COMMENTS ON DRAFT CETA PATENTED MEDICINES (NOTICE OF COMPLIANCE) AND CERTIFICATE OF SUPPLEMENTARY PROTECTION REGULATIONS

1. INTRODUCTION

Innovative Medicines Canada (**IMC**) submits the following representations in respect of the proposed draft *Certificate of Supplementary Protection Regulations* (***CSP Regulations***) and the proposed draft *Regulations Amending the Patented Medicines (Notice of Compliance) Regulations* (***PM(NOC) Regulations***), which were published in *Canada Gazette Part I*, Vol. 151, No. 28 on July 15, 2017 (collectively referred to throughout as the ***CETA Regulations***). IMC is the national voice of Canada's innovative pharmaceutical industry. We advocate for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our members' commitment to being valued partners in the Canadian health and regulatory system.

An Act to Implement the Comprehensive Economic and Trade Agreement between Canada and the European Union and its Member States and to Provide for Certain Other Measures (**CETA Act, formerly Bill C-30**) received Royal Assent on May 17, 2017, but is not yet in force. The CETA Act provides for several key reforms to Canada's *Patent Act* that will have important implications for the pharmaceutical industry including the introduction of patent term restoration *via* Certificates of Supplementary Protection (**CSP**) and changes to Canada's linkage regime. Most of the details of these reforms are being determined in the *CETA Regulations* that are subject to the present consultation.

As a preliminary comment, in view of the significance and sheer volume of reforms presented, IMC is surprised by the short 15-day window of public consultation being provided to interested stakeholders. Prior to the recent *Canada Gazette Part I* publication, the *CETA Regulations* were only accessible to those individuals who had been invited to sign non-disclosure agreements. The lack of transparency surrounding those reforms impacting intellectual property rights has left many other stakeholders, including some companies that will be directly impacted by the amendments, ill-equipped to deal with the significant changes being introduced. This issue was noted by the Senate of Canada standing committee that studied CETA's implementation[1] as well as by the Member States of the European Union (EU). While IMC appreciates that a Canada Gazette consultation has been undertaken, a 15-day consultation is both unprecedented in the history of linkage reforms and represents an insufficient and pro forma response to the reasonable questions raised with respect to the lack of public consultation and transparency. Indeed, the short consultation period is inconsistent with Treasury Board guidelines with respect to draft regulations

[1] *See Standing Senate Committee on Foreign Affairs and International Trade, Observations to the Eleventh Report of the Standing Senate Committee on Foreign Affairs and International Trade (Bill C-30) (May 11, 2017), paragraphs 3-4.*

pertaining to international treaty obligations, which are typically accorded a 75-day consultation period[2]. Nor can the many delays with respect to CETA's implementation justify the abbreviated consultation period. While IMC and many other stakeholders have supported CETA since the start of the negotiations, for the reasons set out below, our industry is concerned that the draft regulations do not reflect the letter or the spirit of the treaty.

2. OVERVIEW OF IMC'S SUBMISSION

IMC makes the following overarching submissions on the proposed *CETA Regulations*. These submissions are followed by a chart outlining IMC's specific clause-by-clause representations on the *CETA Regulations* and accompanying Regulatory Impact Analysis Statements (**RIAS**).

The reforms negotiated in the CETA text with respect to the pharmaceutical industry were intended to elevate Canadian intellectual property (**IP**) standards closer to those of the EU. IMC is concerned that the current implementation scheme proposed in the *CETA Regulations* will not achieve this important objective.

The linkage regime was implemented to counteract any abuse arising from generic manufacturers' ability to early-work patented inventions as an exception to patent infringement under the *Patent Act*. To this end, the negotiated CETA text stipulates that "patent linkage" systems must provide all litigants with "equivalent and effective rights of appeal". CETA simply requires Canada to correct the imbalance caused by this fundamental injustice. Outside of any CETA obligations, however, the government further stated its intent to end the practice of "dual litigation" whereby unsuccessful linkage litigants can subsequently pursue regular patent infringement/invalidity remedies under the *Patent Act*. As a result, the CETA Act authorizes replacing the current summary linkage proceedings with full rights of action. The details of this regime have been determined by way of extensive proposed amendments to the existing *PM(NOC) Regulations*.

IMC recognizes that the negotiating parties have some discretion over how to implement CETA. The changes to the *PM(NOC) Regulations*, however, have proven to be far more extensive than necessary to comply with the CETA obligation to simply provide both parties with "equivalent **and effective**" rights of appeal.

First, despite adopting significantly more procedural complexity under the new regime, including full pleadings, discovery and trials in order to make final patent determinations in a single proceeding, the draft regulations have maintained the same 24-month statutory stay that governed the old summary system. However, 90% of patent infringement/invalidity actions in Canada take over two years to be determined. It is unclear to IMC that the Federal Court is being appropriately resourced to adapt to such significant changes. The innovative industry is therefore concerned that patentees will now be forced to choose between the surrender of procedural rights and obtaining a meaningful injunction under the new regime, raising questions regarding whether appeal rights under the proposed system will be "effective" in practice. For greater certainty, parties to CETA agreed to the following text: "If a Party relies on "patent linkage" mechanisms whereby the granting of marketing authorisations (or notices of compliance or similar

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[2] *Treasury Board of Canada Secretariat, "Guidelines for Effective Regulatory Consultations", 2007, at page 3.*

concepts) for generic pharmaceutical products is linked to the existence of patent protection, it shall ensure that all litigants are afforded equivalent and effective rights of appeal."[3]

Second, innovators litigating under the new regime are now also exposed to increased liability for damages in the event there is a finding of delayed generic market entry due to the statutory stay. Further, these damages continue to be awarded in artificially advantageous first-mover generic markets.

IMC is troubled that the new linkage regime allows generics to maintain all of the benefits of early-working patented inventions, while the merits of those same inventions risk no longer being determined in advance of generic market entry. Ending dual litigation by diminishing longstanding patent protections is contrary to international obligations to protect intellectual property rights. Further, as revealed by the proposed *PM(NOC) Regulations*, the policy intent to eliminate "dual litigation" has not been achieved. A separate litigation track is being maintained to litigate those patents not eligible for listing on the patent register. The elimination of dual litigation for a stated purpose of streamlining and creating efficiencies may have the opposite impact by generating greater uncertainty, increased costs and more pharmaceutical patent litigation in Canada.

Third, IMC recognizes that the introduction of the CSP regime partially addresses a longstanding issue in the Canadian pharmaceutical IP system by adopting a term of up to two years of patent term restoration. However, the further adoption of restrictive time limits and eligibility criteria will unreasonably limit CSP eligibility in Canada in a manner that is contrary to the intent of CETA. In addition, the proposed implementation of the manufacture-for-export exception is inconsistent with similar systems in Europe or the United States and will further undermine this protection. Although permitted by CETA, we urge that, if this exception is implemented, there must be safeguards (e.g. notification requirements) to ensure that the exception is limited to the terms articulated in the agreement.

The implementation of the CETA text into legislation and regulations must not undermine the intent of the CETA agreement, nor the delicate balance achieved by Canadian and European negotiators in the overall CETA itself. Implementation should preserve the spirit of the agreement and should certainly not prejudice those existing rights afforded under the current regime. CETA's implementation for pharmaceutical patentees should not be a matter of "one step forward and two steps back".

To this end, IMC addresses its detailed concerns with three key areas of the proposed regime:

- **(a) Extend the s. 6 stay**: the current proposed 24-month stay must at minimum be extended to 30 months, along with greater discretion for the courts and parties to moderate its length;
- **(b) End s. 8 "windfall" damages**: the language "in the absence of these Regulations" must be removed from s. 8(2) in order to prevent generic claims for future loss from turning into "windfall" damage awards that are already being awarded to generics under the current regime; and
- **(c) Remove overly restrictive CSP eligibility criteria**: overly restrictive CSP eligibility criteria concerning different definitions of "authorization for sale" and "variations" should be removed while

[3] *CETA, at article 20.28.*

the timely filing requirement (s. 106(1)(f)) should be extended from one to three years in order to ensure that otherwise reasonable eligible applicants obtain CSP rights.

a. Extend the s. 6 Stay

Despite the proposed move to a "single track" system, whereby s. 6 proceedings will now proceed by way of significantly more lengthy and procedurally complicated actions, the 24-month stay has not been lengthened to accommodate this complexity.

i. No Evidence that a 24-month Stay is Sufficient

There is no evidence that s. 6 actions can be completed in 2 years. No single patent infringement/invalidity action has been determined within 2 years since the Federal Court first introduced its *Notice on Streamlining Complex Litigation* in May of 2009 – the purpose of which was the very same – to rely on case management to marshal and schedule trials within 2 years of the commencement of the proceeding.

With respect to the duration of pharmaceutical patent actions in the Federal Court, the data demonstrates unequivocally that a 24 month stay is inadequate: (1) 90% of pharmaceutical patent infringement/invalidity actions took over 24 months to reach trial, with 32% requiring 24-36 months; 26% requiring 36-48 months; 10% requiring 48 to 60 months; and 23% requiring over 60 months. Of the 10% determined within 2 years, all pre-date 2009 and likely no longer reflect current court resources or jurisprudence.

Few procedural changes have been addressed in the new *PM(NOC) Regulations* to foster this new system in favour of leaving discretion to the parties and the Court. The streamlining procedures that are included in the *PM(NOC) Regulations* are extremely limited, and will present new complications susceptible to increasing litigation.

Given that generic litigants have consistently launched at risk of "dual litigation" following determinations under the *PM(NOC) Regulations*, IMC believes that generics will continue to launch at risk if the two-year stay expires before adjudication. This point is crucial. The evidence demonstrates that the average innovative market share is captured almost entirely within a mere three months of generic entry.[4]

The draft amendments have effectively undermined the very purpose for which the *PM(NOC) Regulations* were created: to ensure that the early-working exception to patent infringement (a valuable advantage to generic manufacturers) is not abused:

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[4] *Shajarizadeh, Grootendorst & Hollis, "Newton's First Law as Applied to Pharmacies: Why Entry Order Matters for Generics" (2015) Int. J. of the Economics of Business, Vol. 22, No. 2, p. 202. See also PMPRB, "Generic Drugs in Canadian Private Plans, 2005-2013 (page 3 figure on market update for generic atorvastatin show a 97% generic market uptake in Ontario by month two, with most provinces achieving over 80% generic uptake by month three; See also: Ian Cockburn & Genia Long, "The importance of patents to innovation: updated cross-industry comparisons with biopharmaceuticals" (2015) Expert Opinion on Therapeutic Patents, 25:7, p. 740.*

- **In 1993**: "These Regulations prohibit the Minister of Health and Welfare from granting a marketing approval (a Notice of Compliance) for a drug, that relies upon the earlier approval of a related drug until all the relevant product and use patents pertaining to the earlier approved medicine have expired." [RIAS, Canada Gazette Part II, Vol. 127, No. 6 (24/3/93), p. 1387]

- **In 1998**: "The link between the patent status of a drug and approval for a generic version of the drug is being maintained, to provide effective enforcement of patent rights, while at the same time ensuring that generic drugs can enter the market as soon as possible; either as soon as it is determined that they are not covered by a patent, or, where they are covered by a patent, immediately after the expiry of the patent." [RIAS, Canada Gazette Part II, Vol. 132, No. 7 (4/4/98) p. 1057]

- **In 1999**: "The *Patented Medicines (Notice of Compliance) Regulations* (Regulations) were enacted to ensure that second and subsequent entry manufacturers who apply for a notice of compliance (NOC) for their version of a patented drug will not obtain a NOC until the relevant patent expires, or until disputes respecting patent infringement or invalidity are resolved by the courts". [RIAS, Canada Gazette Part II, Vol. 133, No. 21 (12/10/99)]

- **In 2006**: "Thus, while early-working is intended to promote the timely market entry of generic drugs by allowing them to undergo the regulatory approval process in advance of patent expiry, the PM(NOC) Regulations are intended to provide effective patent enforcement by ensuring the former does not result in the actual issuance of a generic NOC until patent expiry or such earlier time as the court or innovator considers justified have regard to the generic company's allegation." [RIAS, Canada Gazette Part II, Vol. 133, No. 21 (2006-10-18)]

- **In 2015**: "As a balance to the early working exception, the PM(NOC) Regulations are intended to provide effective patent protection by ensuring that a notice of compliance is not issued to the generic manufacturer until expiry of all relevant patens or such earlier time as the court or innovator is satisfied with the allegation by the generic manufacturer that no valid patents relating to the drug would be infringed. [RIAS, Canada Gazette Part II, Vol. 149, No. 13 (2015/07/01) p. 2205]

Under the current regime, the surrender of procedural rights in favour of summary determinations within 24-months has long been justified by the opportunity to pursue patent infringement outside of the *PM(NOC) Regulations*. This justification no longer exists. Under the new regime, it appears that patentees will now be forced to choose between the surrender of procedural rights and obtaining meaningful injunction, while the merits of patent rights, presumed to be valid, are now determined *in rem*. In this context, it is reasonable to question whether the proposed system provides innovators with an "equivalent and effective" right of appeal, as required under CETA.

ii. More Discretion Over the Stay should be Provided

In the face of increasingly complicated s. 6 proceedings, and with no evidence that such proceedings can be appropriately accommodated by the courts, the *PM(NOC) Regulations* fail to bolster the courts' jurisdiction to lengthen (or shorten) the 24-month stay to accommodate the unquestionably more lengthy action proceeding – in fact, the proposed *PM(NOC) Regulations* further curtail discretion over the stay. Contrary to

the current *PM(NOC) Regulations*, not even the parties themselves will be able to consent to lengthen (or shorten) the stay.[5]

Restricting jurisdiction over the stay in this manner: (1) limits patentees and generics from negotiating against a generic launching at risk prior to obtaining a judicial determination on the merits; (2) will result in more litigation as patentees seeking to protect their markets will have to seek injunctive relief and negotiate a separate damages undertaking to extend the stay which could then result in both a s. 8 damages action and a damages reference action; and (3) removes discretion from the Court to oversee its own proceedings as it sees fit.

The latter point is of particular interest given the lack of evidence suggesting that the Court is sufficiently resourced to appropriately deal with litigation under the new regime in a timely fashion. In contrast, in the case of an interlocutory injunction, which IMC understands that s. 8 is now supposed to more closely emulate, the Court would retain full authority to dictate the terms of the injunction, including its duration.

Finally, although first persons will now be able to renounce the stay, this can only be done at the time of commencing the action. There is no rationale for imposing such restrictions on the ability to renounce the stay, especially since generics are no longer bound by allegations made in the NOA. An entirely new case can be presented to the innovator in the defence, on discovery, pre-trial – and the stay should be subject to renunciation accordingly.

The draft *PM(NOC) Regulations* propose a new regime where generics maintain all of the benefits of early working, but patent rights risk no longer being determined in advance of generic market entry. Ending dual litigation by removing longstanding patent protections necessary to prevent abuse of the early working exception is contrary to CETA and many other related international obligations to protect intellectual property rights.

IMC Proposal: Extend the s. 6 Stay

- The stay should be extended to at least 30 months. If it becomes apparent at some later time that these proceedings can be accommodated more quickly, the *Regulations* can be adjusted. At this time, any evidence-based approach suggests that this is simply not the case.
- At the very least, the *PM(NOC) Regulations should* provide for the ability of the parties to bring a motion to extend the stay on consent or where the Court cannot accommodate a timely trial date. The Court should also be afforded greater discretion over the stay to govern its own proceedings in the interests of justice.

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[5] *See s. 7(5)(a)(b) of the Regulations whereby the court has jurisdiction to shorten or extend the stay at any time during the proceeding on consent of the parties, or for a party's failure to reasonably cooperate in expediting the application.*

b. End s. 8 "windfall" Damages

According to the proposed PM(NOC) RIAS, the proposed amendments seek to ensure that s. 8 better achieves its purpose within the context of *PM(NOC) Regulations* that continue to be intended to strike a balance between the rights of the innovative and generic industries. Despite this aim, the amendments exacerbate "windfall" damage awards to second persons while discriminating against the innovative industry by imposing joint and several liability for no apparent reason.

i. The Language of paragraph 8(1)(a) [proposed 8(2)] is contrary to General Damages Principles

Failure to adhere to the compensatory function of section 8. As a result of the language of paragraph 8(1)(a) [proposed 8(2)], generic entry is automatically considered in the context of an artificially constructed hypothetical market scenario in which every s. 8 claimant is afforded a "first mover advantage" whether or not the s. 8 claimant holds the earliest patent hold date amongst their generic competitors. By failing to place the s. 8 claimant in the position they truly would have been but for the invocation of s. 6 of the *PM(NOC) Regulations*, s. 8 fails to adhere to basic common law damages principles and provides an automatic "windfall" to all s. 8 claimants despite the fact that s. 8 has been held to be a solely compensatory scheme.

Windfalls exacerbated by potential for future damages. The problems associated with the language of paragraph 8(1)(a) [proposed 8(2)] will be exacerbated by the decision to remove any limits to the period of a first person's liability under s. 8 of the *PM(NOC) Regulations*. The proposed amendments will give all s. 8 claimants a guaranteed "first mover advantage" AND they will now be entitled to claim indefinite future losses stemming from the loss of that statutorily granted "first mover advantage" not only into the future, but indefinitely.

Punitive cumulative effect of multiple section 8 actions. The cumulative impact of this windfall-effect will be further exacerbated where innovators face multiple s. 8 claims. For example, take two generics each initiating a s. 8 action with pleadings that suggest that one was approvable 5 years in advance of the other. By virtue of the scheme of the *PM(NOC) Regulations*, both will argue for a "first mover" advantage and the s. 8 defendant will be subject to a cumulative damages award that is based on what cannot possibly occur in a real world market scenario: two generics coming to market as "first movers" (i.e., not tied for first) with sole market advantage with all that is entailed in terms of market share, pricing and rebate levels resulting in artificially higher generic lost profits.

The windfall associated with this combined effect of the failure to strike the language "in the absence of these Regulations" from s. 8(2) and allowing future losses with the potential for multiple s. 8 claims will take s. 8 damages beyond their compensatory function while violating basic common law damages principles which seek to ensure a plaintiff is compensated "no more, no less" for their actual loss[6].

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[6] *Pfizer Canada Inc. v. Teva Canada Limited 2016 FCA 161 at para. 47.*

Windfall not causally related to the first person's invocation of a stay. The automatic granting of a "first mover advantage" also violates the original intention that s. 8 damages be causally linked to the stay associated with the failed prohibition proceedings. Rather, the proposed *PM(NOC) Regulations* award "windfall" damages that result from a statutory construction divorced from a true assessment of a second person's actual losses or the first person's actions.

ii. Discriminatory Imposition of Joint and Several Liability

There is no basis supporting the need for the imposition of joint and several liability: s. 8 judgments in Canada have all been satisfied without the need for Court intervention let alone the intervention of the Governor-in-Council. The case law is clear that the corporate veil will not be pierced, even where complete domination by a parent corporation over a subsidiary is present, in the absence of wrongdoing akin to fraud in the establishment of or use of the corporation[7]. The proposed amendment imposing joint and several liability subverts this basic principle of corporate separateness and alleviates the burden on generics to justify piercing the corporate veil. It is unclear why innovative pharmaceutical companies in Canada should be treated differently than other corporations under the law.

IMC Proposal: End s. 8 Windfall Damages

- Remove s. 8(1)(a) [proposed 8(2)] language "in the absence of these Regulations". This language is not necessary to fix the start of liability which presumptively remains the s. 8 claimant's patent hold date subject to the court's discretion to choose a more appropriate date. Removing this language is necessary to ensure that artificial generic monopolies are not created by statute, but can be both attained and challenged on the evidence alone.[8]
- Remove the imposition of joint and several liability on defendants to a s. 8 action.

c. Remove Overly Restrictive CSP Eligibility Criteria

The CETA Act and *CSP Regulations* introduce patent term restoration for pharmaceutical inventions into Canada for the first time. The innovative industry signals, however, that CETA's gains on this front risk being lost owing to complex eligibility requirements imposed by the *CSP Regulations*, which are inconsistent with both the letter and the spirit of the treaty.

i. The Timely Submission Requirement must be Extended

Under article 20.27 of the CETA text, Canada must provide a period of *sui generis* protection for pharmaceuticals to compensate for delays in drug marketing approval, subject to certain specified

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[7] *Yaiguaje v. Chevron Corp. 2017 ONSC 135 at paras. 63-66.*

[8] *This proposal does not reflect the "open season" methodology discussed in Ramipril (i.e., no generics are subject to the Regulations), but rather maintains that all generics are subject to the Regulations, as they are in the real-world. See* Apotex Inc. v. Sanofi-Aventis *2014 FCA 68 paras 155-164, aff'd 2015 SCC 20.*

conditions. In particular, at paragraph 3(a), CETA provides that: "Each Party may provide a period of *sui generis* protection only if the first application for the marketing authorization [e.g., a new drug submission (**NDS**) in Canada] is submitted within a reasonable time limit prescribed by that Party" [emphasis added].

Section 106(1)(f) of the CETA Act and the accompanying *CSP Regulations* introduce a new and complex CSP application requirement whereby only those Canadian regulatory submissions filed within one year of any first international drug submission filed for the same drug (in any of EU, US, Australia, Switzerland or Japan) will be CSP eligible (**Timely Submission Requirement**). The Timely Submission Requirement is a novel requirement in Canada that is unprecedented amongst the patent term restoration regimes of Canada's major trading partners, including the EU.

IMC is concerned that the one year time limit being enforced under the Timely Submission Requirement is not evidence-based given that there are no equivalent requirements in any other patent term restoration regime, and thus cannot be a "reasonable time limit" as negotiated under CETA. It will inappropriately bar otherwise deserving and eligible innovative medicines from benefiting from the period of *sui generis* protection that Canada agreed to provide under CETA.

Research based upon Health Canada, FDA and EMA approval data from 2009 to 2015[9] indicates that:

- 40% of Canadian NDSs are submitted after Canada's one year "Timely Submission Requirement" benchmark;
- Of those NDSs submitted after Canada's one year "Timely Submission Requirement" benchmark, the majority consist of submissions made by smaller companies and/or for rare diseases; and
- The earlier an NDS is filed in Canada, the longer it takes for Health Canada to review.

An evidence-based approach suggests that: (1) 40% of potential, and otherwise eligible, CSP applicants will be denied CSP protection in Canada; (2) those smaller companies most in need of the intellectual property protections afforded by CSP will be denied access; and (3) filing early in Canada defeats the very purpose that the Timely Submission Requirement is ostensibly supposed to achieve (i.e., earlier access to new medicines for Canadians) because the evidence shows that Health Canada will still take longer to review these submissions.

A survey of IMC's own members on factors influencing drug submission filing decisions in Canada indicates that submission decisions are multi-factorial. Most companies believe that, in a majority of cases, Health Canada requires more and/or different data than other regulators. It is telling that the Timely Submission Requirement to any Canadian harmonization metric with the approval processes of the EU, the US, Japan, Australia or Switzerland.

IMC strongly supports policy measures that will increase access to innovative medicines for Canadians. However, this objective can only be achieved through a combination of regulatory, Health Technology Assessment, listing and pricing policy measures, and cannot be achieved solely through changes to IP

[9] *Innovative Medicines Canada, Regulatory Considerations on question of timely filing – Bill C-30.*

regime. In this context, limiting the Timely Submission Requirement for CSP eligibility to one year (18 months for the first year), without any evidence that the limitation will increase access to innovative medicines in Canada, is both arbitrary and unreasonable. It is also inconsistent with the obligation under CETA to provide CSP protection to those drug submissions submitted within a "reasonable time limit", which cannot possibly have been negotiated with the intent to disqualify 40% of innovative medicines from CSP eligibility.

ii. Eligible Medicinal Ingredients Criteria too Restrictive

Similar to other jurisdictions, the Canadian patent term restoration regime requires that CSP-eligible medicinal ingredients be "first" approvals. Unlike other jurisdictions, Canada has further implemented a list of "variations" of medicinal ingredients and other prior drug approvals that will automatically exclude new drug submissions from possible CSP eligibility.

First, Canada has adopted different definitions of "authorization for sale". On one hand, a broad definition is adopted for certain provisions such that previously approved natural health products and non-prescription drugs, for example, – that do not have to meet new drug submission approval standards – can nevertheless defeat CSP eligibility of new drugs. On the other hand, a narrow definition is adopted for other provisions such that those same non-prescription drugs themselves will not be eligible for CSP protection, as they do not receive the necessary form of market authorization (i.e., notice of compliance).

Second, s. 2 of the *CSP Regulations* provides "variations" of medicinal ingredients that will be considered the "same medicinal ingredient" and thus a bar to CSP eligibility, including: a variation in any appendage within the molecular structure of a medicinal ingredient that causes it to be an ester, salt, complex, chelate or clathrate or any noncovalent derivative, or variation that is an enantiomer or mixture of enantiomers or a solvate or polymorph, variations caused by post-translational modifications, or any combination of these variations.

It would appear that the proposed CSP language would result in the same variations being excluded from CSP as are excluded from the current definition of "innovative drug" under the data protection provisions of Canada's *Food and Drug Regulations* (salt, ester, enantiomer, solvate or polymorph). The use of different, and potentially broader, language raises the prospect that additional variations are also intended to be excluded, but this remains unclear from the proposed language.

IMC submits that rather than a list of exclusions, a better solution is to allow flexibility in the definitions pertaining to eligibility of medicinal ingredients (i.e., no enumerated list of exclusions) so that this can be determined on the basis of a complete evidentiary and factual record on a case-by-case basis. The EU Regulation on supplementary protection certificates, for example, does not provide an enumerated list of exclusions but rather broadly defines the term "medicinal product". This is more consistent with the goal of the CSP regime to offer a term compensating for the time spent in research and development and regulatory approval. Neither the US nor EU patent term extension regimes provide enumerated lists of excluded variations ineligible for CSP.

Another approach would be to at least remove "salts and esters" (i.e., medicinal ingredients that are considered to be different chemical forms of a medicinal ingredient,[10] and to be nonidentical[11] by Health Canada) from the list of variations constituting the "same medicinal ingredient". Under the US patent term extension regime for example, a new ester or salt of a previously approved acid is eligible for patent term extension.[12] Moreover, recent EU case law also suggests that new approved uses of previously approved medicinal ingredients can be eligible for patent term extension.[13]

IMC is concerned that the proposed definition of the "same medicinal ingredient" will be overly restrictive and severely limit CSP eligibility to a subset of drugs that: (1) are eligible "innovative drugs" for data protection; and (2) also have eligible patents. This will result in an even narrower subset of drugs being eligible for CSP than data protection. Such narrow eligibility criteria are contrary to the purpose of granting a term meant to provide compensation for the time spent in research and development and expanded during the regulatory approval process.

Having adopted the minimum term of patent term restoration negotiated under CETA (i.e., the term is capped at two years of a possible five years) IMC is concerned that the further adoption of restrictive time limits and eligibility criteria will unduly and unreasonably limit CSP eligibility in Canada in a manner that is contrary to the intent of the negotiation and the CETA text itself.

Companies with drug approvals that are otherwise eligible for CSP should rightfully benefit from the new regime without being deprived of eligibility based on international filings that they otherwise had no notice over and insufficient means to control. CSP eligibility should not be further circumscribed by overly restrictive enumerated exclusions on medicinal ingredients and patents.

IMC Proposal: End Overly Restrictive CSP Eligibility Criteria

- The s. 106(1)(f) timeframe under the CETA Act, and s. 6 of *CSP Regulations* should be fixed at 3 years to ensure that the majority of NDS applicants are eligible for CSP consistent with CETA.
- The s. 6 selection of benchmark countries must be linked to harmonization metrics in those jurisdictions. To the extent that Canada wishes to tie CSP eligibility to marketing authorization processes in other countries, it must also adopt a regulatory approach that is consistent with those countries. Regulatory harmonization will serve Canada's stated goal of achieving "early introduction of innovative drugs into the Canadian market" [RIAS, Canada Gazette Part II, Vol. 151, No. 28 (15/7/17) p. 3298].

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[10] *Health Canada, Guidance Document: Patented Medicines (Notice of Compliance) Regulations (2010/11/01), p. 8.*
[11] *Health Canada, Policy Interpretation of "Identical Medicinal Ingredient" (2003/07/09 and June 16, 2015 Interim Update), p. 2, para. 4.3.*
[12] *FDA, Frequently asked questions on Patent Term Restoration; USPTO, 2751 Eligibility Requirements, II Meaning of Product.*
[13] *See for e.g., C-130/11 Neurium Pharmaceuticals (1991) Ltd v. Comptroller-General of Patents (Court of Justice of the EU); Vienna Higher Regional Court, January 21, 2016 (re: Botulinum Toxin).*

- The timelines and jurisdictions assigned under s. 106(1)(f) and the accompanying *CSP Regulations* can be revisited after an appropriate period of time has enabled the collection of real world evidence to make reasoned and evidence-based policy decisions.
- Regulatory processes in Canada and elsewhere are not static, but change over time. A timeframe in the *CSP Regulations* that is reasonable today may not be reasonable several years from now if either Canadian or non-Canadian regulatory approval processes change. The regulatory mechanism should provide flexibility to change over time.
- The broad "definition of authorization for sale" under s. 1(2) of the *CSP Regulations* should be narrowed to only include authorization by way of notice of compliance.
- There should be no enumerated list of variations under s. 2 of the *CSP Regulations* that constitute the "same medicinal ingredient". Alternatively, the list of excluded variations should be narrowed.

3. THE PROPOSED DRAFT *PM(NOC) REGULATIONS* – DETAILED COMMENTS

a. Draft *PM(NOC) Regulations*

No.	Draft Section of the PM(NOC) Regulations	View of Innovative Medicines Canada (IMC)	Proposed Change
1	<u>**The Register: addressing appeal rights**</u> **3(2.1)** The Minister is not permitted to make a deletion referred to in subparagraph (2)(c)(iii) **[patent ineligible listing]** based on a decision by the Federal Court before the later of the day on which the period for appealing that decision to the Federal Court of Appeal ends and the day on which any appeal of that decision to the Federal Court of Appeal is discontinued or dismissed. **3(2.2)** The Minister shall add any patent or certificate of supplementary protection to the register that has been	This amendment addresses when the Minister can delete a patent or CSP from the Register following a decision that the patent or CSP is invalid under the *Patent Act*, or has been declared ineligible for listing under subsection 6.5(1). <u>**Impact of Appeal and Appeal Rights on the Register**</u> • IMC submits that s. 3(2.1) should further address leave/appeal of any decision to the Supreme Court of Canada. • IMC submits that it is further unclear why s.3(2)(c)(ii) has also not been included under s. 3(2.1).	**3(2.1)** The Minister is not permitted to make a deletion referred to in subparagraph <u>(2)(c)(ii) or (iii)</u> based on a decision by the Federal Court before the later of the day on which <u>any appeal has been finally disposed of</u>. ~~the period for appealing that decision to the Federal Court of Appeal ends and the day on which any appeal of that decision to the Federal Court of Appeal is discontinued or dismissed.~~ [p. 3337]

No.	Draft Section of the PM(NOC) Regulations	View of Innovative Medicines Canada (IMC)	Proposed Change
	deleted under subparagraph 2(c)(ii) **[patent invalid]** or (iii) **[patent ineligible listing]** based on a decision that subsequently is reversed or set aside on appeal. [p. 3337]		
2	**The Register: Minister's discretion to de-list** **3(2.3)** The Minister may review the register to determine whether any patents or certificates of supplementary protection do not meet the requirements for inclusion on the register and, if the Minister conducts that review, shall delete any patent or certificate of supplementary protection that is determined not to meet those requirements. [p. 3337]	This provision should be amended to be consistent with the statement in the RIAS that "the person who submitted the patent for listing will be provided with notice and an opportunity to respond before any deletion takes place following such a review." [RIAS, p. 3323] Otherwise, this provision improperly implies that the Minister has been granted a broader and unfettered discretion to go back in time and de-list patents or CSPs. Any such review must include providing proper notice to the first person/patentee as well as an opportunity to make submissions. Creating a sense that patents or CSPs are liable to be de-listed at any time is contrary to the increased levels of litigation certainty that these new regulations are otherwise seeking to achieve.	**3(2.3)** The Minister may review the register to determine whether any patents or certificates of supplementary protection do not meet the requirements for inclusion on the register and, if the Minister conducts that review, shall delete any patent or certificate of supplementary protection that is determined not to meet those requirements. No such deletion can occur until the first person or patent owner has been provided with notice and an opportunity to make submissions to the Minister. The Minister shall further provide a final decision in writing [p. 3337]
3	**Form V/NOA Requirements** **5(2.1)** The statements or allegations required for the submission or the	This amendment addresses second person/generic Form V requirements at the time of ANDS filing.	**No Unilateral Consent** • For example, s. 5(2.1)(a) could read: "a statement that the owner of that

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	supplement, as the case may be, are — with respect to each patent included on the register in respect of the other drug and with respect to each certificate of supplementary protection in which the patent is set out and that is included on the register in respect of the other drug — the following: **(a) a statement that the owner of that patent has consented to the making, constructing, using or selling in Canada of the drug for which the submission or supplement is filed by the second person**; (b) a statement that the second person accepts that the notice of compliance will not issue until that patent or certificate of supplementary protection, as the case may be, expires; or **(c) an allegation that** (i) the statement made by the first person under paragraph 4(4)(d) is false, (ii) that patent or certificate of supplementary protection is invalid or void, iii) that patent or certificate of supplementary protection	**No Unilateral Consent** • A second person generic manufacturer should not be able to unilaterally declare that they have consent of the patent owner to the "making, constructing, using or selling" of the drug in Canada. Any such consent must come directly from the patent owner. As such, this provision should be amended to be consistent with the statement in the RIAS that "[s]uch statements must be supported by evidence of consent from the patent owner before NOC issuance is possible." [RIAS, p. 3324] **Requirement to Address all Patent Claims for Listed Patents Unclear** • It is not clear from the language in this provision that a second person/generic manufacturer will be required to address all claims in the patent (and not just the four types of claims relevant to listing).	patent has consented to the making, constructing, using or selling in Canada of the drug for which the submission or supplement is filed by the second person. Such statement must be supported by evidence of consent from the patent owner;" [p. 3339] • Or, consider if the language in this provision should mirror that of the other first person/patentee consent requirement under s. 7(2), which states: s. 7(2) "Subsection (1) does not apply in respect of a patent or a certificate of supplementary protection if the Minister has been provided with evidence from the owner of the patent of their consent to the making, constructing, using or selling of the drug in Canada by the second person. [emphasis added]. [p. 3348] **Requirement to Address all Patent Claims for Listed Patents Unclear** • For example, 5(2.1)(c)(iv) could read: "that no claims of the patent or certificate of supplementary protection would be [...]"

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	is ineligible for inclusion on the register, (iv) that patent or certificate of supplementary protection would not be infringed by the second person making, constructing, using or selling the drug for which the submission or the supplement is filed, (v) that patent or certificate of supplementary protection has expired, **or** (vi) in the case of a certificate of supplementary protection, that certificate of supplementary protection cannot take effect. [pp. 3339-40]		
4	**Notice of Allegation/ANDS** **Paragraphs 5(3)(c) and (d) of the Regulations** **are replaced by the following:** (c) serve the following documents with the notice **[…]** (iii) a searchable electronic copy of the portions of the submission or supplement **that are under the control of the second person** and relevant to determine if any patent or certificate of supplementary protection	This amendment addresses that generics must serve portions of the ANDS relevant to any non-infringement allegations with the NOA. **Address Generic Product Samples** • In certain cases involving allegations of non-infringement concerning the composition or process of the product (not use), the ANDS is insufficient to assess infringement and product testing is required. Where such allegations are put into play by the generic, the	• **Address generic product samples as follows:** 5(3)(c)(iii) a searchable electronic copy of the portions of the submission or supplement that are under the control of the second person and relevant to determine if any patent or certificate of supplementary protection referred to in the allegation would be infringed, and an attestation that relevant product samples are available to be provided at the request of the first person, and **[…]**

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	referred to in the allegation would be infringed, and (d) provide, without delay, to the first person any portion of a submission or supplement referred to in subparagraph (c)(iii) that is changed on or before the later of the 45th day on which the notice of allegation is served and the day of the disposition of any action that has been brought under subsection 6(1); and […] **[p. 3340]**	generic should further be required to advise that the product is immediately available for testing at the request of the first person. • It is important to address access to generic product since innovators will not be able to access generic product on the market in a *quia timet* action. On this point, there is a serious potential for injustice in view of estoppel principles adopted in the *PM(NOC) Regulations* under "single-track" [s. 6.01]. Facilitating early testing can further facilitate early settlement. • If access to generic samples is not addressed, there is a risk that this will become a litigious matter that will lengthen the overall proceeding. Procedural issues should be settled through amendments rather than further strain Court resources on interlocutory motions. This can only serve to assist the Court in resolving the action within the limited 24-month timeframe allotted. <u>Not under generic control</u> • Where relevant portions of the submission or supplement are not served with the NOA	<u>6.03 (2) The person bringing the action may serve on the second person at the same time as their statement of claim a request that relevant generic product samples be provided within 10 days.</u> <u>6.03(3)</u> The person bringing the action […] • **Where submission not under generic control:** <u>6.01(2) Subsection 6.01(1) shall not apply if, (a) relevant portions of the submission or supplement are not served with the notice, including for the reason that they are not under the control of the second person, and b) no statement alleging that the patent or certificate of supplementary protection is invalid or void is made in the notice, but is subsequently pursed by the second person in defence or counterclaim to any action commenced under subsection 6(1).</u> • **Further, see language proposed under s.7(8) below as grounds to extend the stay.** • **A provision should be added to require early production of patent hold**

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		because they are not under the "control of the second person" the estoppel principles under s. 6.01 should not apply. The first person and patentee may not have access to the appropriate information to determine whether or not to commence an action for infringement. This should also be grounds for extending the 24-month stay if additional time is required to obtain such information. **Early production of patent hold letters** • First persons should have information on when their liability period begins, especially since generics are not being required to serve NOAs within a fixed time after filing the ANDS/submission. • S. 8 is being otherwise amended to be more akin to an undertaking in damages, which should include notice of the start date of liability. • This provision is otherwise consistent with requirements to serve documents in a timely fashion in order to secure efficient proceedings.	**letters:** 5(3)(e) provide, within 10 days of receipt, to the first person any notice of the day, as certified by the Minister, on which a notice of compliance would have been issued in the absence of these Regulations. 5(3)(f) provide to the Minister […]
5	**Generic request for "invention documents"**	**Address privacy and procedural implications on inventor contact**	**Address privacy and procedural implications on**

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	(5) Subsection 5(4) of the Regulations is replaced by the following: **(3.1)** A second person who makes an allegation that the patent or certificate of supplementary protection is invalid or void may, when the notice of allegation is served, request **(a)** the name of and contact information for any inventor who might have information relevant to the allegation, along with an indication as to whether that inventor is an employee of the first person or of the patent owner; and **(b)** any laboratory notebook, research report or other document that **may be relevant** to determine whether a particular property, advantage, or use asserted by the second person to be part of the invention was established as of the filing date of the application for the patent, if the second person identifies the specific allegation in the notice of allegation that is relevant to the request and the portion of the patent in which that property, advantage or use is set out. [p. 3341]	**(re: s.5(3.1)(a)** Privacy concerns and legalities in various jurisdictions will need to be considered before personal contact information for inventors can be provided, if it even can be provided (i.e., last known address) when inventors are not, or are no longer, company employees of the first person. Where the inventors are current employees, it is not appropriate for generic counsel to contact them directly in any event. In practice, generics do not contact inventors directly, but arrange contact through innovators to exercise any Rule 237(4) right to examine an assignor (i.e., inventor). A better and more practical solution under the regulations would have the second person simply advise if they intend to discover the inventor on a specific allegation in the context of a proceeding. Having been so advised, the innovator can advise that it has contacted the inventor. This will further ensure that such discovery can occur in a timely fashion. **Address the Supreme Court abolishing the Promise Doctrine** The language in s. 5(3.1)(b) should be amended to reflect the Supreme Court of Canada's recent decision in *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36	**inventor contact (re: s.5(3.1)(a)** s. 5(3.1) A second person who makes an allegation that the patent or certificate of supplementary protection is invalid or void may, when the notice of allegation is served, request (a) to discover any inventor who might have information relevant to the allegation in the context of a proceeding. [...] [p. 3341] s. 6.03(1) If a second person makes a request under subsection 5(3.1), the person who brings the action must serve on the second person at the same time as their statement of claim (a) a document setting out confirmation that any inventor has been contacted and the documents referred to in paragraph (3.1)(b); [...] [p. 3341] **Address the Supreme Court abolishing the Promise Doctrine** **s. 5(3.1)(b)** any relevant laboratory notebook, research report or other document ~~that may be relevant~~ sufficient to determine whether ~~a particular property, advantage, or use~~ the utility of the subject matter of the invention as claimed asserted by the second person

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		abolishing the Promise Doctrine in Canada and clarifying once again that "a patentee is not required to disclose the utility of the invention to fulfill the requirements of s. 2" (para. 58). **Remove "may be" relevant re: "invention documents"** The language of this provision is overly broad and could result in open-ended requests and unjustified fishing expeditions that would otherwise not be tolerated under the existing rules and jurisprudence. IMC submits that the reference to the second person's ability to request documents that "may be relevant" to "whether a particular property, advantage, or use…was established as of the filing date of the application of the patent" appears to be a drafting oversight. There is no basis for applying a broader scope of relevance to these documents. The language "may be relevant" is inconsistent with reciprocal requirements placed on second person generic manufacturers to: (1) deliver portions of the submission or supplement that are "relevant" [see for example s. 5(3)(c)(iii)] and; (2) including under a motion to compel [see s. 6.04(1)]. The language "may be relevant" is	~~to be part of the invention~~ was established as of the filing date of the application for the patent, if the second person identifies (1) the specific allegation in the notice of allegation that is relevant to the request ~~and~~ , (2) the subject matter of the invention as claimed, and (3) why the subject matter of the invention as claimed is asserted to lack utility ~~portion of the patent in which that property, advantage or use is set out~~. [p. 3341]

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		also inconsistent with the language, standard and definitions of relevance that appear in the *Federal Courts Rules* and jurisprudence in respect of actions. See for example, Rules 222(2), 225. As shown in the strikethrough above, this language should be modified to "relevant" in order to be consistent with the other provisions of the Regulations, the Rules and jurisprudence.	
6	**Confidentiality** 5(3.5) The second person may impose on the first person referred to in paragraph 3(a) and any owner of a patent to whom a document is forwarded under subsection (3.3) any reasonable rules for maintaining the confidentiality of any portion of a submission or supplement referred to in subparagraph (3)(c)(iii). 5(3.6) Those confidentiality rules are binding and enforceable by the Federal Court, which may award any remedy that it considers just if they are not respected. 5(3.7) On motion of the first person or of the owner of the patent — or on its own	These amendments address confidentiality of certain documents produced during the s. 6 proceeding. **Clarify "reasonable rules" and implications of unilaterally imposed terms of confidentiality** • The unilateral imposition of "binding and enforceable" confidentiality rules raises potential for abuse and has unclear implications with respect to possible enforcement. What constitutes "reasonable rules" is entirely subjective to the party. For example, a party may consider a "counsel's eyes only" restriction to be "reasonable". Further guidance should be provided in the RIAS at a minimum. • With respect to s. 5(3.8), a	• **S. 5(3.8) should be removed**. Form IVs direct service in Canada. The confidentiality order proposed by the first person can stipulate that non-Canadians, not called to the bar (jurisdictional equivalent thereof), be first required to attorn to the jurisdiction of the Federal Court prior to receiving any material designated confidential.

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	initiative after giving an opportunity to be heard to that first person, that owner and the second person — the Federal Court may set aside or vary any or all of those confidentiality rules in any manner that it considers just. 5(3.8) A second person who is, under subparagraph (3)(c)(iii) or paragraph (3)(d), required to serve or provide a document may – if there is reason to believe that the intended recipient of the document is not in Canada – refuse to do so unless that recipient attorns to the jurisdiction of the Federal Court with respect to the confidentiality of the information set out in the document. [p. 3342] **[…]** 6.03(2) The person bringing the action may impose on the second person any reasonable rules for maintaining the confidentiality of the information set out in any document provided under paragraph (1)(a). 6.03(3) Those confidentiality rules are binding and enforceable by the Federal Court, which may award any	second person should not be able to refuse to serve the documents altogether to the first person located in Canada (Form IVs require a name and address for service in Canada). The confidentiality rules being imposed by the first person can require that non-legal professionals receiving the information outside of Canada must first attorn to the jurisdiction of the Federal Court. The provision presently reads as if service can be refused altogether based on any belief that it will be provided to someone external to Canada. Such broad discretion over service of documents will only serve to delay delivery of relevant documents to innovators facing an already very limited 45-day window of time to determine whether or not to commence an action. • It is unjust to allow such grounds as a means to refuse service of relevant documents, yet still impose onerous estoppel consequences (including stay renouncement) on first persons within 45 days.	

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	remedy that it considers just if they are not respected. 6.03(4) On motion of the second person or on its own initiative, after giving an opportunity to be heard to the parties to the action, the Federal Court may set aside or vary any or all of those confidentiality rules in any manner that it considers just. [pp. 3344-5]		
7	**Right of Action** 6 (1) The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) **would infringe any patent or certificate of supplementary protection** that is the subject of an allegation set out in that notice. **[…]**	This amendment addresses the innovator right of action and remedy against the second person. **Right of Action** • Ability to address all claims: It is not clear from the language of s. 6(1) that the first person/parties claiming may now assert any claim in a listed patent, and not just those claims eligible for patent listing. • For example, 6(1) could read: "…would infringe any claim of the patent or certificate of supplementary protection …" • Stipulate bifurcation: a provision should be included in the *PM(NOC) Regulations* to stipulate that this action will be bifurcated (liability from remedy) to ensure that no	6 (1) The first person or an owner of a patent who receives a notice of allegation referred to in paragraph 5(3)(a) may, within 45 days after the day on which the first person is served with the notice, bring an action against the second person in the Federal Court for a declaration that the making, constructing, using or selling of a drug in accordance with the submission or supplement referred to in subsection 5(1) or (2) would infringe any claim of the patent or certificate of supplementary protection that is the subject of an allegation set out in that notice. [pp. 3343-4] **[…]** 6(5) For any action commenced under subsection (1), the issues of electing remedy and/or quantifying remedy shall be

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	6 (4) If the Federal Court makes a declaration referred to in subsection (1), it may order any other remedy that is available under the *Patent Act*, or at law or in equity, in respect of infringement of a patent or a certificate of supplementary protection. [pp. 3343-4]	generic litigant can contest any request for a bifurcation order (thereby lengthening the overall proceeding). • Exempt "persons claiming under the patent": a provision should be included in the *PM(NOC) Regulations* that the first person and patentee are not required to name "all persons claiming under the patentee" (under s. 55(1) of the *Patent Act*) until the remedy proceeding (if any). This provision is necessary to prevent unwarranted discovery of such persons during the liability phase of the action, which would unduly lengthen the proceeding. Such a provision is also necessary to preserve innovator rights to include such parties in the litigation at the remedy phase.	bifurcated at the request of the first person, and all persons claiming under the patentee need not be joined as parties to any action commenced under subsection (1) without prejudice to being joined at the subsequent remedy phase, if any.
8	**Estoppel** 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,	This amendment provides that failure to bring a s.6(1) action against the second person under the *PM(NOC) Regulations* precludes all other rights to bring an infringement action with respect to a listed patent against the second person (subject to establishing a lack of material basis for bringing the action). **No estoppel where insufficient information**	6.01(1) […] **No estoppel where insufficient information** 6.01(2) Subsection 6.01(1) shall not apply if, (a) relevant portions of the submission or supplement are not served with the notice, including for the reason that they are not under the control of the second person, (b) no statement alleging that the patent or

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	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. [p. 3344]	• Where relevant portions of the submission or supplement are not served with the NOA because they are not under the "control of the second person" the estoppel principles under s. 6.01 should not apply. The first person and patentee may not have access to the appropriate information to determine whether or not to commence an action for infringement. This should also be grounds for extending the 24-month stay if additional time is required to obtain such information. • Generics are no longer bound by the NOA, however, generics should be required to put their best foot forward in the NOA since it still forms the basis to start the action and activate the stay. There should be consequences where generics fail to address allegations in the NOA that could have been reasonably raised. **Generic Estoppel** • The generic/second person should also be estopped from bringing a later invalidity action if they fail to bring a counterclaim for invalidity under s. 6(3). Otherwise, a generic could defend on the	certificate of supplementary protection is invalid or void is made in the notice, but is subsequently pursed by the second person in defence or counterclaim to any action commenced under subsection 6(1). **Generic Estoppel** 6.01(3) No action, other than one brought under subsection 6(3), may be brought against the first person for a declaration under subsection 60(1) or (2) or 125(1) or (2) of the *Patent Act* for 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).

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		basis of non-infringement and/or invalidity only under s. 6; then, if unsuccessful, pursue a second action for impeachment of the Patent or CSP. Such a result runs contrary to Canada's stated intention to eliminate "the costly and inefficient practice of dual litigation" as stated in the RIAS. [RIAS, p. 3318]	
9	**Motion to Dismiss Action** 6.08 An action brought under subsection 6(1) may, **on the motion of a second person**, be dismissed, in whole or in part, on the ground that it is redundant, scandalous, frivolous or vexatious or is otherwise an abuse of process in respect of one or more patents or certificates of supplementary protection. [p. 3346]	This amendment addresses the right of a second person only to bring a motion to dismiss the action, in whole or in part. **Redundant of Rule 221** • It is unclear why this provision is necessary in the *PM(NOC) Regulations* (where patent decisions will now be made *in rem*) as it appears redundant of rights already available under R. 221 of the *Federal Courts Rules*. It is confusing to provide the same right of action across multiple pieces of legislation. • It is further unclear why this right is being limited to the generic's right to dismiss a s. 6(1) action. No reciprocal right is provided to innovators to dismiss generic counterclaims. CETA text that requires Canada to provide "equivalent and effective" rights of appeal to	Delete 6.08.

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		both parties.	
10	**Case Management** 6.1(1) An action brought under subsection 6(1) shall be a specially managed proceeding in accordance with the *Federal Courts Rules*. (2) The case management judge who is assigned the specially managed proceeding shall conduct a case management conference as soon as feasible after the 10th day after proof of service of the statement of claim in the action is filed. [p. 3346]	This amendment addresses the role of case management under the *PM(NOC) Regulations*. **Early Trial Date Request** • A provision should be included in the *PM(NOC) Regulations* that a trial date may be requested at this first case management conference in order to fix a trial date as early as possible and facilitate a hearing within the 24-month stay. This provision is necessary to prevent second persons from contesting early requests to fix a trial date, which would unduly lengthen the proceeding.	6.1(1) An action brought under subsection 6(1) shall be a specially managed proceeding in accordance with the *Federal Courts Rules*. (2) The case management judge who is assigned the specially managed proceeding shall conduct a case management conference as soon as feasible after the 10th day after proof of service of the statement of claim in the action is filed. (3) A request to schedule a trial date may be submitted by either party to the case management judge. Such request should be made as early as possible in order to facilitate a hearing within the period fixed by paragraph 7(1)(d).
11	**The Stay** 7(1) The Minister shall not issue a notice of compliance to a second person before the latest of … (d) the day after the expiry of the 24-month period that begins on the day on which an action is brought under subsection 6(1); [p. 3348]	This amendment addresses the maintenance of the 24-month stay despite the move to proceedings by way of action. **The 24-Month Stay is Insufficient** • IMC refers to its submissions above and further reiterates that the period of the stay be extended to 30 months.	7(1) The Minister shall not issue a notice of compliance to a second person before the latest of … (d) the day after the expiry of the 30-month period that begins on the day on which an action is brought under subsection 6(1);
12	**Renouncing the Stay** s. 7(5)(b) each of the parties	**Renouncing the Stay:** Further, with respect to	s. 7(5)(b) each of the parties who brings an action referred to in subsection 6(1) in relation to

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	who brings an action referred to in subsection 6(1) in relation to a given notice of allegation provides, when they bring the action, a notice to the second person and the Minister that they renounce the application of that paragraph. [p. 3349]	renouncing the stay, the first person and patent owners should be given the right to renounce the stay at any time. Such recourse is fairly provided for a number of reasons: (i) In view of the limited time being provided to innovators to assess generic allegations (45 days) prior to commencing an action; (ii) generics will no longer be bound by NOAs such that new matters could arise in the pleadings such that the innovator may no longer wish to avail itself of the stay. There is no rationale for imposing such restrictions on the ability to renounce the stay. An entirely new case can be presented to the innovator by the generic in the defence, on discovery, pre-trial – and the stay should be subject to renunciation accordingly; (iii) possible increased exposure to damages under new s.8; (iv) ending the stay earlier can result in earlier generic market access; and (v) in any event, innovators will still be liable for any damages suffered while the stay was in effect. An alternative would also be to allow innovators to opt out of the stay within the first 6 months, or by some other extended, yet fixed period of time.	a given notice of allegation provides, when they bring the action, or at any time thereafter, a notice to the second person and the Minister that they renounce the application of that paragraph. [p. 3349]
13	**Stay Extension** 7(8) As long as the Federal Court has not made a	This amendment addresses the limited jurisdiction of the court over the stay.	7(8) As long as the Federal Court has not made a declaration referred to in

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	declaration referred to in subsection 6(1), it may shorten or extend the 24-month period referred to in paragraph (1)(d) if it finds that a party has not acted diligently in carrying out their obligations under these Regulations or has not reasonably cooperated in expediting the action. [p. 3349]	**Jurisdiction to extend stay** • IMC refers to its submission above and further reiterates that the parties be able to consent to extend the stay (as they are able to do under the current regulations); and that the court be provided with discretion to extend the stay in the event the court is unable to accommodate a trial date within 24-months.	subsection 6(1), it may shorten or extend the 24-month period referred to in paragraph (1)(d) if (a) it finds that a party has not acted diligently in carrying out their obligations under these Regulations or has not reasonably cooperated in expediting the action, (b) the first and second person consent to it, (c) the Federal Court is unable to schedule a hearing prior to the end of the period in paragraph 1(d), (d) the second person is unable to serve relevant portions of the submission or supplement that are not under its control, (e) it will otherwise serve the interests of justice.
14	**Section 8** 8 (1) A second person may apply to the Federal Court or another superior court of competent jurisdiction for an order requiring all plaintiffs in an action brought under subsection 6(1) to compensate the second person for the loss referred to in subsection (2). (2) Subject to subsection (3), if an action brought under subsection 6(1) is discontinued or dismissed or if a declaration referred to in subsection 6(1) is reversed	**Remove "in the absence of these Regulations" from proposed 8(2)** • See detailed submissions in overview. **Remove Joint and Several Liability** • See detailed submissions in overview. • Joint and several liability should be removed from the *PM(NOC) Regulations*, as follows: • The proposed amendment imposing joint and several liability contravenes the basic principle of separate	8 (1) A second person may apply to the Federal Court or another superior court of competent jurisdiction for an order requiring ~~all plaintiffs in an action brought under subsection 6(1)~~ the first person to compensate the second person for the loss referred to in subsection (2). (2) Subject to subsection (3), if an action brought under subsection 6(1) is discontinued or dismissed or if a declaration referred to in subsection 6(1) is reversed on appeal, ~~all plaintiffs in the action are jointly and severally, or solidarily, liable to~~

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	on appeal, **all plaintiffs in the action are jointly and severally, or solidarily, liable to the second person** for any loss suffered after the later of **[…] [p. 3349]**	corporate personality and alleviates the burden on generics to justify piercing the corporate veil which the law has long held cannot be pierced in the absence of wrongdoing akin to fraud in the establishment of or use of the corporation, even where complete domination by a parent corporation over a subsidiary is present (*Yaiguaje v. Chevron Corp*. 2017 ONSC 135 at paras. 63-66). • Innovative pharmaceutical companies in Canada should not be treated differently than other corporations who hold Canadian patents. **Require delivery of patent hold letters** • See submission and draft language above under s. 5(3).	~~the second person~~ the first person may be found liable for any loss suffered after the later of the day on which the notice of allegation was served, the service of which allowed that action to be brought, and of the day, as certified by the Minister, on which a notice of compliance would have been issued ~~in the absence of these Regulations~~. [p. 3349]
15	**Transition** 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. (2) For greater certainty,	This amendment addresses the transitional provision and dictates that it will be driven by the service of a notice of allegation. **Transitional Provision Should be ANDS-based** • IMC submits that the new *PM(NOC) Regulations* should only apply to those generic ANDS filed after the Regulations come into force. Otherwise, basing the transitional provision on	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 submission described in subsection 5(1) and (2) filed by the second person ~~notice of allegation served on a first person~~ before that day. 9(2) section 6.01 shall not apply

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	sections 6 to 8 of the Regulations Amending the *Patented Medicines (Notice of Compliance) Regulations*, SOR/2006-242, continue to apply in respect of the provisions set out in those sections. [p. 3351]	service of the NOA provides generic incentive to hold off on serving NOAs until the new Regulations are passed to access more lucrative s. 8 awards. Later NOAs result in greater exposure to s. 8 damages for innovators and also impact the timeliness of generic market entry. • IMC further submits that the new *PM(NOC) Regulations* should only apply to patents listed on the Register after the Regulations come into force. Alternatively, those patents listed on the Register before the passage of the Regulations should be exempt from s. 6.01 estoppel provisions.	to those patents listed on the register before the day on which these Regulations come into force. 9(3) […]

b. Draft RIAS - *PM(NOC) Regulations*

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16	**Issues (re: inaccurate description of lack of effective appeal right)** "Innovators could appeal a court decision refusing to grant a prohibition order. **However, such appeals could be dismissed as moot if the NOC had already issued. This raised concern that innovators lacked effective appeal rights under the**	This statement is not reflective of actual practice and significantly understates the reality that courts never exercised discretion to hear moot appeals once the generic NOC issued. As a result, this comment diminishes the lack of effective innovator appeal rights under the current	"Innovators could appeal a court decision refusing to grant a prohibition order. However, such appeals ~~could be~~ have always been dismissed as moot if the NOC had already issued. As a result, ~~This raised concern that~~ innovators lacked effective appeal rights under the regime. In view of the volume of cases litigated

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	regime." [p. 3316]	regime.	under the PM(NOC) Regulations since 1993, the lack of effective appeal rights for patentees/first persons has caused imbalance in the jurisprudence over time and has been a matter of significant concern to the innovative industry. [p. 3316]
17	**Issues: (re: use of affirmative language on untested outcomes)** "This approach resolves the problem of mootness that previously arose in appeals. At the same time, it allows for more robust scrutiny of issues and **greater overall efficiency**." [p. 3317]	In view of the magnitude of changes proposed to the *PM(NOC) Regulations* that remain entirely untested, affirmative statements on outcome are undue. In terms of achieve "greater overall efficiency" no explanation has been provided as to how the current court system has been resourced to accommodate these new rules, and the additional procedures entailed, within the confines of the same 24-month stay.	"This approach resolves the problem of mootness that previously arose in appeals. At the same time, it ~~allows~~ is intended to allow for more robust scrutiny of issues and greater overall efficiency [elaborate on management of court resources]." See also for e.g., at p. 3317 "...with full actions ~~resulting in~~ is intended to result in..." and throughout the RIAS.
18	**Background: (re: generic position should be stated)** "Aside from concerns about appeal rights, complaints were raised that applications under the Regulations could not provide desired legal certainty prior to generic market entry." [p. 3317]	This has never been a complaint of the innovative industry and should be attributed appropriately. This is particularly the case in view of the limited commentary provided under the "Consultation" section at p. 3334.	"Aside from concerns about appeal rights, complaints were raised by the generic industry that applications under the Regulations could not provide desired legal certainty prior to generic market entry." [p. 3317]
19	**Background: (re: inaccurate description of actual**	There has actually been little issue in resolving s. 6	Omit.

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	<u>experience)</u> "At the same time, proceedings under the Regulations became complex and time-consuming, raising questions about the usefulness of these procedural compromises." [p. 3317]	proceedings by way of application within two years for some time now. This unattributed observation does not reflect actual experience.	
20	**<u>Background: (re: CETA compliance)</u>** "In the face of these criticisms **and to meet Canada's obligations under CETA,** the Government concluded that Canada's patent linkage regime needed updating in order to better serve its purpose." [p. 3318]	This statement is false since the only obligation under CETA is to provide an effective right of appeal to innovators.	"In the face of these criticisms ~~and to meet Canada's obligations under CETA~~, the Government concluded that Canada's patent linkage regime needed updating in order to better serve its purpose." [p. 3318]
21	**<u>Objectives: (re: inaccurate statement on measure on the 24-month stay)</u>** "In some cases, unique features are being proposed to account for time pressures arising from the 24-month bar on NOC issuance and the possibility of damages being awarded for delayed generic market entry." [p. 3318]	This statement is misleading by implying to readers that "real measures" have been put in place to mitigate against the potential loss of rights flowing from the court's inability to hear the matter and render a decision within the 24-month timeframe. Under the current proposal, the court will have no jurisdiction to extend the stay for this reason, nor will the parties even be permitted to consent to an extension – a right that actually currently exists in the present regime [s.7(5)(a)], and is being removed under the new regulations.	Omit.

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22	**Objectives: (re: elimination of dual litigation)** "The costly and inefficient practice of dual litigation **would be eliminated, leading to greater legal and market certainty**." [p. 3318] **Rationale**: "This change **will also eliminate** the practice of dual litigation, **resulting in greater overall efficiency and less legal uncertainty at the time of generic market entry**." [p. 3335]	The reference to dual litigation being "eliminated" is inconsistent with the fact that that only patents eligible for listing are fully addressed under the proposed new regime. To the contrary, the RIAS and new linkage regulations contain opportunities for additional litigation under the new regime, including: (1) parallel *quia timet* actions for unlisted patents outside of the regulations; (2) multiple generic actions for the same listed patents (consider if generics do not seek declarations of invalidity in rem for example); (3) motions based on inadequate ANDS or invention document disclosure; (4) proceedings to overcome estoppel allegations; (5) proceedings for interlocutory injunctions over: unlisted patents, renounced 24-month stay, or upon stay expiry; (6) multiple section 8 actions (as new section 8 incentives make it increasingly valuable for generics to litigate); (7) actions to recover undertaking in damages where injunctions are either successful or issued on consent; (8) continued access to generic actions in damages outside of the regulations	"The costly and inefficient practice of some dual litigation ~~would~~ may be diminished ~~eliminated, leading to greater legal and market certainty~~." [p. 3318] This change ~~will~~ is also intended to diminish ~~eliminate~~ the practice of dual litigation~~,~~ ~~resulting in greater overall efficiency and less legal uncertainty at the time of generic market entry~~. [p. 3335]

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		(i.e., Statute of Monopolies cases); (9) litigation to unravel the myriad of implications of generics launching at-risk upon expiry of the 24-month stay (e.g., market access, public/private reimbursement, price).	
23	**Objectives: (re: s. 8 damages assessment)** "Fourthly, the proposed amendments address concerns about how damages arising from delayed market entry are currently assessed." [p. 3318]	None of the innovative industry's concerns about how s. 8 damages have been addressed. This comment should be attributed appropriately.	"Fourthly, the proposed amendments address generic industry concerns about how damages arising from delayed market entry are currently assessed." [p. 3318]
24	**Available Remedies**: "If a NOC issues prior to a declaration of infringement being made, **the availability of injunctive relief** against the second person would provide alternate means of preventing infringement." [p. 3320]	The availability of injunctive relief outside of the *PM(NOC) Regulations* will only "provide alternate means of preventing infringement" if it is reasonably obtainable. Since this is not the case under the current jurisprudence for pharmaceutical patents, statements should be included to encourage the court to grant such injunctions in the context of the new regime.	"If a NOC issues prior to a declaration of infringement being made, the availability of injunctive relief against the second person ~~would~~ shall now provide a real and alternate means of preventing infringement. For example, loss of brand market share, and brand price erosion, especially in a public payer market, are factors capable of justifying an injunction in the context of pharmaceutical litigation." [p. 3320]
25	**Patent Listing Requirements: (re: adding CSPs to the Patent Register)** "With respect to CSPs, they would be added to the register if the patent set out in the CSP is	The reference to "no further application is necessary" is unclear. Does this mean that once a CSP is issued by the Minister of Health, it will be automatically added to the Patent Register in all cases? In	The RIAS needs to elaborate on the specific process for adding a CSP to the Patent Register once issued: "With respect to CSPs, they would be added to the register

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	already included on the register in respect of a submission or supplement and the submission or supplement relates to a drug with respect to which the CSP grants the rights, privileges and liberties referred to in section 115 of the Act. **No further application would be necessary**. To facilitate the listing of a CSP, an expired patent that is set out in a CSP may be listed on the patent register." [p. 3322]	other words, there will be no equivalent Form IV requirement devised for listing a CSP on the Patent Register. The process for adding a CSP to the patent register is also not clear in s. 3 of the proposed draft *PM(NOC) Regulations*.	if the patent set out in the CSP is already included on the register in respect of a submission or supplement and the submission or supplement relates to a drug with respect to which the CSP grants the rights, privileges and liberties referred to in section 115 of the Act. In all circumstances, once a CSP is issued, the Minister of Health will automatically record its issuance on the Patent Register. No further application would be necessary. To facilitate the listing of a CSP, an expired patent that is set out in a CSP may be listed on the patent register." [p. 3322]
26	**Notices of Allegation and accompanying documents:** "The NOA must provide the legal and factual basis for any allegation made in the submission or supplement. This would facilitate early consideration of issues likely to be raised in litigation. **This requirement does not circumscribe or otherwise limit the issues and arguments that may be raised in a proceeding brought under the proposed Regulations**. The scope of proceedings would be defined by the pleadings in accordance with prevailing rules and practices."	Although generics will no longer be bound by allegations made in the NOA, they should continue to be held to certain standards. This is important since, as noted by the RIAS, "*The requirement to provide detailed invalidity allegations and supporting documents is intended to allow first persons and patent owners who choose to bring a proceeding under the Regulations to begin reviewing and assessing these documents without having to await service of the second person's pleadings*" [p. 3325]. It is also important since the	"The NOA must provide the legal and factual basis for any allegation made in the submission or supplement. This would facilitate early consideration of issues likely to be raised in litigation. This requirement does not circumscribe or otherwise limit the issues and arguments that may be raised in a proceeding brought under the Proposed Regulations. The scope of proceedings would be defined by the pleadings in accordance with prevailing rules and practices. Asserting significant amounts of new prior art or invalidity allegations by way of

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	[p. 3324]	first person's decision on whether or not to waive the stay needs to be made at the time of commencing the action. As a result, it should be explicitly noted that the emergence of significant amounts of new prior art or invalidity allegations by way of counterclaim, which should have been reasonably anticipated in the NOA, will be considered a failure to act with diligence thereby triggering the court's discretion to lengthen the stay where appropriate.	counterclaim, however, that should have been reasonably anticipated in the NOA can be considered a failure to act with diligence thereby triggering the court's discretion to lengthen the stay where appropriate. Further, the inability to comply with paragraph 5(3)(c)(iii) by reason that relevant documents are not under the control of the second person may also trigger the court's discretion to lengthen the stay where additional time is required to produce these documents. [p. 3324]
27	**Invalidity Allegations: (re: inventor contact)** "Where the second person has alleged invalidity, it may request **contact information for any inventor** who might have information relevant to the allegation and information as to whether the inventor is employed by the first person or the owner of the patent." [p. 3325]	See submission above under s. 5(3.1).	"Where the second person has alleged invalidity, it may request to discover the inventor on a specific allegation in the context of the proceeding." [p. 3325]
28	**Invalidity Allegations: (laboratory notebooks etc.)** "The second person may also request laboratory notebooks, research reports, or other documents that may be relevant to establishing the existence of **a**	See submission above under s. 5(3.1).	"The second person may also request relevant laboratory notebooks, research reports, or other documents ~~that may be relevant~~ sufficient to establishing the ~~existence of a particular property, advantage, or use~~ utility of the

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	particular property, advantage, or use asserted by the second person to form part of invention as of the filing date of the application for the patent." [p. 3325]		subject matter asserted by the second person to form part of invention as of the filing date of the application for the patent." [p. 3325]
29	**Confidentiality of Mandatorily Produced Documents:** "The Proposed Regulations would further stipulate that the Court shall, upon request, treat confidentially any document subject to such confidential rules, subject to such conditions as it considers just. The provision would allow confidential treatment of documents by the Court, while granting the Court some discretion to ensure that requests for confidential treatment are no broader than necessary and do not cover information that must be disclosed to ensure the integrity of the Court process." [p. 3327]	Documents that are required to be exchanged between the parties by the *PM(NOC) Regulations*, outside of the standard discovery process, must be treated as confidential, including a right to file such documents with the Court under seal.	"The Proposed Regulations would further stipulate that the Court shall, upon request, treat confidentially any document subject to such confidential rules, subject to such conditions as it considers just. The provision would allow confidential treatment of documents by the Court, including the right to file this confidential information under seal, while granting the Court some discretion to ensure that requests for confidential treatment are no broader than necessary and do not cover information that must be disclosed to ensure the integrity of the Court process." [p. 3327]
30	**Case Management: (re: not new)** "Early and active case management will help contribute to the timely resolution of proceedings. **To this end, it is proposed that case management be required for proceedings brought under the Regulations**." [p. 3327]	In practice, and by Practice Direction of the Federal Court, case management is already required for all proceedings brought under the *PM(NOC) Regulations*. This statement is misleading in the implication that something new is being provided to gain procedural efficiencies.	"Early and active case management ~~will help~~ is intended to contribute to the timely resolution of proceedings. To ~~this end~~ officially recognize the already established practice it is proposed that case management ~~be required~~ is now reflected as a requirement for proceedings brought under

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			the Regulations." [p. 3327]
31	**<u>Case Management: (re: matters to cover at first CMC)</u>** "The Proposed Regulations would specifically require that a case management conference be convened shortly after a proceeding is commenced. While the Court will be free to address any issue it wishes in the case conference, it is expected that the following types of issues will be addressed: a possible schedule for the proceeding; the extent to which the parties have complied with their obligation to provide documents and information under the Regulations; whether a party seeks to vary or set aside any imposed confidentiality rules; whether the plaintiff(s) intend to seek a sample of the generic product and conduct testing on it; how claims charts can best be used to expedite resolution; the timing for service of any expert evidence; and, the most efficient and effective means of educating the Court about any scientific or technological matters raised in a given case." [p. 3327]	The matter of bifurcation is a key procedural issue that must be addressed at the outset of the proceeding in order to ensure that the case proceeds in a timely manner and those parties with a financial claim stemming from patent infringement can be joined in a subsequent damages action, if any. IMC further reiterates its submission above that bifurcation should be mandated in the *PM(NOC) Regulations*. Trial date scheduling must be accommodated as early as possible so that hearings can be provided within 24 months. The timing of service of expert evidence has been omitted as it is encompassed by the earlier reference to set a schedule. Claim charts and educating the court about scientific matters should be omitted. These are important matters for discussion with the trial judge and case management, but are not necessarily appropriate at the first case management conference. These matters should be left to the discretion of the court	"The Proposed Regulations would specifically require that a case management conference be convened shortly after a proceeding is commenced. While the Court will be free to address any issue it wishes in the case conference, it is expected that the following types of issues will be addressed: <u>bifurcation and inclusion of "persons claiming under the patent";</u> a possible schedule for the proceeding <u>including setting a trial date within 24 months;</u> the extent to which the parties have complied with their obligation to provide documents and information under the Regulations; whether a party seeks to vary or set aside any imposed confidentiality rules; whether the plaintiff(s) intend to seek a sample of the generic product and conduct testing on it; **<u>and the possibility of any other interlocutory motions.</u>** ~~how claims charts can best be used to expedite resolution; the timing for service of any expert evidence; and, the most efficient and effective means of educating the Court about any scientific or technological matters raised in a given case.~~" [p. 3327]

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		and the parties so that no one feels bound to enter into premature discussions.	
32	**Duty to Act Diligently and Reasonably Cooperate:** "Those subject to the proposed Regulations would be expressly required to act diligently in carrying out their obligations under the Proposed Regulations and to reasonably cooperate in expediting any infringement action brought under the Regulations. Where a person fails to comply with these requirements, the Court may shorten or extend the 24-month period during which the Minister is prohibited from issuing an NOC and may also consider such a failure when awarding costs." [p. 3328]	These provisions, including cost sanctions, already exist under the current *PM(NOC) Regulations* [see e.g., s. 6(9)(10), 7(5)], and have long been established to be ineffective owing to the difficulties of establishing that another party failed to act diligently or to cooperate. Accordingly, these are new provisions. Further, no explanation has been provided as to how these provisions will be more effective and/or remedy the failure of the existing provisions.	Omit or clarify that this is not a new provision.
33	**Motions to Dismiss:** "Under the proposed Regulations, a second person may bring a motion to dismiss a proceeding on the ground that it is redundant, scandalous, frivolous, vexatious, or otherwise an abuse of process. This provision would supplement, but would not displace, Rule 221 of the *Federal Courts Rules* (which governs motions to strike pleadings). Parties would remain free to bring motions under that rule if they choose to do so.	It remains unclear to IMC as to why this provision is necessary and not fulfilled by Rule 221. The elaboration provided in the RIAS only further confirms this interpretation. A body of case law unique to the features of the *PM(NOC) Regulations* can still emerge under Rule 221. It is further unclear why a special provision would be provided for a motion to strike, but not for other interlocutory motions, such as	Omit.

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	Inclusion of this provision would, if appropriate, permit development of a body of case law that can account for the unique features of the proposed Regulations." [p. 3328]	a motion to obtain generic product samples. Finally, any right to strike under the *PM(NOC) Regulations*, if included, should not be limited to second persons. A first person should also be able to bring a motion to strike any counterclaim of the second person.	
34	**Compliance with s. 5:** "Given the proposed new requirements placed on second persons under section 5 and the fact that the Minister would no longer be a party to proceedings under the proposed Regulations, it would not be practical to require the Minister to assess compliance with other requirements of that section (e.g. the adequacy of required documentary production). Upon being served with an NOA and accompanying documents, the first person and patent owner would be in a position to bring a proceeding under the proposed Regulations. Whether the second person has failed to comply with broader requirements in section 5 is something that could, if appropriate, be addressed in Court (e.g. in the context of the proceeding or in a subsequent action for infringement)." [p. 3329]	Under s. 7(1) of the current *PM(NOC) Regulations*, the Minister shall not issue an NOC until the second person "complies with section 5". Under the draft *PM(NOC) Regulations*, the Minister need only ensure that the second person complies with paragraph 5(3)(d), which requires only that the second person provide to the Minister: (i) proof of service of the notice of notice of allegation on the first person; and (ii) a copy of the notice of allegation. The draft RIAS justifies this change on the basis of, among other things, that the first person will be in a position to bring a proceeding upon receipt of NOA and accompanying documents. However, a first person will not have access to all the documents referred to in s. 5 to confirm that a second person has complied with the	Omit and amend *PM(NOC) Regulations* accordingly to ensure that the Minister continues to monitor generic compliance with s. 5.

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		requirements. As a result, it is unclear how a first person will address any deficiency in the proceeding (where it only has a right of action in infringement) or in a subsequent action for infringement (whatever subsequent action is being referenced here is entirely unclear). In particular, under s. 5(1), the second person must include the following in their submission to Health Canada (as set out in s. 5(2.1) of the draft Regulations): (a) a statement that the owner of that patent has consented to the making, constructing, using or selling in Canada of the drug for which the submission or supplement is filed by the second person; (b) a statement that the second person accepts that the notice of compliance will not issue until that patent or certificate of supplementary protection, as the case may be, expires; or (c) an allegation that (i) the statement made by the first person under paragraph 4(4)(d) is false [first person owns patent or has an exclusive licence or has	

No.	DRAFT RIAS	IMC Comment	Proposed Change
		consent to list the patent] (ii) that patent or certificate of supplementary protection is invalid or void, (iii) that patent or certificate of supplementary protection is ineligible for inclusion on the register, (iv) that patent or certificate of supplementary protection would not be infringed by the second person making, constructing, using or selling the drug for which the submission or the supplement is filed, (v) that patent or certificate of supplementary protection has expired, or (vi) in the case of a certificate of supplementary protection, that certificate of supplementary protection cannot take effect. [pp. 3339-40] This requirement is substantially similar to the current requirements under s. 5(1). The Minister should still be required to ensure generic compliance with these provisions.	
35	**<u>Renouncing the 24-month bar on NOC issuance</u>** "As before, the proposed Regulations would bar issuance	IMC reiterates its submissions above on the stay. In view of the significance of the length of the stay to	"As before, the Proposed Regulations would bar issuance of an NOC for a period of up to 24 months from the bringing of an

No.	DRAFT RIAS	IMC Comment	Proposed Change
	of an NOC for a period of up to 24 months from the bringing of an infringement action under the proposed Regulations. However, first persons and patent owners could renounce the application of this provision at the time they bring an action under the proposed Regulations. If each party that brings an action in response to the NOA renounces application of the 24-month bar on NOC issuance, the bar would not apply and the Minister would be free to issue a NOC once all requirements under the *Food and Drug Regulations* are met." [p. 3330]	stakeholders, it is reasonably expected that the government should comment on this particular issue in order to explain the consultation process and why the 24-month stay has been retained despite the introduction of more complicated procedures under the right of action.	infringement action under the Proposed Regulations. **[Further commentary required to address the rationale for maintaining the 24 month stay and how it will be accommodated when the proceeding is becoming more complex]** However, first persons and patent owners could renounce the application of this provision at the time they bring an action under the Regulations, **or at any time thereafter upon notice to the second person and the Minister**. If each party that brings an action in response to the NOA renounces application of the 24-month bar on NOC issuance, the bar would not apply and the Minister would be free to issue a NOC once all requirements under the *Food and Drug Regulations* are met."[p. 3330]
36	**Section 8: Liability** "Plaintiffs would be made jointly and severally, or, in Quebec, solidarily, liable **to ensure the second person is made whole**." [p. 3332]	The bolded language is misplaced since the imposition of joint and several liability ensures *enforceability* of a section 8 judgment and not the quantum of the judgment as this language would suggest.	"Plaintiffs would be made jointly and severally, or, in Quebec, solidarily, liable **to assist the second person in the satisfaction of a section 8 judgment**." OR "Plaintiffs would be made jointly and severally, or, in Quebec, solidarily, liable." [p. 3332]

No.	DRAFT RIAS	IMC Comment	Proposed Change
37	**Transitional Provisions:** "The proposed Regulations would come into force on the day section 59 of the *Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act* comes into force and would apply to any matter, other than those that arose or would arise in relation to a NOA that was served before that date. Accordingly, the Regulations as amended would apply immediately upon coming into force to any submission or supplement filed before that date, to the extent that no NOA had yet been served by that date. The current Regulations would continue to apply to any matter that relates to a NOA served on a first person before that day. If a second person had made a statement agreeing to await patent expiry prior to the coming into force of the amended Regulations, that statement would continue to apply to bar NOC issuance until the proposed Regulations are complied with." [p. 3334]	See IMC submissions on the transitional provision above.	"The proposed Regulations would come into force on the day section 59 of the *Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act* comes into force**.** ~~and would apply to any matter, other than those that arose or would arise in relation to a NOA that was served before that date.~~ Accordingly, the Regulations as amended would apply immediately upon coming into force to any submission or supplement filed ~~before~~ after that date**.** ~~to the extent that no NOA had yet been served by that date.~~ The current Regulations would continue to apply to **any submission or supplement filed** ~~any matter that relates to a NOA served on a first person~~ before that day. If a second person had made a statement agreeing to await patent expiry prior to the coming into force of the amended Regulations, that statement would continue to apply to bar NOC issuance **under** ~~until~~ the proposed Regulations ~~are complied with~~." [p. 3334]
38	**Consultation** "Consultation with stakeholders was done on the enabling authority in the Act and the	IMC reiterates its concerns regarding the consultation process.	" … In view of the scope of changes being implemented, the Government will formally solicit comments on its implementation of the

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	proposed Regulations. Both generic and innovative industry members were involved in these consultations over the past two years. In addition, people with particular legal expertise in this area were also consulted. Input gained in consultations was fully considered by the Government." [p. 3334]		proposed Regulations within two years and make any appropriate amendments."

4. THE PROPOSED DRAFT *CSP REGULATIONS* – DETAILED COMMENTS

a. Draft *CSP Regulations*

No.	Draft Section of the CSP Regulations	View of Innovative Medicines Canada (IMC)	Proposed Change
1	<u>Definition of authorization for sale</u> **1(2)** In these Regulations and for the purposes of section 104 of the Act, ***authorization for sale*** means an authorization under the *Food and Drugs Act*, or any predecessor enactment relating to the same subject-matter, that permits the sale of a drug in Canada, but does not include an interim order permitting the sale of a drug under section 30.1 of that Act, a certificate issued under section C.08.015 of the *Food and Drug Regulations*, an exemption permitting the sale of a drug under subsection C.10.002(1) of those Regulations, an authorization under section C.05.006, C.05.008 or C.08.010 of those Regulations or section 67 or 71 of the *Natural Health Products Regulations*. [p. 3302]	Only a medicinal ingredient or combination of medicinal ingredients issued a first NOC is eligible for CSP [s. 106(1)(c) CETA Act; s. 4 *CSP Regulations*]. In contrast, the broad definition of "authorization for sale" in this provision operates in Bill C-30 to allow products previously authorized for regular sale in Canada by way of lesser approval status, (i.e., Drug Identification Number (DIN) or Natural Health Product Number (NHPN)) to bar CSP eligibility of medicinal ingredients approved as new drugs and issued an NOC. Allowing lesser product approvals that require less data or pivotal clinical trials is contrary to the stated purpose of CSP protection: "to partly compensate for time spent in research and obtaining marketing authorization…" [RIAS, p. 3294] DIN and NHPN drugs do not have to satisfy the same onerous New Drug Submission (**NDS**) requirements, and should not be able to bar a medicinal drug approved by way of NDS for the first time from being eligible for CSP.	Apply the definition of authorization for sale set out in s. 4 of the CSP Regulations.
2	<u>Prescribed variations</u> 2. For the purposes of	This provision addresses those variations that will be considered	• Omit, there should be no enumerated list of

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	subsections 105(3) and (4) of the Act, the prescribed variations are (a) a variation in any appendage within the molecular structure of a medicinal ingredient that causes it to be an ester, salt, complex, chelate, clathrate or any non-covalent derivative; (b) a variation that is an enantiomer, or a mixture of enantiomers, of a medicinal ingredient; (c) a variation that is a solvate or polymorph of a medicinal ingredient; (d) an in vivo or in vitro post-translational modification of a medicinal ingredient; and (e) any combination of the variations set out in paragraphs (a) to (d). [p. 3302]	the "same medicinal ingredient" and are thus not entitled to a subsequent individual CSP. • IMC reiterates its submissions above on the prescribed variations, including notably: (1) there should be no enumerated list of excluded variations; (2) salts and esters should be removed from the list; and (3) the proposed list is overly restrictive unduly limiting CSP eligibility.	excluded variations. • Alternatively, salts and esters should be removed from the list.
3	**<u>Timely Filing Requirement</u>** **Countries and period** 6 (1) For the purposes of paragraph 106(1)(f) of the Act, (a) the prescribed countries are (i) the European Union and any country that is a member of the European Union, (ii) the United States of America, (iii) Australia,	This provision addresses the international filing benchmark countries and timeframe. • IMC reiterates its submissions above that the Timely Filing Requirement should be extended from 1 to 3 years.	(b) the prescribed period for filing the application for the authorization for sale is […] (ii) <u>3 years</u> ~~12 months~~, in any other case. [p. 3304]

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	(iv) Switzerland, and (v) Japan; and (b) the prescribed period for filing the application for the authorization for sale is (i) 18 months, if the application for a certificate of supplementary protection was filed no later than the first anniversary of the day on which section 59 of the *Canada–European Union Comprehensive Economic and Trade Agreement Implementation Act* comes into force, and (ii) 12 months, in any other case. [pp. 3303-4]		
4	**CSP Eligibility Exception** **6(3)** For the purpose of subsection 106(4) of the Act, the prescribed period preceding the expiry of the term of the patent under section 44 of the Act, without taking into account section 46 of the Act, is two years. [p. 3304]	Any patent expiry cut-off from CSP eligibility should be as short as possible, and without regard to any hypothetical conflict proceeding, given that those patents closest to expiry represent the circumstance of the longest delay between patent filing and NOC issuance, and are thus most in need of the CSP extension. A 30-day period will maximize the 2-year period of *sui generis* protection that was agreed to under CETA.	**6(3)** For the purpose of subsection 106(4) of the Act, the prescribed period preceding the expiry of the term of the patent under section 44 of the Act, without taking into account section 46 of the Act, is ~~two years~~ three months. [p. 3304]
5	**CSP Application** **6(4)(b)** the filing date of the application for the patent, the	[p. 3304] This provision addresses information to be included in the CSP application.	**6(4)(b)** the Canadian filing date of the application for the patent, the date on which the patent was

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	date on which the patent was granted and the date on which the term of the patent will expire; [p. 3304]	• The provision should specify the specific application filing date required (e.g., Canadian).	granted and the date on which the term of the patent will expire; [p. 3304]
6	**CSP Application Fee** 9 (1) The fee payable on filing an application for a certificate of supplementary protection is $9,011. Beginning on April 1, 2018, the fee increases annually by an amount equal to 2% of the fee payable in the previous year, rounded up to the nearest dollar. [p. 3305]	This provision addresses the CSP application fee. IMC submits that this fee is excessive based on a number of comparators: • Average SPC/Patent term extension fees in key EU countries (limited to maintenance at 2 years) are approximately $5200 CAD; • Patent term extension fees in the US are approximately $1760 USD; • The proposed CSP fee exceeds even those government fees due to register and maintain a regular entity patent for 20 years (approx. $6400). There can be no rationale for this excessive charge given the limited 2-year cap placed on CSP in Canada being far lower than the maximum 5-year cap available in other jurisdictions, yet achieved with significantly lower fees. Further, no statement in the RIAS or *Regulations* addresses whether or not there will be warning notices and/or grace periods, or if CSP protection can be revoked for	• Omit fee. • Alternatively, decrease fee to the EU average at 2 years of approximately $5000 CAD.

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		non-payment.	
7	**Transition** No transition provided.	CSP eligibility does not apply retroactively, and only those drug products issued market authorization after CETA comes into force can be CSP-eligible. A transitional provision, however, similar to that previously employed upon the 2006 introduction of data protection, e.g., eligible for NOCs issued after publication in Gazette I, should be included in the legislation.	Add a transition provision to provide earlier access to CSP for those NOC's issued after *Canada Gazette* Part I.

b. Draft RIAS – *CSP Regulations*

No.	DRAFT RIAS	IMC Comment	Proposed Change
8	**a) Same Medicinal Ingredients (re: appendage)** "The word "appendage" in the context of medicinal ingredients, is intended to refer to a portion of the molecule that is connected or joined to a larger or more important part. It is meant to signify the non-principal part of the molecule which is not principally responsible for the mechanism of action of the medicinal ingredient." [p. 3296]	As previously stated, "appendage" is an unclear use of terminology in this context. The attempt at describing "appendage" on page 3296 of the RIAS, in the second paragraph, does not clarify "appendage", as the explanation remains confusing and may not be correct for all molecules.	• Omit, there should be no enumerated list of excluded variations. • Alternatively, salts and esters should be removed from the list.
9	**b) Authorizations for Sale (re: limited to NOC)**	Only a medicinal ingredient or combination of medicinal	"To be eligible, the medicinal ingredient or combination

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	"To be eligible, the medicinal ingredient or combination cannot have been the sole medicinal ingredient or the combination of all medicinal ingredients in a drug previously authorized for regular sale in Canada (e.g. by way of a Notice of Compliance, Drug Identification Number, Natural Health Product Number)." [p. 3297]	ingredients issued a first NOC is eligible for CSP [s. 106(1)(c) CETA Act; s. 4 *CSP Regulations*]. In contrast, the broad definition of "authorization for sale" in this provision operates in Bill C-30 to allow products previously authorized for regular sale in Canada by way of lesser approval status, (i.e., Drug Identification Number (DIN) or Natural Health Product Number (NHPN)) to bar CSP eligibility of medicinal ingredients approved as new drugs and issued an NOC. Allowing lesser product approvals that require less data or pivotal clinical trials is contrary to the stated purpose of CSP protection: "to partly compensate for time spent in research and obtaining market authorization…" [RIAS, p. 3294] DIN and NHPN drugs do not have to satisfy the same onerous New Drug Submission (**NDS**) requirements, and should not be able to bar a medicinal drug approved by way of NDS for the first time from being eligible for CSP.	cannot have been the sole medicinal ingredient or the combination of all medicinal ingredients in a drug previously authorized for regular sale in Canada (~~e.g.~~ by way of a Notice of Compliance, ~~Drug Identification Number, Natural Health Product Number~~)." [p. 3297]
10	**c) Patent Eligibility (re: remaining patent term)** "The proposed Regulations prescribe that a patent must be in force, which is a condition that applies at the	Any patent expiry cut-off from CSP eligibility should be as short as possible, and without regard to any hypothetical conflict proceeding, given that those patents closest to expiry	Further, in order to apply for a CSP, the patent specified in the application must have at least ~~2 years~~ 3 months remaining of its 20 year term in order to provide sufficient time […] [p. 3297]

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	time of filing a CSP application and at the time of the issuance of a CSP by the Minister. **Further, in order to apply for a CSP, the patent specified in the application must have at least 2 years remaining of its 20 year term** in order to provide sufficient time for the completion of potential conflict proceedings, and administrative action by the Minister." [p. 3297]	represent the circumstance of the longest delay between patent filing and NOC issuance, and are thus most in need of the CSP extension. A 30-day period will maximize the 2-year period of *sui generis* protection that was agreed to under CETA.	
11	**c) Patent Eligibility (re: claims directed to the formulation)** "Also, **claims that are directed to a formulation containing the medicinal ingredient, including compositions, preparations or similar claim types, do not make a patent eligible for a CSP.** A claim to a formulation does not protect the medicinal ingredient or combination of medicinal ingredients *per se*. **A claim to a formulation may be directed, for example, to the improvement of the stability of medicinal ingredients.** This is consistent with CETA, which only requires the protection of the medicinal ingredient or combination of medicinal ingredients when claimed "as such." [p. 3298]	The language in this paragraph needs to be amended to prevent excluding otherwise eligible patents. Many patents that are not "formulation patents" (i.e., the invention is not the formulation) also contain claims for "compositions", "medicaments", "pharmaceutical dosage forms", etc. as a matter of drafting style. The statement is that "[a] claim to a formulation may be directed, for example, to the improvement of the stability of medicinal ingredients." Claims for "compositions", etc. may also be directed to capturing different types of infringing activity related to a medicinal ingredient. For example, a claim for compound X captures infringement in, for example,	A) This paragraph should be removed. Or, alternatively: B) "Also, patents in which the invention is a new formulation, ~~claims that are directed to a formulation containing the medicinal ingredient, including compositions, preparations or similar claim types, do not make a patent~~ are not eligible for a CSP. ~~A claim to a formulation may be directed, for example, to the improvement of the stability of medicinal ingredients.~~ This is consistent with CETA, which only requires the protection of the medicinal ingredient or combination of medicinal ingredients when claimed "as such". [p. 3298]

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		the form of making the active ingredient, whereas a claim for a pharmaceutical composition of compound X captures, for example, sale of a finished product.	
12	**d) Timely Submission** To incentivize the early introduction of innovative drugs into the Canadian market, filing of a Canadian application for authorization for sale for a drug containing the *same* medicinal ingredient as that contained in a drug for which an equivalent submission for a marketing approval was previously filed in any of the countries prescribed in paragraph 6(1)(a) of the proposed Regulations must be done within a reasonable period **(timely submission requirement)**. The proposed Regulations prescribe the period and the relevant countries. [p. 3298]	In addition to the above submissions, IMC further rejects that this provision be referred to as the "timely submission requirement". It is an entirely new provision that does not exist as part of any other CSP/patent restoration scheme in the world. The connotation that any new drug submission filed after the arbitrary one year cut-off selected is "untimely" is without basis or justification. There is no deadline by which a new drug submission needs to be filed in Canada.	Delete reference to the "timely submission requirement"
13	**"One-for-one" Rule** "Given that the CSP regime is being established and largely defined by the *Canada-European Union Comprehensive Economic and Trade Agreement Implementation Act*, which is amending the *Patent Act*, the	IMC disagrees that the proposed regulations will not independently increase or decrease the administrative burden on businesses, or that this burden is "limited". The proposed regulations will increase administrative burden on the innovative pharmaceutical industry in	Omit and/or address.

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	proposed Regulations will not independently increase or decrease the administrative burden on businesses. Limited additional burden on the pharmaceutical industry may result from obligations under CETA, which are non-discretionary and cause the proposed Regulations to fall under a "One-for-One" rule carve-out (i.e. regulations that implement non-discretionary obligations)." [p. 3300]	cost and in resources. IMC also does not agree that the additional burden on the innovative pharmaceutical industry results from obligations under CETA. Much of the additional burden comes from the amendments that have been made that are not required under CETA, for example, the "timely filing requirement" requiring a Canadian drug submission filing within 1 year of other prescribed jurisdictions in order to be CSP-eligible.	
14	**Small business lens** "The small business lens does not apply to this proposal, as there are insignificant costs on small business." [p. 3300]	The costs to small businesses are not "insignificant". For example, the requirement to file a regulatory submission by a certain date to qualify for a CSP could be very costly in terms of resources required. Further, the application fee is not an insignificant cost for a small business.	Omit and/or address.
15	**Consultation** "Consultations with stakeholders were done on the CSP regime outlined in the Act and the proposed Regulations as well as the application fee. Both generic and innovative industry members were involved in the consultations conducted over the past two and a half years. These consultations included	IMC reiterates its concerns regarding the consultation process.	" ... In view of the scope of changes being implemented, the Government will formally solicit comments on its implementation of the proposed Regulations within two years and make any appropriate amendments."

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	input from the various stakeholders which was fully considered by the government." [p. 3300]		