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October 24, 2016

Patented Medicine Prices Review Board
(Rethinking the Guidelines)
Box L40, 333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1
CANADA

Via e-mail to: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

RE: Questions to initiate the discussion on modernization of the Patent Medicines Pricing Guidelines

Dear Patented Medicine Prices Review Board:

I write on behalf of the Section of Intellectual Property Law of the American Bar Association ("the Section") to express its interest in ensuring that new patented medicines in Canada maintain pricing levels that correspond to their innovation and benefit to patients as well as encourage continued innovation and improvement in the treatment of medical disorders. These views have not been approved by the House of Delegates or the Board of Governors of the American Bar Association and, accordingly, should not be construed as representing the position of the Association.

New medicines are developed for the improvement of patient health and for the advancement of science. However, this development is an expensive endeavor. According to PhRMA, the development costs required to bring a new drug to market today are around $2.6 billion. Not surprisingly, these costs need to be recovered to maintain the development process. Moreover, commercial interests require some level of profit to maintain viability and to encourage further innovation and improvement.

Reinvesting Revenue into Research and Development

Research and development (R&D) spending for the biopharmaceutical industry is among the highest of any industry. According to recent studies, the average R&D spend for the industry is approximately 18% of revenues. Only the semiconductor industry is higher, reverting between 25 to 28% of revenues back into R&D, with most other industries reverting much less. These include the chemical, aerospace and defense, and electronics industries, all of whose R&D spend is in the low single digits. Success from this massive investment in biopharmaceutical R&D is far from assured. This reinvestment of revenue into R&D by the biopharmaceutical industry benefits patients throughout the world, through the introduction of new medicines as well as the advancement of science.

Importantly, this benefit to patients and science is global, regardless of where the R&D occurs. Thus, the price of a new, therapeutically beneficial, patented medicine should not be diminished based on where the R&D for that medicine occurred. The location of R&D facilities depends on many factors: the size and global reach of the entity performing the research; the business, regulatory, and legal environment in the R&D location; the ability to attract and retain skilled researchers on location, etc. The location of drug research and development in no way negatives the therapeutic benefit or innovation associated with a new drug, and should have no impact on its price.

Relevant Factors for Determining Therapeutic Benefit, Innovation, and Pricing

Certainly, the costs of medicines should be based on the costs of development with some level of reasonable profit which is not excessive. Nonetheless, determining whether a price for any product is reasonable or excessive is a difficult endeavor.

The Section believes that categorizing new patented medicines based on the degree of therapeutic benefit is rational. The currently used "primary factors" of increased efficacy and/or reduction in incidence or grade of important adverse reactions should continue to weigh heavily in the pricing determination. The "secondary factors," including considerations such as compliance improvements leading to improved therapeutic efficacy and disability avoidance, are also important measures.

Additionally, the innovation associated with a new patented medicine is helpful in categorizing the medicine. For example, several factors which are not generally considered (*viz.*, mechanism of action, new chemical entity, or different pharmacokinetic profile) are indeed indicative of innovation and may be associated with treatment of different and, often, new patient populations. When new patients become treatable due to the inventiveness of a patented drug—no matter how small the treated population is—that drug should be considered among the highest level of therapeutic benefit and should be eligible for pricing that is justified by its therapeutic benefit.

Receiving a patent is a quid pro quo for providing an improvement over the prior art. Similarly, a new patented medicine that is an improvement over medicines currently available deserves to receive a higher price. Such improvement can come in many ways. The Section believes that limiting what is considered an improvement, such as, for example, by decreasing the factors used to demonstrate therapeutic improvement for the simple purpose of limiting the price of a patented medicine, would be very detrimental to innovative efforts.

Even in the Canadian pharmaceutical market, pricing is often fundamentally driven by competition. This is true even among medicines which are not true equivalents. If a drug that has greatly improved therapeutic benefits is allowed to compete in the market, purchasers will decide between all the choices available to them. For example, if a drug is too expensive, either it will not receive approval for listing on the provincial formularies or buyers will purchase an older or generic product that may not be quite as efficacious or may have different side effects but is lower in cost than the name brand product. However, if a patented medicine is therapeutically beneficial and reasonably priced, some

purchasers will buy this product and patients will benefit. If the drug is highly beneficial, a disproportionate amount of spend on that drug could result. However, it is important to note that the use of therapeutically beneficial drugs often results in an overall positive impact on future healthcare costs related to the disorder. For example, improved treatment of diabetes may avoid hospitalizations, amputations, and even patient blindness. Just because a patented medicine works so well that many patients purchase it to improve their health thereby resulting in a large percentage of money being spent on that drug, simply does not indicate or support the premise that the drug is excessively priced.

Bargaining power of the purchaser also weighs into the purchase price. In many countries, large purchasers negotiate the price for large quantities of medicines, providing rebates and discounts based on guaranteed amounts. The established purchasing system in Canada is segmented, not consolidated among the provinces and territories, and accordingly has diminished bargaining power. However, the setup of the Canadian system is a separate issue and should not affect the maximum price set for a patented medicine on the open market, which can be negotiated downward by the purchasers.

Of the section 85 factors used to determine whether a patented drug is being sold or has been sold at an excessive price, the first factor—the prices at which the medicine has been sold in the relevant market—is the most useful. This is especially true because of the manner in which drug prices are listed and then negotiated downward through rebates and discounts. It is difficult to establish what the true price is in other markets, and this value will likely be higher than the actual price. However, the prices at which the drug is sold in the relevant market (i.e., Canada) can be determined and compared. It is also difficult to compare the price of a certain drug to other drugs in the "same" class, as many different factors relate to the therapeutic benefit and innovation of a patented medicine. The most important factor should be the one which is measurable without requiring extrapolation to prices in other countries or comparative factors among different drugs; it should be based on the price at which the drug was actually sold in the relevant market.

Periodic Reassessment of Pricing

The Section believes it is reasonable to reassess the pricing for patented medicines periodically to ensure that the pricing is consistent with the marketplace. According to IMS Health in 2016, the invoice prices of branded U.S. drugs have increased by 12 to 14% over each of the past two years; however, the true price increases (including rebates and discounts) have been less than 3%. This amount is consistent with consumer price index increases, which are allowed in the current Canadian pricing system as well as other pricing systems around the world. Periodic reassessments would allow for such changes while ensuring that the pricing remains reasonable and not excessive. Notably, pricing for branded biopharmaceuticals do not typically rise by the large percentages which have been seen recently for unbranded drugs.

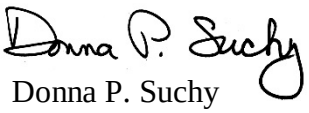
We suggest that any changes that are made to the pricing Guidelines based on the current consultation should be applied only to new patented medicines going forward and not to all medicines that are currently in the system. It is possible that, if the Guidelines

are changed, some medicines which are currently on the market and beneficially treating patients in Canada will no longer be considered commercially sustainable and will be pulled from the market. Such a removal could harm patients currently using that drug. By applying the changes prospectively, companies will decide before launch whether the product will be commercially viable under the Guidelines and such disruption of treatment will not occur.

ABA IP Law Section's Interest in Future Consultation

The Section, as a stakeholder which is extremely interested in intellectual property and the pricing of patented medicines globally, wishes to thank the PMPRB for this opportunity to express its opinions. We would appreciate an invitation to participate in stakeholder hearings and future public consultations on the topic as it progresses. If you have any questions or would like to discuss any of the comments above, either I or another member of the Section's leadership will gladly respond.

Very truly yours,



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