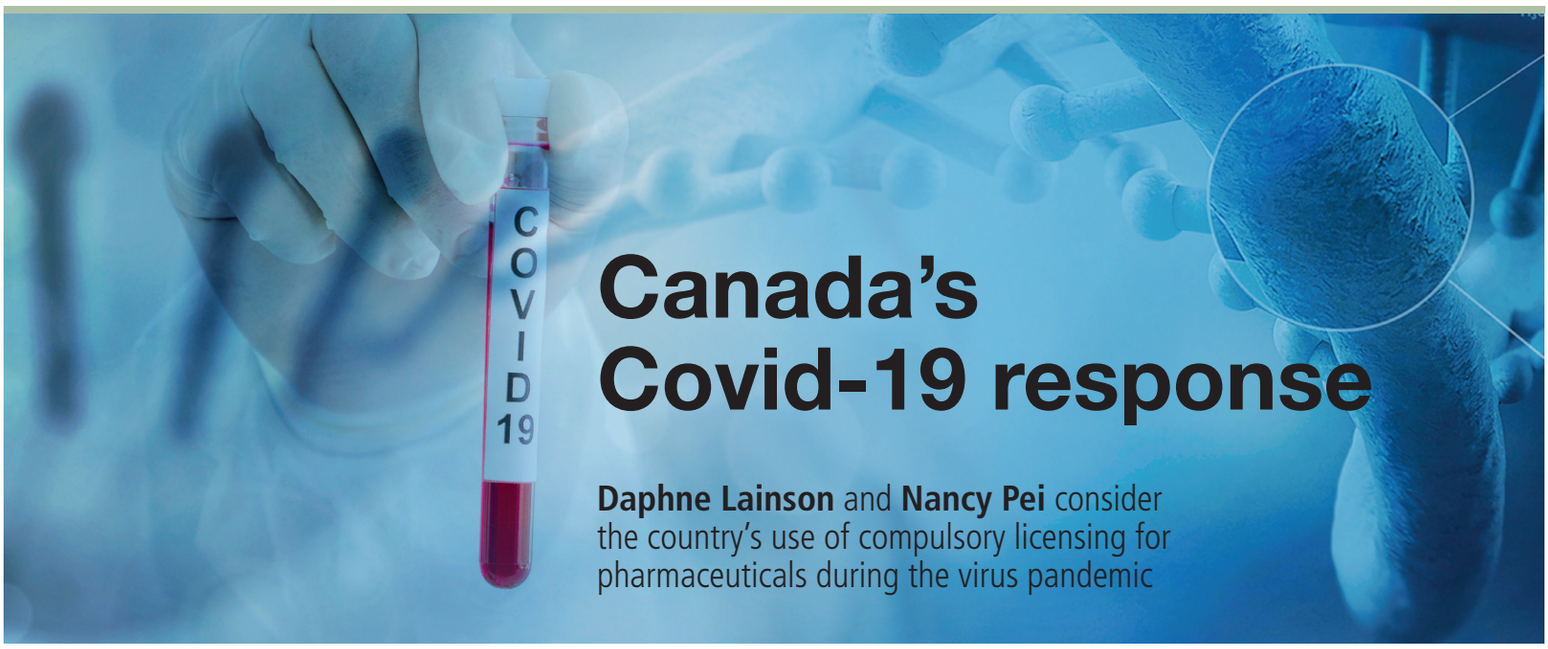

Canada's Covid-19 response

Daphne Lainson and **Nancy Pei** consider the country's use of compulsory licensing for pharmaceuticals during the virus pandemic

There is a long shadow cast by compulsory licensing in Canada; so, when the government passed legislation on 25 March 2020 to introduce a new form of compulsory licensing, this caused a stir within the IP community.

The new provisions do not send us back to the 1970s and 1980s when compulsory licensing was broadly available and allowed generic drug companies to thrive in Canada. Rather, the new provisions build on existing ones that allow limited use of patented inventions for more publicly minded purposes.

Sections 19-19.4 of the Patent Act

Prior to passage of the Covid-19 Emergency Response Act (Covid-19 ERA) on 25 March 2020, the Patent Act had long allowed the government to make use of a patented invention. These provisions have rarely been used and have been relied upon historically in times of war or for matters of national defence. The current iteration of these provisions is found in sections 19 to 19.3 (enacted in 1993), and the Covid-19 ERA builds on these sections by adding new section 19.4 to the Patent Act, providing the commissioner of patents (commissioner) new powers to grant relief.

Highlights of the new provisions are best understood within the context of the old provisions as shown in table 1.

New section 19.4 raises several questions discussed further.

Public health emergency

The public health emergency may be broader than treatment of Covid-19 in Canada. Public health emergencies are not defined in the Covid-19 ERA or the Patent Act, and unlike s 19(2) of the Patent Act, the authorisation is not predominantly to address a domestic emergency, although the chief public health officer must confirm her belief that there is a public health emergency that is a matter of national concern.

Identification of patents

The minister of health in her application to the commissioner is required to specifically identify relevant patents, unlike under section 19, which does not include specific application requirements. It is not clear how the minister of health will be able to identify relevant patents absent input from the patentee.

Compensation

The commissioner has little guidance in the Patent Act to assess the amount of compensation that may be payable under section 19.4. This is also an open question in respect of section 19, for which there are no reported authorisations.

The provisions in the Patent Act that had permitted compulsory licensing of patented pharmaceutical products to generic companies for commercial use were repealed in 1993. One of the many criticisms of this former regime was that it provided no real compensation to patentees. In the 1970 decision of *Frank W Horner Ltd v Hoffman-La Roche Ltd* (1970), 61 CPR 243 (Commr of Pat), involving the drug diazepam, the commissioner selected a royalty rate of 4% of the net selling price, which was generally followed in subsequent decisions. This case law has little application to section 19, and now section 19.4.

Historically, compensation awarded under earlier versions of section 19 was much more reasonable than under the now defunct compulsory licensing provisions in the Patent Act. Indeed, earlier versions of section 19 specifically referred to "reasonable compensation", which had been considered as the amount which would be arrived at between a willing licensor and a willing licensee bargaining on equal terms.[1]

Notably, section 55(2) of the current Patent Act also provides for "reasonable compensation" for an act committed prior to patent grant and after the patent application became open to public inspection that would constitute patent infringement post-grant. The courts have considered a reasonable royalty to constitute reasonable compensation under this provision of the Patent Act.[2] These decisions may provide some guidance to the commissioner in how to approach the issue of compensation under sections 19 and 19.4.

Other authorised uses

The Patent Act also permits other limited uses of patented inventions, including to grant a licence (or revoke a patent) in instances of abuse, or for international humanitarian purposes to address public health concerns.

For abuse, the circumstances of such authorisations are narrowly prescribed; eg, requiring:

- Demand for the patented article not being adequately met in Canada on reasonable terms;
- Refusal by the patentee to license the patent on reasonable terms, with prejudice to trade or industry in Canada, and with the licence being in the public interest;
- The patentee has attached conditions to use of the patented article or process that unfairly prejudice trade or industry in Canada; or
- Use by the patentee of a process or

Table 1: Sections 19-19.4 of Canada's Patent Act

	Pre-Covid-19 Emergency Response Act	Covid-19 Emergency Response Act
Applicant	• Government of Canada (s 19(1)). • Government of a province (s 19(1)).	• Minister of Health (s 19.4(1)).
Authorised user	• The governmental applicant (s 19(1)).	• Government of Canada (s 19.4(1)). • Any person specified in the application (s 19.4(1) & (2)(d)).
Basis	• Efforts to obtain authorisation from patentee on reasonable commercial terms and conditions were unsuccessful within a reasonable period (s 19.1(1)); or • National emergency or extreme urgency, or for a public non-commercial use (s 19.1(2)).	• Public health emergency (s 19.4(1) & (2)(c)). • Chief public health officer to confirm belief that there is a public health emergency that is a matter of national concern (s 19.4(2)(b)).
Limits on authorisation	• Limited to purpose for which use is authorised (s 19(2)(a)). • Non-exclusive (s 19(2)(b)). • Non-transferable (s 19(6)). • Predominantly to supply the domestic market (s 19(2)(c)). • Semi-conductor technology can only be authorised if it is a public non-commercial use (s 19.1(4)). • Proposed user must comply with prescribed conditions in the case of pre-scribed uses (s 19.1(3)).	• Limited to making, constructing, using and selling the patented invention for the purposes of responding to the public health emergency, as described in the application (s 19.4(1)). • Non-transferable (s 19.4(6)).
Term	• No statutory limit. • Patentee can apply to Commissioner to terminate authorisation if circum-stances that led to the authorisation have ceased to exist and are unlikely to recur, subject to conditions to protect legitimate interests of authorised user (s 19(5)).	• Authorisation must be granted by 30 September 2020 (s 19.4(9)). • Maximum one-year term from grant (s 19.4(3)(b)). • Minister of Health may notify Commissioner authorisation is no longer necessary to respond to the public health emergency set out in the application (s 19.4(3)(a)).
Notice	• The government must use reasonable efforts to negotiate with the patentee prior to making application, except in cases of national emergency or extreme urgency, or for a public non-commercial use (s 19.1(1) and (2)). • Patentee to be notified after authorisation granted (s 19(3)).	• Patentee to be notified after authorisation granted (s 19.4(4)).
Patentee compensation	• Commissioner is to decide "adequate remuneration in the circumstances, taking into account the economic value of the authorisation" (s 19(4)).	• Commissioner is to decide "adequate remuneration in the circumstances, taking into account the economic value of the authorisation and the extent to which they make, construct, use and sell the patented invention" (s 19.4(5)).
Deemed non-infringing activity	• No specific deeming provision.	• Use or sale in relation to public health emergency of patented invention made or constructed in accordance with authorisation is not an infringement (s 19.4(7)).
Appeal/judicial review	• Any decision of the Commissioner subject to appeal to Federal Court (s 19.2).	• Patentee may apply to Federal Court for order to "cease making, constructing, using or selling the patented invention in a manner that is inconsistent with the authorisation" (s 19.4(8)).

product-by-process patent involving materials not protected by the patent to unfairly prejudice the manufacture, use or sale of any materials in Canada. Such relief is available under section 65 and is only available three years after patent grant. These provisions are rarely used.

Use of patents for international humanitarian purposes are also limited in application. Sections 21.01-21.2 were added to the Patent Act in 2005 further to the World Trade Organization's General Council decision of 30 August 2003 "to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." To date, only a single licence (for Apo-TriAvir, for export to Rwanda) has been granted.

Summary

In 2001, the government rushed to enter into an agreement with a generic manufacturer to supply an antibiotic that could be used to prevent anthrax. At that time, the antibiotic was patent protected, and there were international concerns of an anthrax attack. The government was publicly criticised, including for not contacting the patentee or applying for a licence under section 19 of the Patent Act. Ultimately, an agreement was reached between all parties, the details of which were not made public.

In the extraordinary circumstances of Covid-19, encroachment on rights of patentees may seem justified. However, careful balancing of competing needs is still required. Involving patentees in the process of assessing a section 19.4 application, as was ultimately the case in 2001, would seem to be the best way to achieve that balance.

Footnotes

1. *R v Irving Air Chute Inc,* [1949] SCR 613 (SCC); *R v Canada* (Secretary of State), [1953] 1 SCR 417 (SCC); and *Pathfinder Camping Products Ltd, Re* (1982), 65 CPR (2d) 119 (Commr of Pat).
2. *Jay-Lor International Inc v Penta Farm Systems Ltd*, 2007 FC 358.

Authors


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