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• COMPETITION BUREAU ANNOUNCES MARKET STUDY OF CANADA'S DIGITAL HEALTH CARE SECTOR •

Antonio Di Domenico, Partner, and Victoria Mitrova, Associate,
Fasken Martineau DuMoulin LLP

• In This Issue •

Antonio Di Domenico

Victoria Mitrova

In light of the COVID-19 pandemic, Canadians have increasingly turned to digital means to access and obtain health care services. The promotion of competition and innovation in Canada's health sector is also strategic priority for the Competition Bureau (the "Bureau").[1]

Having regard to these circumstances, the Bureau recently issued a market study notice in relation to its ongoing review of the Canadian health care sector.[2] The newly-announced market study (the "Study") will focus on digital health care in the country with the aim of improving understanding of existing or potential impediments to innovation and choice in the field.

The Bureau, an independent law enforcement agency responsible for the administration and

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Please address all editorial inquiries to:

LexisNexis Canada Inc.
Tel. (905) 479-2665
Fax (905) 479-2826
E-mail: rmchc@lexisnexis.ca
Web site: www.lexisnexis.ca

enforcement of the *Competition Act*, uses market studies to identify laws, regulations, policies, or other factors that can impede competition in a particular sector, and to determine whether changes to these impediments can foster newer and more efficient ways of delivering products and services in that sector.

Last year, the Bureau identified the need to improve its understanding of the competitive dynamics of the health care sector to enable it to make recommendations on how best to support digital health care in Canada. The Bureau recognized that the COVID-19 pandemic accelerated the use of digital health care, which in turn increased the need for technologies and tools to help provide care through digital means. To facilitate the development of these tools and technologies, the Bureau decided to examine existing policies in the health care sector lens in order to encourage the adoption of pro-competitive policies.

In July 2020, the Bureau announced that it would conduct a market study of Canada's health care sector. As a first step, the Bureau launched a public consultation to obtain information from industry stakeholders on factors that impede access to digital health care, or limit innovation and choice in the health care sector.[3] Additionally, in December 2020, the Bureau conducted a voluntary online survey to learn from Canadians about their experiences with accessing and using digital health services.

THE STUDY

Based on the information it received through the public consultation and online survey it conducted in 2020, the Bureau has identified three broad topics which it intends to examine as part of the Study:

1. Data and Information: The Study will explore ways to increase access, use and sharing of digital health data and information to improve the competitive landscape and accelerate the development and use of digital health care. To do so, the Study will aim to identify regulatory and non-regulatory barriers that prevent the access, use and sharing of such data and information, and to determine what effect these barriers have on the competitive landscape

for digital healthcare. The Study will also try to find ways of reducing these barriers to encourage competition and innovation in the field.

2. Products and Services: The Study will review barriers limiting the development, approval, procurement and commercialization of digital products and services intended for health care providers and will consider how pro-competitive rules could reduce those barriers.
3. Health Care Providers: The Study will investigate the ability of health care providers to provide digital care to Canadians in order to find potential opportunities to increase access to care. As part of this, the Study will review issues related to billings, compensation, licencing, and providers' scope of practice, how these issues impede the provision digital care, and steps that can be taken with respect to these issues to facilitate the delivery of health care via digital means.

NEXT STEPS

The Bureau has invited those with an interest in the Canadian health sector to contribute to the Study by providing submissions by July 2, 2021. The Bureau intends to conduct its analysis of all gathered information over the course of the 2021 year, with a view to publishing a final report on the Study in spring 2022. Given the significance of the Bureau's final report and any recommendations arising from it, stakeholders in the Canadian health sector should consider contributing to the Study to ensure that the Bureau's information gathering and perspective is as informed as possible.

[***Tony Di Domenico*** *is a Partner and Co-Leader of the firm's Competition, Marketing and Foreign Investment Group. As former counsel to Canada's Commissioner of Competition (Department of Justice Canada) and having served as counsel in many of Canada's most significant competition matters, Tony is widely recognized as one of Canada's leading practitioners in competition law and litigation. Tony's expertise is recognized in numerous national and international legal directories, including Chambers, Who's Who Legal, Global Competition Review, Best Lawyers, Legal 500, Benchmark Litigation and Lexpert. Clients note that Tony has "a practical, pragmatic approach to litigation and advisory matters", has "a strong international presence" and "is an absolute pleasure to work with." (Chambers and Who's Who Legal).*

Victoria Mitrova *is engaged in a corporate/commercial practice within the Health Law Group at Fasken. Victoria assists with transactions and advises clients on regulatory and legal matters in the health and not-for-profit sectors. Victoria is a graduate of Osgoode Hall Law School. Prior to completing her law degree, she obtained a Bachelor of Arts and Science degree with Combined Honours in Biology from McMaster University.*]

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1 Government of Canada, "The Competition Bureau's Strategic Vision for 2020-2024" (February 11, 2020), online: https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/Strategic-Vision-2020-24-En.pdf/$file/Strategic-Vision-2020-24-En.pdf.

2 Government of Canada, "Market Study Notice: Digital Health Care" (April 8, 2021), online: https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04579.html.

3 Government of Canada, "Digital Health Survey: What We Heard from Canadians" (February 24, 2021), online: https://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04573.html.

• PATENTABILITY OF DIAGNOSTIC METHODS – HAS THE CANADIAN PATENT OFFICE DRAWN THE LINE? •

David Schwartz, Partner, Smart & Biggar LLP

David Schwartz

The importance of medical diagnostic technologies has been brought to the fore with the COVID-19 pandemic. Rarely does a day pass when the media does not report on matters of approval and availability of tests, testing protocols and capacity. As of March 6, 2021, Health Canada had approved 60 COVID-19 testing devices, and 111 applications for authorization were under evaluation. At the same time, patentability of diagnostic technologies has been as fractious an issue in Canada as it has been in the United States.

Intellectual property offices have grappled with whether a medical diagnostic constitutes a traditionally patentable concrete or physical method or instead is merely an unpatentable and intangible abstract idea, untethered to the physical world. It is a difficult problem because although a new diagnostic tool typically is embodied in a physical device or method, often the principal advance lies in the recognition of a previously unknown correlation.

Until recently, the Canadian Patent Office drew a distinction between a diagnostic method that "solves a data acquisition problem" and one that "solves a data analysis problem," generally only the former being considered patentable. There is an attractive simplicity to the logic behind this division. An invention solving a data acquisition problem — *e.g.* providing a new molecular biology technique for detecting "protein X" in a biological sample — inevitably involves a new method of manipulating or transforming matter, the patentability of which has never been in dispute. But an invention instead solving a data analysis problem — *e.g.* being the first to relate the presence of "protein X" from a biological sample to the likelihood a subject suffers from "disease Y" — might be seen as involving merely a disembodied abstract idea.

If protein X is a known and well-characterized protein, and techniques for quantifying protein X in a sample from a subject are also known, should someone who later discovers that a level of protein X in the blood above a particular threshold indicates that the subject is at risk of developing disease Y be rewarded with a patent? The patentee has the exclusive right to make, use and sell the patented invention, and may exclude others from doing so. What would constitute infringement of the patent? Indeed, perhaps it was already routine practice to measure a subject's protein X level using a commercially available assay. Would the patent be infringed by a physician reading a patient's medical records, noting an elevated level of protein X, and now appreciating that the patient may be at risk of disease Y?

This is a polarizing example, and much hinges on precisely what is claimed in the hypothetical patent, but the broad issue remains. If all that is new is the discovery of the relationship between protein X and disease Y, is that the proper subject of patent protection? Indeed, if the inventor instead published a scientific article disclosing the correlation, the public could make use of the discovery with existing technologies (an assay for protein X). One might argue that granting a patent in such circumstances removes a mere scientific principle or abstract idea from the public domain.

But the discovery of the link between protein X and disease Y is of undisputable practical value

in healthcare, and such innovation should be encouraged. It is consistent with the fundamental patent bargain to promote and reward such advances with time-limited exclusive rights. An analogy can be made patents for second medical uses. Patents routinely grant for new uses of known medicines, *e.g.* for a different therapeutic indication. The discovery that a known compound has a further therapeutic utility is as much a mere scientific principle or abstract idea as the discovery that a known molecule can be used to diagnose a disease condition. Both are valuable innovations that should be encouraged.

Notably, the Canadian Patent Office has recently broadened its interpretation of patent eligibility in the medical diagnostics field, following a decision of the Federal Court holding that the "problem-solution" approach to subject-matter eligibility discussed above is improper, albeit in the context of a computer-implemented invention for selecting and managing a securities portfolio.

Pursuant to new Examples of Patentable Subject-Matter Analysis published in November 2020,[1] the Patent Office indicates that the following claim would fall within the definition of "invention" in section 2 of the *Patent Act* as being directed to a patentable "art" or "process":

> A method of diagnosing whether a human subject is at risk for developing cancer, comprising:
>
> > measuring the level of X in a biological sample from the subject; and
> >
> > comparing said level to the level of a non-cancerous reference sample, wherein an increase in the level of X relative to said reference indicates the subject is at risk for cancer.

This is a broad claim, as it appears the "comparing" step might encompass a purely mental process. But the claim also includes the clearly physical "measuring" step and the Patent Office acknowledges that the two elements of the claim must cooperate in order to arrive at a diagnosis of cancer risk, such that the requirement of physicality is satisfied.

In contrast, the Patent Office indicates that the following claim would not be patentable, having no physical steps whatsoever:

> A method of diagnosing whether a human subject is at risk for developing cancer, comprising:
>
> > receiving a report summarizing the level of X in a sample from the subject; and
> >
> > comparing said level to the level of a non-cancerous reference sample, wherein an increase in the level of X relative to said reference indicates the subject is at risk for cancer.

Indeed, in the latter case, a physician reviewing a patient's medical record and noting that the patient has an abnormally high level of X arguably might infringe the claim merely by recognizing that the patient may have an elevated risk of cancer. Merely thinking about something clearly should not constitute patent infringement!

In any event, the recent guidance from the Patent Office is a welcome step forward, even if it cannot provide all the answers in this difficult area. The "problem-solution" approach underpinning the Patent Office's previous approach to analyzing medical diagnostic method claims involved deeming as "non-essential" (*i.e.* reading out) those claim elements that were not considered to contribute to solving the problem addressed by the invention. Any approach to examination that does not give patentable weight to all express claim limitations appears doomed from the start. If there can be no fundamental agreement as what the language of the claims means, and what claim limitations or elements will be taken into account in assessing patentability, substantive examination cannot proceed. Perhaps the Patent Office's recent guidance will allow this impasse to be resolved, and attention turned to assessment of novelty, inventiveness, and sufficiency of disclosure. Rejecting patent applications concerning medical diagnostics on the basis that what is claimed does not constitute a "method" at all is a blunt tool for assessing patentability in this complex and important area. Diagnostic technologies are of vital importance, and

the patent system must find an appropriate balance to encourage innovation in this area.

[***David Schwartz** is a partner at Smart & Biggar LLP. He is a long-standing and highly respected IP leader who brings nearly 30 years of experience in patent law. An experienced IP leader, David advocates for biotech clients in complex patent prosecution. He has taught patent law at Queen's University and the University of Ottawa, and he is the Past-President of the Intellectual Property Institute of Canada.*]

[1] Government of Canada, "Examples of Patentable Subject-Matter Analysis", *Canadian Intellectual Property Office* (November 3, 2020), online: https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr04861.html.

• THE *ADVANCING OVERSIGHT AND PLANNING ONTARIO'S HEALTH SYSTEM ACT, 2021*; THE PROPOSED REGULATION OF PERSONAL SUPPORT WORKERS, PHYSICIAN ASSISTANTS AND BEHAVIOUR ANALYSTS •

Lindsay Kantor, Partner, Torkin Manes LLP

Lindsay Kantor

Every day, thousands of Ontarians receive vital care from unregulated health care providers including personal support workers ("PSWs"), physician assistants, and behaviour analysts. The critical role that these providers play in our healthcare system has only been further highlighted by the COVID-19 pandemic. This is particularly the case in the long-term care and retirement home setting, where the Ontario government has committed to investing significant funds over the coming years to create thousands of new positions for PSWs, among other healthcare providers. However, some have argued that the lack of fulsome regulation for these positions may lead to inconsistencies in the quality of care which is rendered to the public.

On April 27, 2021, the Ontario government introduced the *Advancing Oversight and Planning in Ontario's Health System Act, 2021*. If passed, this legislation would:

- Create a new framework for the regulation of PSWs by a new regulatory body known as the Health and Supportive Care Providers Oversight Authority;
- Require physician assistants to be regulated by the College of Physicians and Surgeons of Ontario;
- Require behaviour analysts to be regulated by the College of Psychologists of Ontario.

With respect to PSWs, this new regulatory framework would include establishing consistency in education, training, and standards of practice. With respect to physician assistants, the proposed legislation would solidify their role as extensions of physicians, and could permit for the communication of certain diagnoses and the prescribing of medications and/or assistive devices. Finally, the regulation of behaviour analysts will provide consistency in the treatment provided to members of particularly vulnerable sectors of society, such as those with dementia, developmental disabilities, acquired brain injuries and/or psychological and psychiatric disorders.

If passed, the *Advancing Oversight and Planning in Ontario's Health System Act, 2021* will surely lead to extensive consultation with the relevant sectors to develop necessary regulations, rules and guidelines for these burgeoning areas of the regulated healthcare workforce. If done correctly, this could ensure better and more efficient health care for Ontarians in the future.

[***Lindsay Kantor*** *is a partner in Torkin Manes' Litigation Group. Lindsay practices in all areas of civil litigation, with a particular expertise in health law and professional discipline. Lindsay provides advice and represents healthcare practitioners in a wide range of civil, regulatory and administrative proceedings.*]

• GETTING BEHIND COVID-19 VACCINE INNOVATORS •

Noel Courage, Partner, Bereskin & Parr LLP

Noel Courage

PART I: SCALING UP PRODUCTION FAST

There is an ongoing need to rapidly increase vaccine supply to defeat the global pandemic. Some politicians and non-governmental organizations have claimed that vaccine patents are affecting supply and they have demanded legislation to override the patents.[1] Petitions of support for overrides are circulating.[2] The US government recently supported a draft proposal at the World Trade Organization to waive certain COVID-19 patent rights.[3]

It is understandable that people want to pull every lever that may alleviate a public health emergency. Patent overrides would miss the mark. It is an oversimplification to suggest that getting rid of patents would increase vaccination. This article explains why innovator companies should be considered as partners, not adversaries, in order to increase vaccine access. Part I of this article addresses rapid scale-up and Part II addresses safety factors. Part III addresses vaccine equity.

Rapid Tech Transfer

Initial patents are filed at a very early stage of development, and do not include the necessary know-how to commercially scale up and produce vaccines. Patents also do not provide guidance on quality assurance steps to ensure that a copy of a vaccine is safe and effective. Much of the knowledge to make safe and effective vaccines is in the unpublished know-how of the experienced companies that originated them. It is not possible to turn off the patent taps one day and turn on the taps for vaccine copies the next. Creating your own 'unauthorized' version of an off-patent vaccine takes substantial time, experimentation, money, as well as significant regulatory scrutiny.

The most efficient route to increased vaccine supply is for innovator companies to license and engage other experienced vaccine manufacturers, and transfer their knowledge to those manufacturers. This is shown by GSK and Novavax entering into an agreement for GSK to provide fill and finish services for the COVID-19 vaccine developed by Novavax.[4] GSK described the collaboration as a, "rapid technology transfer between the two companies beginning immediately." This is a more productive and certain way to increase vaccine supply than by overriding Novavax IP and waiting to see if other companies develop their own copy of the Novavax vaccine and get approval from regulators.

Innovator Vaccine Companies are Already Cooperating

There have been assertions that vaccine companies are restricting access to vaccines. These assertions are not accurate because there have been many cooperative arrangements put in place to increase vaccine supply. Vaccine supply has increased so quickly that the rate limiting step has sometimes been supply of raw materials.[5]

In some cases, private companies have struck deals between themselves. Moderna, J&J and BioNTech have all licensed a leading multinational vaccine company, Sanofi, that will produce hundreds of millions of COVID-19 vaccine doses.[6] AstraZeneca has licensed the Serum Institute of India, which is one of the largest vaccine manufacturers in the world.

Innovator companies have also contracted out pieces of manufacturing to ramp up capacity, as in the GSK – Novavax example above.

Governments have facilitated COVID-19 vaccine partnerships. US government funding will allow Merck to use its facilities in the United States to produce vaccine drug substance, formulate and fill vials of Johnson & Johnson's vaccine.[7]

These partnerships are not limited to first-world countries. AstraZeneca has partnerships with non-governmental organizations, such as the Coalition for Epidemic Preparedness Innovations (CEPI) and a vaccine organization, Gavi, backed by the Gates Foundation.[8] AstraZeneca started this process in 2020 for its vaccine as part of a plan to be able to produce up to 2 billion vaccine doses, with up to 1 billion of those doses allocated to low- and middle-income countries.[9]

AstraZeneca and its licensees are also supporting the WHO COVAX COVID-19 vaccine program.[10] AstraZeneca plans additional licenses with manufacturers in developing nations such as Brazil and Ghana.[11]

Holding Innovator Companies' Feet to the Fire

It is clear that both government and non-governmental organizations on the front lines of the pandemic recognize that a rapid and massive scale up in vaccine production should primarily rely on COVID vaccine originators as partners, as well as leveraging other experienced vaccine makers. The job of building manufacturing capacity is getting done - for example, AstraZeneca recently announced that it is on track to deliver 200 million doses a month.[12] Moderna is going to provide 500 million low cost doses to COVAX.[13] Other companies are also scaling, licensing and increasing production. Keep building on these efforts that are working.

PART II – INCREASING VACCINE ACCEPTANCE

As discussed in Part I of this article, the fastest and most effective way to increase the supply of vaccines is to rely on vaccine innovators as partners in scaling up. Part II of this article will address the public safety benefits of relying on innovators. Supporting innovator companies will increase vaccine acceptance.

Relying on Innovator Companies Will Increase Safety and Public Acceptance of Vaccines

Producing sufficient supply of vaccine is only one major obstacle in trying to vaccinate the world out of the pandemic. Another major challenge is ensuring that enough people are willing to be vaccinated to create "herd immunity". The latter issue is already becoming a serious concern in the vaccine-rich USA.[14] Some experts believe that it is unlikely the US will reach herd immunity.[15] There is going to be a public health battle to try to sway those on the fence to accept a vaccine. These days, every delivery delay or significant rare adverse event with a COVID vaccine can become front page news and undermine confidence in vaccines.

Any solution to vaccine shortage has to address both supply and hesitancy. It is not easy to make a massive amount of high quality vaccine. Even with all its experience in manufacturing, AstraZeneca has experienced public relations challenges with its clinical trial data in the US and Europe,[16] as well as its manufacturing.[17] The vaccine originator should therefore be closely involved in this process of building vaccine capacity, to avoid reinventing the wheel. Originators are more likely to successfully transfer technology to licensed manufacturers, minimizing risk of incidents that would undermine public confidence in vaccines. AstraZeneca has created many of its own manufacturing sites,[18] and as of March 2021, it reported having set up

manufacturing in 15 countries and 25 sites.[19] That experience has tremendous value when transferred to a licensed partner.

The challenges faced by less-experienced vaccine manufacturers, even after technology transfer, were demonstrated by AstraZeneca stopping use of a US company as a subcontractor to make its vaccine. Overriding AstraZeneca IP to allow other companies to take a shot at making their own version may well backfire if those companies, less experienced with the vaccine, end up with quality problems that create vaccine hesitancy.

IP Licenses Ensure Quality and Control

An IP license agreement can include limited and strict permissions to make, use and sell under an originator company's patents, know-how and trademarks. These license terms allow the originator to effectively control the licensee. If there is no patent or other IP on a vaccine, then no license is needed, and any company can develop its own vaccine formulation, for better or worse. The originator will not be involved and has no control over unauthorized vaccines. If the originator company is involved in the technology transfer as licensor, then the licensee benefits from the originator's knowledge and experience with the product, and problems can proactively be avoided. If problems cannot be resolved, the license can be terminated to revoke permission to make the vaccine.

The WHO recently called for additional licensing efforts to resolve vaccine inequities.[20] This is a more productive approach than patent overrides. A free-for-all of vaccine production by unlicensed vaccine manufacturers may lead to lower quality vaccines and decrease public acceptance of vaccines. Innovator companies that are already licensing their IP will be able to do more licensing, and should be encouraged to do so in a manner that ensures consistently high product quality. Governments and other organizations should investigate how to better support vaccine innovators to undertake rapid technology transfer to capable manufacturers.

PART III – THERE IS MUCH NEW SUPPLY FROM INNOVATORS THAT IS NOT BEING EQUITABLY DISTRIBUTED

Licensing and technology transfer for innovative vaccines can address vaccine equity. This final part addresses what needs to be done after there has been rapid output of safe innovator vaccines.

Typically, large vaccine companies own, or can partner with, vast distribution networks to get innovative vaccines distributed globally. Governmental and non-governmental organizations can help vaccines penetrate even farther. Patents are not the reason why these networks are currently being underutilized. In some cases where innovator companies have already increased vaccine supply, their efforts have been undermined by governments prioritizing their own countries' interests. The innovator companies' hands are tied by contracts or laws that prevent vaccine export. Governments can loosen these contract restrictions and laws, if they choose to do so. Ethics experts are debating the extent to which vaccine-rich countries should share and when.[21] Licensing innovator vaccines further could help fill global distribution networks while diplomatic negotiations try to free up vaccines for countries most in need. As noted in prior parts of this article, licensing and technology transfer from innovator companies is faster and safer than overriding patents and waiting on "home brew" solutions to arrive.

The US government has stockpiled about 60 million of doses of the AstraZeneca vaccine that has not yet been not approved in the US,[22] and that a top public health official has said may not even be needed there.[23] The US government does not intend to release these vaccines to other nations until the US FDA has approved the product, which is prudent, but does not appear to consider the urgency of the global need. The benefits of increased vaccine supply are only realized when shots are in arms, not sitting on shelves. Perhaps let other countries that already approved the vaccine receive and decide whether to deploy these unused doses. There are also calls for the US to share other vaccines.[24]

The Canadian government said that it intends to take 1.9 million doses of vaccine from the WHO COVAX initiative for third world vaccine (as Canada is entitled to do),[25] even though Canada has lined up tens of millions of doses from other sources.[26] Canada is also eyeing requesting a share of the US AstraZeneca stockpile, despite the more urgent, deteriorating situation in other countries, such as Brazil and India.[27] The Canadian government's plan for its excess vaccine doses remains unclear, and may involve a hybrid of deferring delivery and donating to other countries.[28] Some other countries have already committed to giving excess vaccine doses back to COVAX. Calls for Canada to do more are growing.[29]

When diplomatic negotiations do not provide fair vaccine access, patents become a scapegoat, and patent overrides become a desperate do-it-yourself solution. No country should have to resort to "home brew" out of frustration, when licensed, safe vaccine supply should be available. Diplomatic logjams must be resolved, and nationalism must give way to global cooperation. This includes both sharing the increased supply of innovator vaccines, as well as increasing the licensing out of innovator vaccine manufacturing knowledge to others that can manufacture. Equitable access to vaccines is essential before the world can move past COVID-19.

[***Noel Courage*** *is a partner in the leading intellectual property law firm Bereskin & Parr LLP. His practice focuses on licensing and commercialization of cutting-edge technology. His has provided patent advice to both innovator companies and generic companies.*]

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1 Some vaccine manufacturers have stated that they will not enforce COVID-19 related patents during the pandemic. There is debate, beyond the scope of this article, as to whether these assurances have been sufficient to address alleged patent risks. See: @jbkrell, " So this is a common question to ask -- if Moderna has pledged to not enforce their patents, why can't we start production everywhere? Three reasons:", *Twitter* (May 4, 2021), online: https://twitter.com/jbkrell/status/1389719926181613573.

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