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June 28, 2017

Attention: Patented Medicines Regulations Consultations
70 Colombine Driveway, Tunney's Pasture
Mail Stop 0910, Floor 10, Building Brooke Claxton Building
Ottawa, Ontario K1A 0K9
Canada

Re: Response to Patented Medicines Regulations Consultations

On behalf of several of the leading life sciences innovation organizations in Canada, I am writing to express our deep concern regarding the potential negative impact and unintended consequences on Canada's innovation ecosystem stemming from the proposed changes to the PMPRB regulations.

The federal government has publicly stated the importance of innovation to the future of the Canadian economy, and backed this up recently with an "innovation budget." Within this federal innovation budget there are many commitments to promoting an innovation economy: a nearly \$1B supercluster initiative, a renewed VCAP program, and a commitment to develop a Canadian IP strategy to support the innovation agenda – just to name a few. We applaud this commitment and significant investment of public funds to continuing to grow Canadian innovation.

However, we are concerned with the recent PMPRB consultation paper released to Health Canada. The language used and some of the proposed changes in this document run directly counter to the federal government's innovation agenda.

Patents and IP Policy

Patents were created to reward and encourage innovation. Patents in of themselves are not monopolies; labelling them as such has been termed an "obfuscation" by U.S. Judge Howard T. Markey, who, as Chief Justice of the United States Court of Appeals, was a prominent intellectual property jurist.¹ While we acknowledge the need to ensure value for taxpayers, undermining the very nature and purpose of patents is a slippery slope for a country whose economic future is vested in knowledge-based industries. Whatever changes are implemented to PMPRB should be viewed through this lens and carefully articulated so as to not devalue the importance and impact of IP in Canada.

Science is changing at an ever-increasing pace and as the pharmaceutical industry adapts to these changes, policy makers need to adapt as well. Our understanding of the human genome is enabling personalized and more targeted medicines but it also means smaller patient populations. This is particularly true in areas of rare diseases. Regulatory hurdles to ensure patient safety and therapeutic efficacy have also become more stringent, adding to the cost of clinical trials and drug development. Many of the most innovative new medicines are now complex biologics which are more difficult to manufacture and commercialize than traditional small molecule drugs. All of these factors weigh into the cost of a new medicine; companies must recoup their investments in short timelines while facing the threat of competition from other innovators and eventually, generics. Canadian policy makers must ensure that pharmaceutical innovators have a predictable and stable IP and procurement environment that rewards innovation appropriately.

There is also a clear articulation in the consultation paper that favourable pricing does not equate to increased R&D investment by the pharmaceutical industry. However, the consequence of an unpredictable and hostile

¹ Chief Justice Howard T. Markey; Carl Schenck, A.G. v. Nortron Corp., 713 F.2d, 782, 786 n. 3 (Fed. Cir. 1983), source: www.ipwatchdog.com: Debunking the Myth that Patents Create a Monopoly, Gene Quinn, Feb. 2017

pricing and IP environment will most certainly be reduced investments in R&D, clinical trials, and other forms of investments. And Canada does have plenty to lose.

Our Capacity for “Made-in-Canada” Innovation

Canada’s pharmaceutical industry is an anchor for the nation’s life sciences sector and innovation economy. In Ontario alone, this industry represents a third of the total employment in life sciences and more than half the total revenues of the entire life sciences sector.² It is also the highest-paying sub-sector, with average annual wages 30 per cent higher than the provincial average¹, with similar data applicable to the province of Quebec. In 2016, there were 23 biopharmaceutical companies on the list of the top 100 corporate R&D spenders in Canada, accounting for 13.3% of the national total, which is a 16.4% increase from the prior year.³ Furthermore, 4 of the top 10 most research-intensive firms were biopharma companies (including all of the top 3) and, biopharma represented 7 of the top 10 companies by growth of R&D expenditure year over year.

There is also an implication that PMPRB policies only impact large, multinational firms but this too is an obfuscation. The point of government investments in life sciences innovation is to create a “Blackberry of Biotechnology” – a made-in-Canada global success story. However, any Canadian success story in biopharma will be subject to the same legislation, pricing, and IP environment to which we subject multinational companies. In essence, we are making our policy bed and eventually we will have to lie in it. Worse, these policies will decelerate our ability to create and sustain made-in-Canada successes.

One of the world’s largest pharmaceutical companies, Johnson & Johnson, chose Toronto for its first JLABS innovation centre outside the United States, and recently announced a first-of-its-kind JLABS POD in Edmonton. Merck also recently announced the launch of the Oncopole in Quebec, an investment of \$15 million that will translate to advances in oncology patient care. Clearly, Canada currently has the scientific and entrepreneurial prowess to attract this calibre of investment. These partnerships also demonstrate pharma’s commitment to work with Canadian innovation centres to fill gaps in funding and commercialization expertise. However, we cannot expect this support by multinational pharmaceutical companies to continue indefinitely without reciprocation. We must demonstrate, as a nation, that we are committed to innovation by aligning our public policies to match our values.

PMPRB continues to use an antiquated approach to assessing R&D investments of pharmaceutical firms by limiting metrics to SR&ED eligible expenditures. As such, it fails to recognize a significant portion of commonly occurring R&D expenditures. The lack of recognition of these expenditures serves as an additional disincentive to further R&D investments.

Impact of Pharmaceutical Pricing

The discussion paper also focuses much time and effort on determining what constitutes “excessive” pricing of pharmaceutical products. Life sciences organizations across Canada recognize the immense challenges associated with managing public healthcare costs and ensuring patients and taxpayers receive innovative interventions at a non-excessive price. However, PMPRB must recognize that pharmaceutical development is a complex process that varies widely from product to product, taking into account: biologics versus small molecule; disease pathways and mechanisms of action; and personalized medicine and market size (i.e. rare diseases). These are just a few factors that can increase the development cost of pharmaceutical products and, in turn, the price for the end user.

PMPRB has a duty to acknowledge, understand, and factor in these complexities when determining what constitutes excessive pricing based on comparison with other markets. This is especially important with new medications that treat an unmet need. To ignore these complexities by comparing new medicines to other

² Life Sciences Ontario Sector Report 2015

³ RESEARCH Infosource Inc.; Canada’s Top 100 Corporate R&D Spenders

therapeutic classes devalues scientific discovery and undermines innovation. It directly contradicts the very kind of policy approach needed to build a viable innovation agenda for Canada.

The best way PMPRB can address these complex factors is through fair market comparison with treatments for the same disease or condition. PMPRB has a well-established system for international market comparison, including the highest international price comparison (HIPC) test, which is demonstrated to be effective and fair. Arbitrarily changing this system to a lowest international price comparison (LIPC) to artificially lower prices by preferentially excluding certain markets such as the US is likely to create negative consequences, including divestments in R&D, a stalling of innovation, and the unavailability of new medicines in Canada.

In conclusion, Canada's significant investments in research and education have resulted in world-class scientific discoveries. Governments at all levels are developing policies to nurture and further develop these assets in order to grow Canada's knowledge economy and ensure our future prosperity. In reviewing pricing policies, PMPRB must look through this innovation lens to align with these values. Failing to do consider these larger and long-term goals will be contrary – and ultimately detrimental – to Canadian innovation.

Sincerely,

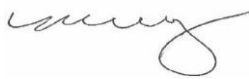


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Cc: The Hon. Jane Philpott, Minister of Health

The Hon. Kirsty Duncan, Minister of Science

The Hon. Navdeep Bains, Minister of Innovation, Science and Economic Development

The Hon. Eric Hoskins, Ontario Minister of Health and Long-Term Care

The Hon. Reza Moridi, Ontario Minister of Research, Innovation and Science

The Hon. Gaétan Barrette, Quebec Minister of Health

The Hon. Dominique Anglade, Quebec Minister of Economy, Science and Innovation

The Hon. Sarah Hoffman, Alberta Minister of Health

The Hon. Deron Bilous, Alberta Minister of Economic Development and Trade