BROGAN INC.

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By Fax: 613-952-7626

April 15, 2005

Dear Ms. Dupont:

Brogan Inc. has worked with pharmaceutical manufacturers for 15 years to ensure that the rules of the PMPRB are understood and prices are not excessive. The PMPRB has invited comments on its proposed changes to the Regulations published in January 2005 and Brogan Inc. is in an informed position to provide such feedback.

The published document indicates that the overall rationale for the changing of the Regulations is to "modernize" the rules and increase the efficiency by which the PMPRB carries out the price review process. This objective is admirable. However, the changes proposed do not appear to move toward more efficient review. In fact, these proposals are either unnecessary or counterproductive in this regard. Furthermore, I suggest that at least two of the proposed changes are completely precluded by the wording of the Patent Act.

The proposal requiring patentees to provide the intended price to the PMPRB in advance of first sale is in direct contradiction to the wording of the Patent Act. The Board's position is that: "Regulations to include proposed price when the patentee has formed the intent to sell would be consistent with the Act". Section 82 (1) of the Patent Act is very clear in regards to the information that is required from patentees. Price is not part of the legislated requirement. However, Section 82 (2) states that the Board has the authority "by order" to compel a patentee to provide price information. Section 82 (4) further clarifies that even where a Board order is issued, the information cannot be required more than 60 days before the intended date of first sale. A regulation requiring the provision of this information more than 60 days in advance of the first sale is contradictory to this provision.

Section 82 of the Act is the only provision in which information relating to the future is contemplated. The proposal to require notification of a proposed price increase is recommended for addition to Section 4 of the current Regulations. Section 4 of the Regulations is intended for the purpose of paragraphs 80 (1) (b) and (2)(b) of the Patent Act, cited below:

80 (1) (b) The price at which the medicine is being or has been sold in any market in Canada and elsewhere.

80 (2) (b) the price at which the medicine was sold in any market in Canada and elsewhere during the period in which the person was a patentee of the invention

The wording of these provisions very clearly excludes any future intention. Only current and past pricing can be requested based on the above-cited sections of the Act.

The two proposed changes to the Regulations relating to the provision of intended prices exceed the limitations stipulated in the Act and are inappropriate and likely unlawful.

The Patented Medicine Prices Review Board was set up due to the amendment of the Patent Act. Its mandate was carefully defined to comply with the constitutional delegation of responsibilities between the federal and provincial levels of government. Federal Parliament implemented a scheme within the Patent Act that called for a review of patented drug prices for that reason. Since the Constitution has not changed, one may suspect that this move toward price control is not within the powers of the Federal government. In addition, the PMPRB espouses the principle of Voluntary Compliance and has gone to great lengths to establish a set of transparent Guidelines to permit this principle to be carried out by the industry. By requiring advanced notification of pricing, the Board is abandoning this founding principle. Nowhere in the proposal document has this intention been expressed or justified.

Furthermore, in rationalizing the notification of proposed price, the Board provides no further insight into the benefit gained from this change. If efficiency is the only sought after gain, adding an additional step of reviewing an intended price does not appear to achieve the stated objective. Thus, no justification is provided as to why this advanced information is necessary for new product.

A justification was provided, however, for requiring notification of a proposed price increase. "Making notification of a proposed price increase a mandatory reporting requirement under the Regulations would ensure that the PMPRB receives this information in a timely manner thereby allowing the prompt review of any price increase. This would allow the PMPRB to notify patentees sooner if there appear to be pricing issues." Nevertheless, these proposed regulatory changes remains outside the framework of the Patent Act.

In both of the proposals under discussion, the review of the price in advance of implementation increases the regulatory burden both for patentees and the PMPRB. This adds an additional step to the already cumbersome process and decreases efficiency thus cannot be expected to improve the timeliness of reviews, unlike the stated objective.

The rationale for proposing changes to the Regulations requesting details on the calculation of net prices and revenues is, for the Board, to have a better understanding on how the patentee arrived at the calculation of the average price per package for a medicine. It is not clear how this information is necessary given that the Board generally achieves its mission by "promoting voluntary compliance with Guidelines" and "reviewing prices and taking remedial action when necessary". Requesting detailed information from patentees now will increase significantly the regulatory burden on patentees. This increased burden is not justified since there is no evidence that current practice is not adequate for the Board to carry out its mandate in a timely and efficient manner.

In addition, it is not clear what type of information is required by the patentee, what is the level of detail to be provided and in which form will this information be provided. The Board should provide a copy of the "appropriate form" they referred to in the proposed change in order to give an idea of what sort of information needs to be provided by the patentees. Patentees can then assess the feasibility and burden level of providing such detailed information to the Board, in particular given its necessity for the Board. Brogan Inc. is of the idea that providing detailed information to the Board on the calculation of the net price and revenues of patented medicines will only increase the burden on patentees and significantly increase the workload of the Board Staff creating possible inefficiencies in the price review process.

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Furthermore, it is evident that the Board is seeking open-ended authority to compel disclosure of business strategies that may be highly commercially sensitive. These disclosures may require significant resources to compile and would add to an already significant regulatory burden imposed by the federal government. The vagueness of the current drafting is incongruent with the existing requirements, which are clearly laid out in the Regulations and supported by forms included within the regulatory document. Again, no rationale is provided to justify the need for additional information. The only rationale provided is to gain "a better understanding". That is not a justification and regulation cannot be promulgated for the purpose of a "fishing expedition" by the PMPRB.

It is surprising that the fourth change proposed by the Board is to include the product monograph. Currently in the Guidelines, patentees are required to file product monograph. In addition, the Board implemented a new practice in January 2005 stipulating the deadline for provision of product monograph if a patentee wishes that its product be reviewed in the next Human Drug Advisory Panel meeting. Clearly, insufficient time has past since the publication of this new deadline to assess its efficacy in optimizing the timeliness of monograph receipt by PMPRB Staff.

One thing that is not addressed by the Board's Notice & Comment document is the consequence of failing to comply with the Regulations. Under Section 101 of the Patent Act the Board is granted the power to create Regulations and to levy penalties against patentees who fail to comply with the data filing requirements in the Regulations. "On summary conviction", these include imprisonment and fines of up to $25,000 per day. Thus, regardless of the policy implications of the specific additions to the Regulations being proposed, these will increase the simple number of potential punishable offences.

The ongoing efforts by the PMPRB to decrease the review time for new and existing drug prices is commendable. The proposals are contrary to the intent, and in some case the clear wording, of the Patent Act. Given the rare instances of the need for action by the PMPRB, increased regulation is unnecessary. After all, the number of cases of excessive pricing is very small over the 15 years the PMPRB has been in place. All but a few have been resolved through voluntary action by the patentee.

Sincerely,

Tom Brogan
President

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