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## 3D Printing, Patent Infringement, and the Coronavirus

### *Patently-O*

Never waste an opportunity in a pandemic to incur a PR disaster. That appears to be the mantra – if initial reports are believed – of an Italian company who holds a patent on a valve used in breathing machines that are critical for coronavirus patients. The company could not meet the surging demand for its valves. In response to the shortage, two engineers used 3D printers to make these essential devices locally near Brescia in northern Italy, a region the coronavirus has hit particularly hard. In response, the patent holder allegedly threatened a patent infringement lawsuit against them.

In a remarkable testament to the speed and flexibility of 3D printing technology, on the same day the engineers learned about the shortage of valves, they were able to create a digital version of the valve and 3D print working valves. Within a day they had made over 100. (As an aside, 3D printing is at the core of a rapid move to create an open source ventilator to combat shortages.)

To be fair, the company, and one of the individuals doing the 3D printing, denies a threat was made. Although the company did refuse to share the design file with the individuals, forcing them to create a 3D printable digital file from scratch.

Regardless, this episode represents the first widely publicized instance of 3D printing technology being used to (arguably) infringe a patent on a medical device. Patent infringement and 3D printing involves several interesting patent issues on which I have previously written here (with Professor Tim Holbrook) and here.

The key to appreciating the unique patent infringement issues with 3D printing is to keep in mind the difference between the digital and physical version of the patented device. In just about every case, the patent covers only the tangible object, not the digital version of it. Therefore, merely creating a 3D printable file of the device is *not* an act of direct infringement.

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## Direct Infringement

On the other hand, anyone who prints the physical valve commits direct infringement for “making” the patented device. But even the issue of who performs the actual printing will not always be clear. For instance, assume that X makes the digital file, but does not have the appropriate 3D printer. X takes the file to Y, an on-demand 3D print shop, who prints the object on X’s behalf. Did X or Y “make” the invention? In the copyright context, companies like YouTube have avoided liability for direct infringement by arguing they are passive conduits for their users’ actions. Perhaps 3D print shops will be able to make the same argument.

## Indirect Infringement

Getting back to the digital file, although the engineers printed lots of valves for local use, they declined to share the file with others out of fear of patent liability. Their fear was not misplaced. A person can be liable for indirect patent infringement for helping or inducing others to commit direct patent infringement. And the person can be potentially liable in any and all countries where the direct infringement occurred or was facilitated (unlike the US, many other countries do not require a specific act of direct infringement as a precursor to indirect liability).

In the US, the relevant indirect liability would be inducement under 35 U.S.C. § 271(b), which states simply that, “Whoever actively induces infringement of a patent shall be liable as an infringer.” Although the statute does not say so, liability for inducement requires that the accused have knowledge of the specific patent and that the induced acts constitute patent infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 765-68 (2011). If the engineers in Italy were in fact warned of a specific patent, that would likely be enough to meet the knowledge requirement.

Knowledge can be negated by a good faith belief of noninfringement, but it cannot be negated by a good faith belief in the patent’s invalidity. *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1928 (2015). Courts have not had an opportunity to explore what is required for an individual, as opposed to a company, to form a good faith belief of noninfringement. Would a layperson’s study of the patent suffice, or must they incur the huge expense of a formal legal opinion?

In most European countries, indirect liability applies where someone

supplies or offers to supply in [the country] . . . with any of the means, relating to an essential element of the invention, for putting the invention into effect when he knows, or it is obvious to a reasonable person in the circumstances, that those means are suitable for putting, and are intended to put, the invention into effect in the [the country].

See, e.g., UK Patent Act § 60(2). (Most European countries have similar provisions because their statutes are all based on the 1975 Community Patent Convention.) Although the statute requires actual or constructive knowledge, the details of that knowledge requirement are unsettled: must the infringer have knowledge of the specific patent or merely knowledge of the acts that the direct infringer will take. If courts only require knowledge of the induced acts, liability would attach regardless of any specific knowledge of the patent.

In short, creators of 3D printable files, especially those with knowledge of a relevant patent, should be wary of making them available for others on the internet.

### **Love Your Neighbor, or At Least Your Reputation**

Although the coronavirus pandemic inflames passions when needed medical equipment is in short supply, it is important to remember that in emergencies Article 31 of TRIPS, the key international patent treaty, provides flexibilities for governments to use – and authorize others to use – patents without the consent of patent holders.

The above analysis focuses only on the legal issues. Even if the patent holder is more interested in making money than saving lives, it may be wise to consider the reputational and other costs associated with denying live saving equipment to hospitals in need. Others, including patent holders relating to vaccine development, have initially threatened patent infringement suits only to backtrack after a storm of public outrage. So even if the patent holder made a threat to someone in Italy (and it is not at all clear that it did), it would be no surprise that it decided to change tactics.

### **Related People**

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