INNOVATIVE MEDICINES CANADA / MÉDICAMENTS NOVATEURS CANADA

Submission

Consultation on Canada's New Intellectual Property Strategy

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INTRODUCTION

Innovative Medicines Canada (IMC) is the national voice of Canada's innovative pharmaceutical industry. We advocate for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our members' commitment to being valued partners in the Canadian health and regulatory system.

Innovators cannot undertake the tremendous expense and experimental risks associated with the development of new medicines without some reasonable assurance of intellectual property (IP) protection and – by extension – reasonable and stable market exclusivity. As such, we congratulate the Federal Government for announcing the Innovation and Skills Plan in Budget 2017 and for its commitment to develop a new comprehensive IP strategy. IMC appreciates this opportunity to submit comments to the Government of Canada towards the development of Canada's new IP strategy.

In this document, we encourage the Federal Government to continue to pursue legislative, regulatory and policy initiatives that demonstrate meaningful commitments to strong IP protection, innovation, and appropriate reward for value in Canada's biopharmaceutical industry. We also express our support for IP-driven, public-private collaboration for fostering innovation and bringing research to life, and make recommendations for financing innovation and setting standards within the Canadian Intellectual Property Office (CIPO).

IMC is also willing to meet with government representatives to discuss the contents of this proposal in more detail, and would welcome any opportunity to participate further in the implementation of the IP Strategy.

1. STRENGTHEN INTELLECTUAL PROPERTY RIGHTS

Canada's IP regime is a key driving force behind the generation of IP and, by extension, innovation in the biopharmaceutical sector. Strong and predictable IP is especially important given that, although a patent lasts for 20 years in Canada, it takes on average 10 years or more for a new medicine or vaccine to go through all the requisite trial and approval stages – often leaving companies on average less than 10 years to recover their investment[1]. Developing complex treatments to fight such illnesses as diabetes, heart disease or cancer is extremely expensive, time consuming and risky.

These risks are growing alongside Canada's rapidly evolving biopharmaceutical market: new product development is on the rise in areas such biologics and orphan drugs. Some of the most promising therapeutic products are biologic drugs that are the result of advances in human genomic research. The average biologic does not cover its research and development (R&D) costs until 17 years after it starts being sold[2]. It is a similar situation with "orphan drugs", which refers to medications used to treat rare diseases, typically affecting fewer than five in 10,000 people. Appropriate protection of IP rights has the potential to mitigate these risks by acting as an incentive for biopharmaceutical companies to make the enormous R&D investments necessary for new medicines and vaccines while also encouraging homegrown R&D.

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[1] J JA DiMasi, HG Grabowski and RW Hansen (2014). "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. Briefing: Cost of Developing a New Drug". November 18, 2014, online: Tufts Center for the Study of Drug Development at Tufts University http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf, last accessed 12 May, 2016.

[2] John A. Vernon, Alan Bennett & Joseph H. Golec, "Exploration of potential economics of follow-on biologics and implications for data exclusivity periods for biologics," (2010) 16 *BUJ Sci. & Tech. L*. 55.

We encourage the Federal Government to continue to pursue legislative, regulatory and policy initiatives that demonstrate meaningful commitments to strong IP protection, innovation, and appropriate reward-for-value in Canada's biopharmaceutical industry. We highlight priorities for our membership that are deserving of decisive government action below, specifically with regards to regulatory data protection, patent term restoration (PTR), and IP resolution mechanisms.

(a) Regulatory Data Protection

The protection of undisclosed test data submitted for the approval of innovative drugs seeks to incentivize local and foreign pharmaceutical companies to make the enormous R&D investments necessary for new medicines and vaccines by protecting the confidential clinical trial data that manufacturers must submit to Health Canada for health and safety approval.

In Canada, data protection regulations were enacted in 2006 under the *Food and Drug Regulations*[3] in order to implement the data protection obligations under both NAFTA and TRIPS.[4] The *Food and Drug Regulations*, at section C.08.004.1, entitle innovative drugs to an eight-year term of data protection (plus a possible additional six months for submissions that include pediatric studies), and prevent a second-entry manufacturer from filing a submission for a copy of that innovative drug for the first six years of the eight-year period. Canada's eight-year base term of data protection applies to all drugs, including biologics.

However, both Health Canada and Canadian courts have interpreted and upheld a strict interpretation of the "previously approved" and "variation" aspects of the definition of "innovative drug" – thereby diluting the benefits of the data protection to a certain extent. New drugs are being improperly excluded from this benefit even though their regulatory approval similarly required voluminous undisclosed data, the origination of which involved considerable effort and expense.

Although IP has been addressed as a trade barrier in Canada's recent trade agreements and negotiations, data protection has only been considered in terms of the length of time innovative drugs must be protected. While the base term of data protection is clearly important, by not harmonizing Canada's rules and interpretation that classify a drug as an "innovative drug", Canadian innovators are limited in their ability to compete on a more even playing field with international pharmaceutical firms under these trade agreements. Further, the current interpretations discourage foreign investors from placing additional pharmaceutical R&D funds in Canada. Most importantly, the narrow interpretation of what products qualify for data protection is detrimental for Canadian patients, who may not have access to innovative drugs available to patients in other nations[5].

Accordingly, the data protection provisions of the *Food and Drug Regulations* should be amended to address the restrictive case law that has emerged from the judicial system. Section 30(3) of the *Food and Drugs Act*[6] forms the basis for the legislative authority regarding the data protection regulations. These regulatory amendments should be accompanied by a Regulatory Impact Analysis Statement that clearly describes the underlying intent: to protect innovation and to encourage companies to submit products to Health Canada for safety approval to improve access for Canadian patients to new medications.

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[3] *Food and Drug Regulations*, CRC, c 870.
[4] *Ibid* at C.08.004.1 (2).
[5] Kendall, Megan, and Declan Hamill. "A Decade of Data Protection for Innovative Drugs in Canada: Issues, Limitations, and Time for a Reassessment." *Biotechnology law report* 35.6 (2016): 259-267.
[6] *Food and Drugs Act*, RSC 1985, c F-27.

Moreover, consideration should be given to adapting data protection regulations to reflect the rapid rise in new product development in the area of biologics. In order to encourage research and investment in biologic drugs, consideration should be given to offering longer periods of data protection to help drug developers recover their R&D costs – for example, a 12-year period as provided in the United States.

(b) Patent Term Restoration (PTR)

As in other countries, Canada's drug approval processes significantly erode the effective duration of the 20-year patent term for biopharmaceutical products of innovative companies. PTR is remedial time that can be added at the end of a patent's life to help compensate issues such as clinical trial time, unreasonable patent office delays, or delays due to marketing approvals. Since innovators and the patients that would benefit from their therapies are being penalized for regulatory and other delays beyond their control, these gaps make it harder for Canada to compete for investment internationally since other developed nations have recognized that innovators should be entitled to recoup some of their R&D costs to encourage further innovative activity.

As a demonstration of its role in fostering innovation on a global scale, PTR has been negotiated with the IP obligations under several of Canada's most important international trade treaties. Notably, the final text of the Canada-European Union (EU) Comprehensive Economic and Trade Agreement (CETA) indicates that Canada has agreed to implement a "*sui generis* protection" period of between 2 to 5 years[7] (noting, however, that the Government of Canada separately stated that it only plans to implement the minimum level of 2 years required by CETA). The US, in comparison, offers patent restoration terms of up to 5 years, depending upon the length of the clinical and/or regulatory delays (as does Australia, Switzerland, the EU's Member States, and Japan).

Bill C-30 (the CETA implementation act) created a set of conditions that must be satisfied in order for patentees to be eligible to apply for PTR by way of a Certificate of Supplementary Protection (CSP), including for situations where a foreign application for marketing approval is submitted in another country (for the same medicinal ingredient or combination of medicinal ingredients) before the filing of a marketing application in Canada. In those cases, companies will only be eligible to apply for a CSP in Canada if the Canadian marketing application is filed before the end of a 1-year prescribed "reasonable" period that will begin on the day the first application for marketing approval was submitted.

With respect to the draft CETA implementation regulations (the *CSP Regulations*) that specify both the countries in question and the "reasonable" period, we have advanced a number of principles that we feel should be incorporated:

- To the extent that Canada wishes to tie CSP eligibility to marketing approval processes in other countries, Health Canada should adopt a regulatory approach that is consistent with those other countries. Otherwise, it is unreasonable to mandate that regulatory filings in those countries will be used as the metrics to assess whether or not a filing in Canada is indeed timely;
- Conversely, to the extent that Canada's regulatory approach differs from other countries, we recommend that the prescribed timeframes account for the fact that a significantly longer period of time will be needed by companies to adopt their non-Canadian submission materials to meet Canadian requirements; and
- Finally, we understand that regulatory processes in Canada and elsewhere are not static, but will inevitably change over time. A timeframe in the regulations that is reasonable today may

[7] Canada-European Union Comprehensive Economic and Trade Agreement, at Article 20.27(6).

not be reasonable several years from now if either Canadian or non-Canadian regulatory approval processes change. The CSP regulatory mechanism should acknowledge this principle and be flexible enough to change over time.

IMC encourages the Canadian Government to enhance the new PTR mechanisms for delays caused by both regulatory processes and by patent office delays. Moreover, any implementation of PTR that does not confer full patent rights, e.g., that would provide an exception for "manufacturing for export" or other infringing activities, would not be consistent with the fundamental purpose of restoring a portion of the patent term lost during the marketing approval or reimbursement review processes and should not be permitted.

(c) Effective Resolution Mechanisms for Patent Disputes

The effective enforcement of patent rights relies upon mechanisms such as patent linkage and effective preliminary injunctive relief, which provide for the early resolution of patent disputes before potentially infringing follow-on products enter a market.

Canada's linkage proceedings are governed by the *Patented Medicines (Notice of Compliance) Regulations* [the *PM(NOC) Regulations*], which include several deficiencies that weaken Canada's enforcement of patents, including the nature of patent dispute proceedings and a lack of an effective right of appeal for patent owners. Recent jurisprudence under the regulations has also resulted in a heightened level of liability for patent owners akin to punitive damages.

Under the Canadian *PM(NOC) Regulations* regime, Health Canada must withhold regulatory approval for a generic drug up to a maximum of 24 months for an expedited judicial process to test infringement and/or invalidity. If an innovator fails in its application to uphold its patent, a generic may be granted an NOC shortly thereafter and the Canadian Federal Court has held that it would not hear any appeal by an innovator company. Conversely, should a generic lose its NOC proceeding, it retains its right to appeal.

Meanwhile, the CETA text contains a commitment to provide all litigants with equivalent and effective rights of appeal in countries, such as Canada, that rely on "patent linkage" mechanisms. The intention behind this negotiated outcome was to address this asymmetry in legal rights that flows from Canada's current *PM(NOC) Regulations* regime under which patent owner and generic producers do not have equal rights of appeal.

Bill C-30 provides a framework for establishing patent linkage mechanisms under the current *PM(NOC) Regulations* relating to pharmaceutical products, but also provides new regulatory-making powers regarding such actions, including defences, remedies, joinder, rights of action, consolidation, the decisions and orders the court may make and any appeals from those decisions and orders. As per the amended *PM(NOC) Regulations* that have recently been released for public consultation, it has become clear that litigants will continue to have to navigate even more complex post-CETA pharmaceutical actions within the same 24 month stay period that exists under the current system. There is no evidence that such complex actions can be completed in two years. To the contrary, not a single patent infringement/invalidity action has been determined within two years since May 2009.

The Canadian Government should agree to early and effective resolution mechanisms for patent disputes, and provide an opportunity to assert all relevant patent rights prior to generic launch without regard to whether there is a patent listed on the patent register. The Canadian Government should further seek to address any asymmetry in legal rights that flows from the parties' linkage regimes. Since the *PM(NOC)*

Regulations are being substantially altered as a result of CETA, the stay period should be extended by six months to a maximum of 30 months. In addition, the Court should be granted jurisdiction to extend the stay if the Court is unable to come to a decision within 30 months. The CETA text to provide all litigants an equivalent and effective right of appeal should form the basis for this position.

2. PUBLIC-PRIVATE IP COLLABORATION

(a) Transfer of Patent Rights

IMC strongly supports the Government's interest in improving access to IP, as indicated by the present consultation's questions regarding information and knowledge exchange. It is in this context that IMC wishes to express its support for improved public-private collaboration in IP.

The U.S. offers one example of how legislated public-private collaboration can successfully enable technology transfer to the benefit of the economy. The University and S*mall Business Patent Procedures Act of 1980*, better known as the "Bayh-Dole Act" was passed with the objective of improving the commercial development of federally-supported research. Specifically, it sought to address the fact that – without clear patent rights and the economic incentive of exclusive licensing – private firms would not devote scarce resources to the highly uncertain development efforts needed to bring laboratory research to the pharmaceutical market.

The Bayh-Dole Act allows schools and other institutions to own title to the patents arising directly from their research activities and license the rights to promising technologies to private sector partners for commercialization. These companies then assume the full risk of development and cost for commercializing the few technologies that eventually prove to be technically and economically viable products. The Act has been credited with a tenfold increase in patents generated by U.S universities (between 1980 and 2002, alone)[8], as well as having a significant impact on the U.S. economy (with one studying finding that between 1996 and 2013, academia-private sector patent licensing across all industries bolstered U.S. GDP by up to $518 billion and supported up to 3,824,000 U.S. jobs[9]).IMC recommends that the Government explore the potential for public-private initiatives when devising programs under its new IP strategy to facilitate the innovation ecosystem in Canada.

(b) Knowledge Exchange

There is also room for growth with respect to information exchange about the value of IP for innovators. Canada's new IP Strategy presents an opportunity for ISED and CIPO to develop and improve outreach and educational programs to promote the value of IP amongst university and small- and medium-sized enterprise (SME) researchers.

For example, the Johnson & Johnson family of companies (of which Janssen is an IMC member) launched JLABS in 2016, with a vision of providing a capital efficient and flexible platform where emerging companies could transform scientific discoveries into breakthrough healthcare products. JLABS supports entrepreneurs

[8] PhRMA, "How the Bayh-Dole Act Propelled U.S. Global Leadership in Life Sciences", online: http://phrma-docs.phrma.org/sites/default/files/pdf/bayh-dole-act-white-paper-summary.pdf, last accessed 14 July, 2017.
[9] Pressman L, Roessner D, Bond J, Okubo S and Planting M. "The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2013". Mar 2015., online: https://www.bio.org/sites/default/files/BIO_2015_Update_of_I-O_Eco_Imp.pdf, last accessed 11 July, 2017.

by helping them overcome common barriers to discovery and development, such as the large initial investment of time and money that is necessary to establish working labs and other business infrastructures.

JLABS is a clear demonstration of IMC's membership's willingness and ability to collaborate with governments and other stakeholders to increase knowledge with respect to the importance of IP rights in the life sciences sector.

3. TAX INCENTIVES

As noted above, a reasonable and predictable life sciences IP regime will help to secure investments in innovation. In addition to this, IMC notes the potential benefits of subsidies, grants, or tax incentives to encourage Canadian companies to file for IP protection. Quebec's First Patent program, for example, provides a non-repayable contribution of up to 50% of eligible expenses, to a maximum of $25,000, for patent applications made by Quebec SMEs. Likewise, the provincial government in Saskatchewan recently announced the creation of a "Patent Box", providing tax incentive for Saskatchewan companies that commercialize patented technologies in the province. The European Union offers another model from which to draw best practices, with at least 12 European countries operating "IP Box" regimes that provide substantially reduced rates of corporate tax for income derived from important forms of IP.

Tax incentives have also been implemented to encourage innovation in the area of orphan drugs. The vast majority of the rare diseases for which orphan drugs would be beneficial are linked to genetic factors, so development of new treatments is very costly and the market is very small, making cost recovery more difficult than for drugs with larger potential patient populations. In order to encourage research and investment in orphan drugs, many countries have launched incentive programs, several of which offer significant terms of market exclusivity[10] and tax credits to lower the cost of conducting human clinical trials on such a small population. Under the *Orphan Drug Act* in the U.S., for example, biopharmaceutical firms that receive an orphan drug designation are entitled to a 50 % tax credit for clinical trial expenses. Individual member countries of the EU, as well as Japan and Taiwan, also offer their own separate tax incentives to firms.

IMC supports financial incentives as a key mechanism for improving innovation in health care, and recommends that the Government consider implementing IP Boxes across Canadian jurisdictions. In order to derive the maximum benefit for Canadian patients, we recommend that consideration be given to a strategy that includes a tax credit for income generated from products where significant clinical trial work has been conducted in Canada.

4. UPDATE CIPO SERVICES AND POLICIES

IMC views the IP Strategy as an opportunity to update CIPO services and policies, several of which present obstacles to patenting amongst our member companies. Better funding, human resources, and technical assistance have the potential to improve issues in the following areas:

- Client-centred behaviour of the Commissioner of Patent and Registrar of Trademarks;
- Implement reliable and accountable system for electronic filing/prosecution of IP applications, including correspondence, and fees;
- Efficiency and accountability of CIPO in the handling of client files;
- Provide appropriate legal training to Examiners, including up-to-date training on jurisprudence;

[10] Eligible orphan drugs in the US can qualify for 7 years of market exclusivity; up to 10 years of market exclusivity is available in Europe.

- Improve the quality of examination to focus on search and substantive matters rather than formalities;
- Reliability and consistency of staff; and
- Online access to CIPO documents and records, including more efficient patent database search tools, full patent file histories and current patent application status. The substantive part of CIPO file wrappers are available on-line although the ease of download user interface could be improved.