

# An Economic Development Imperative

#### Why IP is Important to Business

#### Pro-business intellectual property (IP) rights are good for innovation and economic growth.

When a business or institution creates something – a process, device or other solution – it can retain ownership of that creation through intellectual property. Forms of intellectual property include copyrights, patents and trademarks.

Strong IP rights for businesses incentivize them to innovate, invest in R&D, and create. Likewise, guaranteed ownership encourages businesses to further scale those innovations and bring them to market. Why would a business spend time and resources to innovate when their ideas can be easily taken and replicated with no benefit to them?

Currently, Canada and Ontario are global leaders in protecting IP. This is good, as it encourages foreign businesses to invest and create here – knowing their ownership over their solutions will be safeguarded. In fact, foreign IP claims grew by 139% between 2009 and 2018 as Canada embraced pro-business policies.

#### Right now, however, Ontario's pro-business IP rights are at risk.

In 2020, the provincial government announced a made-in-Ontario Intellectual Property Action Plan to ensure the benefits of taxpayer-funded research stays in the province. This includes an initiative to share more public health data so people can innovate solutions for COVID and other health issues. However, the government has taken the stance that the IP for any solution derived from that public health data is owned by the government.

The Board's members are concerned this sets a dangerous precedent for the future of IP in Ontario. The government should absolutely continue to share public data — this is an invaluable resource to solve for problems in today's world, and the government is best positioned to collect and safeguard that information. Yet there is no incentive for businesses to access that data and innovate if they do not retain IP ownership over their solutions.

#### We ask the government to reassess its relationship with public data, businesses, and IP.

Rather than own IP for an innovation derived from public data, the government should have the right to step in – under strictly defined circumstances, agreed upon by both government and institutions – to impede or control the intellectual property developed if a clear issue concerning public safety or maintenance of the public good arises.

But ultimately it is business – not government – that drives innovation and gets solutions to market. As such, businesses should own and commercialize their good ideas within guardrails set by the government.

#### **Context Setting**

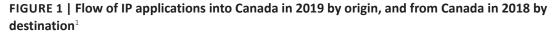
A robust intellectual property (IP) policy and legal structure is one of the most critical elements of the economic development prospects of a jurisdiction. The ability to control intellectual property is needed if institutions, firms, and individuals are to have reason to develop and invest in new ideas, practices, or technology. Absent a guarantee that rights to retain IP will remain intact and robust, increased operational risks abound as uncertainty weighs on the future prospects of projects and initiatives that rely on the ability to profit from research and development.

Robust IP rights are, for example, critical to the development of new and innovative medical treatments, which can cost billions of dollars to develop; without a robust guarantee that institutions will be able to realize a return from the time and money invested in the development of a treatment, there is little reason to make the investment in the first place. Similarly, if a robotics manufacturer is unable to attain guarantee of the right to own what it develops in a given jurisdiction, its business model will simply be untenable in that jurisdiction. Weakening or hindering the ability to develop intellectual property will deincentivise investment in Canada, as international entities look elsewhere to develop intellectual property assets. Restricting IP ownership rights or hindering their development therefore has the effect of limiting innovation and investment, which is ultimately to the detriment of economic development. IP policies must be in-sync with society and economic development imperatives if they are to be effective.

Canada and Ontario are global leaders in the creation and protection of IP. The robust structures that support IP in Canada ensure that innovation can take root, and that foreign innovators are able to invest in the Canadian economy. Ensuring that these structures remain robust is critical to the continued economic success of Ontario and Canada. Over the past decade and a half, Canada has been successful in facilitating both domestic expansion into foreign markets and involvement of foreign entities in Canadian markets through successful implementation of a portfolio of international IP agreements.

Over the past decade, non-resident applications for intellectual property in Canada grew at a rate of 4% for patents, 60% for trademarks, and 33% for industrial design. These trends suggest a persistently high level of confidence in Canada's IP system from the international business community. When looking at a comparison, we can see Canada's reputation in the numbers—as illustrated in the below graph (Figure 1)—Inflows of intellectual property exceed that of home-grown IP, highlighting the value foreign IP investment has within the Canadian economy.

Canada has also asserted itself as one of the leading nation states to grow and mature IP, with Canadian applications for foreign IP claims growing by 139% between 2009 and 2018. Most notably, Canada has proven itself to be one of the more prominent nations producing IP related to COVID-19. As demonstrated in Figure 2, again taken from the Canadian Intellectual Property Office's 2020 report, Canadian institutions have a high-degree of specialization in 'pandemic-fighting technologies', evidencing Canada's potential to be a global leader in combating advancement of COVID-19.



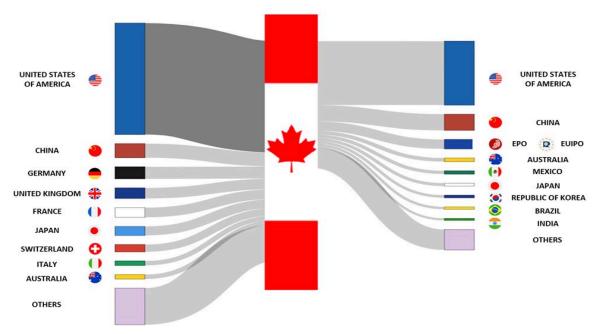
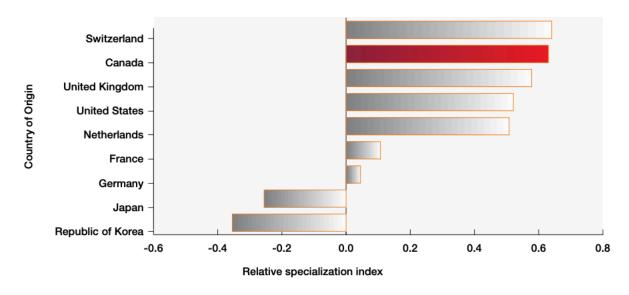


FIGURE 2 | Relative Specialization Index by institution's country of origin for pandemic-fighting technologies<sup>2</sup>



This comparison is made using the Relative Specialization Index (RSI), where an RSI of greater than 0 indicates a high level of specialization, while the opposite is true for values less than 0

<sup>1</sup> Department of Innovation, Science and Economic Development, Government of Canada. "IP Canada Report 2020." (2020)

<sup>2</sup> Department of Innovation, Science and Economic Development, Government of Canada. "IP Canada Report 2020." (2020)

#### **Economic Implications**

In 2020, the Ontario government announced a made-in-Ontario Intellectual Property Action Plan to help ensure the tremendous social and economic benefits of taxpayer-funded research and innovation stays in the province (see new release).

The government also convened an expert panel populated with individuals from a range of backgrounds that produced the following <u>report</u>, which comments on how the province can use policy to bolster Intellectual Property and innovation within the province.

The Board has heard from members across different sectors that the Ontario government's approach to implementing the recommendations of its expert panel may inadvertently limit the ability of innovators and researchers to helm development over the discoveries and innovations they generate. This in turn creates fundamental barriers to market access and commercialization opportunities.

# Ontario Health Data Platform (OHDP): A Case Study

The pandemic has inflicted numerous and immeasurable horrors and transformations on society. Though we endeavour to put our best foot forward in combating the pandemic's tumultuous course, mistakes are inevitable and to be expected. While humanity has experienced many pandemics, none of this scale has come in the modern, globalized world. Estimating the potential impact of a particular course of action may have is greatly hindered by the lack of historical precedent, and by the numerous and unknown variables inherent to the modern era (e.g. globalization, health technology advancement, geopolitics). Therefore, we must be diligent in not only documenting outcomes, but actively analyzing ways we can apply these learnings to better understanding future outcomes. While we can't blame ourselves for making poor decisions based on limited information, we can certainly assign blame if we're unwilling to learn from our mistakes; it's not about what happened, but our inability to heed opportunity to *learn* from what happened.

Gazing into an unknown future made inscrutable by new variants, we are faced with one such opportunity to learn: the Ontario government, prompted by public outcry, has worked to collect information on health outcomes throughout the course of the pandemic. The now labelled *Ontario Health Data Platform* (OHDP), located at Queen's University, is poised to cultivate a wealth of COVID-19 health data. This data could be of potential great value to researchers throughout Canada and possibly the world. It is critical to our future success that these data be made accessible to researchers and institutions so that it may be effectively leveraged to augment our collective understanding of how to mitigate the progression of COVID-19.

As researchers work to develop solutions and learn from our past, they need to maintain control over what they develop. If, through what is an invariably laborious and costly process of research and development, institutions find something of interest, intellectual property (IP) rights afford them the ability to protect and control their innovation. This control allows them to steward their discoveries through to practice, policy, and commercialization, allowing society opportunity to benefit from their discoveries, refining science and understanding in the process.

This brings us to the crux of the problem: As it currently stands, institutions which use the OHDP to build intellectual property will not have the ability to control it. In its proposed licenses for use of the data offered through the OHDP, the Ontario government is mandating that it be given the ability to either control or hinder development and commercialization of IP. This of course has serious implications for the ability of institutions to utilize the data. The institutions that support the development of research, both financially and academically, will be unwilling to invest the valuable time and money needed to develop a piece of medical technology or practice if there is risk that the resulting IP will simply be taken away, if and when the government deems it appropriate.

The precedent such licensing terms could set for broader industry will likely prove even more problematic. Development of nascent technology, such as AI, often requires access to historical data. And, similar to the data which comprises the OHDP, historical data used for other pursuits are also often derived from private individuals (i.e. publicly derived data), as it is those private individuals who will ultimately benefit from the technology. Development of nascent technology requires data to not only understand the problem the technology is intended to solve, but to make sure it is effective in achieving its purpose. This efficacy and efficiency are achieved by using historical data to test and refine the products or services being developed in the hope that the historical data somewhat mirrors our future challenges, offering better insight into how we might go about developing technologies and practices to better reconcile those future challenges.

The Board understands that, in an effort to maintain privacy (i.e. to act as responsible stewards of the platform and the data it manages) and to ensure that research derived from the OHDP serves to advance the public good, the government moved to require that control of the IP created through usage of the OHDP data be fully or partially ceded to the government. The initial terms which make this stipulation are found in the Terms of Mutual Benefit Agreement (appendix A) and must be agreed upon and 'signed' in advance of accessing the data.

Though the government is well intentioned in its aim to align OHDP with the recommendations outlined in the Intellectual Property Action Plan, the impact the restrictions could have on the ability of the economy to innovate and attract investment to advance COVID-19 treatments and mitigation practices could be gravely detrimental.

Institutional buy-in, such as from universities and research hospitals, is critical to IP development in the health care sector, as they possess both the funding and expertise required to invest in experimental research and push the envelope of understanding. However, experimental research taken on by institutions which aims to advance the forefront of medical understanding comes with tremendous risk, as there is little certainty that the experimental research will yield results that show promise of further development or value to society. This elevated risk means that the research projects looking to make the biggest strides in medical understanding are also those most vulnerable. Institutions looking to make the biggest impact will therefore tend towards working in, and with, jurisdictions that understand the value a commercially viable IP governance structure offers, so they can be assured that all opportunities to mitigate project risk are available to them.

If the research agreement needed to attain access to the OHDP platform requires that institutions cede control over the IP they create to the government, they would have little incentive to complete the research in Ontario using the publicly derived resources the province has worked so hard to compile. Such work would likely look for an alternative jurisdiction, that allows the institution greater confidence that the IP created is assigned to the institution and the individuals overseeing the research.

Similar problems also arise with small businesses if IP is encumbered: as with cutting-edge experimental research, small businesses are also highly vulnerable to risks given their limited financial and operational capacity. Hurdles placed in the way of IP development disincentivize smaller businesses from making investments in research, because they simply don't have the resources to undertake the litigation needed to claim their IP. While larger businesses have the financial capacity to ensure their interests are preserved, smaller firms don't have the ability to liaise with government to ensure their interests in a certain project or line of research are maintained. Overly burdensome regulatory or legal policy hurdles therefore often serve to benefit larger businesses by thinning the competition from smaller firms.

The intellectual property landscape is heavily interconnected, with advances made in otherwise discretely defined topics drawing from discoveries throughout the scientific community. As demonstrated by the illustration below, IP supports a highly interconnected web of research and development. A single IP application may serve to support a plethora of interrelated research initiatives.

Notably, while the landscape is heavily interconnected, it is not evenly dispersed. As illustrated in Figure 3, digital health and information processing is a veritable mountain in the IP landscape, aiding development of all pandemic-fighting research. Access to information, such as through the OHDP is a critical component to technologies and research advancement. Without access to real world data, researchers are limited in their ability to decipher the efficiency and efficacy of the digital health tools, to aid health data synthesis and analysis, and in turn advance 'rapid detection and diagnostics' and 'therapeutics and vaccine development'.

As firms throughout the region look to advance technology and practice, they must have access to the resources and information needed to do so. In addition to sufficient funding, labour, and infrastructure, firms require access to a wealth of data and information to ensure their value offering is not only market viable, but that it works. Data is especially valuable in COVID-19 research – access to prior information on health outcomes is invaluable to ongoing efforts to develop strategies to limit the virus's spread. As described by the Canadian Intellectual Property Office, "the creativity of businesses, both at home and globally, will play an important role in managing the ramifications of the COVID-19 pandemic and ensuring resilience in the Canadian economy."

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FIGURE 3 | International patent filing trend for pandemic-fighting technologies by institution's country of origin between 1999 and 2018<sup>3</sup>

### What History Tells Us

Fortunately, unlike COVID-19, decisions impacting where IP is seated do carry historical precedent. Before the advent of the American federal <a href="Bayh-Dole Act">Bayh-Dole Act</a> in 1980, the government controlled all intellectual property funded by taxpayers. The policy in place prior to 1980 was simply intended to ensure that the taxpayers who paid for the intellectual property to be developed reaped a commensurate benefit. However, by virtue of dispossessing the intellectual property from the institutions and researchers

Derwent Innovation's ThemeScape mapping tool was utilized to produce this visualization, using the frequency of keywords from a patents title and abstract and other algorithms to cluster patents based on shared language. The result is a patent landscape map, which resembles typical topographic map. Sections are comprised of peaks, some of which have bright white peaks, representing the highest concentration of patents and are labelled with key terms that tie common themes together. Turquoise is used to separate terms where there is no commonality between them. Areas pertaining to Digital Health are highlighted in red, areas pertaining to Rapid Detection and Diagnosis are highlighted in purple and regions pertaining to Therapeutics and Vaccine Development are highlighted in yellow. Canada's strength in Therapeutics and Vaccine Development is clear as it takes up almost two-thirds of the map. In addition, most of these areas are related to chemical compositions of vaccines which could indicate that Canadian institutions are specialized in the development of vaccines.

that created it, the institutions had no incentive to seek opportunities to commercialize what they had developed—to find ways in which society could derive value from them. This government control meant that the technologies and practices developed in universities, hospitals, national laboratories, and non-profit institutions sat stagnant. Of the 28,000 patents the American government owned in 1980, fewer than 5% had been licensed to industry or commercialized by 1980. The policy therefore had the ironic effect of depriving society of the fruits of its investment. Although taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return.

While the intention of the proposed policy restricting control of IP created from the OHDP differs from that of the American government's pre-1980s policy concerning development of IP, the consequence is the same: institutions and researchers are forced to relinquish control of their creation.

The Bayh-Dole act did two big things in a single stroke:

- 1. It transferred ownership of an invention or discovery from the government agency that had helped to pay for it to the academic institution that had carried out the actual research.
- 2. And, it ensured that the researchers involved got a piece of the action.

Overnight, universities across America became hotbeds of innovation, as entrepreneurial professors took their inventions (and graduate students) off campus to set up companies of their own. Since 1980, American universities have witnessed a tenfold increase in the patents they generate, spun off more than 2,200 firms to exploit research done in their labs, created 260,000 jobs in the process, and now contribute \$40 billion annually to the American economy.

# Implications for Innovation in Other Sectors

Beyond medical sciences, the need for historical data will likely begin to permeate all industry as technology endeavours to advance. Artificial intelligence for example—a capability that will likely underpin 21<sup>st</sup> century technology—requires a wealth of historical information to ensure its viability in new applications. Toronto, as it happens, has a nascent yet globally significant artificial intelligence industry. Development of Al applications, for health care and beyond, requires an exhaustive amount of historical data to make sure the Al is as efficient and effective as possible in achieving its purpose. An Al developed to recognise illicit financial transactions requires that those who are developing the Al have access to as many historical financial records as possible, to ensure the Al is effectively trained to recognizing problems.

One of the areas where AI has shown to be particularly promising is in aid of radiology. Radiology, a discipline many have cited to be as much an art as it is a science, is looking to enhance the ability of a radiologist to make the 'correct' call in identifying problematic masses within images produced from MRI, X-ray, or CT scans. This ability carries a sometimes-literal life or death consequence. If an AI were to improve the ability of a radiologist to interpret an image by a mere fraction of a percent, which preliminary testing suggests it can, the benefits would be tremendous. Critically, the efficacy of an AI in this pursuit and others like it is restricted by the historical data that it is able to use to inform the AI's suggestion or contribution. The precedent of limits to data access, such as those currently suggested for the OHDP, must therefore be weighed against the opportunities more open access may offer.

The need to access historical datasets will only become stronger and broader as technology advances. Future use cases might therefore include industries which had previously little need for such data, such as traffic and driving data to improve self-driving cars.

When making decisions that look to restrict or control IP development, government sends a strong signal to industry that it is unwilling to work with industry to cultivate innovation. As demonstrated by the surge of innovation following the Bayh-Dole Act, restriction of IP results in stagnant incentive to IP development. Such a signal, though domestic in purview, has broader international implications. Ontario is a significant player in the global market. When international firms are examining opportunities to invest in Ontario to

leverage its prolific academic institutions, highly skilled labour force, and world-class infrastructure, policies that limit IP development weigh strongly in a decision to invest in Canadian research and development. Even if only in an adjacent industry, the signal is similarly clear: it evidences an unwillingness on the part of government to work with industry to develop policy that benefits both society and the economy.

The investment needed to bring innovation to market can often be 10- or even 100-fold the cost of the initial research or innovation. Such tremendous, long-term investments, which often draw on global capital, require a solid, demonstrated commitment from government that it isn't going to pull the rug out from under them.

Public discussion of how to create a policy approach able to effectively and efficiently uphold both privacy and commercialization concerns is still new in Ontario, spurred most recently through the government's stewardship of the Ontario Health Data Platform.<sup>4</sup> The precedent set by policy around the OHDP will likely shape future policy in other sectors.

## What We're Calling For/Call to Action

Over the past 39 years, the Bayh-Dole Act has successfully fostered early basic research and helped ensure such findings are translated into new medical innovations. Before the Bayh-Dole Act, no drugs had been created from federally funded inventions. In contrast, after its enactment in 1980, more than 2000 new drugs and vaccines have been developed through public-private partnerships facilitated in part by the Bayh-Dole Act. As The Economist notes, the Bayh-Dole Act "unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money."<sup>5</sup>

The government's decision to control IP created through the OHDP is primarily born from concerns over use and stewardship of the data. Privacy, given the nature of the data, is of course a chief concern. However, such a problem is again not without precedent: the Institute of Clinical Evaluative Sciences (ICES) has realized great success in developing similar platforms that offer similarly sensitive data. Both the federal and provincial government, have robust regulatory structures in places that have thus far been successful in allaying privacy concerns.

The solution we propose is simple and emulates that again of the celebrated Bayh-Dole act. In effort to acknowledge concerns the government has over public use of the data, it could exercise what are referred to in the Bayh-Dole act as 'march in rights'. March in rights provide the government, under a strictly defined set of circumstances, the opportunity to step in and either impede or control usage of the IP. This ensures that issues concerning public safety and advancement of the public good are kept top of mind and ensures accountability.

Effective utilization of march in rights for both institutions and government would of course require that the circumstances be discretely defined and established co-operatively with industry. Such a process would be critical to both, ensuring institutions and industry have sufficient incentive to invest the large sums needed to advance research and development, and confidence in assigning risk and contingency within the long-term planning of associated organizations.

While the information held within the confines of the OHDP has potential to demonstrate tremendous value to ongoing COVID-19 research and development, it is the precedent that policies such as these impose on our future that is of greatest consequence. As technology advances at an ever-increasing pace, the value historical data offers is becoming more and more valuable.

Announced in June 2020, the Ontario Health Data Platform (OHDP), a publicly-derived resource, provides enterprising individuals such as academics, researchers, and health system partners with access to anonymized health data. Using the data gleaned from the OHDP, these individuals can better understand health challenges and work to develop novel solutions to tackle burgeoning health care issues.

<sup>5 &</sup>quot;Innovation's Golden Goose," The Economist. (2002)

The Board's ask of government is simple: to leverage innovative policy structures that have shown promise in augmenting both the public good and economic development. The 'march in rights' utilized by the Bayh-Dole act are an excellent example of the collaborative approach to policy development needed to incentivize industry to bring innovation to market, imbuing it with capabilities society can drive value from. Prior, concrete, establishment of when a government might be able to 'march in', allows institutions clearer foresight into how they can most effectively allocate investment and plan for future research.

In collecting and promulgating these publicly derived resources, the government must act as prudent stewards of the data, ensuring that the granularity of data available is sufficiently matched with the public's or individuals' desired framework for privacy protection. Conversely, government must also ensure the public is well apprised of the value that access to publicly derived resources offer research, and how it can advance the public good and the region's continued economic competitiveness.

By their very nature, history offers little visibility into the value of foregone opportunities. Avoidance is the safe choice; it buries the cost of inaction within the confines of a linear historical path. Affirmation on the other hand—acknowledgment of the evolving nature of technology and humanity—offers far greater opportunity for advancement. This is the government's opportunity to say 'yes' to innovation and affirm its commitment to work alongside global innovators instead of against them.

#### Other Resources

"Innovation's Golden Goose," The Economist. (December 2002) <a href="https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose">https://www.economist.com/technology-quarterly/2002/12/14/innovations-golden-goose</a>

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