IP Update

# *COVID-19 Emergency Response Act* permits Canadian government to use patented inventions and make regulations to address drug shortages.

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Nancy Pei and David Schwartz

This week Canada rushed to implement new laws in response to COVID-19, including addition of Section 19.4 of the *Patent Act*. Bill C-13, entitled the *COVID-19 Emergency Response Act*, was introduced in Parliament on March 24, 2020 and received Royal Assent on March 25, 2020. The Bill includes temporary financial and other measures to address the COVID-19 pandemic. These measures include an expansion of government powers to use patented inventions and to address drug shortages.

## Government use of patented inventions

The Canadian *Patent Act* already permits encroachment on privately held patent rights by the federal or a provincial government in certain circumstances.

Specifically, pursuant to sections 19 to 19.3 of the Act, the Commissioner of Patents may, on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government. Such authorizations are not transferable.

The Commissioner shall settle the terms of any such authorized use in accordance with the following principles:

(a) the scope and duration of the use shall be limited to the purpose for which the use is authorized;

(b) the use authorized shall be non-exclusive; and

(c) any use shall be authorized predominantly to supply the domestic market.

The Commissioner must notify the patentee of any use of the patented invention that is authorized, and the authorized user is required to pay to the patentee such remuneration that the Commissioner considers to be adequate in the circumstances, taking into account the economic value of the authorization.

An authorization may subsequently be terminated where the Commissioner is satisfied that the circumstances that led to the granting of the authorization have ceased to exist and are unlikely to recur, subject to such conditions as the Commissioner deems appropriate to protect the legitimate interests of the authorized user.

The Commissioner may not authorize the use of a patented invention under sections 19 to 19.3 unless the applicant establishes that:

(a) it has made efforts to obtain from the patentee on reasonable commercial terms and conditions the authority to use the patented invention; and

(b) its efforts have not been successful within a reasonable period.

Notably, the requirement for the federal or a provincial government to seek the patentee's authorization to use the patented invention does **not** apply in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.

Semi-conductor technology is treated exceptionally under sections 19 to 19.3 of the Act—the Commissioner of Patents may not authorize any use of semi-conductor technology other than a public non-commercial use.

Thus, even before Bill C-13, the *Patent Act* provided a mechanism by which the federal or a provincial government may be permitted to use a patented invention without the patentee's consent in the event of a national emergency, in cases of extreme urgency, or if the use is for a public non-commercial purpose.

## New section 19.4 of the *Patent Act*

Part 12 of Bill C-13 amends the *Patent Act* by enacting new section 19.4, within the existing provisions concerning use of patents by government.

Pursuant to new section 19.4, the Commissioner of Patents shall, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application.

An application under section 19.4 must:

(a) set out the name of the patentee and the patent number;

(b) include a confirmation that the Chief Public Health Officer believes that there is a public health emergency that is a matter of national concern;

(c) include a description of the public health emergency; and

(d) specify a person, if any, that is to be authorized to make, construct, use and sell the patented invention for the purposes of responding to the public health emergency.

Authorizations under section 19.4 can have a term of no more than one year after the authorization is granted, and no authorization may be issued after September 30, 2020.

Many aspects of new section 19.4 are similar to the existing provisions of the Act concerning government use of patented inventions:

- As in the broader case of a national emergency or extreme urgency, there is no requirement under section 19.4 to seek the patentee's consent to use the patented invention when providing an authorization to respond to a public health emergency that is a matter of national concern.
- The Commissioner must notify the patentee of any authorization granted and provide the details concerning the authorization.
- The Government of Canada and any person to whom an authorization is granted shall pay the patentee remuneration the Commissioner considers to be adequate in the circumstances, taking into account the economic value of the authorization and the extent to which they make, construct, use and sell the patented invention.
- An authorization is not transferable.

- An authorization ceases to have effect when the Minister of Health notifies the Commissioner that the authorization is no longer necessary to respond to the public health emergency set out in the application (with the above-discussed further limitation that an authorization can be in effect for no more than one year).

There are also differences between new section 19.4 and the existing provisions of the Act that possibly may make section 19.4 of broader application in some aspects:

- The existing provisions specify that an authorization may be granted to the Government of Canada or the government of a province *per se*. In contrast, new section 19.4 explicitly permits authorizations to be granted to other persons.
- Section 19.4 contains no exception for semi-conductor technology. Thus, it is possible that an authorization could be granted under section 19.4 for use of patented semi-conductor technology in responding to a public health emergency and the authorization could not previously have been made because the use is not a public, non-commercial use.
- The existing provisions specify that any use shall be authorized predominantly to supply the domestic market. Section 19.4 does not contain a parallel restriction and does not explicitly state that the public health emergency that is a matter of national concern must be within Canada.

## Expanded regulation-making authority under *Food and Drugs Act*

Bill C-13 also amends the *Food and Drugs Act* to provide broad powers to make regulations: (i) requiring persons to provide information to the Minister of Health in respect of food, drugs, cosmetics or devices in circumstances other than those provided in the Act and (ii) that are considered necessary "for the purpose of preventing shortages of therapeutic products in Canada or alleviating those shortages or their effects, in order to protect human health". These provisions will be repealed on October 1, 2020. We will report on any corresponding new regulations, once released.

*The preceding is intended as a timely update on Canadian intellectual property and technology law. The content is informational only and does not constitute legal or professional advice. To obtain such advice, please communicate with our offices directly.*

## RELATED PEOPLE

Nancy Pei

E nppei@smartbiggar.ca
T: 416.595.2761

David Schwartz

E deschwartz@smartbiggar.ca
T: 613.232.2542