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Life Sciences Update: Companies Not Only Sharing IP, They Are Enabling Others to Copy Their Products

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Many life sciences companies have been willing to permit others to access their IP to help increase the supply of equipment and development of new treatments during the COVID-19 pandemic. In view of the urgency of the situation, this has recently gone beyond permitting access to IP. A leading medical device innovator, Medtronic, has now enabled others to copy some or all of its ventilator products by releasing full design specifications. As discussed below, the immediate benefit of this new approach is shown by a Canadian company announcing it will now develop and build its own ventilator using the Medtronic open access IP and design specifications.

This article will address below some ways that IP is shared.

Patent Pool—Group Sharing

One way IP can be shared is through a patent pool, where companies put their patents into a system (the pool) which has an administrator that grants licenses to those who wish to take a license and meet the pool's criteria. Licenses from the pool are typically available to others on a fair, reasonable, and non-discriminatory basis. A royalty may be payable in a commercial patent pool but is often not charged in the case of patent pools used for medicine, such as the HIV/AIDS patent pool, established many years ago. There may be license limitations on certain aspects, such as the countries covered, which has caused pools to draw some public criticism. The WHO is recommending that a patent pool be created for COVID-19–related patents.

Companies Unilaterally Permitting Access to IP

Companies may also choose to take unilateral actions themselves to make IP available. For example, some pharmaceutical companies have permitted access to patented drug IP for COVID-19 clinical trials and drug development.[1] To do this, pharmaceutical companies may freely grant licenses or, in some cases, put patents into the public domain.

Even where IP rights are not being given up, pharmaceutical companies have contributed to the cause by using their IP to help others, for example, by donating drugs or acting as a resource for clinical trials. An early example was Gilead donating its expertise and the drug remdesivir for testing in COVID-19 clinical trials in Asia and North America.

Sharing and Enabling Others to Make Copies

There may be a new trend developing that goes beyond just making IP available, and it extends to enabling others to use and fully exploit the IP. Medtronic, a U.S. company well known for its ventilator technology, made all its ventilator IP available for its Puritan BennettTM560 (PB560) ventilator. The design specifications were also made available to the public on the Medtronic website—not just the patents, but all the associated know-how to allow others to make the ventilators. These design specifications included engineering designs (*e.g.*, circuit board designs), source code software, and manufacturing information. This is a huge difference compared to making an IP license available because it allows others to readily make ventilators. Patents provide a monopoly right, and a disclosure of an invention, but they leave much development work to be done to design and scale a commercial product.

There were already open source ventilators available and there have also been rapidly developed

prototypes by enterprising designers. These open-source devices typically require further work to reach medical grade, and the lack of a track record makes them a less desirable choice to be thrown into a medical emergency. It is a big deal that a leading and trusted commercial manufacturer like Medtronic is disclosing a product's full design specifications.

The Canadian company Baylis Medical is now participating in this open-source initiative. Baylis is going to rely on some of the Medtronic design specifications as it prepares to make ventilators in Canada in conjunction with a private group of entrepreneurs and philanthropists called Ventilators for Canadians (V4C).

The Canadian arm of the French company bioMérieux has transferred its secret, proprietary reagent know-how to the National Microbiology Laboratory in Winnipeg. This will allow the National Lab to manufacture reagent to add to the supply for DNA diagnostic tests.

Vaccine titans, and competitors, Sanofi and GSK are going to share each other's technology to develop a COVID-19 vaccine.

Companies that are retooling to make personal protective equipment are also sharing designs and manufacturing know how. An example of a retooled Canadian company that enabled others to make medical face shields is InkSmith, a 3D printer, and robotics company, which made its 3D print file for a face shield headpiece publicly available and encouraged others to print it. Bauer, the Canadian hockey equipment company, makes sports visors, so it was logical that Bauer could retool part of its business to make medical face shields. It has made a manufacturing package available on its web site to show how to make face shields. In the interest of fighting the pandemic, these companies have shared their designs and know-how online. The 3D printed face shields are not a commercially significant product for InkSmith and Bauer, but it is still a notable trend that such manufacturing knowledge, normally confidential, was openly shared so that other companies can copy it. Many non-commercial designers have always freely shared 3D print information.[2] Companies making medical products typically would, however, keep this type of IP under wraps for competitive reasons, and for liability reasons (*e.g.*, if there was a product liability issue with the face shield design). There are likely to be more IP and design specifications voluntarily made available by companies in the future. This will be important to help expand the supply of medical equipment, so it is a worthwhile trend for the IP and life sciences community to support.

1. This voluntary sharing of IP is different than compulsory (forced) licensing of IP, which is being implanted by some governments.

2. There also many grassroots efforts to share knowledge about manufacturing PPE, particularly in the area of 3D printing face shields, and the US government has collected some of these efforts into one web location.