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EXPERT ANALYSIS

Preserving the Value of Medical Device Patents During the Rise of Three-Dimensional Printing

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The highly anticipated technology of three-dimensional printing promises to open an entirely new channel for distribution of physical articles and devices and, by the same token, a new channel for infringement of patents covering those physical articles and devices. In the medical field, particularly, 3D printing is expected to drastically reduce hospital costs associated with surgical implants and open new doors in the area of custom implants.

Current patent drafting practices and recent developments in the law, however, may create difficulty for the patent holder in finding a suitable party against whom to assert patents. Assertions of direct infringement against the hospital printing the item and assertions of indirect infringement against digital model suppliers are both less than optimal strategies. For this reason, a reassessment of a claim drafting strategy will prove useful in maximizing the assertion value of a medical device patent portfolio in the face of this burgeoning new technology

Additive manufacturing, commonly known as "3D printing," is a manufacturing process that enables the production of physical objects based on a digital model. Unlike subtractive manufacturing methods, wherein a piece of raw material is machined to remove portions and essentially sculpt the desired object, 3D printing builds the desired object by placing layer upon layer of material. Utilizing the source digital model, a microcontroller guides the placement of each layer; this computerization enables the production of items with levels of intricacy that would be either impossible for a human or require such a high degree of skill that relatively few human workers would be able to reproduce the item.

Many forms of additive processes have been developed; these include the fused deposition modeling process used by hobbyist printers to build objects out of simple materials such as thermoplastics. Commercial printers, in contrast, have many more capabilities than hobby printers currently have. For example, granular processes such as direct metal laser sintering enable the manufacture of items of other materials such as ceramics or metal alloys.[1]

This opens 3D printing to many additional applications such as the creation of metal hardware, electronic resistors and orthopedic implants. Other commercial printers are capable of creating more complex machines such as a crescent wrench, with no post-fabrication assembly necessary.[2]

Three-dimensional printing will possibly bring the greatest benefit in the medical field. In orthopedics, some companies have already recognized benefits of the technology, including the ability to create lattice structures for promoting osseointegration as well as custom, patient-specific instruments.[3] New lifesaving techniques are also possible, such as the use of 3D-printed biopolymer to create a tracheal splint for an infant.[4]

After the initial outlay for printer hardware, hospitals will be able to print devices for the cost of only the raw materials; alternatively, hospitals may contract with third-party printers to create medical

devices on-demand at a low cost. As such, 3D printing appears to be an attractive option for cutting hospital expenditures, as is the case in one United Kingdom hospital that has already turned to 3D printing for generating bone models.[5]

It is a distinct possibility that medical device manufacturers may turn to 3D printing technology as a new distribution channel. Traditional device manufacture may give way to the sale of digital device models to hospitals for in-house, on-demand production.

Existing patents in the medical device field are largely drafted without digital distribution in mind. Thus, they may be more difficult to enforce against the non-manufacturing device designer that creates digital models of medical devices for sale and distribution to hospitals.

In the area of medical devices, claims are typically drawn to the device itself or to a surgical method of using the devices. Such claims are primed for enforcement against competing device manufacturers through either direct infringement or indirect infringement. With 3D printing, however, there may be a change in the party who actually manufactures the device: in many cases, it may now be the hospital and not the device designer that creates the claimed device.

This shift will render the typical medical device claims less effective in precluding competing device designers from providing digital designs of infringing products. This decreased effectiveness in protecting market share will devalue many existing medical device patents.

In the medical field, 3D printing is anticipated to drastically reduce hospital costs associated with surgical implants and open new doors in the area of custom implants.

A direct infringer is identified as any entity that makes, uses, sells, offers to sell or imports a patented invention.[6] Under the traditional distribution model, the medical device designer-manufacturer makes and sells medical devices to hospitals; as such, if the medical device infringes any claim of an issued patent, the designer-manufacturer is liable for direct infringement.

However, with distribution of 3D printers, the designer and manufacturer are decoupled. Now, the medical device designer may only sell a digital model that may be used to make the infringing device and, as such, may not be liable as a direct infringer. Instead, the hospital, medical professional or a third-party printer is the entity that manufactures the infringing device.

For many reasons, it is undesirable to pursue hospitals and medical professionals on claims of infringement or for patent licenses. Strategically, moving the focus from a handful of competitors to the numerous customers of those competitors creates difficulty in terms of scale.

Identifying, approaching, negotiating with and potentially litigating against each infringer becomes a much larger and more costly endeavor. Moreover, from the business standpoint, it is probably unwise to take such an aggressive stance against potential customers.

In a scenario in which a hospital contracts with a third-party printer to produce devices based on a device designer's models, the problems of scale probably remain. The relatively low skill associated with operating a 3D printer to create a device based on a pre-created model, as opposed to designing the new medical device, would open the door for a much greater number of third-party printers than medical device designers.

In addition, the desire to have devices created locally for on-demand availability would also encourage third-party printers to set up shops near every hospital that follows such a model. Again, with such numbers, the job of assertion to protect market share becomes much more difficult.

This is not to say that the typical medical device claims would be wholly unenforceable against the competing device designer under this distribution model. Two forms of indirect infringement may be suitable for enforcing these claims against the device designer: contributory infringement and induced infringement.[7] However, additional hurdles associated with proving both forms of indirect infringement make this route less attractive than pursuing a directly infringing competitor.

A contributory infringer is defined as one who "sells ... a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention."[8] In addition, the component must be a "material part" of the patented invention and lack substantial non-infringing uses.[9]

Viewing device models for 3D-printed fabrication through the lens of contributory infringement, one discovers that it is difficult to make a strong case for contributory infringement of claims covering the resultant device. Even though digital models for a patented medical device may lack substantial non-infringing uses, software processes have been previously identified as not being a material part in claims that do not specifically recite the contributing steps.[10] Accordingly, software instructions directing a 3D printer to make a medical device would probably not be material to a patent for the medical device itself, so a critical element for contributory infringement would be lacking.

Induced infringement, although better suited for claims against competing device designers, is still not a complete replacement for the direct infringement claim available with regard to competing device manufacturers. Unlike claims of direct infringement, to prevail on a claim of inducement, the patent holder must show that the alleged induced had both knowledge and intent that the induced acts amount to infringement.[11] Thus, legally, the patent holder begins with an increased burden of proof when pursuing a competitor on a theory of inducement.

Beyond the increased difficulty posed by the additional elements of proof alone, recent developments in the law of intent provide defendants with a relatively easy means of escaping liability for inducement. Specifically, the Federal Circuit has found that opinions from independent counsel are valuable in resolving the issue of inducement. For example, a defendant's failure to obtain an opinion has been held to be evidence of willful blindness, thereby fulfilling the intent element of induced infringement.[12]

More interestingly, opinions also can be used by defendants to preclude liability for inducement; a good-faith belief in the invalidity or non-infringement of a patent by a defendant on the basis of an independent opinion serves to negate the intent prong entirely.[13] In other words, by simply obtaining an invalidity or non-infringement opinion, a defendant can escape liability for induced infringement. This easy escape from liability, coupled with the increased burden placed on plaintiffs, renders induced infringement a viable but uncertain option for enforcement of medical device patents.

If the typical claims included in medical device patents are ill-equipped for assertion against competing medical device designers that utilize in-hospital 3D printing as a method of distribution, then what is needed is a claim type that is currently atypical to the medical device field to preserve the ability to pursue the competitor as a direct infringer.

Although digital distribution may be new to the medical device industry, it is not an entirely new concept in patent law. In many software-based industries, digital distribution has become a primary channel. Furthermore, the problem of casting, as a direct infringer, a competing distributor of digital products used by the customer to practice a new invention has also been addressed in these fields.

In the computer and software fields, the *Beauregard* claim has become a mainstay of patent drafting.[14] This style of claim, directed to a "computer-readable medium," is well suited for direct assertion against parties who provide software but otherwise do not make, use, sell or import the invention itself.

The *Beauregard* claim may be easily adapted for use in the medical device field in claims directed to instructions for creating or defining the various parts of the new device. For example, in a patent claiming a set of forceps, the draftsman may include the following:

> A non-transitory computer-readable medium encoded with instructions for creating a pair of forceps, the medium comprising: instructions for defining a first forceps arm; and instructions for defining a second forceps arm, wherein the second forceps arm is structured to be pivotally attached to the first forceps arm.

Assuming this claim issued in spite of its clear issues under 35 U.S.C. § 102, the claim could be directly enforced against a competitor who distributes digital files that can be used by a 3D printer to print the described forceps. By simply creating the digital model for distribution (and storing it on a hard drive), the competitor has "made" the claimed computer-readable medium

Unlike subtractive manufacturing methods, wherein a piece of raw material is machined to remove portions and sculpt the desired object, 3D printing builds the object by placing layer upon layer of material.

and is a direct infringer. As such, the patent may be asserted against the competitor without the necessity of proving intent associated with indirect infringement.

Introduction of the *Beauregard* claim in this new context raises multiple new considerations to be taken into account while drafting a patent application. For example, the specification should be drafted to support the claim by specifying the structures encompassed by the "computer-readable medium." These structures may include read-only memory, random access memory, magnetic storage, flash storage and optical storage media.

It is also a best practice for the specification to explicitly cover distribution of digital models for use by 3D printers. A disclosure explaining that such a digital model qualifies as including "instructions for defining" the structure will help to ensure that the claim is interpreted to encompass such digital files.

For purposes of compacting prosecution, it is advisable to specify in the claim that the medium is "non-transitory." Since the Federal Circuit held "transitory signals" to be non-patentable subject matter under 35 U.S.C. § 101, the U.S. Patent and Trademark Office has often rejected *Beauregard* claims for lacking this simple preamble recitation and recommends inclusion of it.[15] By specifying the medium as non-transitory, the claim will be limited to physical storage devices including the recited instructions. Again, best practices would dictate that the specification be drafted to specify that volatile memory devices, such as RAM, are encompassed by the term "non-transitory."

Software instructions directing a 3D printer to make a medical device would likely not be material to a patent for the medical device itself, a critical element for contributory infringement.

An important consideration relating to 3D printing specifically is that the operation of 3D printers must be taken into account when drafting the claim. For example, although it is within the capabilities of some printers, other printers may not be capable of printing machines with moving parts; instead, the printer may be used to print each part separately to be assembled by a human.

To address both possibilities, the claim should be drafted such that each part may be separately defined and such that no interconnections are actively recited. Instead, the elements may recite that the parts are *capable* of being connected in some manner.

To save on claims fees, practitioners may be tempted to write a *Beauregard* claim as dependent from a device claim. For example, one might draft a dependent claim that says, "A non-transitory computer-readable medium encoded with instructions for defining the device of claim 1."

According to the Manual of Patent Examining Procedure, a claim is an improper dependent claim if "it is conceivable that the ... claim can be infringed without infringing the base ... claim."[16] In this case, not only is it conceivable that the base product claim may not be infringed while the dependent *Beauregard* claim is infringed, but the entire purpose of including the claim was to provide a claim that would be infringed by a device designer who has escaped infringement of the device claim.

As such, presenting the *Beauregard* claim as a dependent claim defeats the purpose of including the claim at all. *Beauregard* medical device claims should therefore be presented as independent claims.

CONCLUSION

Although 3D printing's promise of revolutionizing general distribution channels and medical techniques may not be fully realized for many years, the prudent patent portfolio manager will prepare for this future technology now.

Potential paradigm changes due to the new technology may render current drafting and claiming practices suboptimal for protecting market share against competitors. By including claims that will be directly infringed by a party who provides digital device designs for use with 3D printers, assertion options, and concomitantly the value of the patent portfolio, may be preserved against this changing landscape.

NOTES

[1] Metal 3D Printing, GPI Prototype & Manu-facturing Services Inc., *available at* http://gpiprototype.com/services/metal-3d-printing.html.

[2] *Known Universe: Construction Zone* (Nat'l Geographic television broadcast June 9, 2011), *available at* http://www.youtube.com/watch? v=jQ-aWFYT_SU (*see* segment on 3D-printed wrench).

[3] EOS GmbH, Orthopaedic Technology, eos e-Manufacturing Solutions, *available at* http://www.eos.info/industries_markets/medical/orthopaedic_technology.

[4] Clay Dillow, *This 3-D Printed Bioplastic Windpipe Saved A Baby's Life,* POPULAR SCI., May 23, 2013, *available at* http://www.popsci.com/science/article/2013-05/3-d-printed-piece-bioplastic-saved-babys-life.

[5] Brit Liggett, *3D Printed Bones Are Saving a UK Hospital Thousands in Fees,* INHABITAT.COM (Nov. 4, 2011), *available at* http://inhabitat.com/3d-printed-bones-are-saving-a-uk-hospital-thousands-in-fees/.

[6] 35 U.S.C. § 271(a).

[7] *See* DONALD S. CHISUM, CHISUM ON PATENTS § 17.01 5-17 (Matthew Bender).

[8] 35 U.S.C. § 271(c).

[9] *Id.*

[10] *See Vita-Mix Corp. v. Basic Holding,* 581 F.3d 1317, 1327 (Fed. Cir. 2009); *Fujitsu Ltd. v. Netgear Inc.,* 620 F.3d 1321, 1331 (Fed. Cir. 2010).

[11] *DSU Med. Corp. v. JMS Co.,* 471 F.3d 1293, 1304-06 (Fed. Cir. 2006) (*en banc* as to section III.B.); *see also* CHISUM, at 5-17; *Global-Tech Appliances v. SEB S.A.,* 563 U.S. ___; 131 S. Ct. 2060; 179 L. Ed. 2d 1167 (2011).

[12] *Broadcom Corp. v. Qualcomm Inc.,* 543 F.3d 683, 699 (Fed. Cir. 2008).

[13] *DSU Med.,* 471 F.3d at 1307; *Commil USA LLC v. Cisco Sys.,* No. 07-CV-0341, slip op. at 9 (E.D. Tex. June 25, 2013).

[14] *In re Beauregard,* 53 F.3d 1583 (Fed. Cir. 2005).

[15] *In re Nuijten,* 500 F.3d 1346, 1357 (Fed. Cir. 2007); MANUAL OF PATENT EXAMINING PROCEDURE § 2016(A) (2012).

[16] Manual of Patent Examining Procedure § 608(II) (2012).

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