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# Patent Marking regarding Software Medical Devices

### I. Introduction

This paper provides an overview of patent marking-related case law and its application regarding software and medical devices. The paper explores law in multiple countries, including the United States, the United Kingdom, France, and Germany.

Marking issues are considered for different types of medical devices and/or related software platforms, including, for example, external software medical devices, implantable software medical devices, cloud-based medical devices, and third-party or client/edge devices.

### II. U.S. Patent Marking Perspectives

In the United States, patent holders can provide constructive notice that an article is patented "by fixing thereon the word 'patent' or the abbreviation 'pat.', together with the number of the patent, or by fixing thereon the word 'patent' or the abbreviation 'pat.' together with an address of a posting on the Internet, accessible to the public without charge for accessing the address, that associates the patented article with the number of the patent, or when, from the character of the article, this cannot be done, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice." 35 U.S.C. § 287(a). Absent such marking, the patent holder can only recover damages for infringement occurring after the infringer is provided with actual notice of infringement. *Id.*

The Federal Circuit has clarified that substantially all of a patent holder's patented products must be marked to take advantage of the notice provision in § 287(a). *Nike, Inc. v.*

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*Wal-Mart Stores, Inc.*, 138 F.3d 1437, 1446-47 (Fed. Cir. 1998). Furthermore, the marking must be substantially consistent and continuous. *American Medical Sys. v. Medical Eng'g Corp.*, 6 F.3d 1523, 1538 (Fed. Cir. 1993) *Cert. denied*, 511 U.S. 1070. However, the Court adopts a "rule of reason" approach in determining the sufficiency of marking. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996). A similar flexible analysis is applied in determining whether it was reasonable to mark the packaging of an article rather than the article itself. *Global Traffic Technologies LLC v. Morgan*, No. 14-1537 (Fed. Cir. 2015).

In view of this, the sufficiency of marking in the U.S. is a highly fact-specific analysis. The U.S. Supreme Court has consistently given patentees a degree of deference in allowing them to mark a product's packaging rather than the product. *See, e.g., Sessions v. Romadka,* 145 U.S. 29, 50 (1892) (stating "in a doubtful case, something must be left to the judgment of the patentee"). The primary purpose of Section 287 is to provide information to the public concerning "the status of the intellectual property embodied in an article of manufacture or design." *Bonito Boats, Inc. v. ThunderCraft Boats, Inc., 489 U.S. 141, 162 (1989)*. Thus, courts generally adopt "a practical common sense approach … when dealing with issues of compliance for the marking provisions of § 287." *Rutherford v. Trim-Tex, Inc.*, 803 F. Supp. 158, 162 (N.D. Ill. 1992).

### A. Software in an External Device (Ryan Phelan)

When software is part of a medical-based device, how can the relevant product be marked? This section provides an overview regarding the locating and consideration required to mark a product, such as a software-based medical information platform, external to a human body.

***McKesson Automation, Inc. v. Swisslog Holding AG. – Where multiple software applications communicate with one another, failure to mark the software product that actually practices claims(s) of a respective patent can preclude damages based on 35 U.S.C. § 287***

In *McKesson Automation, Inc. v. Swisslog Holding AG*, plaintiff McKesson Automation, Inc. ("Plaintiff" or "McKesson") asserted that the PillPick System of defendants Swisslog Italia S.p.A. and Translogic Corporation (collectively, the "Defendants" or "Swisslog") infringed the patents-in-suit, namely McKesson's U.S. Patent Nos. 5, 468, 110 ("the '110 patent") and 5,593,267 ("the '267 patent") (the "patents-at-issue"). Civ. No. 06-28-SLR-LPS, 2009 BL 365581 at *1 (D. Del. Oct. 30, 2009) (Stark, Mag. J.).

The accused PillPick System was a system for dispensing medications in hospitals. *Id.* at *1. Plaintiff McKesson had competing products, Robot-Rx and Connect Rx, which were automated systems for selecting and delivering packages to fill orders, such as patient prescriptions. *Id.*

A dispute arose as to whether McKesson has sufficiently marked the Robot-Rx and/or Connect Rx products pursuant to 35 U.S.C. § 287. Swisslog sought to limit damages to those accruing after January 13, 2006, which was the date McKesson filed suit against Swisslog. *Id* at *37-*38 Swisslog argued that McKesson had failed to mark its Robot-Rx product and Connect Rx software as required by 35 U.S.C. § 287. *Id.* at *38. In the alternative, Swisslog argued that damages should be limited to those accruing after December 16, 2005, the day McKesson provided a cease-and-desist letter to Swisslog with its accusation that the PillPick System infringed the patents-in-suit.

The magistrate judge sided with Swisslog, finding that damages should be limited to the date of the cease-and-desist letter (and not earlier) for the following reasons.

Importantly, it was found that plaintiff McKesson had marked the wrong product. That is, while the Robot-Rx software product practiced the claims of the patent-in-suit, McKesson failed to mark this product and instead marked its different software product Connect-Rx with the patents-in-suit. This was fatal to McKesson's attempt to show marking pursuant to Section 287.

This was found despite the fact that the two software products (Connect-Rx and Robot-Rx) communicated with one another. In particular, McKesson had argued that Connect-Rx displays the patents-in-suit every time a user of the Robot-Rx system logs in using an associated computer running the Connect-Rx program. *Id.* at *39. However, as the magistrate judge noted: "McKesson admits that its Robot-Rx is an embodiment of the patents-in-suit and that it never marked this product itself or any packaging in which the Robot-Rx is contained with the numbers of the patents-in-suit." *Id.* at *38.

The magistrate judge found that failure to mark the software product (i.e., Robot-Rx) itself, which actually practiced the claims of the patents-in-suit, doomed McKesson's marking attempt, i.e.: "Marking the Connect-Rx software is not sufficient to satisfy § 287 's marking requirement for the Robot-Rx hardware. It is undisputed that the Connect-Rx software is not an embodiment of any claim of the [patents-in-suit]." *Id.* at *39.

Further, the magistrate judge found that marking was not sufficient because McKesson described its Connect-Rx software on its website as being used with a wide array of products offered by McKesson for use in hospitals." *Id.* at *39. Moreover, Connect-Rx and Robot-Rx were listed on McKesson's website as separate products. *Id.* On this point, the magistrate judge agreed with defendant Swisslong: "Marking the patent numbers on software associated with a wide variety of products that do not use the patents in no way satisfies McKesson's obligation to specifically inform the public that the Robot-Rx system is covered by the patents." *Id.* at *39. Further, the judge found that "[t]he Robot-Rx is a tangible product capable of being marked, but it was not." *Id.*

Accordingly, the magistrate judge recommended that McKesson was not entitled to damages pursuant to Section 287. *Id.* Instead, McKesson was limited to a damages date beginning when McKesson sent its cease-and-desist letter (December 16, 2005).

The court later adopted this recommendation. *See McKesson Automation, Inc. v. Swisslog Italia S.P.A.*, 712 F.Supp.2d 283 at *297 (D. Del. 2010) ("The court concludes that the marking displayed by the Connect–Rx software does not sufficiently apprise the public that the Robot–Rx is covered by the patents-in-suit. Accordingly, McKesson may seek damages accruing after December 16, 2005, when Swisslog was placed on notice of its potential infringement through receipt of the cease and desist letter.")

### B. Software in an implantable device (Chris Karlen)

The application of a patent marking to an implantable medical device can raise a number of interesting issues under 35 U.S.C. § 287. These issues arise from unique aspects of implantable medical devices that include the size of implantable medical devices, the public's ability to view implantable medical devices both prior to and after implant in a patient and how courts have flexibly interpreted the statutory text of 35 U.S.C. § 287 that considers the "character of the article."

Implantable medical devices are subject to various design constraints, including anatomical considerations, hermeticity, size, shape, power management, operating temperature, signal interference considerations, and ease of implantation. As a result, many implantable medical devices may be small in size, unique in shape or surface texture, and primarily out of public view for substantially the life of the device. Indeed, an implantable medical device may primarily exist out of public view while residing in its product packaging and within the patient after implantation. The only time an implantable medical device may be visible is during the sterile unpackaging process immediately prior to surgical implantation. During this time, the device may only be visible to a small group of medical professionals who may not be focused on close inspection of markings on an implantable medical device as they prepare for the actual implantation procedure. If the public policy rationale for 35 U.S.C. § 287 is to encourage patent owners to give notice to the public that their products are patented, then certain patent marking precedents for devices that are not implantable may not be suitable to determine whether patent markings satisfy the requirements of 35 U.S.C. § 287.

The size and shape of an implantable medical device often pose the first set of patent marking challenges for medical device manufacturers. Under 35 U.S.C. § 287, patent markings must be directly applied to the "patented article" itself, except "...when, *from the character of the article, this cannot be done*, by fixing to it, or to the package wherein one or more of them is contained, a label containing a like notice." Implantable medical devices such as pacemakers, electrodes, stimulation devices, stents, and monitoring devices often have limited surface real estate and/or irregular surfaces, which may not accommodate an extensive listing of patents or even a URL of reasonable length. Medical device manufacturers therefore face difficult tradeoffs whether to reduce the font size or other font characteristics of patent numbers or URLs disposed on surfaces of such medical devices – or mark the product packaging instead, which an alleged infringer is likely to challenge as non-compliant with 35 U.S.C. § 287. Furthermore, medical device manufacturers may need to consider how often the outward appearance of such

devices can practically be modified to ensure accurate listings of non-expired patents, while considering commercially reasonable constraints like costs and additional regulatory approvals.

In addition to size and shape considerations, implantable medical devices face marking challenges arising from the inherent tension between the statutory language of 35 U.S.C. § 287 that requires patent markings be applied directly to the patented article and the public policy considerations of encouraging patent owners to give notice to the public that their products are patented. A patent marking applied directly to a stent or heart valve surface that is difficult to read or even discover may technically satisfy the requirements of 35 U.S.C. § 287 but may also frustrate the goal of providing notice to the public that the device is patented. In such instances, a medical device manufacturer may reasonably conclude that applying such patent marking directly to the patented article may not satisfy the requirements of 35 U.S.C. § 287 and therefore mark the product packaging instead. Several Federal Circuit cases treated below provide helpful guidance for these and other patent marking considerations for implantable medical devices.

***Global Traffic Technologies LLC v. Morgan* – Placing the Patent Marking on Packaging of Device that is Installed Out of Public View is Sufficient to Satisfy the Marking Requirement pursuant to 35 U.S.C. § 287**

In *Global Traffic Technologies LLC v. Morgan*, 620 Fed.Appx. 895 (2015), Global Traffic asserted U.S. Patent No. 5,539,398 against Morgan. The '398 patent purported to provide a traffic control preemption system for emergency vehicles that used data from a global positioning system. *Id.* at 898-99. The patented system would adjust the traffic signal programming appropriately to allow the emergency vehicle to pass through an intersection. Among the various issues litigated in *Global Traffic,* Morgan argued that Global Traffic failed to properly mark the patented article under Section 287(a).

The patented system sold by Global Traffic was packaged and further contained multiple components that were separated once unpackaged. *Id.* at 906. This is similar to implantable medical devices, which may be packaged with insertion tools or other accessories necessary for surgical implantation. Global Traffic's expert testified that components of the patented system were not in the public view once installed and that other companies had marked the product in the same way. *Id.* at 906-07. For example, when the patented components are installed in a traffic control system, the component is installed inside of a traffic control cabinet that is locked and out of public view. *Id.* at 906.

The court started its analysis by noting that 35 U.S.C. § 287 requires an analysis of the "character of the article." *Id.* at 905. While identifying the size of the article as one factor in whether the article itself or the packaging must be marked, the court expressly stated that it is not the only attribute of the article to be considered. The court went further to state:

> There may be many other aspects of a patented article that can affect whether marking the article provides sufficient constructive

> notice to the public. Because we do not pretend to know all of the possible types, characteristics, or components of patented—and yet to be patented—machines and systems, we cannot construct a bright line rule regarding what aspects to consider in determining whether marking the packaging amounts to "substantial compliance."

*Id.*

The court acknowledged that "marking the individual components of the system may not have the desired notice effect of providing public notice because such markings may mislead the public into believing that the marked components themselves are patented, as opposed to the entire multi-component system." *Id.* And, focusing on the visibility of the patent marking, "patented articles may be immediately installed out of the public view once unpackaged. Again, in this example, the public may be better notified with marking on the packaging, as opposed to the article itself." *Id.* Having addressed both size and public view as factors relevant to the "character of the article," the court held that "[b]ecause there may be many factors that affect the character of a patented article, we hold that, when a patentee marks the packaging rather than the article, the district court should evaluate the specific character of the article at issue." *Id.*

Analyzing the patented traffic control system and the application of patent markings to the product packaging, the court found that Global Traffic complied with the marking requirements 35 U.S.C. § 287. The court concluded that "it was reasonable for the jury to conclude that marking the packaging of Opticom—the only time when all of the components that made up the patented system were together and in full view of the public—adequately served the purpose of providing constructive notice to the public that the entire Opticom system was patented." *Id.* at 906. Although the technology in *Global Traffic* does not include an implantable medical device, it provides several of the following important takeaways.

First, the court's conclusion that Global Traffic complied with 35 U.S.C. § 287 was based in part on the fact that components of the system would be "immediately installed out of the public view once unpackaged." *Id.* at 905. Similarly, implantable medical devices, packaged until implantation, will more likely than not be immediately implanted out of the public view once unpackaged. Therefore, *Global Traffic* provides important guidance for applying patent markings to implantable medical devices. Implantable medical device manufacturers should consider whether the device itself may be within the public view. In cases where such devices are primarily out of the public view, marking product packaging may better align with the public policy underlying 35 U.S.C. § 287 and the holding of *Global Traffic.*

Second, the court expressly acknowledged that size of the patented article is an important factor in discerning the "character of the article." *Id.* Many implantable medical devices are small in size to accommodate anatomical design constraints. Manufacturers of implantable medical devices should carefully consider the guidance provided by *Global Traffic* to determine whether patent markings are more appropriate on the device or packaging based on the size of the implantable device. Manufacturers of implantable medical devices should also consider that

at least one court has stated "[w]here the patented article has markings or printing on it, other than the appropriate patent marking, then the alternate form of patent marking on the package is not sufficient compliance with the statute." *Ethicon Endo-Surgery, Inc. v. Hologic, Inc.*, 689 F. Supp. 2d 929 (S.D. Ohio 2010) (*citing Rutherford v. Trim-Tex, Inc.,* 803 F. Supp. 158 (N.D. III. 1992) (*citing John L. Rie, Inc. v. Shelly Bros., Inc.,* 366 F. Supp. 84, 90-91 (E.D. Pa. 1973) (E.D. Pa. 1973))).

Another noteworthy commentary on marking implantable medical devices exists in *Stryker Corp. v. Intermedics Orthopedics, Inc.*, 891 F. Supp. 751 (E.D.N.Y. 1995). In this case, the patent owner, Osteonics (a subsidiary of Stryker), contended that it was not medically feasible to mark the patent number on a femoral prosthesis, because etching and engraving on the implant would have a "deleterious effect" on the implant's performance. Instead, in accordance with what it described as “accepted practice in the orthopedic implant industry,” Osteonics claimed that it met the marking requirement of the statute by displaying the patent mark in nationally distributed literature about the product. *Id.* at 829. The court found that Osteonics failed to meet the marking requirement of 35 U.S.C. § 287, in part because this would allow the patent owner to place an advertisement of the patented product in the newspaper or a trade journal which refers to the patent mark, and thereby meet the marking requirements of the statute without having to mark the product's packaging. *Id.* at 830. This case is important because it raises another consideration in the “character of patented article” analysis reviewed in *Global Traffic*, i.e., whether applying a patent marking to an implantable medical device may have a "deleterious effect" on its operation or use. Because the *Stryker Corp.* court determined that the patent marking was non-compliant based on the use of product literature, rather than on the “deleterious effect” argument (*see id.* at 832), such arguments may still be viable in future patent marking disputes where concerns about printing, etching, embossing, or otherwise applying a patent marking to an implantable medical device may be in tension with regulatory obligations or patient safety considerations that require safe and effective operation and use.

Finally, *Global Traffic* provides important guidance that “...***there may be many factors*** *that affect the character of a patented article*, [and] we hold that, when a patentee marks the packaging rather than the article, the district court should evaluate the specific character of the article at issue” *Global Traffic Technologies,* 620 Fed.Appx. at 905 (citing *Sessions v. Romandka*, 145 U.S. 29, 49-50 (1896)). This echoes guidance from the court in *Ethicon*, which stated “‘[a]lternative marking of the package may sufficiently comply with the statute when there is some reasonable consideration presented for not marking the article due to physical constraints or other limitations, or, for reasons that go to the very purpose of the statute, marking the article itself would not provide sufficient notice to the public.’ In addition to *giving due consideration to a* ***variety of factors***, including, but not limited to, defacement, custom of the trade, and expense, the *Rutherford* court "notes that above all, a **practical common sense approach *must be taken*** when dealing with issues of compliance for the marking provisions of § 287.” *Ethicon Endo-Surgery*, 689 F. Supp. 2d at 945. The court in *Ethicon* went further to state, “the Court finds that the best approach is to ***not create a hard and fast rule***…” and to consider the notice function of patent markings under 35 U.S.C. § 287 in the context of the specific patented article. *Id.* at 946. From this guidance in *Global Traffic, Ethicon,* and *Stryker*, it

is important to evaluate the fact-specific nature of the patented article and the particular attributes that may affect the "character of the article." As *Global Traffic, Ethicon,* and *Stryker* have shown, courts take a flexible approach to the patent marking analysis when determining whether a patented article complies with 35 U.S.C. § 287.

***Acantha LLC v. DePuy Orthopaedics Inc. – Placing the Patent Number on Surgical Guides is not enough to satisfy the Marking Requirement pursuant to 35 U.S.C. § 287***

While this case does not include a software-related device, it does include a medical-related device. Nonetheless, this case provides an overview of the outcome regarding a medical device (e.g., whether it has software or not) when a patentee marks something (e.g., a medical guide or manual) other than the product itself.

In *Acantha LLC v. DePuy Orthopaedics Inc.*, the patent-at-issue (i.e., U.S. Patent RE43,008 (the "'008 patent")) was owned and asserted by Acantha, Inc. The '008 patent included claims for an "orthopedic implant assembly." 2018 Us Dist Lexis 69493, 2018 WL 1951231 (E.D. Wis. Apr. 25, 2018). In March 2002, David Talaber, one of the patent's inventors, sent letters to several medical device companies, including several defendant entities and their predecessors, notifying them of Acantha's intellectual property as well as the types of products it covered and inquiring into their interest in licensing the technology. *Id.* at *1 (citing Pl.'s Proposed Findings of Fact (PPFOF) ¶ 28, ECF No. 176)). In 2003, Acantha entered into an exclusive license agreement for Acantha's patent with Stryker Spine SA. *Id.* at *1-*2. Pursuant to the agreement, Acantha allowed Stryker to manufacture and sell products under the patent. *Id.* The agreement only identified Stryker's Reflex product as a licensed product. *Id.* at *2 Stryker agreed to mark the covered product's packaging: "Beginning . . . after the execution of this Agreement and at all times thereafter, the Licensed parties shall place, in a conspicuous location on the packaging for the Products . . . the words 'U.S. Patent No(s).' followed by the number(s) corresponding to the relevant U.S. Letter(s) Patent, subject to the reasonable approval of Licensor." *Id.*

A dispute arose with respect to a Vectra-branded product manufactured by Synthes Spine, which later merged with DePuy Orthopaedic. Acantha accused the Vectra product of infringing the '008 patent. *Id.* at *2. As part of its defense, DePuy Orthopaedic argued that Acantha was limited to recover damages going back to March 19, 2014, the date DePuy Orthopaedic received claim charts asserting that its products violated Acantha's patent. *Id.* In particular, DePuy Orthopaedic asserted that it did not receive "actual notice" of infringement until that date and that no "constructive notice" existed because Acantha and Stryker did not mark the patented products or their packaging labels in accordance with 35 U.S.C. § 287(a). *Id.* In response, Acantha maintained that it expected Stryker, a sophisticated company experienced in licensing, to comply with this provision. *Id.*

Acantha argued that its listing of the patent number on surgical technique guides (as provided to surgeons using the Reflex-branded product) was sufficient to demonstrate marking pursuant to 35 U.S.C. § 287(a); however, the court found that this was not enough.

In particular, Acantha argued that as early as 2004, Stryker listed Acantha's patent number on the surgical technique guides for the licensed Reflex products. *Id.* at These technique guides, Acantha noted, were distributed to hospitals and at trade shows and are published on Stryker's website. *Id.* Acantha further contended that surgeons viewed and used the technique guides during the surgeries in which the device was used. *Id.* at *3. Still further, Acantha argued that it reviewed the technique guides, noted the guides contained the Acantha patent number, and confirmed Stryker's oral representations that the licensed products were being marked. *Id.* In response, DePuy Orthopaedic countered that there was no evidence that all packaging on the products being sold was updated with sufficient marking. *Id.*

The court sided with DePuy Orthopaedic. In particular, the court found that Acantha's "reasonable efforts" and diligence to ensure its licensee (Styker) marked products covered by the patent were not enough. *Id.* at *5-*6. Further, the court found that marking on surgical technique guides (and not the products themselves) was insufficient to satisfy Section 287(a)'s marking requirement. *Id.* The court took issue with Acantha's approach:

> Even though Stryker did not mark the licensed products or their packaging with Acantha's patent number, Acantha contends that the fact that Stryker listed the patent number in the surgical technique guides for these products as early as 2004 satisfies § 287(a) 's marking requirements. These guides are distributed to hospitals and at trade shows and are published on Striker's website." "Acantha contends these measures were sufficient to show that it exercised reasonable efforts to ensure Stryker's marking and complied with § 287(a).
>
> But reasonable diligence, absent substantial compliance, is not enough."
>
> *Id.* at *6.

Accordingly, the court granted defendant DePuy Orthopaedic's motion for summary judgment, limiting the damages that Acantha could recover from March 19, 2014.

### C. Cloud-based medical device software system (Chris George)

As noted above, software generally poses some unique difficulties when it comes to marking a patented product or system. Some question still exists regarding when marking is necessitated under the statute. For example, marking requirements do not apply to the enforcement of method claims. Marking requirements do apply to system/apparatus claims. How does the marking requirement apply to computer-readable medium claims storing instructions to execute a method? To be safe, marking should be applied. However, what is the "product" to be marked?

With amendment to 35 U.S.C. 287 through the America Invents Act (AIA) in 2011, virtual marking is allowed as an alternative to physical marking, typically taking the form of a URL

identifying a website that lists patents and associated products. As set forth in 35 U.S.C. 287, "[p]atentees ... may give notice to the public that the same is patented ... by fixing thereon the word "patent" or the abbreviation "pat." together with an address of a posting on the Internet, accessible to the public without charge for accessing the address, that associates the patented article with the number of the patent...." For cloud-based software, where no physical media is delivered to a customer, physical marking of any associated processor, memory, etc., would be unseen by anyone outside the software provider, virtual marking is the only effective mechanism for notice to potential infringers.

So far, some courts have found that the software constitutes a "software product," which is a patented article that must be marked. *See, e.g.*, *Lexos Media IP, LLC v. Jos. A. Bank Clothiers, Inc.*, No. 17-1317-LPS-CJB, 2018 WL 2684104, at *3 (D. Del. June 5, 2018) ("[The products] are software products, and there is legal support for the proposition that software can be subject to the marking requirement."). Where there is a webpage or user interface for the software, a patentee's safest course of action is to provide patent marking on that webpage or graphical user interface. *See Limelight Networks, Inc. v. XO Commc'ns, LLC*, 241 F. Supp. 3d 599, 608 (E.D. Va. 2017); *see also IMX, Inc. v. Lendingtree, LLC*, No. Civ. 03-1067-SLR, 2005 WL 3465555, at *4 (D. Del. Dec. 14, 2005) ("The website is intrinsic to the patented system and constitutes a tangible item to mark by which notice of the asserted method claims can be given." (internal quotations omitted)); *Soverain Software LLC v. Amazon.com, Inc.*, 383 F. Supp. 2d 904, 909 (E.D. Tex. Aug. 8, 2005).

According to at least one Federal Circuit decision, "substantial compliance" may be sufficient to satisfy the marking statute. *Global Traffic Techs. LLC v. Morgan*, 620 Fed. App'x 895, 906 (Fed. Cir. 2015) (citing *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1111 (Fed. Cir. 1996)). Additionally, cloud-based software typically runs on a server, often purchased from another entity, that is also hosting other programs. As such, marking the physical server, which competitors and users cannot see, fails to serve a notification purpose. However, by providing a virtual marking on the graphical user interface or webpage through which the cloud-based software functionality is accessed, a patent-holder should feel fairly confident that they have satisfied the marking requirements of 35 U.S.C. 287.

Such marking can take the form of providing an address or link to a patents or IP webpage. The patentee must be careful, however, not to simply provide a laundry list of their patents. Instead, patents should be associated with the particular software to which they apply. *See Mfg. Res. Int'l, Inc. v. Civiq Smartscapes, LLC*, 397 F. Supp. 3d 560 (D. Del. 2019). Further, care must be taken to add new patents as they are granted and to remove old patents as they expire. Leaving expired patents without a periodic refresh can expose the patent holder to a charge of false marking. While false marking requires deceptive intent and is now only available to parties suffering a competitive injury as a result of the erroneous (e.g., expired) marking, it is certainly preferable to avoid engaging in such litigation in the first place by being careful to keep the patent listing up-to-date. *See* Pequignot v. Solo Cup Co., 608 F.3d 1356 (Fed. Cir. 2010).

While not specific to medical devices, the cases highlighted above provide a path forward to satisfy the marking statute and provide notice when medical software is provided via a cloud-based system. Helping clients be aware of the marking requirement, available options to satisfy that marking requirement, and the responsibility to keep such marking correct and current enables them to maximize the damages recovery available to them for infringement by other parties. A link to a patents or intellectual property webpage, provided on an startup screen or initial interface to the software product, that identifies products and lists relevant, active patent numbers should be sufficient to satisfy the marking obligation for a software product delivered to user devices remotely via "the cloud."

### D. Third-party devices having medical-based software (e.g., an app on a smartphone) (**Mal Kind**)

There are a wide range of technological and commercial approaches for distributing software that is protected by patents. The best strategy for marking products embodying such software depends on the details of how the software is distributed. In the simplest case, the patentee distributes the software in a tangible medium (e.g., on a flash drive or CD) and has computer-readable medium claims. Thus, the medium used to distribute the software can be marked with the relevant patent number(s). However, the analysis becomes for complicated for claims covering systems (e.g., smartphones or laboratory computers) on which the software is installed).

In *Egenera, Inc. v. Cisco Sys. Inc.*, the patentee authorized third parties to manufacture hardware with its software pre-installed. 547 F. Supp. 3d 112, 127 (D. Mass. 2021). The patentee argued that it could not mark the software, so it included patent marking in user references manuals packaged with the software.[2] *Id.*, 126. However, the court held that the patentee could have required the third-party manufacturers to physically mark the hardware covered by the patents, so physical marking was required. *Id.*, 127 (citing "*Amsted Indus. Inc. v. Buckeye Steel Castings Co.,* 24 F.3d 178, 185 (Fed. Cir. 1994). Thus, this suggests that patentees that are licensing software to be pre-installed on hardware would be prudent to consider including contractual requirements that such hardware is marked with any relevant patent numbers.

Increasingly much software is not provided on tangible media or pre-installed on hardware. Rather, end users often install software onto devices from the cloud. In this scenario, patentees cannot reasonably ensure that devices that are covered by their patents once the software has been installed are marked. Thus, marking by displaying the patent numbers within the software or in documentation provided with the software is a viable alternative. Patentees should be cognizant of the statutory requirement that the marking clearly identifies the patented product and ties it to the relevant patent(s). In *McKesson Automation, Inc. v. Swisslog Italia S.P.A.*, the patentee's software caused display of patent numbers that covered the hardware as configured by the software on the log-in screen of the software. 712 F.Supp.2d 283 (D. Del.

[2] The patentee's marking was also found defective for not sufficiently tying the patent to the patented product, but that does not impact the analysis finding that physical marking was required.

2010). However, the court found the notice insufficient because it did not provide notice that it was the hardware that was covered rather than the software alone. *Id.*, 297. Therefore, where a patentee wants to provide notice that third-party hardware with their software installed is covered by a patent, any notice provided either within the software itself or in documentation provided with the software should clearly indicate that it is the hardware configured by the software that is covered by the patent.

In sum, for patents relating to software that is installed on third-party devices, patentees should carefully consider what marking options are feasible and ensure that any marking provided clearly ties the patents(s) to the covered article.

## III. European Marking Perspectives

The European Patent Convention, the European patent with unitary effect and the unified patent jurisdiction do not specifically address the issue of patent marking.

As a result, assessment has to be done country by country. Examples are provided below.

### A. United Kingdom (Nikesh Patel)

There is no requirement in the UK for patented products to be marked with patent details. In the UK, the benefit of marking is that it effectively puts the potential infringer on notice of the existence of a patent application or patent such that it will be difficult for them to plead ignorance if proceedings are brought against them. This is related to section 62(1) of the UK Patents Act (UKPA), which states that:

> In proceedings for infringement of a patent damages shall not be awarded, and no order shall be made for an account of profits, against a defendant or defender who proves that at the date of the infringement, he was not aware, and had no reasonable grounds for supposing, that the patent existed; and a person shall not be taken to have been so aware or to have had reasonable grounds for so supposing by reason only of the application to a product of the word “patent” or “patented”, or any word or words expressing or implying that a patent has been obtained for the product, unless the number of the patent or a relevant internet link accompanied the word or words in question.

In order to be effective in the UK, the marking of patent details should be in a form identifying the patent application or patent number rather than simply the words “Patent Pending” or “Patented”. Example wording such as “Patent Pending” along with the UK patent application number (GBXXXXXXX.X) for pending UK applications or “Patented” along with the granted UK patent number (GBXXXXXXX B) for granted UK patents should be acceptable for marking products. Once a patent application has been granted, the application number should be replaced with the official patent number.

As is apparent from the above statute, an internet link can be provided instead of the number of the patent application / patent. The link should relate to a web address that can be accessed free of charge and clearly associates the product with the number of the relevant patent (section 62(1A) UKPA). For example, the product could be identified by including any relevant model numbers and variants that exist. The home page web address may not be sufficient unless the home page includes the association between product and patent number.

UKIPO guidance suggests that a QR code will not itself provide all members of the public with notice of relevant patent rights. This could be provided in addition to providing the patent number or web address. It is to the courts to decide whether sufficient notice has been provided to third parties if a dispute arises.

If the marking is provided clearly on packaging or product literature that is sold with the product (rather than the product itself), this would be an indirect “application to a product” even though it is a more practical application of the marking. From a legal standpoint, it is unclear whether this provides the benefits relating to notification of the existence of a patent application or patent. Nevertheless, there may be some benefit such as acting as a deterrent from copying provided it is accurate marking information and showing that a product is innovative (given below consequence of incorrect marking).

It is an offense in the UK to falsely represent that a product is patented or to represent that a patent has been applied for a product when either no such application has been made or any such application has been refused/withdrawn. Contravening this provision could lead to summary conviction or a fine. Care should therefore be taken throughout the lifetime of a patent application or patent, as a change in status of the patent application or patent may require a change in the marking of the product.

There do not appear to be specific provisions in the UK with respect to patent marking of software-based medical devices.

### B. France (Dominik Franz)

The issue of patent marking is not specifically addressed by the French Intellectual Property Code (IPC), and there is no legal requirement for patent holders to mark their products with information regarding the patents protecting them.

In France, the absence of patent marking does not affect the possibility of compensation or the amount of compensation that a patent holder can claim. On the contrary, it is considered that professionals are aware of patents that their products may potentially infringe. However, in order for a potential infringer to be held accountable, the IPC requires in some cases prior knowledge of the respective patent for some acts of infringement (e.g. offer for sale) and while in other cases no prior knowledge is needed (e.g. fabrication, importation).

Thus, although it is not required, marking of products protected by patents may be helpful in cases where prior knowledge of infringement acts is required.

Misleading information on a product may be considered as unfair competition and any person falsely claiming to be the holder of a patent may be sanctioned (L615-12 IPC).

Abbreviations that appear to be acceptable for marking products are *"Brevet"* (patent) combined with the number of the granted patent, or simply *"breveté"* (patented) for the case of a granted patent, and *"brevet déposé"* (patent filed) or *"brevet demandé"* (patent applied for) for the case of a pending application. No legal provisions regarding virtual patent marking seem to exist in France.

No particular dispositions seem to exist in or for France with respect to patent marking of software medical devices.

### C. Germany (Dominik Franz)

In Germany, patent holders are not required to provide information on their products with respect to patents protecting them in order to be awarded compensation by an infringer of the patents. On the contrary, it is presumed that a potential infringer knew or should have known about the patent. Nevertheless, patent marking has the advantage that a malicious act of a potential infringer can be more easily argued.

The issue of patent marking is addressed by § 146 of the German Patent Act, specifying that, when products comprise any type of patent marking, the patent holder is legally obliged to provide information of the granted patent or patent application upon request by third parties.

However, according to § 5(2)(3) of the German Unfair Competition Act (UWG), misleading information on a product may be sanctioned under unfair competition rules. A commercial practice is deemed misleading if it contains false or deceptive information.

Common abbreviations used for patent marking of products are *"D.B.P"* for *"Deutsches Bundespatent"* (Geman federal patent), *"patentiert"* (patented) or *"patentrechtlich geschützt"* (protected by patent) for a granted patent and *"D.B.P. angemeldet"* or *"D.B.P. angem."* (applied for) for the case of a pending application. No legal provisions regarding virtual patent marking seem to exist in Germany.

No particular dispositions seem to exist in or for Germany with respect to patent marking of software medical devices.