Additive manufacturing, also referred to as 3D printing is often considered disruptive technology in medical device manufacturing. It is a growing process and shows no signs of slowing in the coming years. But before you fully embrace the technology, learn more about the impact 3D printing has with regard to infringement on intellectual property; the technologies and applications for 3D printing; and the benefits for designers of medical devices.
3D printing at home
By Marcus Thymian, McDonnell Boehnen Hulbert & Berghoff LLP

Consumer-grade 3D printing has moved beyond its infancy – we’re now well into the terrible twos. Affordable yet capable, 3D printers currently allow consumers to easily manufacture their own eyeglass frames, bone splints, syringes, hose couplers, and skull models. More complex objects, and objects made of metal (including biocompatible titanium) and ceramic, are largely still the domain of more sophisticated machines used by companies and universities. But not for long.

Medical technology companies can expect headaches from widespread unauthorized manufacture of devices or device components, even those protected by patents.

A patent gives its holder the right to exclude others from making, using, selling, or importing the patented item. Typically, a patent holder enforces its patents by identifying infringers, and then, requesting or demanding that the infringer cease and desist from the infringing activity – often leading to licensing discussions or litigation. While many experts are currently debating the impact of patent assertion entities (sometimes referred to as patent trolls), this long-standing model has worked reasonably well for dealing with conventional patent infringers, but it is not suited to home 3D printing.

**Difficulties in enforcing patents**

Many consumers print an object only once, because they are manufacturing for themselves, rather than to make money by selling to others. Single-instance patent infringers are typically not seen as economically feasible targets because patent lawsuits are expensive, an injunction against the individual would be relatively worthless, and the costs of the lawsuit would far exceed any awarded damages.

In addition, it is difficult to identify patent infringement. The patent holder will have to determine sites where an infringing design is posted, downloaders of the infringing design, and whether the downloading individual actually printed the design to manufacture the protected article. That task is almost impossible in the current legal landscape.

Some compare the current 3D-printing surge to the music-downloading free-for-all we saw in the mid-1990s. However, downloading music illegally implicates copyrights, not patents. For copyright infringement, the simple act of downloading is enough. Downloading an MP3 file results in a copy being stored on the consumer’s computer, which, if unauthorized, constitutes copyright infringement. Conversely, a consumer’s downloading of a 3D-print file would not typically constitute patent infringement. Under current law, patent infringement would only occur once the consumer manufactured the article by printing the file. So, even if a company is able to determine that a 3D-print file has been downloaded by a consumer – not a simple matter – additional investigation would be necessary to determine whether that consumer took the next step.

**Considerations for companies**

To determine how to respond to the 3D-printing surge, your company should first identify which of its parts and/or components are candidates for 3D printing at home. Most inexpensive (under $2,000) 3D-printing machines are limited to printing with polymers, using fused deposition in a layer-by-layer process. In addition, large parts are not presently printable with home machines, unless they can be assembled from smaller
printable portions. Therefore, the articles most at risk are plastic parts that are smaller than a gallon of milk. Complex architectures are typically not a huge obstacle, unless the complexities are accompanied by a need for strict tolerances. 3D scanning allows an individual to scan an image of an article to assist in making the design file. Articles having stalactite-type structures are difficult to print, unless the structures are accompanied by temporary supports that must be removed during post-processing.

Once at-risk parts or components are identified, your company should next determine the commercial significance of those parts or components. Is the part or component critical to reliability of a larger system? Perhaps it’s easy for a consumer to print a plastic seal or gasket, but what if that seal or gasket leaks as the (possibly inferior) plastic breaks down? Do the technical specifications of a part or component require tolerances that can’t be obtained using presently available consumer 3D printing machines? Your company’s product reputation may suffer even though it wasn’t your company’s part that failed. Safety is another huge concern. Does unauthorized printing of a part or component of your company’s product put at risk a certification or approval that you’ve worked hard to attain?

For some parts or components, you may find that it’s not worth your time or effort to prevent or control unauthorized manufacturing. A storage tray or case might be unique and perhaps even patented, but not worth the time and expense of patent enforcement.

For parts or components you deem to be significant, the best strategy will depend on many factors, including:

- The scope and extent of your patent protection
- The extent of perceived infringement (are you losing profits due to widespread in-home manufacturing, or is it just a case of one-offs here and there?)
- The existence of repeat infringers (i.e., those who have printed your part more than once in the past and are likely to print more in the future)
- Your customers’ attitude toward patents, in general.
- Any strategy is likely to impact your company’s reputation, so the decision should be well reasoned.

Your company could adopt the strategy taken by the music industry in the late-1990s to combat illegal music downloads. The recording industry filed thousands of suits against individuals who downloaded copyrighted music. Most settled for small, but noticeable amounts; however, some suits resulted in judgments of hundreds of thousands of dollars against the illegal downloaders. The suits received lots of press and likely changed the behavior of many people. The subsequent development of authorized music download sites has successfully provided high-quality music files to listeners ever since.

Would such an approach work in 3D printing though? The recording industry contains a relatively small number of major record labels, and their enforcement strategy helped to develop a gloves-off/no-compromise reputation for the labels. That reputation wouldn’t likely attach to a single company trying to enforce a patent on one of its 3D-printable parts or components.

One strategy for enforcement would be to go after sites like Thingiverse, Shapeways, MyMiniFactory, and Threeding that serve as hubs for people to upload their design files for other people to download and manufacture a variety of objects using their own 3D printers. These sites (analogous to what Napster was for music uploads and downloads) could potentially be subject to suits for inducing patent infringement, where the actual direct infringement is by the consumers who download and manufacture (print) using the downloaded files. However, most of these sites have provisions in their user agreements banning the submission of unauthorized content that would infringe the intellectual property rights of others.
More importantly, most sites have procedures in place for accepting notification from intellectual property owners of perceived infringement that purportedly leads to removal of the unauthorized content. For example, Thingiverse has two sets of procedures: one for suspected infringement of copyright, and one for suspected infringement of other intellectual property rights, such as patents or trademarks. The procedures are fairly unobtrusive and provide one mechanism for controlling unauthorized manufacture by 3D printing. All that would be required is consistent monitoring of these sites (using keyword searching, for example) to identify instances of possible patent infringement.

Another strategy would be to embrace the proliferation of 3D-printing technology, at least partially. Sites like Shapeways allow users to sell 3D-printed articles by allowing them to upload files for articles that are printed on-demand using Shapeways’ 3D printers.

For certain parts, a company could conceivably upload its design files to serve as a source of authorized replacement parts to be printed and shipped by Shapeways, according to the company’s specifications. We might be a ways off from the quality-control standards that might be needed for such a scheme, but if the replacement parts are priced appropriately, then consumers might opt to buy the authorized 3D-printed part, rather than search for unauthorized files that would allow them to print similar, but sub-standard, parts at home.

Join them?
Recently, Cubify (a 3D printing hub) teamed up with Sony to offer cell phone cases branded with imagery from the movie, “Cloudy with a Chance of Meatballs 2.” Rather than fighting infringement of its intellectual property, Sony chose to treat it as a marketing opportunity. As the home 3D-printing industry matures from its childhood to adolescence, how will your company take advantage of opportunities while also protecting its intellectual property? Our current intellectual property laws don’t contemplate the challenging scenarios we are likely to see in home 3D printing. The best approach may be to learn about the 3D-printing industry and the players – including consumers – to see how it develops, before formulating any enforcement strategies.

3D printed biomedical technologies, applications
Oxford Performance Materials, Yale University in joint research program to develop innovative and cost-effective patient-specific solutions.

Oxford Performance Materials Inc. (OPM) officials announced the commencement of an extensive joint research program with Yale University to develop innovative and cost-effective 3D printed biomedical technologies and applications. This initiative will add renowned clinical expertise to OPM’s comprehensive platform for device development, made up of OPM’s proprietary OXPEKK(R) formulation of the high performance polymer polyether-ketone-ketone (PEKK), the company’s additive manufacturing process, and its streamlined regulatory framework.

The Yale-OPM joint research program will consist of ten distinct projects, featuring seven Yale faculty members, exploring a range of biomedical applications for 3D printing and PEKK. Projects include the development of new
PEKK-based cranial and facial devices that support direct tissue attachment and 3D printed PEKK prosthesis for rib replacement. Projects also include 3D printed PEKK devices that deliver therapeutics for improved vertebral fusion as well as devices that deliver antibiotics to combat the pressing burden of implant-associated infections.

"We are excited to announce this broad collaboration with Yale's distinguished team of biomedical engineering and clinical experts," said Dr. Adam Hacking, PhD, chief scientific officer, Oxford Performance Materials. "Our comprehensive medical device development platform will support the innovation and dedication to improving patient care for which Yale and its faculty are recognized. Together, we foresee the development and delivery of new medical technologies and applications in ways that were previously not possible. OPM has made significant progress with our PEKK-based platform, and we are continuing to advance this technology to improve patient outcomes with our partners at Yale."

"This joint research program between Yale University and Oxford Performance Materials is a prime example of the types of collaborations that we are working to develop and nurture here in Connecticut," said Connecticut Governor Dannel P. Malloy. "Our state has long been an incubator for scientific, technological, and medical innovation, and this program has the potential to yield significant benefits to society through 3D printing, advanced materials science and strategic partnership between private industry and academia. This is how innovation is fostered in the 21st century economy, and we are proud to support both Yale and OPM as they embark on this groundbreaking research right here in Connecticut."

In 2013, the Connecticut Department of Economic and Community Development supported the expansion of OPM's South Windsor, Connecticut manufacturing facility with a $3.2 million loan for new machinery and equipment, as well as building upgrades.

"PEKK is biocompatible, radiolucent, strong and durable. 3D printing enables the facile fabrication of complex geometries. In combination, these technologies present new and previously unavailable opportunities to develop and deliver customized, patient-specific therapies that are also economically viable," said Professor Mark Saltzman, PhD, Yale's Goizueta Foundation Professor of Chemical and Biomedical Engineering and Chair of..."
Biomedical Engineering. "We are looking forward to working with Dr. Hacking and his team at OPM on these joint research initiatives that are designed to improve how personalized medicine is developed and delivered to patients."

Since 1999, the founders of OPM have been developing advanced applications of PEKK and proprietary manufacturing processes for biomedical, aerospace, and industrial products. The result of this development is a superior value proposition known as "high performance additive manufacturing" or HPAM(TM). OPM is a pioneer in personalized medicine. In February 2013, OPM became the only company to receive FDA clearance to manufacture 3D printed polymeric implants for its PEKK cranial devices, and OPM received a second FDA clearance for its patient-specific facial implants in July 2014. OPM was also the recipient of the New Economy "Most Innovative Company in 3D Healthcare Technology" Award in 2014.

3D-printed medical mold components

Sample thermoplastic elastomer prototype parts allow medical designers to test the look and feel of the device.

By Elizabeth Engler Modic

Development costs and times are critical considerations for today's medical manufacturers when creating prototype parts. Accurately evaluating the geometry, design, performance, and feel of plastic injection-molded parts is necessary before creating final production molds. Typically, prototype plastic parts are created using molds made of soft steel to ensure the manufacturability and dimensional accuracy of the plastic parts and to evaluate the product's final material. However, creating a soft steel mold is expensive and time consuming.

**Challenge**

Coloplast, a global medical device company, needed sample parts produced in a thermoplastic elastomer (TPE) to test the feel of a new urology device. Engineers there were uncertain about the durometer it required because the product would be squeezed repeatedly by the user, and the material's proper compression resistance was an important factor. Coloplast approached Diversified Plastics to produce sample TPE parts using a prototype mold so it could analyze the durometer and wall thickness before proceeding to production.

**Solution**

The Coloplast prototype mold would normally have been built in soft steel, but engineers at Diversified Plastics recommended producing the mold using a new, cost-effective 3D additive manufacturing process. Diversified Plastics had recently acquired a Stratasys Objet Polyjet printer that was capable of producing highly accurate injection mold components for creating prototype parts. The idea of printing the mold components was of great interest to the Coloplast R&D engineer.

3D-printed plastic molds are not designed the same as steel molds. Injection gates need to be twice as large for effective molten plastic flow and more draft is required to allow for easier part ejection.
from the mold. After Coloplast’s tool design file was downloaded into the Polyjet 3D printer, it took approximately 11 hours to build both halves of the mold and center core. The tooling department then inserted the printed mold components into an existing mold base.

The components could just have been bolted onto the injection machine’s mold plates, but a base already used for a similar part was available. Using this existing base saved time and reduced the overall cost because the ejector system was already in place.

**Outcome**

Engineers from Diversified Plastics presented Coloplast with a few parts molded in the actual final thermoplastic materials. After evaluating the prototype, Coloplast determined the feel of the parts was too soft to meet its requirements. With this test data, however, the engineers at the company realized what needed to be done to create acceptable parts for their new urology device trainer. Coloplast decided to revise the product design to thicken the wall sections, so the part would be slightly stiffer. It was also decided that a second prototype mold for further testing was not necessary before creating the final production mold. The whole process, from initial conversations with Coloplast, through mold production, to final product prototype, took just five business days.

Since TPE is flexible, it was impossible to machine a prototype, and building a soft steel mold that may not have met the requirements would have been expensive. Using a mold made with 3D additive manufacturing technology to determine if the design was going to meet product requirements saved thousands of dollars and weeks of time.

QUESTIONS? Contact Editor Elizabeth Engler Modic at emodic@gie.net.