

3D printing in the time of COVID-19: A triad of legal perspectives

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Introduction

In the context of the COVID-19 pandemic, 3D printing has entered the spotlight as organizations rely on additive manufacturing processes to develop medical devices, including personal protective equipment (PPE) and ventilators to fill a gap in demand. This article provides a triad of liability perspectives on 3D printing technology.

Intellectual property rights

Although 3D printing technology is still emerging, the first patents on 3D printing were filed decades ago. Patents grant the right to exclude others from making, constructing, using and selling a patented invention in Canada. Accordingly, patent infringement may arise with respect to both the printing process and the printed product itself. Patent infringement also extends to those who induce others to infringe. The printing process raises interesting questions surrounding who may be liable for infringement (e.g. a company distributing CAD instructions, a person printing the product, companies offering 3D printing services, etc.). As part of the government's response to COVID-19, Parliament enacted the COVID-19 Emergency Response Act. It contains amendments to the Patent Act, which effectively introduce a new compulsory licensing regime during the COVID-19 public health emergency. Pursuant to the Patent Act amendments, in response to an application by the Minister of Health, the Commissioner of Patents will 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. Further information on the [COVID-19 Emergency Response Act and IP rights is available](#) online.

While patents cover functional inventions, industrial designs protect the look (shape, configuration, pattern and/or ornament) of a finished article. Making, importing, selling, renting or offering a printed product that looks substantially similar to a registered industrial design may constitute infringement.

There has also been a great deal of commentary on the application of copyright to 3D printing. Copyright covers original works and may cover design files used to program

printers, such as Computer-Aided Design (CAD) files. Copyright may also apply to the printed articles themselves. One example of a copyright infringement defence that could arise is when an alleged infringer prints a useful article that the copyright owner printed more than 50 times.

Trademarks include, among other things, words and three-dimensional shapes which distinguish one person's goods or services from those of others. Printing using a product displaying someone else's trademark may also constitute trademark infringement.

Product liability

The novel method of manufacturing 3D products brings along additional considerations surrounding the liability of those involved in its manufacturing. In this novel model, it remains to be seen who is considered to be a manufacturer. Will it be the entity who wrote the code, or the entity who pressed print, or both? The case law has not dealt with this conundrum as of yet, but as these technologies increase in prevalence, the issue is likely to be clarified through statute or the jurisprudence. Absent such clarity, enterprises involved in the manufacturing of 3D printing products may best discharge their duty of care to:

- Manufacture products free of defects in the ordinary use of such products;
- Warn of dangers inherent in the use of the product that such entity knows or ought to know; and
- Design the product to avoid safety risks and make the product reasonably safe for its intended purpose.

In the context of 3D medical devices, the Canadian government has been considering regulatory responses since as early as 2016. Beginning with the Canadian Senate adopting an Order of Reference authorizing the Standing Committee on Social Affairs, Science and Technology to examine and report on innovated technologies in health care, to releasing a [draft guidance document](#) in 2018 on 3D printed implantable medical devices, the Canadian government has recognized the importance of addressing the emerging technology in this space.

As part of Health Canada's response to the COVID-19 pandemic, the regulator released specific [guidance on 3D printing and manufacturing of PPE](#). The regulator clarified that anyone wishing to manufacture or distribute PPE through 3D printing or other innovative means must hold either an [authorization under the Interim Order](#) respecting the importation and sale of medical devices for use in relation to COVID-19 (the IO) or have a valid Medical Device Establishment License, subject to certain exceptions. The IO allows for expedited authorization for the importation or sale of medical devices used in the diagnosis, treatment, mitigation or prevention of COVID-19. We previously highlighted some of the measures Health Canada has introduced under the IO as well as some important considerations for [manufacturers, importers and distributors of 3D printed devices](#). Health Canada is also encouraging stakeholders to reference the U.S. Federal Drug Administration's (U.S. FDA) [guidance on 3D printing medical devices](#) during COVID-19.

Labelling and marketing also requires close consideration. A review of top of mind considerations on [labelling and advertising in the context of COVID-19](#) can be found on our website.

International trade

3D printing may disrupt the rules based trading system designed for economies that trade in manufactured goods and not digital goods. 3D printing allows manufacturers to produce goods locally instead of importing goods from countries with more efficient manufacturing processes. As 3D printing technology advances, and its use increases in manufacturing sectors, it may displace imported goods and the customs revenue generated by the duties applied to those goods. Instead of relying on air cargo or container ships to transport tangible goods, a seller in the exporting country sends 3D printing code over the internet to a purchaser in an importing country.

The advent of 3D printing illustrates the gaps in the world trading system, in particular, the taxation of digital products and the application of rules of origin to digital products. New trade agreements such as the Comprehensive and Progressive Trans-Pacific Partnership and the United States-Canada-Mexico Agreement include digital trade chapters. These chapters, however, predominantly address the digitization of customs processes, privacy, and data localization; they do not address trade in digital services, like 3D printing. If digital products are dutiable in the future, rules of origin and the related tariff shift rules, which determine what goods receive duty-free treatment under regional trade agreements, must adjust to account for the exporting country where source code is created and the importing country where the final product was printed.

In December 2019, the members of the World Trade Organization agreed to extend a moratorium on customs duties to “electronic transmission”, which includes transfers of digital products like software to videogames. This moratorium is in place until June 2020 and continues to fuel a flourishing digital economy. Some member countries, namely India, Indonesia and South Africa, hope to end the moratorium and begin to tax digital services to replace lost customs revenues. As 3D printing continues to develop and replace traditional trade flows, this argument may gain traction with more members.

Conclusion

The global pandemic supply interruptions have created an opportunity for 3D printing technology to fill a gap in demand. 3D printing manufacturers and distributors are cautioned to carefully consider intellectual property, product liability and trade considerations in moving forward with production plans so to mitigate as against regulatory and litigation risks that may crystallize down the road.

By

[Milos Barutciski, Jeff Gordon, Julia Webster, Edona C. Vila](#)

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BLG Offices

Calgary

Centennial Place, East Tower
520 3rd Avenue S.W.
Calgary, AB, Canada
T2P 0R3

T 403.232.9500
F 403.266.1395

Ottawa

World Exchange Plaza
100 Queen Street
Ottawa, ON, Canada
K1P 1J9

T 613.237.5160
F 613.230.8842

Vancouver

1200 Waterfront Centre
200 Burrard Street
Vancouver, BC, Canada
V7X 1T2

T 604.687.5744
F 604.687.1415

Montréal

1000 De La Gauchetière Street West
Suite 900
Montréal, QC, Canada
H3B 5H4

T 514.954.2555
F 514.879.9015

Toronto

Bay Adelaide Centre, East Tower
22 Adelaide Street West
Toronto, ON, Canada
M5H 4E3

T 416.367.6000
F 416.367.6749

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