



## **Final Report for Industry Canada**

**With respect to the study**

**International Patent Strategies for  
Biopharmaceutical Small and Medium-sized  
Enterprises (SMEs) in Canada**

March 2013

# INTERNATIONAL PATENT STRATEGIES FOR BIOPHARMACEUTICAL SMALL AND MEDIUM-SIZED ENTERPRISES (SMEs) IN CANADA

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# Key Findings

The following are the key findings of this Report:

- Patents are critical to an SME's success, regardless of whether its success depends on attracting investors or attracting deals from large international pharmaceutical companies, referred to in this Report collectively as a group as "Big Pharma" or individually as "a/the Big Pharma."
- A sound patent strategy must include both offensive and defensive aspects because patent litigation invariably accompanies a successful biopharmaceutical product.
- Executive and board attention to the patent strategy of an SME is a necessity.
- SMEs could benefit from learning from the patent strategies of SMEs that have been successful in attracting investment from investors or deals with Big Pharma. Successful patent strategies are typically those that include the involvement of management in their formation and execution, repeated and consistent alignment between the patent strategy and the business strategy, rigour in cost control and preparedness in answering difficult patent-related questions from potential investors and partners as well as from Big Pharma.
- Successful SMEs in Canada are often characterized by having an innovation that is capable of being put into practice, that is patentable, that has a commercial market and that someone will pay for.
- SMEs that are interested in attracting deals from Big Pharma would benefit from following a patent strategy that aligns with the growth strategies of the Big Pharma that they are targeting (strategies such as conforming to trends in the industry and geographical areas for expansion).
- Given the challenging investment climate for SMEs in Canada, the patent strategy of an SME is under increased scrutiny while it seeks out investments.
- The "patent cliff" facing Big Pharma works to SMEs' advantage in that Big Pharma is continuing to look for licensing deals or to acquire SMEs; patents are a critical part of those deals.
- Ownership of patents must be dealt with early and effectively. Questions or uncertainty regarding the ownership of intellectual property rights can extinguish deals very quickly.
- Because companies need substantial resources to be successful, a Canadian strategy of putting more resources, including patent strategy support, into a smaller number of carefully selected SMEs is likely to lead to increased success in this sector.

# Background, Methodology and Approach to the Study

This Report was commissioned by Industry Canada to determine the current state of international patent strategies for biopharmaceutical small and medium-sized enterprises (SMEs) in Canada. The authors were selected to prepare the Report on the basis of their significant U.S., Canadian and international expertise in the subject matter of this Report.

The authors prepared this Report by drawing on their decades of experience in

- deals involving international patent strategies of SMEs;
- advising investors (U.S., Canadian and international) in SMEs on the viability of patent strategies; and
- advising Big Pharma to assess whether to license patents from SMEs or to acquire SMEs because of the value of their intellectual property (IP).

The Report was reviewed by other experts in the field at Torys LLP (including Conor McCourt and Andrew Shaughnessy) and in consultation with CEOs and other executives of SMEs, Big Pharma and investors in the sector. Some experts the authors spoke to, have provided their input, but wished to remain anonymous. The authors are grateful to and thank all of those persons involved.

# Main Content

## a) Overview of the Biotechnology Industry in Canada

### i. Current state of biotechnology industry

“Biotechnology” enterprises are enterprises that manufacture, process, use and otherwise exploit biological materials. Biotechnology enterprises exist in various sectors. In Canada, the market can be segmented into five sectors: (1) medical/healthcare; (2) food and agriculture;<sup>1</sup> (3) environment and industrial processing; (4) service providers; and (5) technology services.<sup>2</sup> Medical/healthcare is the largest segment of the biotechnology market in Canada.<sup>3</sup> It accounts for 67.4% of the market’s total value and brought in total revenues of \$2.3 billion in 2011.<sup>4</sup> This Report focuses on the medical/healthcare (i.e., biopharmaceutical) sector.

Funding for Canadian biopharmaceutical companies declined after the 2008 global financial crisis. However, biopharmaceutical companies with innovations that are protectable, have good market potential and strong management teams are able to obtain various sources of funding, including angel, venture capital (VC), private equity and non-dilutive government and quasi-government funding.<sup>5</sup> Moreover, recent success by U.S. venture capitalists and other foreign investors investing in Canadian biopharmaceutical companies bodes well for foreign funding of other high-quality small and medium-sized biopharmaceutical enterprises (SMEs). While investors are more selective than they were prior to 2008, the Canadian biotechnology market is expected to grow with a forecasted compound annual growth rate of 6.8% in the period 2011–2016.<sup>6</sup> Canadian biopharmaceutical companies would benefit by this projected growth.

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<sup>1</sup> Food and agriculture accounts for 23.8% of the market and contributed revenue of \$0.8 billion in 2011. MarketLine Industry Profile: Biotechnology in Canada, July 2012, at page 9.

<sup>2</sup> *Ibid.*

<sup>3</sup> *Ibid.*

<sup>4</sup> *Ibid.*

<sup>5</sup> Ernst & Young, Beyond Borders: Global Biotechnology Report 2012, at page 1.

<sup>6</sup> MarketLine Industry Profile: Biotechnology in Canada, July 2012, at page 11.

**A sound patent strategy and robust patent position for the key assets of the Company have always been, and remain, one of the pillars for building value in a biotech company. Firms need to consider, and act on, both defensive and offensive strategies with respect to filing, prosecution and licensing in order to accomplish this. Additionally, attention must increasingly be paid to the competitive IP position of the Company in the emerging markets that play an expanding role in the growth strategies of the pharmaceutical industry. Early and continued executive and Board attention to the construct, maintenance, and growth of the Company's IP position is a must-have in biotech.**

*Peter Thompson, MD — OrbiMed Advisors LLC<sup>7</sup>*

The extent to which companies that manufacture, use or sell products rely on patents to exclude other companies from manufacturing, using or selling the products claimed in the issued patents differs by sector. Although the biopharmaceutical sector relies heavily on patents for these purposes, in general, some parts of the sector, including healthcare, are less dependent on patents (though healthcare continues to explore the availability of software patents and business method patents).

For a Canadian biopharmaceutical company to commercialize a product or process that is an innovation, the following four criteria must be met: (1) the innovation must be capable of being put into practice; (2) the innovation must be protectable; (3) the innovation must have a commercial market; and (4) the innovation must be one that someone will pay for. Many innovative products of SMEs meet one or two of these criteria, but few products meet all four. International patent strategies must be developed on the basis of these criteria. Thousands (and even millions) of dollars can be spent on an international patent strategy; but if the product of the SME does not have a market or if there is no assurance that someone will pay for the product, the chances of the SME succeeding are low.

## **ii. Current state of biopharmaceutical companies**

The biopharmaceutical market in Canada is characterized by well over 200 start-ups and SMEs and a small number of large pharmaceutical companies, many of which manufacture or sell biopharmaceutical products.<sup>8</sup> Big Pharma with an interest in biopharmaceutical products in Canada includes Abbott, AbbVie, Amgen, AstraZeneca, Biogen Idec, Bristol-Myers Squibb, Celgene, Eisai, Eli Lilly, Genentech, Genzyme, Gilead, GlaxoSmithKline, Hoffmann-La Roche, Janssen (Johnson & Johnson), Merck, Monsanto, Novartis, Pfizer, Sanofi, Shire, Takeda and Teva.

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<sup>7</sup> Peter Thompson, MD, is currently a venture partner with OrbiMed (San Francisco, CA). He has over 20 years of industry experience. He co-founded and was CEO of Trubion Pharmaceuticals, co-founded Cleave Biosciences, and serves on the boards of Cleave, Anthera, Methygene, Principia Biosciences and Response Biomedical.

<sup>8</sup> See membership list of BioteCanada, the Canadian industry organization whose members have an interest in biotechnology products and services ([www.biotech.ca](http://www.biotech.ca)).



Historically, Canada has produced proportionately many more early-phase biopharmaceutical companies than the United States and other countries with vibrant biotech industries. However, the lengthy and risky path to product development and commercialization, the large amounts of capital required and the difficulty in obtaining such capital have led to a contraction in the number of SMEs in the sector in Canada. Some of this contraction is a necessary result of market forces, which over time will likely produce a stronger group of industry players. A Canadian strategy of allocating more resources to a smaller number of carefully selected SMEs is likely to lead to increased success in this sector because companies need substantial resources to succeed.

In 2012, Canada saw a number of large acquisitions in the biopharmaceutical sector: Enobia, a phase II drug company was acquired by Alexion for an upfront payment of \$610 million and up to an additional \$470 million; YM Bioscience was acquired by Gilead for \$516 million; and Cytochroma was acquired by Opko Health for an upfront payment of \$100 million and up to an additional \$190 million.

### **iii. Current state of spinoff companies from Canadian universities**

Canadian universities' policies regarding IP and ownership vary widely, with some universities taking the position that the inventor owns 100% of the IP, including patents (e.g., University of Waterloo<sup>9</sup>) and other universities taking the position that the university owns 100% of the IP, including patents (e.g., UBC).<sup>10</sup> Canadian academic institutions have lagged behind their U.S. counterparts<sup>11</sup> in commercializing their innovations because of academia's historical views regarding the appropriateness of commercialization; however, due to the large number of invention disclosures and recent efforts to accelerate commercialization and bolster the industry, the country's top hospitals and universities are expected to show strong growth in commercialization. Success will depend in large part on the ability of universities, hospitals and investors to discern the potential commercial winners and their willingness to invest time and resources in only those projects.

Canadian hospitals and universities have enjoyed some success in this area. One such story is Sentinelle Medical Inc., one of whose founders, Cameron Piron, was the first Canadian to be named R&D Magazine's 2008 Innovator of the Year.<sup>12</sup> Piron began developing his new technology as a graduate student working with Dr. Donald Plewes, a senior scientist at Toronto's Sunnybrook Research Institute. In 2004, Piron and two Sunnybrook colleagues co-founded Sentinelle Medical to commercialize the

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<sup>9</sup> <http://uwaterloo.ca/secretariat/policies-procedures-guidelines/policy-73-%E2%80%93-intellectual-property-rights>.

<sup>10</sup> UBC Policy 88 ([www.uilo.ubc.ca](http://www.uilo.ubc.ca)) - <http://www.universitycounsel.ubc.ca/files/2010/08/policy88.pdf>.

<sup>11</sup> <http://triplehelixinnovation.com/canadian-universities-the-innovation-gap-and-leaping-the-landline/3501>.

<sup>12</sup> [http://www.mri.gov.on.ca/english/ontario\\_innovates/sentinelle.asp](http://www.mri.gov.on.ca/english/ontario_innovates/sentinelle.asp).

Vanguard Breast MRI system.<sup>13</sup> The company was eventually sold to Hologic Inc. for \$85 million, plus a two-year contingent earnout.<sup>14</sup>

#### iv. Current state of Big Pharma's interest in Canadian biopharmaceutical companies

**For the pharmaceutical industry, the last days of 2012 will mark the end of the patent cliff, an approximately 18-month stretch during which major drug companies lost exclusive rights to many billion-dollar-selling drugs. The cliff could be seen coming for a long time. Indeed, efforts to mitigate the expected loss in profits kicked in years ago as drugmakers struggled to invent and commercialize replacement blockbuster drugs. As, one by one, those efforts failed, the industry turned to more creative ways of going over the cliff and surviving. They shifted their focus to developing drugs for unmet medical needs, expanding in growing geographic markets, licensing drug candidates from biotech companies, buying biotech companies, partnering with innovative research organizations, and gutting bloated research organizations. Some companies played the “if you can't beat 'em, join 'em” card by bolstering generics portfolios.<sup>15</sup>**

Big Pharma continues to show great interest in biopharmaceutical companies, including Canadian companies. Many high-revenue-producing drugs have gone off patent in recent years and Big Pharma has focused intensely on filling the product pipeline. According to CNBC, “The big U.S. and European drug companies are dealing with a ‘cliff’ of their own as blockbuster drugs lose their patent protection.”<sup>16</sup> It is estimated that the cliff could cost the industry \$25 billion.<sup>17</sup> These companies are looking to SMEs to help them fill their pipeline.

As Canadian SMEs have struggled in recent years to obtain financing, Big Pharma's interest in licensing or acquiring products from SMEs has increased. It is well recognized that changes within Big Pharma, including the patent cliffs, have helped to buoy the biopharmaceutical sector and that Big Pharma no longer prefers its own R&D to outside innovation.

Indeed, one of Canada's leading pharmaceutical companies, Valeant Pharmaceuticals International Inc. (formerly Biovail), is an example of a Big Pharma in acquisition overdrive. Valeant has revamped its strategy in recent years, focusing on M&A to become “the largest publicly traded Canadian-based drug company, sporting a \$20-billion (Canadian) market capitalization.”<sup>18</sup> In recent years, Valeant has cut its

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<sup>13</sup> <https://info.uwaterloo.ca/www/profiles/profile.php?id=149>.

<sup>14</sup> <http://investors.hologic.com/index.php?s=43&item=406>.

<sup>15</sup> <http://cen.acs.org/articles/90/i50/Beyond-Patent-Cliff.html>.

<sup>16</sup> <http://www.cnbc.com>, January 13, 2013.

<sup>17</sup> <http://www.cnbc.com>, January 10, 2013.

<sup>18</sup> <http://www.theglobeandmail.com/report-on-business/rob-magazine/how-valeant-became-canadas-hottest-stock/article8889241/>

own research and development budget (now less than 5% of sales), favouring acquisitions of outside products.<sup>19</sup> Valeant has made 57 acquisitions since 2008.<sup>20</sup>

#### **v. Current state of investors' interest in Canadian biopharmaceutical companies**

The global financial crisis that began in 2008 has had implications for SMEs, particularly because of the capital-intensive nature of biotech R&D. As a result, Canadian SMEs have had to cut costs and develop new and innovative approaches to make R&D more efficient and sustainable. While these efforts have resulted in some improvement, the larger issue facing investors and SMEs is a funding and innovation business model that is out of step with the current environment. SMEs in Canada have responded by partnering with companies from other industries, partnering with the public sector to create investment funds, tapping into public markets and securing VC financing by using a lean start-up methodology that focuses on developing a technology as efficiently and cost-effectively as possible.<sup>21</sup> Attractive Canadian SMEs have also been successful in raising money from countries outside Canada.<sup>22</sup>

In an effort to stimulate innovation and improve access to VC financing, the Canadian government has announced various programs, including the Venture Capital Action Plan, which will make \$400 million available to help increase private sector investments in the next seven to ten years.<sup>23</sup>

#### **vi. Canadian biopharmaceutical SMEs and Contract Service Providers**

One issue that can arise between Canadian biopharmaceutical SMEs and contract service providers relates to the ownership of IP. If the Canadian SME requires a hospital, research institute or another organization to assist in the research, development or early-stage clinical trials of a biopharmaceutical product, the IP-ownership provisions in the contract between the SME and the other entity are key. Specifically, the SME must ensure that the contract contains one of the following options: (1) assigns ownership of all IP developed by the other entity to the SME; (2) provides that all IP is jointly owned and specifies the rights of and restrictions on each party to the jointly owned IP; (3) exclusively licenses all IP to the SME; or (4) gives the SME the option to acquire or exclusively license the IP. From the SME's perspective, the first option – the contract assigns ownership to the SME – is the most desirable and the one on which investors and Big Pharma would place the most value.

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<sup>19</sup> *Ibid.*

<sup>20</sup> *Ibid.*

<sup>21</sup> *Supra* note 5 at page 55.

<sup>22</sup> Richard Blackwell, "Small Canadian biotech firm lands financing," *The Globe and Mail*, July 14, 2011, <http://www.theglobeandmail.com/report-on-business/small-business/small-canadian-biotech-firm-lands-financing/article586920/>; Julius Melnitzer, "Lawyers, U.S. firms filling Canada's biotech void," *Law Times*, June 13, 2010 <http://www.lawtimesnews.com/201006147036/Headline-News/Lawyers-US-firms-filling-Canadas-biotech-void>.

<sup>23</sup> Nelson Wyatt, "Harper reveals venture capital investment details," *The Globe and Mail*, <http://www.theglobeandmail.com/report-on-business/small-business/sb-money/business-funding/harper-reveals-venture-capital-investment-details/article7328067>.

When SMEs reach the stage in which they conduct clinical trials through professional contract service providers or use contract research organizations, the standard IP provisions generally provide that IP developed in the course of the trial is owned by the SME.

## b) Overview of Typical Patent Strategies of SMEs

**When it comes to the life sciences, and biotechnology and pharmaceuticals more specifically, patents are valuable currency that pave the road for investors. It is critical for small and medium enterprises to ensure their key intellectual property (IP) assets are protected, starting with the core IP up to improvements and refinement of product details. SMEs should strive for a robust patent portfolio, which means paying close attention to research developments and seeking patent protection where indicated. Patent strategy should be developed early on and is a dynamic element of the business – a solid strategy will attract investors and development partners who recognize that strong patent protection is an indicator of successful products in the marketplace.**

*Rafi Hofstein, PhD — President and CEO MaRS Innovation*

### i. Different strategies depend on products (chemicals, biologicals, diagnostics / instrumentation)

A brilliant discovery (even one that is Nobel Prize-worthy) must be capable of being put into practice in order to be commercialized. Commercialization typically requires the creation of either a product (i.e., biopharmaceutical) or a service such as a procedure or diagnostic test, which might involve a biopharmaceutical or determine which biopharmaceutical is the recommended drug for a particular indication (i.e., personalized medicine).

**Typical patent strategies.** The typical patent strategies of SMEs have two components: (1) an inward-looking component (protecting the innovations of the SMEs) and (2) an outward-looking component (determining whether competitors' patents may block commercialization or the SMEs' freedom to operate, or FTO). Early-stage SMEs typically focus on the first component (as they should by virtue of prioritizing the allocation of scarce resources).

In a report titled "Challenges of a Biotech Startup" published by the Kellogg School of Management, LeAnne Tourtellotte, COO of Maroon Biotech, a U.S. SME, addressed the patent challenge facing SMEs and stated, "The learning curve (in the patents area) for a biotech startup ... is steep and difficult. A startup has to be willing to hire patent and regulatory consultants to help with these issues early-on in the process. You can't do it correctly the first and second time on your own."<sup>24</sup>

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<sup>24</sup> At page 5, <http://www.kellogg.northwestern.edu/biotech/faculty/articles/startupchallenges.pdf>.

**Difficult patent concepts.** Many early-stage SMEs struggle with the concept of the nature of a patent. They mistakenly believe that a patent gives them the right to practise the invention; it does not. The patent gives the SME the right (once granted) to prevent other persons from practising the invention as claimed. That is why it is critical for SMEs to understand the concepts of the inward-looking component (in-house patent program) and the outward-looking component (FTO), from the beginning. The combination of these two concepts understood in light of the essential exclusionary nature of a patent means that an SME finds itself with a patent position on its technology and, at the same time, a third-party patent-blocking commercialization of its technology – a fairly common situation.

The other concept that SMEs often struggle with is the concept of workarounds (i.e., that a claim can be designed in such a way by competitors as to avoid infringement). The SME must balance, on the one hand, seeking sufficiently broad protection in the patent to protect the innovation (and prevent workarounds) and, on the other hand, seeking protection that is not prohibitively expensive (the broader the claims, the more likely the various patent offices will reject the claims either on the basis of lack of support or utility or on the basis that the claims are broader than the invention; the legal fees required to counter these claims can also be substantial). Early in the SME's product life cycle, compromises are made for budget considerations. As the SME secures substantial financing or is acquired by a Big Pharma, the life cycle management strategy will include strengthening the patent protection for the SME's product to the degree that this can be done effectively after the fact.

**Typical patent life cycle of SMEs.** Most SMEs start thinking about patents early in the product development process. Typically, many file a U.S. provisional patent application to cover the innovation. They then possibly file additional U.S. provisional patent applications within one year of the date of filing of the first U.S. provisional patent (to cover improvements in the innovation). The next step is often the filing of a Patent Cooperation Treaty (PCT) application, sometimes called an “international patent application” (claiming the benefit of the filing dates of the earlier filed U.S. provisional applications).<sup>25</sup> The innovation is published (in the PCT patent application) 18 months after the filing date of the first U.S. provisional patent application. This cycle is repeated multiple times (for different innovations of the SME or for improvements to the original innovation that are considered separately patentable).

**Controlling costs.** The challenge for the SME is that each patent cycle is associated with patent costs that can quickly escalate. If the costs (of the patent filing and prosecution strategy) are not managed or if there is no investor or Big Pharma to help with the costs, the cost of the patent program can be burdensome, especially from a cost-benefit perspective. It is not uncommon for SMEs (or their investors) to acknowledge, several years into the life cycle of the SME, that the SME has spent millions of dollars on patent costs, yet their product is still years away from entering human clinical trials.

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<sup>25</sup> The phrase “international patent application” can be misleading, because it implies that one can ultimately obtain an “international patent.” That is not the case. Ultimately, the requirement is that national (e.g., U.S. or Canadian) or regional (e.g., EU) patent applications must be filed and prosecuted to obtain a patent in each country or region desired.

It is essential for SMEs to control their costs. Compared with other industries, investments in biopharmaceutical R&D, and in patents specifically, often constitute a significant portion of biopharmaceutical SMEs' total expenditures. The World Intellectual Property Organization estimates that biotechnology companies generally invest between 40% and 50% of their total revenues in R&D activities, considerably more than the 5% of revenues that the chemical industry spends or the 13% figure associated with the pharmaceutical industry.<sup>26</sup> Within the biotechnology industry, the amounts spent on R&D typically vary in line with the size of the SME, with smaller companies spending an average of 194% of total revenues on R&D activities and larger companies spending between 45% and 55% over the past few years.<sup>27</sup> Although these are U.S. statistics for companies listed on the Nasdaq Biotechnology Index, we would expect that the findings are generally applicable to SMEs in Canada.

Given the cost pressures, there needs to be a rigorous determination and execution of the patent strategy. A sound patent strategy is one that ensures that the costs of the patent program are controlled. Assume, for example, that innovation is on its way to being put into practice (tested in the lab, etc.) and is capable of protection (i.e., appears to be patentable in view of the prior art and other criteria under applicable patent laws); however, it is unclear whether the innovation has a market or is one for which someone will pay. Until these latter two requirements have positive answers, the SME must have a firm handle on its costs. An SME that has a good grasp and control of its patent costs is easily identified by investors and Big Pharma. Once it is clear that the innovation has a market and that someone will pay for the product, life cycle management would include investing more heavily in patent protection (which in turn is typically easier to do once investors or other partners are committed and invested in the SME and its strategy).

**Quality of patent applications.** The patent applications filed by SMEs vary in quality, with some filed as very rough U.S. provisional patent applications and others filed as top quality U.S. patent applications. The quality of the patent application depends on a number of factors: whether it is filed quickly to ensure that the innovation is protected by a patent application before publication by the inventor (i.e., the inventor's publication or intended publication forces the filing of a quick patent application); whether the SME is financed adequately; whether the inventors wrote all or most of the application or whether the application was a team effort (inventor, other R&D personnel and patent agent); and whether senior management was actively engaged with the patent agent and in the patent strategy. Involvement of senior management can have a significant impact on the quality of the patent application and the overall strategy (i.e., whether the patent application and the strategy dovetail with the SME's business plan). Poor quality patent applications can deter an investor from investing in an SME and discourage Big Pharma from licensing patents from or acquiring an SME.

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<sup>26</sup> World Intellectual Property Organization, "Patents at the Core: the Biotech Business," [http://www.wipo.int/sme/en/documents/patents\\_biotech.htm](http://www.wipo.int/sme/en/documents/patents_biotech.htm).

<sup>27</sup> BDO, "Biotech Industry R&D Spending Jumps Five Percent in 2011," <http://www.bdo.com/news/pr/2263>.

**Academic spinoffs.** If an SME is a spinoff from a university or has founders who are also appointed to Canadian universities or hospitals, there can be pressure to publish the SME's innovations. This brings added pressure to the patent program because the "blue sky" patent strategy is to file the patent application before the innovation is published (blue sky strategy is discussed under (e) below). An SME in this position (i.e., facing its own publications as prior art) is also unable to "roll over" the first filed provisional patent application because to do so would mean that the SME's own publication would be cited against its own patent application as prior art (rendering the claims unpatentable).

**Claiming the innovation.** The ways in which the innovation can be claimed vary, depending on the field (i.e., chemical, biological, diagnostics/instrumentation or ag-biotech). Generally, product claims (e.g., a claim to the active pharmaceutical ingredient, or API, or device/diagnostic/instrument) are regarded as stronger than claims to the dosage form (e.g., tablet, capsule, syringe, patch, kit), the formulation (e.g., extended-release formulation, no-food-effect formulation) or the use (e.g., indicated for the disease or disorder of Y; diagnosing the disease or disorder of Y). Life cycle management of the innovative products of the SME would include considering the patent applications available to be filed from: starting materials, intermediates, final active pharmaceutical ingredients, combination patents (drug-drug or drug-device or other combinations) to dosage forms and formulations, to processes and methods of manufacture, and to methods of treatment, indications and dosing regimens.

Investors generally prefer to invest in SMEs that have patents claiming products rather than patents claiming methods or services. This is because the investors are focused on the four criteria for investment outlined earlier in this Report, two of which include the need for a market and the need for someone willing to pay for the innovation. The market for services or methods tends to be more difficult to evaluate (and invest in) than the market for products. Services (and business methods) can be more challenging to patent or the patents can be more challenging to enforce (i.e., enforcing patents against customers) and this can have an impact on valuation and whether there are barriers to competitors entering the market.

**Lack of data.** An area that is challenging to SMEs (as well as to Big Pharma) is filing for the innovation with limited (or no) data to support the innovation. Early-stage innovations are often characterized by little or no supporting data.

In Canada, there have been recent challenges to patents that have been issued for important drugs but that contain limited or no data. According to a recent publication of the Intellectual Property Institute of Canada, "In Canada, the required utility is normally determined by 'the promise of the patent.' That is, the patent itself is examined to see what utility the inventor has promised, and the patent will be invalid if that utility is not established. *This makes utility more difficult to establish in Canada than in the US or Europe.*"<sup>28</sup> In addition, "evidence post-dating the filing date (of the patent application) such as the result of

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<sup>28</sup> Intellectual Property Institute of Canada, *A Comparative Overview of Canadian, US and European Pharmaceutical Patent Systems*, <http://www.ipic.ca/english/pdf/IPIC%20pharma%20patents%20comparison%20chart%202012.pdf>.

subsequent clinical trials, may not be used to establish utility.”<sup>29</sup> If Canada’s patent laws are out of step with their counterpart laws in Europe and the United States, that can add more of a burden to SMEs in their home country.

**Lack of certainty.** Generally, Big Pharma is looking for some (but not necessarily complete) certainty regarding the soundness of the patents that they are buying or licensing from SMEs. The climate in three areas can cause a lack of certainty: in the courts (i.e., litigation); in the policy of patent offices (i.e., whether patents will be granted and for what scope); and in the laws protecting innovations in the SME’s home country compared with laws in other countries.

The litigation climate relating to the patents of Big Pharma in a given country can have an impact on its level of interest in investing in SMEs. Patent litigators Andrew Bernstein and Yael Bienenstock have considerable experience in patent litigation. They state, “In determining whether the utility requirement for validity is satisfied, courts must answer the question, what does the patent promise the invention will be useful for? Answering this question has a dramatic effect on patent validity.”<sup>30</sup> The litigators suggest that the following principles would help lead to more consistency and predictability in the courts’ determination of promise: “(1) promise should be approached as an aspect of the inventive concept of the claim; (2) promise should be considered on a claim-by-claim basis; (3) the determination of promise should adhere to the principles of claim construction; (4) promise, and whether it has been met, must be analyzed using the same information (in the patent or known to the skilled person); and (5) experts can assist by explaining the perspective of the skilled person.”<sup>31</sup>

**Lack of understanding of the patent/regulatory interface.** It can be challenging to understand the nuances of an international patent strategy, let alone also understand the nuances of the patent and regulatory interface in a given country. However, this is a critical element of an SME’s strategy. Considerations include data protection (protection for regulatory data regardless of the existence of any patents for the product or services); listing patents on the U.S. Orange Book or Canada’s Patent Register; the timing of filing regulatory submissions and the impact of the date of filing patent applications on the eligibility for listing any patents to issue from those applications against the regulatory submissions; the pricing review that can be triggered as a result of patents (e.g., Canada’s Patented Medicine Prices Review Board); whether inventions included in regulatory submissions or supplementary regulatory submissions are patentable; the impact of patents on market access (i.e., customers’ tendering for products); and the impact of patents on public or private payment or reimbursement for products.

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<sup>29</sup> *Ibid.*

<sup>30</sup> “Unpacking the “Promise of the Patent,” Bernstein and Bienenstock. CIPR forthcoming 2013.

<sup>31</sup> *Ibid.*



## ii. Cost considerations and budgets

The costs for a patent program for an SME can vary from \$10,000 in year 1 for a single filing done on a budget to \$10,000–\$20,000 in year 2 (again, for a single filing done on a budget), and the costs typically climb exponentially after that, depending on the countries in which the SME files its patent application. Most SMEs have multiple innovations so their patent costs are a multiple of the foregoing. Patent cost estimators are available for individual countries or for worldwide patent filings,<sup>32</sup> which involve filing costs and other costs (including examination, filing assignments/change of name documents, prosecution costs). However, these are estimates only. The cumulative costs of filing and prosecuting a single patent application (i.e., moving the application forward to an issued patent) in industrialized countries are substantial (over a hundred thousand dollars), especially in the life sciences/biotechnology area.

In selecting countries in which to file the patent application, most Canadian SMEs would, at a minimum, select Canada, United States, Europe and then select from a group of others, including Mexico, Japan, Korea, Australia, India, China and South American countries. The decision regarding the countries in which to file is not made until 30 months (in some countries later) after the filing date of the earliest patent application. This 30-month period is made available by the PCT. It benefits SMEs because it allows them to defer the decision (and concomitant costs) of the countries in which they wish to file a patent application, but affords them the benefit of claiming back to the first date of the filing of the priority patent application in the PCT patent application (or the benefit of claiming back to the filing date of the PCT patent application, if there is no priority patent application). If SMEs make the decision to file without any commitment from investors or Big Pharma to support the filing program, the risk of uncontrolled costs increases significantly. The dilemma is that many SMEs believe in their innovations, believe they will be financed, believe they will partner with Big Pharma and are willing to finance these filings (with help from friends, family and angel investors). There are, however, different strategies that could be used to temper the costs, albeit not without risks. These strategies include rolling over the provisional filing; abandoning the first application before publication and refiling; focusing on improvements to the innovation in the patent program; filing in selected countries; or deferring filings until data support the innovation to be claimed in the patent.

It is common for insufficient rigour to be applied to cost decisions, and the default is often to file broadly. As a result, the costs of such filings have the potential to overwhelm the SME in later years.

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<sup>32</sup> <http://www.globalip.com/>.

## c) Patent Checklists for SMEs

Investors and Big Pharma typically utilize checklists to evaluate the patent program of SMEs. To prepare for such an evaluation, SMEs should be proactive and have answers to the questions in these checklists.

Investors and Big Pharma remark that SMEs make it easy for them to invest in or to continue considering them as targets if the SMEs enable investors and Big Pharma to readily understand their patent portfolios and patent strategies (among other criteria that investors/Big Pharma consider). Furthermore, SMEs that rehearse the answers to difficult questions and have succinct and thoughtful presentations on their patent portfolios and strategies are more likely to advance to the next round of discussions than SMEs that do not prepare adequately for such due diligence.

The following are some sample checklists:

### i. Patent portfolio

1. Provide a chart of all of the patents, patent applications and drafts of patent applications
  - a) owned by the SME
  - b) licensed to the SME
  - c) optioned by the SME
2. Ensure that the chart lists (1) country; (2) application no./registration no.; (3) names of inventors; (4) applicant (i.e., inventors, SME or other); (5) current status (e.g., filed, in prosecution, granted, in opposition); (6) brief description of the invention as claimed.
3. For patents in prosecution, describe the status in detail (e.g., third office action; rejections based on x, y, z; interview planned).
4. Provide a chart of all inventions for which patent applications are to be filed in the coming year and subsequent years.
5. Provide details of any disputes relating to patents, including those (1) asserted by SME, (2) sought by SME and (3) opposed by others (e.g., in Europe).
6. Provide a summary of how the patent strategy dovetails with the current business plan of the company and published financing documents (i.e., documents published to attract investors in the company).
7. Provide any prior art searches or patentability opinions obtained.

## ii. Chain of title ownership/assignments

1. Who are the inventors?
2. Are all the inventors listed in the patent applications?
3. For whom did the inventors work at the date of invention?
4. Did the inventors have an employment (or other) contract regarding ownership and assignment?
5. Did the inventors assign all rights to the company?
6. If there was an intermediary (or multiple intermediaries) involved (e.g., the inventor worked for a university), did the inventor properly assign to the intermediary and did the intermediary properly assign to the company?
7. Are the assignments for worldwide rights?
8. Do the assignments obligate the inventors to assist with prosecution of the patents and to assist with litigation (if the patents require enforcement or are challenged)?
9. Was biological material involved with the invention – if yes, did all persons with a possible ownership interest in that material assign ownership to the company (through proper chain of title)?
10. Were designs/drawings involved with the invention – if yes, did all persons involved assign ownership to the company (through proper chain of title)?
11. Are inventors generally cooperative or will they resist attempts to help prosecute or enforce the patent? (i.e., will the execution of the assignments mentioned in viii above be smooth or challenging?)
12. Are there any claims against the SME relating to ownership in or rights to its innovations – if so, are all details provided?

### iii. Freedom to operate (FTO)

1. Provide a broad overview of FTO strategy.
2. Outline FTO searches conducted:
  - a) how often
  - b) by subject matter (if so, provide terms)
  - c) by individual/company (if so, provide list)
  - d) restrictions, if any, on search
  - e) databases used
  - f) dates of searches
  - g) analysis of searches
  - h) copies of most relevant patents uncovered
  - i) opinions sought/provided
  - j) if one or more patents are highly relevant to FTO, provide
    - strategy relating to those patents (design around; buy; license; invalidate)
    - detailed information on owner of such patents (are they typically aggressive, do they tend to litigate, assert patents proactively or enter into licensing agreements? do they settle if they litigate?)
3. Provide details of any claims by other companies against the SME relating to FTO.

### d) Key Patent Questions That Investors Ask

Over the past decade, investors have become more sophisticated in their due diligence of SMEs before investing. Their questions are drawn from the checklists provided above. Depending on the answers obtained, there may be additional rounds of diligence (including follow-up calls or meetings with inventors; with patent advisers to the SME; and with independent patent advisers to the investor).

## e) A “Blue Sky” Patent Strategy for SMEs

### i. What are investors looking for?

A blue sky patent strategy for SMEs is one that responds to all the questions set forth in the checklists above. In addition, invariably there will be an anticipated challenge (or challenges) in the patent strategy, and investors are looking for management of the SME to be well briefed on how it proposes to overcome the challenge with different options depending on different scenarios.

### ii. What is Big Pharma looking for?

A blue sky patent strategy for Big Pharma is one that makes it relatively easy for it to carry on with the patent program. Most Big Pharma (once it in-licenses or acquires the patents of the SMEs) will expect to be in complete control of the patent strategy. A sound blue sky patent strategy (1) is consistent from country to country; (2) contains no damaging admissions or concessions on the public record (because patent prosecution is public and competitors will read the public record when seeking to attack the patent); (3) is reasonable in approach (i.e., if claims are sought, data in the patent applications support the claims); and (4) contains no mistakes that would be difficult to correct (e.g., the U.S. patent issues, but the SME had prior art relevant to that patent that had been uncovered in patent prosecution in other countries and failed to bring that relevant art to the attention of the U.S. Patent and Trademark Office before the patent issued).

Although Big Pharma will be interested in the SME’s responses to the questions set forth in the checklists above, it typically has seasoned in-house patent attorneys and external counsel and will form its own views on how to handle any anticipated challenge (or challenges) in the patent strategy and the management. Different pharmaceutical companies have different risk tolerances. While some will not be dissuaded from in-licensing even though there is an FTO issue, others will regard that as a deal breaker (e.g., if the Big Pharma is litigation averse). The risk tolerances of Big Pharma are determined by their boards and upper management. If a Big Pharma has become involved in adverse patent litigation, or if the board and upper management are risk averse regarding patent litigation, that will have an impact on whether the company has an appetite to license or acquire patents from the SME if the patents are associated with litigation risks.

### iii. Should the patent strategy differ according to the “exit”?

SMEs cannot always be sure what the future exit will be. Sometimes, the SME may consider the exit to be a public offering or a takeover, but instead it ends up out-licensing the patents and innovations to a Big

Pharma, or vice versa. As a result, the patent strategy should be one that has regard to the budget and optimizing protection on a reasonable basis, and should not depend on the form of exit.

#### iv. Defensive and offensive patent strategies

In the early stages of the development of an innovative product, it is unclear whether the product will succeed and become a blockbuster or will fail in the clinic (or before) – never to be commercialized. A defensive strategy of an SME involves trying to create a patent strategy that can be leveraged if the product becomes a blockbuster. In such a case, litigation can be expected.

**Patent litigation is routine for biotech – investors in companies that employ biotechnology should expect patent litigation. But, companies facing or in lawsuits usually negotiate licensing agreements to allow everyone to move forward because lawyers routinely advise clients that settlements are preferable to rolling the dice – allowing a judge or jury to decide your dispute.<sup>33</sup>**

An additional defensive strategy consists of gathering as much information as possible on any third-party patents that could create problems with regard to the SME's (or a Big Pharma's) ability to take the drug to market. This defensive strategy can include gathering prior art that might invalidate the third-party patents, determining whether the third parties typically grant licences to the patents, seeking to purchase blocking patents and designing workarounds to blocking patents.

Why is this defensive strategy for SMEs a necessity? Because a litigation challenge for a patent covering a blockbuster drug is a virtual certainty. A recent study prepared by PricewaterhouseCoopers LLP concluded that patent litigation continues to increase amid growing awareness of patent value, and biopharmaceutical patent cases are on the rise.<sup>34</sup> Not only are generic companies' strategies based on litigating patents<sup>35</sup> rather than conducting R&D, but a widely held view, particularly in the biopharmaceutical industry, is that it is good policy to encourage potential competitors to challenge current patent holders.<sup>36</sup>

Offensive strategies (asserting patents against other companies) are typically not part of SMEs' strategies, because they are costly and divert management's attention away from product development and towards expensive, uncertain and time-consuming litigation. However, an SME that is further along in its development can have an out-licensing strategy as part of its offensive patent strategies; this would

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<sup>33</sup> <http://www.fool.com/portfolios/rulebreaker/2001/rulebreaker010122.htm>.

<sup>34</sup> [http://www.pwc.com/en\\_US/us/forensic-services/publications/assets/2012-patent-litigation-study.pdf](http://www.pwc.com/en_US/us/forensic-services/publications/assets/2012-patent-litigation-study.pdf).

<sup>35</sup> <http://www.sutherland.com/files/Publication/8ef32e81-b2b1-4a27-af33-4a73e8931775/Presentation/PublicationAttachment/24a0f9d2-7c22-4d9c-90b2-a5fc1c8f14cb/GenericDrugMakersIP.pdf>.

<sup>36</sup> <http://ipjournal.law.wfu.edu/2011/12/blockbuster-drugs-including-lipitor-reaching-the-end-of-their-patents/>.

consist of seeking to assert its patents against third parties and either sell the patents (if they are not core to, or otherwise needed in, the SME's business) or license the patents, thereby creating a revenue stream for the SME to support its commercialization efforts. If the offensive strategy includes litigation, SMEs typically partner with Big Pharma, especially if it is their first encounter with patent litigation and if the market is either the United States or Europe.

#### **f) How Are Patent Strategies Typically Handled in SME–Big Pharma Alliances?**

Alliance agreements can set out patent filing and prosecution strategies in one of several ways: (1) the SME completely controls the strategy after the agreement is executed (rare); (2) the Big Pharma completely controls the strategy after the agreement is executed (more common, especially if the Big Pharma is financing the patent program); (3) the SME controls the strategy after the agreement is executed, with input from the Big Pharma (common); or (4) the Big Pharma controls the strategy after the agreement is executed with input from the SME (common). Big Pharma tends to implement different patent strategies from those implemented by SMEs because they can have a different perspective from that of the SMEs.<sup>37</sup> For example, the Big Pharma will consider (a) how the product of the SME fits in with the rest of the Big Pharma's portfolio; (b) how the SME's patent strategy can be improved; (c) how the Big Pharma's expertise in patent filing and strategy can be leveraged to protect the product in-licensed; and (d) whether the Big Pharma will be taking an aggressive licensing or aggressive enforcement (i.e., litigation) position, vis-à-vis the patents in-licensed from the SME.

Typically, a Big Pharma's blue sky strategy tends to seek control of the patent filing and prosecution strategy. SMEs can resist this position if they have leverage. The downside with giving complete control to a Big Pharma (if the patents are out-licensed by the SME) is that while the patents are still owned by the SME, it can nevertheless lose control of the overall patent strategy.

When a Big Pharma handles the strategy, it typically assigns one in-house patent attorney to be responsible for the portfolio. Generally this attorney has considerable expertise and experience in filing, prosecuting and enforcing patent applications for products worldwide. SMEs sometimes remark that they lose all involvement in the overall patent strategy once the Big Pharma assumes control. The agreement between the SME and the Big Pharma can anticipate this challenge and build in controls, so that the SME is involved in the patent filing and prosecution of its innovations.

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<sup>37</sup> <http://www.fenwick.com/publications/Pages/Monoclonal-Antibody-Patents-Evolving-Law-and-Strategies.aspx>. "Biotechnology patenting and patent strategy have always been markedly different than that of the pharmaceutical industry."

## g) Typical Mistakes Made by SMEs Relating to Strategies

### i. Which mistakes will investors/Big Pharma tolerate? Which mistakes break an investment / deal?

The “show-stoppers” (i.e., issues uncovered in the due diligence that would either terminate discussions between SMEs and investors/Big Pharma or decrease the valuation) tend to be in one of the following categories:

**The SME has not chosen the most advantageous chain of title.** From time to time, the SME will not have identified the chain of title before approaching investors/Big Pharma. This is a serious error. Some founders of SMEs have filed the patent applications in their own names and believe that there is an advantage to having the patent applications held by them personally, as opposed to having them held by the SME. Investors recognize this error immediately and will question why they should invest in an SME that does not hold the most significant asset – that is, the IP. They will also question whether the founder has the best interests of the SME at heart (or whether the founder has diverging interests, is conflicted, is holding back information, etc.). Other founders of SMEs have not considered whether other inventors, research institutes or universities may have an ownership interest in the patent applications; or if founders have considered these possibilities, they have not dealt with how the SMEs plan to deal with this issue before approaching investors. This is another serious error.

**The innovation claimed is not patentable.** Sometimes, there are publications (prior art) or disclosures of the invention (either by the inventors or other persons working in the field) that result in the innovation not being patentable. This information may turn up in due diligence, especially if the investor or the Big Pharma pays more attention to the searches conducted by the patent offices than the SME did, or if the investor/Big Pharma does searches of its own to assess patentability. Sometimes the patent agent/patent attorney of the investor/Big Pharma reaches a conclusion different from the conclusion of the advisers to the SME, finding that the innovation of the SME is not patentable. Sometimes the innovation is not patentable because the laws of certain countries have determined that the innovation is not patentable (i.e., non-patentable subject matter). If the investor or Big Pharma concludes that the innovation is not patentable and there is no way around this in critical markets, that is typically a deal breaker.

**The patent applications do not cover the product.** In certain cases, during due diligence, investors/Big Pharma learn that the patent applications do not actually claim the product (e.g., there is an error in the genetic sequence claimed; the claims contain unimportant restrictions that can be designed around; or the claims are not directed to the product). This is typically a deal breaker unless the SME has a strategy for correcting this error and brings it to the attention of the investors/Big Pharma.

**The SME has a reactive patent strategy.** Some SMEs have a strategy of filing a patent application for each innovation that comes out of the lab – that is, a reactive (rather than a proactive) patent strategy. That can prove to be expensive. A reactive patent strategy is one that is almost routine – as soon as any



invention disclosure is available, a patent application is filed for that disclosure. Certain SMEs boast about the number of patent applications that they have filed, without regard to the quality of those applications or how they fit strategically with the SME's business plan. A proactive patent strategy has the following characteristics: (1) It is based on the SME's business plan and any invention disclosure outside that business plan does not divert time, money or resources of management (or merits a discussion before time, money or resources support that invention disclosure); the preferred strategy is to restrict patent application filings to those innovations that dovetail with the business plan. (2) It identifies gaps in the market and determines how the business plan fills those gaps. (3) It casts an outward gaze on the patent activities of competitors to ensure that it is ahead of market.

Investors/Big Pharma will seek to determine whether the SME has a proactive patent strategy, what the strategy is and how the strategy dovetails with the business plan.

**The SME has no control over costs.** It is relatively easy to identify an SME that does not have a strategy to control patent costs. Such an SME typically does not have answers readily available to the following questions: (1) What is your annual patent budget? (2) What are your cumulative patent costs to date? (3) What steps do you have in place to manage patent costs? (4) How do your patent costs compare with the benchmark? (5) What do you expect your patent costs to be in the next year, in the next five years, and why? (6) What are the patent costs you can control and how are you controlling them? (7) What are the patent costs you cannot control and why?

Each SME should have a patent budget and should determine the breakdown of that budget in the context of its business strategy. Is the budget best spent on filing for the key innovation, filing for variations to the innovation or on freedom-to-operate searches? This is best determined by senior management, who would know from discussions with investors and potential business partners what they regard as the keys to the SME's success. An SME that is disconnected from the concerns of investors or Big Pharma can sometimes make mistakes and not focus on key patent concerns. An SME that attracts investors is one that has a budget and pays as much attention to its patent strategy as to its business strategy (e.g., reporting to the board at each meeting on the patent strategy, offensive and defensive; assessing whether patent performance is achieved each year; having a primary, secondary and tertiary patent strategy for key products and key concerns, such as patents of third parties; and managing costs).

**The patent applications appear to be more theoretical than product-oriented.** For early-stage innovations, it is difficult to provide significant data in the patent application to support the innovation. If every SME were required to produce clinical trial or in-human data in its patent applications, many patent applications would be deferred in their filings for years (to the SME's detriment). On the other hand, filing early, without data to support the innovation, can also be detrimental. (If the SME does not expect to have data to support the innovation within a year of filing of the patent application, the SME is likely filing too

early).<sup>38</sup> An SME is filing too late if it has data to support the innovation and has not yet filed a patent application, or worse, has data to support the innovation and has published that data without having filed a patent application. The four requirements stated earlier in this Report are relevant here. To commercialize a biopharmaceutical product or process in the life science space (i.e., for early-stage SMEs, this means attracting investors), the company needs an innovation that can be (1) put into practice; (2) that can be protected; (3) that has a market; and (4) for which someone will pay. Many innovative products can meet one or two of these requirements, but few are able to meet all four. If the SME is filing too early on its innovation, there is a significant risk that the innovation cannot be put into practice and cannot be patent-protected (i.e., the invention is not enabled, is not supported in the patent applications and does not meet the utility requirements). Investors will expect the SME's strategy regarding data to support the innovation and to advance the patent strategy.

**The patent strategy is run by the patent agent/attorney with no input from senior management.**

Too often, with senior management of SMEs being busy, the patent strategy is delegated to either a person within the SME who is not a member of the senior management team or to outside advisers. This is a mistake. The best patent strategy of an SME is one that involves the input of senior management, the outside patent agent/attorney and the person within the SME who will execute the strategy. It is also critical that these persons meet regularly (e.g., monthly or quarterly, depending on which stage the SME is in) to update the strategy in view of various inputs: feedback from investors; feedback from Big Pharma; feedback from board members; feedback from patent offices; feedback from competitors' activities; feedback from the market; feedback from monthly patent searches; feedback from the regulatory department; feedback from business or scientific team; and input from CFO regarding actual costs versus budget.

**ii. How to fix mistakes?**

For early-stage SMEs, the good news is that most patent mistakes can be fixed or at least ameliorated. If the patent does not adequately cover the product, improvement patents can be filed to the dosage form, formulation or indication. If inadequate data support the invention as claimed, additional patent applications can be filed, seeking to patent the improvements with supporting data. Patents that contain errors can be reissued. Fixing mistakes comes at a cost, one of which is that the mistake is often apparent from the public record after a person seeks to fix the mistake. The question is whether the product is so valuable (i.e., has a market and is an innovation for which someone will pay) to justify the time, effort, cost and public disclosure that are often associated with fixing the mistake. From the viewpoint of the investors and Big Pharma, it is best for the SME to admit right away that there is a mistake and to have a proactive strategy for fixing or managing the mistake. The worst situation would be

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<sup>38</sup> Unless the SME has a generous patent budget and wishes to file patent applications and abandon them and refile them until it has sufficient data.

for investors or an interested Big Pharma to discover the mistake while conducting due diligence and for the SME not to have either admitted the mistake or have a strategy for fixing it.

## **h) Licences as an Integral Part of the IP Strategy**

One of the key mistakes made by SMEs is giving short shrift to their IP licences. Licences vary tremendously. Simply “getting a licence” is not the end of the analysis. The critical question is what rights and obligations are set forth in the licence. A licence can be a non-exclusive licence to use a given diagnostic reagent and, on the other end of the spectrum, can be exclusive and therefore akin to an assignment except on termination or in a bankruptcy scenario. SMEs routinely under-invest in their in-licences and out-licences and find that rights they thought they had are not theirs or can be easily terminated. Sophisticated Big Pharma and investors are very sensitive to the terms of licence agreements, and many SMEs will lose a partner or investor because of inadequate rights under their licence agreements.

Licence provisions that will deter an investor or partner include the following:

### **i. In-licences**

- The in-licence is easily terminable. For instance, often there are termination provisions in the event that certain milestones are not reached within a specified period of time. It is well-known that R&D is unpredictable and generally takes longer to reach a goal than an entrepreneur or inventor plans.
- The scope of exclusivity is not broad enough, thus permitting others to compete.
- Control of prosecuting and maintaining the patents remains with the licensor. This can be problematic if the licensor does not cooperate with the licensee or if there are multiple licensees of the same underlying patent.
- Royalties and other compensation are not clearly defined.
- There is limited ability to sublicense patents. Most SMEs will need to sublicense a patent to commercialize products or to enter into an agreement with a Big Pharma or other partner.

### **ii. Out-licences**

- The licensee is not progressing with R&D or commercialization at the desired rate and the SME is unable to retrieve control of the IP and terminate the licence. The SME does not want a licensee that can shelve the invention.
- The licensee is not required to maintain specified standards.
- The licence is for a field of use that reduces the value of the IP for a potential licence of all fields of use.

- Licences do not include a provision that rights to improvements or inventions in related areas are the property of the SME (licensor).
- Licences do not limit competition by the licensors and their affiliates and partners.

While it goes without saying that for all licences it is critical that the scope of the IP licensed be precisely defined, it is surprising that this is a frequent issue.

There are a myriad of other issues to be considered in a licence. Licence agreements in the biopharmaceutical field are some of the most complex. Those who look for shortcuts often regret it. It is imperative to have a defined strategy, the support and advice of industry experts and the patience to negotiate all important points when putting a licence in place. Once a licence is executed, it is difficult to renegotiate without having to offer concessions of some kind. Unlike a sales agreement that deals with a specific transaction at a point in time, a licence is an agreement on which an ongoing relationship is based.

### **i) Due Diligence Checklist**

A basic checklist of due diligence for licences includes the following:

1. Provide details of any in-licences (or options to in-license) to SME.
2. Provide details of any out-licences (or options to out-license) from SME.
3. Terms to focus on in each of the licences
  - a) grant
  - b) territory
  - c) restrictions on grant
  - d) definition of “product”
  - e) improvements
  - f) compensation
  - g) minimum royalties, milestones, minimum sales or other performance obligations
  - h) obligations of SME
  - i) obligations of licensee/licensor
  - j) provisions that are atypical (e.g., supply provisions)
  - k) termination
  - l) assignability/sublicensing

## j) Establishing a Business

IP issues intersect with business decisions affecting the SME, including when and how to establish the business. For example, if the patents are initially held in the names of the inventors, questions for the SME to ask are (1) when should the SME incorporate? (2) where should it incorporate (in Canada or offshore)? and (3) to which entity should the patents be assigned? There can be tax consequences when transferring patents from an owner to an SME or from an SME to a related or unrelated SME. For that reason, it is important for the SME to consider at the outset how to establish its business and which entity will own the patents and other types of IP. These questions are best addressed before the SME approaches investors for funding or approaches a Big Pharma partner for a deal. With sophisticated corporate and tax planning, a business can significantly enhance the financial value of its patents.

## k) Financial Incentive Programs for Biotech Companies

**General.** A number of government financial incentive programs provide assistance to persons with technological or managerial skills who propose to engage in certain projects that are unlikely to be initiated without government assistance. SMEs would want to consider whether their projects can benefit from these incentive programs. The most general of these programs relate to research and development and can be used as additional financing for research to bolster an IP portfolio and to implement the blue sky patent practices for SMEs that are recommended in this Report.

Some of the financial incentive programs offered by the federal, provincial and local governments apply to a broad range of industries and are available to foreign investors. These programs are intended to promote Canadian industry and technology, increase research and development, encourage new investment and address the particular needs of those regions in Canada that have lower levels of commercial development or employment.

The incentive programs differ from one another in the nature and amount of the incentive offered, the size and type of business eligible for assistance, and the nature and extent of the commitment required from the principals. The mandates of most of the programs are general; therefore, the criteria for determining a particular business's eligibility for assistance are somewhat flexible. The assistance provided under these programs may take the form of grants, subsidies, contributions, repayable contributions, forgivable loans, participation loans, loan guarantees, equity participation or tax incentives. Additional details about these programs are set out in [Appendix A](#).

# Case Studies and Lessons Learned

## a) Specific Questions Posed by Industry Canada

1. How does a biopharmaceutical company's IP protection strategy affect its attractiveness for VC investment? What is the minimum level of IP protection considered necessary to attract the interest of a VC fund for an emerging biopharmaceutical company?

The SME's IP strategy is one of the criteria that determines whether VCs will invest in the SME. The minimum level of IP protection necessary to attract the interest of a VC is (1) IP that is owned by the SME or IP to which the SME has a clear and firm right (e.g., exclusive licence with provisions to the SME's benefit); and (2) IP that covers the products or the services being developed by the SME. The IP typically comprises patent applications, patents and trade secrets. The SME must have a strategy for filing the patents in other important markets (claiming the benefit of the first filing date of the patent application) and a strategy for overcoming publications (prior art), which patent offices could cite against the SME's patent application to object to patentability. Another important element is the presence of third-party IP that conflicts with, or is essential to, the commercialization of the SME's product(s). There needs to be a clear and credible strategy to deal with this third-party IP, by (1) challenging it in litigation or quasi-litigious proceedings such as patent oppositions; (2) acquiring it; (3) in-licensing it; or (4) engineering around it. In the case of in-licensing, care must be taken to avoid the so-called royalty stacking problem, whereby multiple royalties payable by an SME for the use of in-licensed third-party IP are so high that they make effective commercialization impossible.

2. Does the changing pharmaceutical R&D business model towards increased biopharmaceutical SME-Big Pharma MNE alliances and partnerships necessitate a rethink of Canadian biopharmaceutical SMEs' international patent strategies? How can a company position itself favourably for attracting global pharmaceutical partnerships from an IP perspective?

The SME's international patent strategies should not change. SMEs position themselves favourably to attract global pharmaceutical partnerships, from an IP perspective, by following the recommendations outlined in the Report and avoiding costly mistakes that can force an investor or a Big Pharma partner to walk away from the deal.

3. How does a company's product portfolio affect its patent strategy (e.g., biological vs. chemical vs. diagnostic/therapeutic combination products)?

An SME's product portfolio does indeed affect its patent strategy because different products are claimed in different ways. For example, a biologic is claimed with reference to the gene sequence, the expressed protein, the purified protein, the composition containing the protein, the

4. Are Non-Practicing Entities (NPE), so called patent trolls, a threat to Canadian biopharmaceutical companies in international markets? (NPEs are defined as companies that profit by legally enforcing patents, as opposed to developing products.)

NPEs are much more common in the technology and business methods areas than in the biopharmaceutical area. That said, there are NPEs who do assert their patents against biopharmaceutical companies. However, this does not typically happen at the stage of the SME because the NPEs tend to deploy their efforts against Big Pharma or against large biopharmaceutical enterprises that are well funded and can pay large cash settlements.

5. What strategic considerations does a biopharmaceutical SME need to address when filing a patent or seeking to protect an innovation claimed in a patent?

The strategic considerations and related questions are outlined in this Report. They include the following:

- (i) who owns the patent application?
- (ii) have all inventors been identified and has ownership been dealt with?
- (iii) what are the cost/budget considerations for the filing?
- (iv) how to effectively protect the innovation in view of this budget?
- (v) which countries to file in?
- (vi) how to stagger the patent filings in various countries in order to manage costs and timing?

- (vii) has the innovation been published before filing or is the innovation targeted for publication, and are other SMEs or Big Pharma aware of the SME's work?
- (viii) whether to file if there is no or little or marginal data to support what is claimed in the patent application?
- (ix) whether the quality of the patent application will assist in attracting investors or Big Pharma?
- (x) how to deal with improvements to the innovation in the first year after the patent application is filed; in the second year?
- (xi) whether to file a PCT application before the anniversary of the first filing date or whether to file national patent applications rather than a PCT?
- (xii) which countries in which to file the patent application before the anniversary of the first filing date if national filings are the strategy?

## **b) Additional Questions that Torys Answers in its Report:**

1. What is a sound patent-ownership strategy and why does it matter?

The Report answers this question.

2. In the start-up year of an SME, if the budget for patents is constrained (e.g., less than \$5,000; less than \$25,000; less than \$50,000), how is that money best spent?

In all cases, the budget must be strategically managed. For an annual budget of \$5,000, the SME would first assess whether it needs to expend those funds or whether it can defer its patent costs until it is further along in its research. If it decides that it needs to file a patent application, the SME would need to do as much of its patent work as possible on its own, and save the \$5,000 for the disbursements associated with filing the patent applications with the USPTO. An allocation of \$5,000 annually for patents will be extremely challenging to manage.

For an annual budget of \$25,000, which is an excellent start to an SME patent program, the SME should first assess whether it needs to expend those funds or whether it can defer its patent costs until it is further along in its research. If the SME decides that it needs to file a patent application, the SME would want to take the following measures: ensure that at least one patent application properly protects its innovation, assess whether to file improvement patent applications in its first year; prepare itself to file a PCT application to preserve its right to file the patent application in other countries; ensure that it has at least one high-quality patent application sufficient to attract investors; and determine whether additional funds are well spent in monitoring the patents of third parties in order that there is FTO.

For an annual budget of \$50,000, the SME can devise a robust and thoughtful patent strategy. Again, the SME would first assess whether it needs to expend those funds or whether the funds



3. If an SME is granted a meeting with a prospective investor, what are the patent strategy points that the SME must convey in the meeting and why?

The SME must convince the investor that it has a thoughtful and well-managed inward-looking and outward-looking patent strategies and has addressed all the key requirements outlined in the Report.

4. What is the patent filing strategy adopted by most SMEs in Canada and does the strategy work?

Most SMEs have an adequate patent filing strategy, but the strategy can fail for one or more of the reasons outlined in the Report.

5. How can an SME with limited resources undertake an international filing strategy (for India, China, etc.) that will eventually attract global pharmaceutical partnerships?

An SME can undertake an international filing strategy if it is strategic and focused in how it engages outside patent agents/attorneys and is prepared to do much of the legwork itself, be responsive to feedback of investors and other interested parties and dedicate its funds to the disbursements associated with an international patent filing strategy. First, the SME needs to determine the countries that are critical to its success (if the SME's projected exit is a deal with Big Pharma, what are the current markets that are critical to Big Pharma in that disease area; in which countries has Big Pharma launched products in that disease area). Second, the SME would stagger patent prosecution. To have patent prosecution move forward at the same time in several countries can be costly and can result in inconsistency in the international patent strategy. So the SME would pick one or two countries, move patents forward in those countries and defer prosecution in other countries. Third, the SME would instruct outside counsel to keep patent applications alive but not to do any substantive work on the patent applications (e.g., responding to letters from the patent office) without the SME's express instructions. That way, the SME can leverage work done in one country for the benefit of work to be done in another country.

6. If an SME's product is a success, what type of attacks can the SME expect on its patents? How does an SME protect itself from those attacks?

As outlined in the Report, if an SME's product is a success, the SME can expect that the patent(s) for the product will be attacked by third parties. This is because the patent blocks third

An SME can prepare itself for attacks by gathering the necessary underlying information, by being realistic about the weaknesses in its own patent portfolio (since there are always weaknesses) and by having a strategy in place to eliminate or lessen those weaknesses over time. An SME can also prepare for attacks from third parties that may assert patents against the SME; in this case, the SME would have an FTO search strategy that would include having a plan in place to deal with any blocking third-party patents, by doing one or more of the following: (1) allege that the third-party patent is not infringed; (2) allege that the third-party patent is not valid; (3) allege that the third-party patent is not issued or likely to issue in the jurisdictions in which the SME will manufacture, use or sell the product; (4) commercialize the patented product or process, only once the third-party patent expires; (5) plan to seek a licence (exclusive or non-exclusive) to the third-party patent; and (vi) plan to dispute or even litigate the validity or infringement of the third-party patent.

# Appendix A — Financial Incentive Programs for SMEs

## Scientific Research and Experimental Development (SRED) Credits

### i. Federal SRED Credits

The most significant financial incentive program is the federal and provincial refundable tax credits for basic science and clinical research conducted in Canada (Scientific Research and Experimental Development, or SRED, credits) for certain operating expenses and capital expenditures. Subject to certain limits, a Canadian-controlled private corporation (a CCPC) may receive a 35% federal refundable investment tax credit in respect of SRED expenditures incurred in Canada. In general terms, a CCPC is a Canadian corporation that is not a public corporation and that is not controlled, directly or indirectly in any manner whatsoever, by one or more public corporations or non-resident persons. “Control” in this context means both *de jure* control (the right to elect the board of directors where the directors supervise the management of the affairs of the corporation) and *de facto* control. If a company is not a CCPC, non-refundable federal credits of 20% are available.

SRED expenditures include those for work done by the corporation or on its behalf by third parties. Labour, materials and other costs are included where directly incurred in the pursuit of SRED, subject to conditions and percentages; there are limits on the amount that can be included in respect of salaries of certain employees and there are rules that allow for the inclusion of a “proxy” amount, instead of an actual amount, in respect of overhead expenses.

The refundable tax credits are available on the first \$3 million of allowed SRED expenditures per year of a current nature, provided that taxable income of the corporation for the previous year does not exceed \$500,000 and taxable capital for the previous year does not exceed \$10 million (if taxable income for the previous year exceeds \$500,000 or if taxable capital for the previous year exceeds \$10 million, the \$3 million limit (the Expenditure Limit) is reduced and is eliminated if such taxable income exceeds \$800,000 or if such taxable capital exceeds \$50 million). Prior to the 2012 federal budget, SRED expenditures of a capital nature also gave rise to refundable investment tax credits (the investment tax credit rate for such expenditures was also 35%; however, only 40% of the credit arising from capital expenditure is refundable). As a result of the 2012 budget, starting in 2014, expenditures of a capital nature will not give rise to any credits, nor will payments (such as lease payments) in respect of the use of property where the property would be capital property if acquired by the corporation (the Expenditure Limit applies to current and capital expenditures on a combined basis). For SRED expenditures in excess of the Expenditure Limit, there is a tax credit of 20%, of which 40% of such credits (or 8% of the

expenditure) is refundable. Starting in 2014, the tax credit rate for those expenditures will be reduced from 20% to 15% and, again, only current SRED expenditures will qualify.

With respect to qualifying current expenditures, there are special rules regarding salaries, contract expenditures and overhead expenses. Salaries of employees directly engaged in SRED generally qualify; however, there is a limit for those who directly or indirectly own more than 10% of the shares of any class of the corporation or who are considered to not deal at arm's length with the corporation (Specified Employees). For those employees, the limit on remuneration is five times the maximum Canada Pension Plan pensionable earnings (this would amount to a limit of approximately \$250,000 in 2012), and remuneration excludes any bonuses or amounts based on profits. Eligible expenditures generally include contract payments where the corporation has the right to exploit the results. Where a contract payment is made to a person who does not deal at arm's length with the corporation, only SRED costs actually incurred by the contractor will qualify (i.e., any gross profit component will be excluded); under the 2012 federal budget, if the contractor deals at arm's length, only 80% of the contractor's current expenditures will qualify.

The *Canadian Income Tax Act* allows corporations to elect to claim a refundable investment tax credit in respect of a notional or "proxy" amount for qualifying overhead rather than allocating actual administrative and overhead costs to SRED activities. The amount is a percentage of qualifying SRED salaries (not including bonuses and benefits). The 2012 federal budget reduces the percentage from 65% to 60% in 2013 and to 55% starting in 2014. With respect to the remuneration of Specified Employees, the amount thereof is limited for this purpose to 75% of actual remuneration, excludes bonuses and profit participations and is limited to 2.5 times the year's maximum Canada Pension Plan pensionable earnings.

## **ii. Provincial SRED Credits**

Most provinces in Canada have SRED tax incentive programs.

The Ontario Innovation Tax (OIT) is a refundable credit equal to 10% of the lesser of its qualified SRED expenditures and the corporation's expenditure limit for the taxation year. Eligible expenditures are those that qualify for the federal SRED credit. Any corporation with a permanent establishment in Ontario that carries on SRED in Ontario and is entitled to a federal investment tax credit is eligible for the OIT. The expenditure limit is generally \$3 million but phases out in a manner similar to the phase-out of the federal SRED credit by reference to the corporation's taxable income and taxable capital, although the threshold amounts may differ.

Additionally, the Ontario Research and Development Tax Credit is a 4.5% non-refundable tax credit on qualifying Ontario SRED.

Quebec has a refundable SRED credit of 37.5% for salaries of employees in Quebec. The credit is also available for 50% of the consideration paid to unrelated subcontractors for SRED performed by

employees in Quebec. The 37.5% refundable credit applies to the first \$3 million of SRED wages of Quebec employees but is reduced from 37.5% to 17.5% on a straight line if the CCPC and its affiliates have in the preceding year over \$50 million in assets, as assets increase from \$50 million to \$75 million.

The qualified expenditures upon which the federal SRED credit is calculated is reduced by the provincial SRED credits.

### **iii. Summary of SRED Credits**

To the extent a corporation is eligible for SRED and other refundable tax credits with respect to qualified expenditures, the company could receive aggregate refundable tax credits in excess of 50% (up to 56% in Ontario and up to 67% in Quebec) of the first \$3 million dollars for qualifying expenditures of a current nature in any taxable year and thereafter refundable at lower rates.

Moreover, banks will advance loans on the basis of estimated refundable SRED credits. Claims for SRED credits are made to the Canada Revenue Agency at the same time as filing a Canadian income tax return.

### **iv. Other Incentives for Biopharmaceutical Companies**

Each province has additional incentives available, which are largely dependent on a variety of specific factors. Some, but not all, of these programs are discretionary programs and must be applied for. For instance, in Ontario, which boasts 25 research hospitals and over 10,000 research scientists, in addition to SRED credits, government incentives for life sciences include the following:

- Grants are given to approved companies creating at least 100 jobs or investing C\$25 million.
- Repayable loans for up to 50% of cash contributions by certain angel investors and VC firms.
- Several other Ontario funds have grants and loans available for early-stage companies, particularly in the medical technology field.

## Appendix B — Author Biographies<sup>39</sup>



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Eileen McMahon is the co-chair of Torys' Intellectual Property and Drug Regulatory Practice. Eileen practices exclusively in the areas of intellectual property and drug regulatory law, and is one of a handful of Canadian lawyers who advise on regulatory clearance and intellectual property protection of products.

Eileen has worked with most of the top 20 pharma companies (by worldwide revenue) on their patent and regulatory strategies. She has also worked with hundreds of SMEs that have licensed their inventions to pharma, who have been acquired by pharma, or who have been financed by investors.

Eileen has been recognized by leading national and international directories as an expert in patent law, biotechnology law and regulatory law. She is a regular columnist of the *Chronicles of Healthcare Marketing* (“Legal or What”), and a featured speaker at conferences of the biotechnology, pharmaceutical industries.

Eileen is a registered patent and trademark agent in the United States and Canada. She is also a Certified Licensing Professional of the Licensing Executive Society (LES) (2011-2014) in the United States and Canada.

Eileen is one of Canada's Top 100 Most Powerful Women (Women's Executive Network).

Eileen was admitted to the Ontario Bar in 1987. She received her LLB in 1985 from Osgoode Hall Law School, York University and her BSc (Biochemistry and Chemistry) in 1982 from University of Toronto.

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Cheryl Reicin is the Chair of Torys' Corporate Life Sciences Practice. Cheryl's practice focuses on U.S., Canadian and Israeli biotechnology, medical device, health information, health services and other technology-based companies, and representation of private equity/venture capital funds and investment banks that fund such companies. She also represents academic medical centers and universities. Her clients range from inventors and start-ups to OrbiMed, Amgen and Pfizer.

Cheryl assists companies on venture and late stage financings, IPOs, mergers and acquisitions, licensing transactions and joint ventures and alliances with strategic partners. She also advises on domestic and international structuring and strategies for alternative financing. Her expertise includes acting on the largest U.S./Canadian cross-border IPO in life sciences as well as the largest U.S./Canadian cross-border license agreement.

Cheryl is a director of The Hospital for Sick Children, the chairman and founder of Genesis, an incubator for social innovation, and is on the Business Advisory Boards of Health Technology Exchange (HTX) and of The Institute for the Study of Aging. Cheryl is also a Certified Licensing Professional of the Licensing Executive Society (LES) (2011-2014) in the United States and Canada.

Cheryl received her JD in 1984 from Harvard Law School and her BA (summa cum laude) in 1980 from Barnard College, Columbia University. She headed an 85 attorney life science practice in the U.S. before moving to Canada.