Cassels

Changes to the Canadian Compulsory Licensing Scheme

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April 13, 2020

On March 24, 2020, Bill C-13, or the *COVID-19 Emergency Response Act* (the Emergency Response Act), came into force. The Emergency Response Act forms part of the Government of Canada's strategy to respond to and assist with the economic and social impact of the COVID-19 crisis.

In addition to the emergency measures that provide billions in funding assistance for individual workers and businesses, the Emergency Response Act expands Canada's compulsory licensing powers. Specifically, the new legislation "authorize[s] the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention" only "to the extent necessary to respond to the public health emergency described in the application."[1] A compulsory license issued under the Emergency Response Act, may be active for up to one year.

History of Compulsory Licensing in Canada

Unlike many other jurisdictions, Canada is no stranger to compulsory licensing. Since the 1990's, Canada has implemented compulsory licensing measures in the pharmacology sector. Further, as a signatory to the World Trade Organization *Trade-Related Aspects of Intellectual Property Rights* agreement, Canada is already entitled to grant a license of patented pharmacology to a generic drug maker or to a public agency. However, and as further described below, the Emergency Response Act significantly expands and enhances Canada's power to issue a compulsory license until September 30, 2020 for *any* patent – not just a pharmaceutical patent – deemed necessary to respond to the public health emergency presented by the COVID-19 pandemic.

Compulsory Licensing under Bill C-13

The new legislation requires the federal government to provide notice and pay royalties to the relevant patent owner once an authorization is granted. The royalty structure is described as "any amount the Commissioner considers to be adequate remuneration 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."[2] The broad language leaves significant discretion with the government, without any clarity on payment expectations.

Most importantly, while the legislation requires the relevant patentee be notified, the government is not

required to engage in any negotiations or consultations with the patent owner. Furthermore, it appears that there is no mechanism to ensure the patented invention is, in fact, related to a public health emergency. The onus thus lies on the patentee: (i) to demonstrate to the government, in advance of the issuance of a compulsory license, that the patentee is sufficiently able to respond to the public health emergency; and, somewhat akin to a reverse onus, (ii) to bring forward an after-the-fact claim that an authorization for a compulsory license ought not to have been issued for a patented item or process on the basis that the compulsory license was not "necessary" to respond to the COVID-19 pandemic.

There does not appear to be a process for challenging the reasonableness of the Commissioner's determination of adequate remuneration in the circumstances.

Conclusion: Proactive Action may be the Best Defense for Patent Owners and their Licensees

Patent holders are well advised to liaise with government entities at the front end for the purpose of demonstrating the patentee's ability to meet the necessary responsive demand without any government intervention.

Moreover, patentees, those who distribute patented goods or use patented processes, and those who in-license or incorporate patented goods or processes into their own goods, need to take heed and consider what effect an authorization for a compulsory license may have:

(a) on their contractual obligations to their licensees and purchasers with respect to exclusive fields of use and territories of use;

(b) on the economic effect of parallel compulsory licensed goods in the marketplace, including the effect of those parallel goods on contractually obligated minimum product unit volumes or minimum royalty obligations owed by existing patent licensees; and

(c) quality control and patentee liability for the efficacy and safety of goods made by others under a federal government authorization for compulsory license.

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[1] Bill C-13, *COVID-19 Emergency Response Act*, s. 51.
[2] *Ibid*.

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