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Via: electronic mail

RE: Notice of Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017

To Director General:

Intellectual Property Owners Association (IPO) appreciates the opportunity to provide comments in response to the Department of Industry's "Notice of Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, 2017" dated 13 July 2017.

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes around 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans over 30 countries. IPO advocates for effective and affordable IP ownership rights and provides a wide array of services to members, including supporting member interests relating to legislative and international issues; analyzing current intellectual property issues; information and educational services; and disseminating information to the general public on the importance of intellectual property rights.

IPO supports the proposed Regulations, which as before, would allow a second person to seek compensation for losses suffered during the period they were kept off the market as a result of an unsuccessful or discontinued proceeding having been brought against them under the Regulations. IPO wishes to emphasize, however, the importance that any section 8 damages awarded pursuant to a proceeding under the Regulations must be based on damages proven to have actually been suffered by each generic claimant, and that a patentee's total liability for all generic claimants' lost profits under section 8 for a given product may not exceed the profits collectively lost on account of the Regulations. As such, the unit sales upon which loss calculations are based may not collectively exceed 100% of the incremental units of generic product that the generic claimants would have sold had the patentee not brought proceedings under the Regulations.

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IPO also has concerns about changes which have been proposed to the Regulations. IPO-member patent holders might face challenges from multiple second persons pertaining to the same product in Canada. Thus, IPO is more specifically concerned that aspects of the proposed Regulations expand liability beyond damages which have been suffered by a particular second person (or persons).

**Start Date for Liability**

The proposed Regulations specify that all plaintiffs in an infringement action brought under the proposed Regulations would be liable for losses suffered by the second person after the later of (i) the date of service of the NOA that allowed the action to be brought, and (ii) the date when the NOC would have issued in the absence of the Regulations. Despite specific references to these dates, the Court would still have discretion to specify another start date, provided that date is determined to be more appropriate than the date specified in the proposed Regulations.

IPO is concerned that the Regulations as drafted appear to remove any obligation of the second person to serve its NOA promptly after filing for regulatory approval. As such the proposed Regulations diminish the obligation of the second person to mitigate its losses and correspondingly expand the potential liability of patent holders. As drafted, the proposed Regulations negate any link which should exist between the 24-month period and the time it takes for ANDS product approval for the second person. Second persons should have the obligation to promptly engage the Regulations by filing an NOA with minimal delay after filing for regulatory approval with Health Canada.

**End Date for Liability**

The proposed Regulations would no longer limit liability to losses suffered prior to a specified end date. This would allow a second person to seek compensation for any loss suffered as a result of delayed market entry after the date specified in the proposed Regulations. It would be left to the Court to determine whether the loss is properly recoverable.

IPO is concerned that the proposed Regulations could dramatically increase liability and uncertainty for patent holders. Under the current Regulations the first person's liability is bound by a definitive end date. The new proposed Regulations are vague in allowing for compensation by the first person or patent owner on the basis of "any loss" regardless of when the loss is suffered. This proposed change to remove an end date for liability will cause greater uncertainty to first persons and patentees in assessing their potential exposure, both at the outset of a section 6 action and during any subsequent section 8 action. This uncertainty will lead to more litigation proceeding to trial and fewer settlements of section 8 claims, leading to increased litigation costs to the parties and a greater use of Court resources in resolving section 8 disputes under the proposed Regulations.

Furthermore, the proposed Regulations as drafted do not appear to remove that liability if the trial decision is reversed on appeal in favor of the patent holder. Collectively IPO's concerns about the start and end date for liability are compounded by the possibility that the total liability for patent holders may exceed the total damages suffered by second persons (as discussed above).

**Deletion of Invalidated Patents from the Patent Register**

Finally, under the proposed Regulations, a patent declared ineligible for inclusion on the Register would be deleted but not until conclusion of any appeal to the Federal Court of Appeal. The same delay does not apply however to deletions from the Register after an initial filing of invalidity. Patents declared invalid would be added back to the Register if and when that holding is subsequently reversed or set aside.

IPO is concerned that patent holder's enforcement rights are unfairly hindered if a second person files a NOA during the period in which a patent has been removed from the Register but is later reinstated. In this scenario, second persons may circumvent valid patent rights. This is of particular concern when a second persons cross-references another's submission. There is no rationale for treating patents not eligible for inclusion (which are deleted from the Register) and patents invalidated (which are removed from the Register pending appeal). In both circumstances patents should remain on the Register pending appeal.

We thank you for considering IPO's comments and would welcome the opportunity to provide further information that might assist your efforts on these matters. In the future, it would be beneficial if more time can be allowed for submission of comments for important proposed regulation changes such this.

Sincerely,



Mark W. Lauroesch  
Executive Director