Professor Aled Edwards
Chief Executive
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Denis Martel,
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Innovation, Science and Economic Development Canada
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RE: Consultation Period for Canada's New Intellectual Property Strategy

Dear Mr. Martel,

We write in response to the Innovation, Science and Economic Development Canada (ISED) consultation process regarding Canada's New Intellectual Property Strategy. ISED's primary goal is to foster a more robust and competitive innovation ecosystem in Canada with improved outcomes for commercialization and growth. The promotion by ISED of increased uptake and use of the intellectual property system – in particular the patent regime – by those within the Canadian innovation ecosystem, however, may ultimately undermine rather than further this important objective. We submit that ISED should instead promote openness in the generation and commercialization of scientific discovery as its primary policy platform for bolstering innovation in Canada. The process of renewal of Canada's approach to intellectual property under the current government represents an exciting opportunity to become a global innovation leader through open science.

The traditional rationale for patents has been to provide incentives for the generation, disclosure, and commercial exploitation of new innovations. It must be recognized, however, that a patent is, at its theoretical best, a necessary evil in furtherance of these ends. A patent on an innovation creates a government-sanctioned monopoly over products incorporating that innovation, which reduces social welfare through restricted access and higher pricing, with sometimes severe distributive consequences (those least able to pay are, of course, the first to be priced out of an uncompetitive market). A primary theoretical justification for this marked departure from the otherwise bedrock commitment to competitive markets in capitalist economies is that the 'dynamic' benefits of increased generation and translation of knowledge over time outweigh these 'static' costs to society.

In reality, however, despite decades of proliferation of patenting in more and more subject matter domains and earlier and earlier in the innovation process, there is no evidence that this explosion of patenting has improved the rate of innovation or productivity growth in the economy. To the contrary, the excesses in the patent system have become pathological, with negative consequences not just for competitive markets but also for innovation and economic growth. An important reason for this is that the proliferation of monopolies from previously issued patents acts as a real deterrent to new innovators, who are rightly concerned about a web of potential lawsuits and hold-up licensing demands. A new product in a modern technology market incorporates scores of components, each

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potentially subject to a plethora of patents on trivial aspects held by a range of divergent rights holders. As a result, large incumbents engage in costly (and ultimately socially wasteful) arms races to acquire massive defensive patent portfolios that create barriers to entry for new, innovative entrants. Conversely, both large incumbents and would-be entrants must navigate a minefield of patent rights held by non-practicing entities (NPEs) who seek to extract rents without contributing to social value through commercializing competing goods or services.

Even in the drug discovery context – the one area where the patent system is touted as indispensable – the proliferation of upstream patents in the earlier stages of the innovation cycle has led to a number of pathologies. For example, there has been an ongoing decline in R&D productivity, with the current cost of developing a new therapeutic estimated at greater than USD $2 billion (including the cost of failures) and with newly marketed patented medicines costing tens to hundreds of thousands of dollars per year per patient as a result. Attempts to patent genes, proteins, and entire compound classes before therapeutic proof of concept has been achieved in humans, engender lengthy delays in disclosure of research through publication and in sharing of research reagents and data amongst groups of researchers with complementary skill sets but residing at different companies or institutions. This proprietary approach to early stage biomedical research not only retards the rate of progress but also leads to multiple, independent teams investigating the same therapeutic target in secret. If the target ultimately proves undruggable – as many often do for a range of unpredictable reasons – the social resources wasted on research are many times higher than they would have been under a regime of open disclosure.

The utility of patenting in upstream biomedical research is also suspect for a number of other reasons. First, the early stages of drug discovery are often largely funded through government grants at universities. Not only is it morally questionable to provide exclusive rights to private parties over the fruits of publicly funded research, but this public funding also largely abrogates the need to incentivize capital formation to finance these discovery activities, thus vitiating one of the primary justifications for patents. Second, there is really no correlation between the potential social value of a candidate therapeutic and its patentability. For example, a compound and its theoretical use in treating a disease may have enormous potential social value but may very well have been rendered obvious from the perspective of patent law through prior disclosure in the literature. The singular reliance on patenting early in the drug discovery process means this candidate will be discarded because it cannot be patented. Finally, even once on the market, a patented medicine is almost uniformly the subject of extremely costly patent litigation and of strategic behavior by the brand company to extend its monopoly through tactics like ever-greening and product switching.

In the end, the rate of innovation and commercialization in new markets is often driven by first-mover advantages, efforts to establish strong brand recognition, and competitive pressures from other would-be entrants nipping at the heels of those earliest to market. Excess patenting, on the other hand, can promote incumbency and complacency as would-be entrants are bullied out of the market.

As such, we believe that, instead of contributing to the above pathologies by encouraging more and more patenting in the Canadian innovation ecosystem, ISED should embrace open science as its primary innovation policy platform. Where complete openness would lead to an underproduction of innovative activity, industry-specific policy approaches are preferable. For example, in the context of drug discovery, more narrowly drafted patent claims that are specific to later-stage, optimized drug candidates actually entering clinical trials can be encouraged, without promoting the types of broad, upstream patents that slow down or deter innovation by other groups. Moreover, the huge costs associated with commercializing a new candidate therapeutic (largely the costs of late stage clinical trials) can be further incentivized with regulatory exclusivities that apply to the particular therapeutic once it is on the market but that do not gum up the upstream discovery efforts of others or monopolize an entire therapeutic hypothesis. Canada already provides new chemical entity (NCE) exclusivity for new molecules and is considering adopting an orphan drug regime along the lines of what presently

exists in the United States and European Union. These exclusivity regimes can be extended or modified as appropriate without having deleterious consequences across the entire innovation spectrum in the same way as patents. The Canadian government could also increase public funding of late phase clinical trials for locally developed candidate therapeutics, particularly for those resulting from an open innovation ecosystem such as the one we advocate here.

It is worth noting that Canada is already a burgeoning leader in open innovation. For example, the Structural Genomics Consortium, based largely at the University of Toronto and also at Oxford, promotes open drug discovery through patent-free sharing of probe compounds that inhibit new and potentially druggable targets. The SGC's open release and sharing of an inhibitor probe for bromodomain-4 (BRD4), for example, has led to a range of clinical programs investigating candidate therapeutics by different groups for a range of diseases. In a world where the probe was kept in secret or subject to exclusive patent rights, this entire realm of downstream innovation could have been substantially delayed or foregone. As another example, the Montreal Neurological Institute (MNI) at McGill University, one of the world's preeminent brain research centers, has recently adopted a patent-free approach to increasing knowledge dissemination and translation. As a third example, Grand Challenges Canada, an important international player in financing health innovation for development, utilizes a 'Global Access' approach to intellectual property rights in innovations that it supports. While innovators are not discouraged from patenting, they must grant non-exclusive license rights to use their innovations in regions where they themselves are unable to achieve widespread access, including for the poor, and must commit to publishing their results in open access journals shortly after completing their research.

For the foregoing reasons, we submit that, instead of facilitating increased reliance on patenting, Canada's New Intellectual Property Strategy should be to nurture, promote, and replicate these and other approaches to openness across the entire Canadian innovation ecosystem.

Yours sincerely,

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