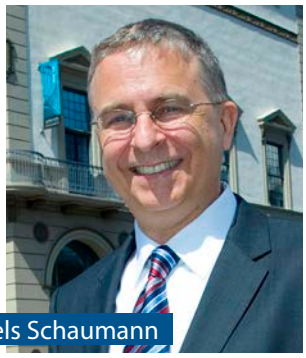
Bioprinting and the Law

Some areas of law could play a large role in a new medical technology

A new development in medicine called bioprinting promises far ranging benefits, from inexpensive test beds of bioprinted human tissue for drug trials—potentially saving time and money on drug development costs—to complete, bioprinted organ replacements—allowing patients to receive healthy organs sooner. Needless to say, this trend holds great promise for the health care field and for consumers.

Recently, I was invited to present a paper at the Cross-Straits Biopharmaceutical Industry Conference, held for Chinese and Taiwanese companies in Taipei, Taiwan late in May 2014. I selected bioprinting as my topic because it is both interesting and promising, it involves copyright law (the area in which I have focused most of my professional writing), and because one of the leading practitioners of the technology is Organovo, a San Diego start-up company.

A form of 3D printing, bioprinting is a technology in which a machine under software control deposits layers of biological material (biological inks) and an inert, biocompatible substance called "hydrogel," one on top of another, until a three-dimensional structure is complete. At that time, the hydrogel is removed, and the tissue (made of living cells) is allowed to grow to maturity.



Niels Schaumann

Although the bioprinting of human tissue sounds rather like science fiction, the technology is here today. Organovo hopes to bring to market this year 3D tissues for experimental use (testing various drugs and agents for possible in vivo application). Several other U.S. startups are developing the technology, each hoping to capture a large share of a potentially enormous market. Eventually the companies hope the technique will generate tissue for direct use in patients to replace damaged tissue, and in the future, possibly entire organs.

As with any technology so potentially important, practitioners are concerned with protecting their innovations for as long as possible, to allow them to exploit their superior knowledge, skill, and inventiveness.

Indeed, the law encourages innovation by means of the intellectual property system—including patents, trademarks, copyrights—and other kinds of unfair competition law, like trade secrets. Usually high tech enterprises like Organovo and its competitors get the most mileage out of patents and trade secrets, with the others playing an important, but subordinate, role.

For bioprinting, however, copyright law could play a key role. This may be surprising, but it shouldn't be: copyright is one of the most-used kinds of protection for software, and bioprinting relies on proprietary software. Patents can also apply to software, but copyright is much easier, faster, and cheaper, and it lasts a lot longer—95 years, compared to 20 years for most patents.

For all that, though, copyright has a drawback—it protects only the "expression" of the software, not the ideas or the functionality. The law has a test for "expression" in software, but it is rather difficult to apply, and the results are frequently hard to predict. About the clearest thing one can say is that if someone copies your software verbatim, you have a case. Beyond that, it gets muddy very fast. But win or lose, when it comes to software, copyright is a key player.

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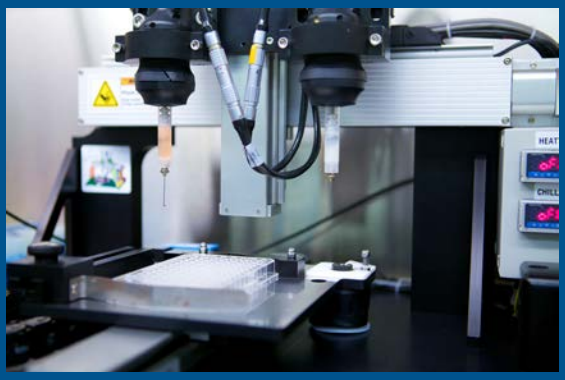

The Novogen MMX Bioprinter® prints fully human, architecturally correct 3D tissue in a variety of different formats, in this particular case into multi-well plates. Bio-ink or hydrogel can be dispensed from each of two print heads.

One of Organovo's tissue engineers oversees the construction of a vascular tissue construct on the Novogen MMX Bioprinter®.

Bioprinting tissues into a multi-well plate format.

Photos courtesy of Organovo, Inc.