3. Proposed Additional Example to Discuss Address Access to CRPs

As the Bureau is aware, over the last five years, CGPA members have found it increasingly difficult to obtain quantities of brand-name (i.e. originator drug companies) Canadian reference products for the purpose of conducting bioequivalence studies that are necessary in order to permit generic drug companies to file comparative submissions seeking approval for lower-cost generic drugs.

Ensuring timely access to cost-saving generic drug competition is a priority for the Government of Canada and its partners in the pan-Canadian Pharmaceutical Alliance. Tactics to delay or block generic market entry by restricting access to CRPs are anti-competitive, not in the public interest and must be addressed.

Difficulty accessing CRPs can lead to corresponding delays in the regulatory approval process. Delayed access to more affordable medicines means higher costs for drug plans and higher co-payments for patients. Drug plans have to pay high costs for older drugs for longer than they should, meaning they can't reinvest those potential savings in important new therapies for patients and have more difficulty controlling expenditures. Delayed market entry also financially harms generic manufacturers, and unjustly enriches originator companies.

The CGPA asked the Commissioner of Competition to investigate these concerns under section 79 of the *Competition Act* on February 12, 2016, and the concerns were the subject of a formal inquiry by the Competition Bureau.

The relevant market and regulatory dynamic is aptly described as follows in a recent filing by the Bureau with the Federal Court of Canada[2]:

> 9. In order to market a generic equivalent to a branded pharmaceutical product in Canada ("**Generic Equivalent**"), it is necessary to obtain marketing approval from the Minister of Health. Generic manufacturers typically establish that their Generic Equivalents are safe and effective by submitting testing to the Minister of Health demonstrating that the generic equivalent is a "bio-equivalent" to branded drug (the "**Canadian Reference Product**") instead of duplicating the initial testing the branded manufacturer conducted to obtain approval for the branded drug. In order to conduct bioequivalence testing that will be acceptable to the Minister of Health, generic manufacturers generally require samples of the Canadian Reference Product. As a result, without access to samples of a Canadian Reference Product a generic manufacturer's ability to seek marketing approval from the Minister of Health for its Generic Equivalents is generally prevented or impeded.
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> 10. The Bureau has obtained information indicating that over the previous several years it has become increasingly difficult for generic manufacturers to obtain certain Canadian Reference Products. The Bureau has identified more than 20 drugs in respect of which have access to Canadian Reference Products has been restricted or refused in at least one instance by a wholesaler, or where generic manufacturers have otherwise encountered barriers that prevented or delayed access to Canadian Reference Products.

Originator companies' attempts to restrict generic companies' access to CRPs is clearly with a view to frustrating the abbreviated new drug submission ("ANDS") regulatory mechanism that is

[2] See Affidavit of Daniel Jensen, affirmed 28 July 2017, in *The Commissioner of Competition v. Celgene Inc.* and Kevin Leshuk, Federal Court File No. T-1246-17.

explicitly contemplated and countenanced in the Canadian *Food and Drug Regulations* (see esp. sections C.08.001.1, C.08.002.1, C.08.003.1 and C.08.004).

Insofar as the *Food and Drug Regulations* have been linked to patent rights by the PMNOC Regulations, this cannot provide any justification for blocking access to CRPs because the ANDS regulatory mechanism (and other similar conduct) is deemed to be non-infringing activity under the Canadian *Patent Act*:

> **55.2 (1)** It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product. [emphasis added]

The significance of these provisions can only be appreciated if they are understood in their historical and policy context. This context is described in great detail in the report of the World Trade Organization (WTO) in response to a trade-dispute initiated by the European Union in 1997 which dispute included a challenge to subsection 55.2(1). The report is illuminating and informative not the least by virtue of its reflection of the Government of Canada's own submissions in connection with the disputed provisions.

The entirety of the WTO Panel decision is available here: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20wt/ds114/r*%20not%20rw*)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#.

The following summarizes the views held and submitted by Canada that are pertinent in the present context.

Commencing in the early 20th century, Canada maintained a policy concern for early access to and affordability of medicines. This concern was reflected, in part, by the system of compulsory licensing for pharmaceutical patents.

In 1991, because of Canada's international treaty obligations under TRIPS and the expected NAFTA, it became clear that Canada would have to abolish its compulsory licensing regime and it was prepared to do so.

However, Canada remained committed to maintaining its policy concern for early access to and affordability of drugs. In order to do so, Canada was actively looking for ways that would ensure or at least facilitate that there could be generic competition for patented medicines as soon as possible after patent expiry – which necessarily meant that generic competitors had to be able to work the patented medicines, solely for regulatory submission and approval processes, before patent expiry.

In order to further that policy, Bill C-91 was passed which included section 55.2. Section 55.2 included among other things:

- a provision allowing for the early working of patented medicines solely for regulatory approval processes (ss.55.2(1));
- a provision allowing for the stockpiling of patented medicines (ss. 55.2(2)); and
- a provision for the making of regulations furthering the goals of subsections 55.2(1) and (2) (ss.55.2(4)). It was pursuant to the subsection 55.2(4) that the *PMNOC Regulations* were enacted.

Canada viewed subsections 55.2(1) and (2) as fundamental to its twin policy goals of early access and affordability/cost containment. In Canada's view:

- The intersection of an originator's patent rights of exclusion with the delays inherent in the regulatory review process for a generic drug gave rise to an "economic distortion" to be avoided as a matter of policy;

- A patentee only had a "legitimate interest" in exploiting and protecting its monopoly during the currency of the patent. Any de facto extension of his monopoly after patent expiry was not justifiable; and

- At the same time, early access and cost containment were legitimate public policy goals. However, it was illusory to expect that generic competition could commence immediately upon patent expiry because of the length development, submission and approval process mandated by the *Food and Drugs Act* and the *Food and Drug Regulations*.

These sentiments are encapsulated in the following position asserted by Canada (highlighting added):

> In response to a question from the Panel, Canada explained that the circumstances facing innovators were different from those facing generic drug manufacturers. The difference was that the only factor which delayed an innovator's market entry was society's requirement that it establish, to the satisfaction of the regulatory authorities, that its product was safe and effective for the use claimed. Given the potential harm that chemical substances might cause, it was difficult to characterize the delay associated with this process as being a "distortion". In contrast to the innovator's position, there were two factors that delayed a generic manufacturer's market entry. The first was its parallel need to demonstrate the safety and efficacy of its product to the satisfaction of the regulatory authorities. As in the case of the innovator, this delay factor was not by itself fairly described as a "distortion". The second factor which delayed generic entry was the presence of an innovator's patent. In order to obtain regulatory approval, a generic manufacturer must make and use a product that would, during its term of protection, infringe an innovator's patent. Absent provisions such as those here in issue, patent owners could exercise their exclusive rights to prevent the commencement of a generic manufacturer's application for regulatory review until the relevant patent had expired. The capacity to prevent such use gave rise to distortions in the legal system which both granted those rights and imposed the relevant regulatory review requirements. The distortion arose because the rights accorded by the patent laws, which were by law supposed to expire on the conclusion of a specified term, could be exercised during their currency before their expiry to convert the requirements of the regulatory review laws, which were designed to protect public health, not private commercial interests, into a de facto extension of patent rights which, under the patent law, had ceased to have any de jure existence. For obvious reasons relating to this prolongation of private commercial rights, the "economic distortion" referred to followed from the distortion of the legal framework defining patent rights and regulatory review requirements. Where, as explained in the foregoing, the distortion referred to only affected one side of the market, there was no distinction in policy approach that invited specific justification.

As a matter of policy, then, subsections 55.2(1) and (2) were included with a view to avoid that distortion in order in fact, to encourage early as possible entry post patent. Stated alternatively, section 55.2 was enacted for the purpose of taking away obstacles (and, in particular, patent

obstacles) and in fact to promote the timely (i.e. early as possible, regardless of patents) filing by generic companies of their regulatory submissions.

It would be fundamentally inconsistent with that policy to countenance (i.e. not act against) different attempts by brand name companies (i.e. patentees) to achieve the same distortions – particularly in the face of subsection 55.2(1) which is still law and which positively declares that early working is not an act of infringement.

If early working is not an act of infringement, then patentees can have no legitimate or colour of right to refusing to sell to someone who is willing pay for Canadian reference product on ordinary trade terms.

The gravity and urgency of the problem in Canada is also reflected by a parallel phenomenon in the United States and some of the responses by the relevant authorities there.

For example, in May 2018 the Commissioner of the U.S. Food and Drug Administration issued a statement (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm) which included the following:

> No patients should be priced out of medicines they need to support their health. As stressed by the President and Secretary Azar last week, one of the Administration's highest priorities is advancing policies that increase competition as a way to help make drugs more affordable and improve access.
>
> There isn't one single action that's going to solve this issue. We will achieve these public health goals through the coordinated effort of different federal agencies working in partnership with industry and other stakeholders. At the FDA, we're taking steps across a broad range of areas to improve new and generic drug competition as a way to improve access and affordability. Among these efforts, we're especially focused on addressing tactics we sometimes hear of branded companies pursuing as a way to forestall expected generic entry.
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> One such abuse that I've spoken about often is a practice by brand companies to create obstacles for generic developers in purchasing samples of their brand drugs. In general, generic drug developers need the samples of the brand drug to develop their generic product and/or to conduct testing to show that their product is bioequivalent to the brand drug for FDA approval. A generic drug developer generally needs 1,500 to 5,000 units of the brand drug to perform what are often relatively straightforward studies for FDA approval. Without these samples, generic drug makers may not be able to develop generic alternatives. Yet, the FDA has heard that some brand companies will adopt tactics to make it hard for the generic companies to purchase these brand drugs at a fair value and in the open marketplace. The FDA is taking new steps to address this issue.
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> Today, we're making public a list of companies that have potentially been blocking access to the samples of their branded products. We hope that this increased transparency will help reduce unnecessary hurdles to generic drug development and approval. We often hear of these tactics when it comes to generic drug developer access to samples when the brand products are subject to limited distribution programs. In some cases, these limitations on distribution may be asserted in connection with a Risk Evaluation and Mitigation Strategy (REMS), a program that the FDA implements for certain drugs to help ensure that the benefits of these drugs outweigh their risks. We have heard that some drug makers have either refused to sell samples of products with REMS with Elements to Assure Safe Use (ETASU) impacting distribution to potential

> generic competitors, or have imposed conditions on the sale of such samples that generic companies find hard or impossible to comply with.
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> In other cases, we understand that brand companies have placed restrictions in their commercial contracts or agreements with prescription drug distributors, wholesalers or specialty pharmacies that limit the ability of these intermediaries in the drug supply chain to sell samples to generic drug developers for testing. But I want to be very clear: a path to securing samples of brand drugs for the purpose of generic drug development should always be available. Even in the case of limited distribution programs such as those required by certain REMS, there should be a path forward for generic drug development.
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> Despite this, the FDA has received more than 150 inquiries from generic drug developers seeking assistance in obtaining samples from brand companies.
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> …
>
> We're committed to advancing policies to help bring more competition to the prescription drug market. We know that enhancing generic competition is an effective way to promote access to needed medicines.

The U.S. Federal Trade Commission has also been active in this field, recognizing that refusals by branded pharmaceutical firms to supply product for bioequivalence testing can undermine the framework for generic drug entry and may violate the antitrust laws.

In March 2013, the FTC filed an *amicus* brief in a private antitrust case involving restrictions placed upon the distribution of two drugs. In that case, *Actelion Pharmaceuticals Ltd. v. Apotex Inc.*, generic firms accused Actelion of preventing them from purchasing the drugs directly and imposing distribution restrictions upon wholesalers, contrary to sections 2 and 1 of the *Sherman Act*. Actelion argued that it has "no duty or obligation" to sell its drugs to rivals. The FTC's brief argues that the framework for generic entry cannot function as Congress intended if generic firms are unable to obtain samples, and that the generic firms' allegations are not barred as a matter of antitrust law.[3]

The following year, in June 2014, the FTC again filed an amicus brief in another private antitrust case, making its views about restrictions upon access to drugs for bioequivalence more explicit. In that case, *Mylan Pharmaceuticals, Inc. v. Celgene*, the FTC explained that refusals to sell to generic rivals may constitute unilateral exclusionary conduct under existing U.S. Supreme Court precedent (including the decision in *Trinko v. Verizon*). The FTC also took the position that vertical agreements between branded firms and wholesalers that imposed restrictions upon resale were not immune from antitrust scrutiny under section 1 of the *Sherman Act*.[4]

The FTC has continued to monitor conduct by branded firms that impedes the ability of generic firms to utilize the framework for generic entry. In testimony before the U.S. House of Representatives' Judiciary Committee in July 2017, an FTC official explained that "certain aspects of the existing structure [for generic entry] have proven susceptible to strategic – and potentially anticompetitive – behavior." In particular, he explained that "some companies have exploited the ability to delay generic entry through abuse of government processes. Since the

[3] See Federal Trade Commission's brief as *amicus curiae* in *Actelion Pharmaceuticals Ltd. v. Apotex Inc.* (March 11, 2013), https://www.ftc.gov/sites/default/files/documents/amicus_briefs/actelion-pharmaceuticals-ltd.et-al.v.apotex-inc./130311actelionamicusbrief.pdf

[4] See Federal Trade Commission's brief as *amicus curiae* in *Mylan Pharmaceuticals v. Celgene Corporation* (June 17, 2014), https://www.ftc.gov/system/files/documents/amicus_briefs/mylan-pharmaceuticals-inc.v.celgene-corporation/140617celgeneamicusbrief.pdf

inception of the Hatch-Waxman framework, some branded firms have employed a variety of strategies, including conduct that violates the antitrust laws, solely for the purpose of delaying generic competition…" The official summarized many of the FTC's actions and views as it concerns access to branded products for bioequivalence testing, but ultimately explained that antitrust is an unsatisfactory tool for protecting the framework for generic entry: "… even if a generic firm is ultimately able to prevail in an antitrust action and all subsequent appeals therefrom, such litigation can create substantial delays in obtaining the needed samples and a corresponding delay in generic approval. Accordingly, even a successful antitrust challenge is unlikely to provide immediate redress."[5]

In July 2018, the FTC made an extensive submission to the US Department of Health and Human Services regarding that department's efforts to lower drug prices. The FTC's submission explained its concerns that branded companies would misuse aspects of the framework for generic entry to "thwart entry by would-be generic competitors," which would "threaten to upset the careful balance between competition and innovation that Congress established." The FTC's submission concluded that "given the potential limitations of antitrust enforcement to address these problems, we also outline and reiterate our support for carefully considered regulatory and legislative efforts to address… abuses."[6]

In light of the significance of this issue in the specific context of Canadian reference products and also in light of the fact that that Parliament has evidenced a clear policy preference of creating a general exemption to infringement in the case of work done for regulatory submissions (i.e. subsection 55.2(1) of the *Patent Act* is not limited to any particular industry or even Canadian regulatory agencies), the CGPA proposes that an additional example be added to the IPEGs, immediately after paragraph 140.

Paragraphs 131 to 138 deal with "Example 9A: Product Switching ("Hard Switch")", an example from the pharmaceutical sector in Canada which involves a brand-name company, "BRAND", deliberately withdrawing one of its dominant products in the market, "Product A" (whose patent protection is about to expire), in favour of another one of its similar products that is subject to longer patent protection, all with a view to thwart the imminent market entry of a generic product, "Generic A" that generic company, "GENERIC", intends to introduce upon patent expiry.

Paragraphs 139 to 140 deal with "Example 9B: Product Switching ("Soft Switch")" which is a variation of Example 9A in which BRAND does not withdraw Product A from the market but rather simply stops promoting it to doctors.

Because the access to CRP issue involves similar market dynamics to Example 9A, i.e. a brand-name company attempting to remove access to Canadian reference products, CGPA proposes the following additional example:

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[5] See the prepared statement of Markus Meier, Acting Director, Bureau of Competition of the US FTC before the US House of Representatives Judiciary Committee Subcommittee on Regulatory Reform, Commercial and Antitrust Law (July 27, 2017), https://www.ftc.gov/system/files/documents/public_statements/1234663/p859900_commission_testimony_re_at_concerns_and_the_fda_approval_process_house_7-27-17.pdf.

[6] See Statement of the FTC to the Department of Health and Human Services regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (July 16, 2018), https://www.ftc.gov/system/files/documents/advocacy_documents/statement-federal-trade-commission-department-health-human-services-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf.

Example 9C: Product Withholding

140A. Consider the same set of circumstances as in Example 9A but instead of withdrawing Product A in favour of Product B, BRAND seeks to prevent GENERIC from obtaining samples of Product A so that GENERIC cannot prepare a regulatory submission for approval of its Generic A (because, in order to do so, GENERIC is required by law to demonstrate that Generic A is bioequivalent to Product A).

140B. BRAND seeks to prevent GENERIC from obtaining samples of Product A by refusing to sell to GENERIC and by imposing resale restrictions in its distribution agreements for Product A with wholesalers.

140C. Without access to sufficient quantities of Product A, GENERIC cannot fulfill regulatory requirements for demonstrating that Generic A is bioequivalent to Product A. As a result, there is a competition concern that GENERIC's entry will be sufficiently impeded and that, through an anti-competitive act, BRAND will successfully maintain its market power, even after patent expiry.

Analysis

140D. If the Bureau was of the view that the purpose for refusing sales to GENERIC was for the purpose of impeding market entry by GENERIC and Generic A, the Bureau would not view BRAND's conduct as a mere exercise of its patent right and thereby conduct exempt under subsection 79(5). The Bureau would also not view the conduct as reviewable under section 32. Accordingly, the Bureau would likely examine the conduct of BRAND under the abuse of dominant position provision (section 79) of the Act.

140E. The Bureau would first seek to define a relevant market that encompasses Product A. Given that GENERIC is attempting to demonstrate that Generic A is bioequivalent to Product A, the Bureau would likely conclude that both drugs are in the same relevant market. The Bureau would also consider whether there are other drugs that are sufficiently close substitutes to Product A to be considered in the relevant market.

140F. If the Bureau determined that BRAND was dominant in a relevant market that included Generic A (if ultimately made available) and Product A, it would then proceed to determine whether BRAND's conduct, including that of impeding GENERIC's access to Product A, constituted a practice of anti-competitive acts. In making this determination, the Bureau would examine the likely effect of BRAND's conduct on the ability of GENERIC to enter and compete in the relevant market. Ultimately, the Bureau would seek to determine whether BRAND's conduct would either significantly foreclose the entry of GENERIC or delay that entry for a significant period.

140G. The Bureau would also examine whether the purpose of BRAND's conduct was to delay or foreclose the supply of Generic A by GENERIC, or whether there was some other legitimate business justification. For example, if BRAND prevented access to GENERIC as a result of supply problems demonstrably out of BRAND's control, or if GENERIC refused to compensate BRAND for the supply of Product A it requested, that might provide a legitimate non-anti-competitive rationale.

140H. If the Bureau concluded that BRAND was dominant in a relevant market and that it had engaged in a practice of anti-competitive acts, it would also assess whether BRAND's conduct had caused a substantial lessening or prevention of competition. As part of this analysis, the Bureau would likely examine the difference between the price of Product A and the price at which Generic A would have been expected to be sold if the latter had not been delayed or foreclosed by BRAND's conduct.

140I. If the Bureau concluded that the constituent elements of subsection 79(1) were met, it would likely seek to negotiate a remedy with BRAND and, failing that, bring an application before the Tribunal.

The CGPA appreciates the opportunity to submit its views about the revised IPEGs. The CGPA commends the Bureau's efforts to ensure the IPEGs take account of developments in law and industry, and the CGPA would be pleased to discuss our comments on the latest draft IPEGs in more detail.

Sincerely,

Jim Keon
President

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