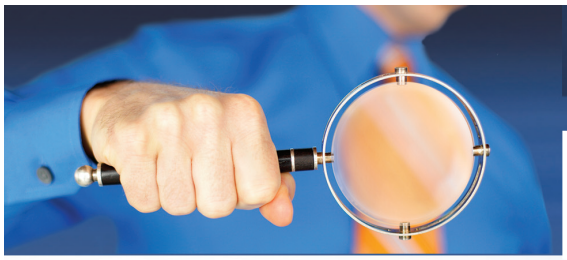

MEDICAL DEVICES

Legal News™

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THE PULSE IS NOW LEGAL NEWS: MEDICAL DEVICES... A MODERN APPROACH TO DELIVERING THE SAME CUTTING-EDGE THOUGHT LEADERSHIP YOU'VE COME TO EXPECT FROM FOLEY.

Legal News is part of our ongoing commitment to providing up-to-the minute information about pressing concerns or industry issues affecting our medical device clients and colleagues. If you have any questions about this issue or would like to discuss these topics further, please contact your Foley attorney or the following individual:

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United States Supreme Court to Decide: Can a Patent Holder Avoid the Fundamental Doctrine of Patent Exhaustion

Steve Z. Szczepanski and Scott R. Kaspar

On January 16, 2008, the U.S. Supreme Court will hear a case which involves defining the boundaries of a fundamental patent doctrine: patent exhaustion (typically when the product is sold, patent rights are "exhausted"). The Court decision may have a significant impact on a wide variety of industries, including the biomedical device industry, which sells products and systems with basic computer components that are the subject of this case.

A patentee has the "right to exclude others from making, using, offering for sale, or selling the invention." 35 U.S.C. §154(a). However, when the patentee sells a product covered by the patent, the patentee's rights are "exhausted" with respect to a patented product when the patented product "passes to the hands of the purchaser." Bloomer v. McQuewan, 55 U.S. (14 How.) 539, 549 (1853). In other words, after a patentee sells a patented product and receives compensation, the patentee may not assert its patent rights against a subsequent user or purchaser of the product he had sold. This doctrine, known as "patent exhaustion" or the "first-sale doctrine," has been uniformly followed by courts. However, questions arise as to whether the patentee may prevent the application of the doctrine by transferring products by arrangements other than outright sales and whether the patentee may improve contractual restrictions on the purchaser.

In the case now before the Supreme Court, Quanta Computer, Inc. v. LG Electronics, Inc. (LG), the patentee, LG, has sought to control downstream sales through a "conditional sale" arrangement whereby LG authorized Intel to sell microchips falling within the scope of LG's patents, but this authorization did not extend to Intel's customers and other downstream consumers. Rather, LG has reserved a right to sue Intel's customers, including Quanta Computer, who have incorporated the microchips into computers sold to end consumers. The Supreme Court has agreed to hear the case to decide whether LG's patent rights were not exhausted by its license agreement with Intel and Intel's subsequent sales of products under the license.

The potential significant impact of the Quanta case on various industries and markets is evident from the numerous amicus curie briefs filed on behalf of 19 corporations, industry groups, and law associations. Of the 14 amicus curie briefs, nine briefs were filed in support of Quanta Computer and argue that the patent exhaustion doctrine should apply to "conditional sales" as well as outright sales. Only one brief, filed by the American Intellectual

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Property Law Association (AIPLA), squarely supports LG and argues that a conditional sale should not trigger patent exhaustion. The remaining four briefs purport to support neither party, so long as the Supreme Court's decision does alter well-established principles of patent exhaustion that have been relied upon in practices of various industries.

For instance, one industry group in favor of Quanta Computer includes computer manufacturers NCR Corporation, Hewlett-Packard, Cisco Systems, eBay, IBM, and the Computer and Communications Industry Association, all of which are customers or downstream customers of Intel and other microchip manufacturers and are similarly situated to Quanta Computer. If LG ultimately prevails, the computer manufacturing industry could be forced to pay licensing royalties to LG and other patent holders of microchip technology.

Another industry group in favor of Quanta Computer includes the automotive aftermarket, as represented by the Automotive Engine Rebuilders Association and the Automotive Parts Remanufacturing Association. Based on LG's success in the lower courts, equipment manufacturers in the automotive industry have begun applying restrictive post-sale patent notices in an attempt to lock out aftermarket sales and repair of patented devices.

The consumer advocacy groups such as the Consumers Union and the American Antitrust Institute and the United States Department of Justice also have submitted briefs in support of Quanta Computer, stating that downstream competition is impaired by providing patent holders with the ability to extract multiple downstream royalties. Some biotechnology companies such as Gen-Probe also have advocated in support of Quanta Computer on the belief that LG's licensing arrangement, if allowed, would stifle downstream competition and ultimately innovation.

The AIPLA, among the last to file its brief, has come out in support of LG, stating that "[t]here is no per se anti-competitive effect in allowing licensors and licensees the freedom to create such agreements." The AIPLA believes that "a patentee may, with adequate notice, require separate licenses at various stages along the downstream chain of sophisticated purchasers and users of its patented invention."

The plant science industry is among the few groups not taking a position in support of either Quanta Computer or LG, but rather seeking to protect other established principles of patent licensing upon which the plant science industry has come to rely. For instance, in its brief, CropLife International urged the Supreme Court "not to call into question the settled principle that inventors of self-replicating crop plants may rely upon the patent laws to enforce limitations upon making subsequent generations of plants and seeds from the patented originals." Similar briefs also were filed by the American Seed Trade Association and the Biotechnology Industry Organization.

The Quanta case will be heard in January 2008, with a decision likely to come around May 2008. As the medical device industry continues to increase utilization of products and systems with high-technology computer components and enter into complex licensing agreements, Quanta should be followed as it has the potential to greatly impact the industry.

At the Razor's Edge: Prosecuting and Defending Against Patent Infringement Claims Post-*KSR*

Jeanne M. Gills

KSR Overview

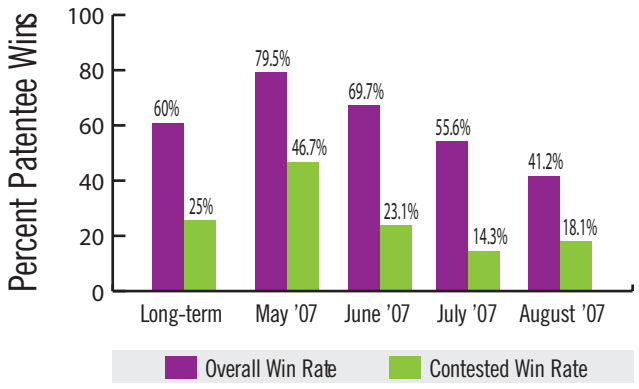
While commentators might disagree over the magnitude of change, there is little dispute that the U.S. Supreme Court's *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) (*KSR*) decision last year has impacted the manner in which plaintiffs and defendants have approached patent infringement claims. For years, practitioners largely relied on the case law driven "teaching-suggestion-motivation" (TSM) test in determining whether it was obvious to put together known elements in the art to meet the asserted claim. The Federal Circuit had likewise long-rejected any "obvious to try" standard. In *KSR*, the Supreme Court held that because the Federal Circuit applied its own TSM test too rigidly, the claim "must be found obvious." The Court further noted that TSM is a "helpful insight," but "when a court transforms the general principle into a ***rigid*** rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs."

This decision has and will continue to impact the ability to procure and defend patents on medical devices. The medical device arena necessarily involves the use of common elements and components — such as needles, pumps, and valves. Thus, *KSR's* directive to exercise common sense and to afford the person of ordinary skill to art areas outside the medical field opens up potential new obviousness challenges that may not have existed before.

In particular, had the *KSR* court merely commented on the

proper application of the TSM test, there may have been little fanfare. Instead, the Court expounded on several aspects of the obviousness inquiry: (i) ***Flexibility***: The obviousness inquiry is an "expansive and flexible approach"; (ii) ***Ordinary Creativity***: "A person of ordinary skill is also a person of ordinary creativity, not an automaton," who will not limit herself to art with the same problem, nor can she be confined to the problem patentee was trying to solve; (iii) ***Obvious to Try***: "[T]hat a combination was obvious to try might show that it was obvious under § 103"; (iv) ***Predictability***: The patent must be more than "the predictable use of prior art elements according to their established functions"; and (v) ***Design Need/Market Pressure***: Products driven by design needs or market pressures — when there are finite number of identified predictable solutions — are likely the result from ordinary skill, not innovation. In applying *KSR*, subsequent courts have quoted these tenets in their findings.

Post-*KSR* Patentee Win Rates



* Data from LegalMetric, LLC

In the seven months since *KSR* was decided, its impact has been felt across many industries, with some industries facing tougher challenges than others. As the trend chart indicates, post-*KSR*, there was a decline in a patentee's overall win rate in the subsequent months following *KSR*, despite a brief upward trend that first month.

Post-*KSR* Medical Industry Cases

Nonetheless, recent cases in the medical technology and medical devices arena show promise for patentees. In *Boston Scientific Corp. v. Johnson & Johnson,* No. 02-00790, 2007 WL 2408870 (N.D. Cal. 8/21/07), in denying summary judgment of obviousness on patents directed to catheters, the Court stressed the need to show that the prior art taught the claimed invention, and emphasized *KSR's* directive to look at the *Graham v. John Deere Co. of Kansas City*, 86 S.Ct. 684 (1966) (*Graham*) for secondary considerations of non-obviousness. In *Boston Scientific*, the first series of patents-at-issue were directed to a bilayered catheter tube design for balloon angioplasty catheters. The bilayered tube was made by co-extrusion of a nylon outer layer and a high-density polyethylene (HDPE) inner layer. Regarding these patents, the Court held that the patentee raised a triable issue as to whether the prior art taught the use of co-extrusion to create a bilayered catheter comprised of HDPE and nylon. Specifically, the patentee presented evidence that it was known that HDPE did not bond well with other materials, including nylon. *Id.* at *6.

The other patent-at-issue in *Boston Scientific* was directed to methods of forming a fusion bond between a catheter and a balloon with a laser, where the catheter and the balloon have high absorptivity. *Id.* Regarding this other patent, the Court found there was a triable issue whether catheter-balloon laser bonding was obvious. While the prior art disclosed a catheter made from bonding with PET balloons, the patentee proffered evidence that the prior art bonding was made using hot jaws and solvents. The prior art's passing reference to laser bonding — as one among eight possible techniques for attaching a catheter body to a balloon — thus failed to disclose a reason to try laser bonding, nor did it necessarily imply that laser bonding was a viable solution. Further, the technological state of laser bonding at the relevant time was unclear. Other prior art proffered by patentee indicated that one skilled in the art would not have considered lasers as a viable method of balloon-catheter bonding, and thus there was a triable issue of fact as to whether the relevant prior art taught away from the use of laser bonding. *Id.* at *7-8. Finally, the Court noted that *KSR's* affirmance of *Graham* "mandated exploration of secondary considerations such as commercial success, long felt need but unresolved needs, and the failure of others to achieve the invention." *Id.* at *8. These secondary considerations also supported denial of summary judgment of obviousness.

In another recent case, *NMT Medical, Inc. v. Cardia, Inc.*, No. 04-4200, 2007 WL 3454403 (D. Minn. 11/8/07), the Court declined to accept defendant's supplemental expert report on obviousness where the defendant argued that the *KSR* decision came after its initial expert reports and summary judgment papers were due. The Court observed that authority had already existed (namely, *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick*

Co., 464 F.3d 1356 (Fed. Cir. 2006)) when defendant submitted its summary judgment papers and thus it could have preserved its obviousness argument for appeal. *Id.* at *2. *See also Cordis Corp. v. Medtronic Ave, Inc.*, No. 2006-1393 et al., 2008 WL 60499 (Fed. Cir. 1/7/08) (declined new trial on obviousness based on pre-*KSR* jury instruction on application of TSM test that was not previously objected to).

The Federal Circuit also recently vacated a Board of Patent Appeals and Interferences (BPAI) obviousness decision in *In re Sullivan*, 2007 U.S. App. LEXIS 20600 (Fed. Cir. 8/29/07). That case involved a patent relating to antivenom composition used to treat venomous bites from a rattlesnake. The BPAI had affirmed the examiner's rejection of certain claims as obvious over two prior art references (that taught use of whole antibodies for use against rattlesnake venom and use of Fab fragments to detect venom of different snake). The Court of Appeals, however reversed the BPAI, finding that the BPAI had failed to give weight to the rebuttal evidence of record. That rebuttal evidence included expert and inventor declarations on why use of Fab fragments as antivenoms was expected to fail and how prior art taught away. *See also Ex Parte Noelle*, 2008 WL 55123 (the BPAI reversed the examiner's finding of obviousness on claims directed to a method for inducing antigen-specific T-cell tolerance where there was no evidence why a person of ordinary skill in the art would purify isolated CD4+ T-cells in view of the ex vivo example using bone marrow in *Noelle's* disclosure).

On the flip side, there have been several recent BPAI decisions (across many technologies) that have found the alleged inventions to be unpatentable as obvious, citing *KSR* favorably. *See, e.g., In re Translogic Technology, Inc.*, 504 F.3d 1249, 1259 (Fed. Cir. 2007) (aff'd BPAI decision of obviousness on claims directed to multiplexer circuits noting that "obvious variants of prior art references are themselves part of the public domain"); *Ex Parte Lewis*, 2007 WL 4591416 (BPAI 12/31/07) (aff'd examiner's obviousness rejection of certain claims involving wireless networks); *Ex Parte Loda*, 2008 WL 55121 (BPAI 1/3/08) (aff'd examiner's obviousness rejection of claims directed to monitoring a product and providing data to a user where the combination of references "would have resulted in a predictable solution that would have been within the technical grasp of one of ordinary skill in the art"); *Ex Parte Michaluk*, 2008 WL 55122 (BPAI 1/3/08) (aff'd examiner's obviousness rejection of claims directed to method of supplying metal material from a supplier or agent to a sputtering target manufacturer where the combined references fall "well within the boundaries of that which would have been within the grasp of one of ordinary skill in the art" given the "limited number of ways" to achieve the claimed result); *Ex Parte Yoakim*, 2008 WL 55124 (BPAI 1/3/08) (aff'd examiner's obviousness rejection of claims directed to a sealed beverage cartridge designed to be extracted under pressure).

Best Practices in View of *KSR*

Upon consideration of the recent cases, the following are best practice litigation pointers for plaintiffs and defendants in enforcing or defending patent infringement claims.

For Plaintiff/Patentee:

- Place more reliance on and substantiate secondary factors (e.g., commercial success, and so forth). Important to establish a nexus between commercial success and claimed invention.
- Use experts to raise issues of fact (e.g., reason to combine, level of skill, and so forth) that require a jury to decide. Many cases post-*KSR* relied heavily on expert reports and testimony.
- Establish that a combination of references yields unpredictable results.
- Establish that the combination of prior art still does not demonstrate all claim limitations.
- Focus on establishing a lower level of ordinary skill in the art, thereby creating a lower likelihood of a reason to combine elements.
- Find instances where prior art teaches away from combining the elements.
- Consider having the patent reexamined prior to litigation. If successful, it will be harder to invalidate in later litigation.

For Defendant/Alleged Infringer:

- Rely on experts to support theories!
- Do not restrict the prior art search to references designed for solving the same problem as the patent allegedly solves.
- Find a strong design or market demand in place that provided a reason to combine elements.
- Check if there was a known problem in the field for which there was an obvious solution as encompassed by the claims look for predictable results.
- See if the patent specification discloses a purpose that leads to a reason for the combination.
- Focus on establishing a ***higher*** level of ordinary skill in the art, thereby creating a higher likelihood of a reason to combine elements.
- Focus obviousness arguments in all three *Graham* factors.
- Argue against presumption of patentability because patent prosecuted under rigid TSM test.
- Determine whether a known and obvious technique was used to improve a device, resulting in a predictable use.
- Consider summary judgment motions to decide obviousness issues.
- Attack commercial success evidence.

Extravagant Arrangements With Physicians Get Device Makers in Big Trouble

Judith A. Waltz and Lena Robins

Device makers, like pharmaceutical manufacturers, have long recognized that their success depends upon making their products known to physicians who will prescribe or recommend the use of their particular product. In addition to their ability to influence current product use, physicians also are in the best position to conduct or oversee research that may expand future market share, including identifying additional clinical uses or adaptations for a product — some of which may not yet be approved by the U.S. Food and Drug Administration (FDA). With respect to many devices, physicians may not be the actual purchaser of the product; rather, a hospital or surgery center, or even a group purchasing organization, may be the actual purchaser for use in facility procedures. Nonetheless, physicians often serve as thought leaders who can directly and indirectly influence product selection by the actual purchaser.

Recent enforcement activity by the United States Department of Justice (DOJ) and the Health and Human Services Office of Inspector (OIG) demonstrates the government's commitment to limiting manufacturer contacts with physicians that may skew independent medical decision making. The federal Anti-Kickback Statute (AKS) is a criminal prohibition against improper remunerations (broadly defined to include virtually anything of value) to referral sources. In addition, enforcement activity may be premised upon the federal Civil False Claims Act (FCA), even though device manufacturers typically do not directly bill Medicare, Medicaid, and other federal health care programs and physicians may not directly purchase the product. The requisite "link" is that the FCA can be violated if an individual or entity either submits a false claim, or causes a false claim to be submitted, seeking reimbursement from a federal health care program. "Kickbacks" may be alleged to "taint" a claim that may give rise to civil false claim liability under the FCA even if there is insufficient evidence to support the criminal intent required for an AKS violation. The FCA also includes whistleblower provisions that allow private recoveries to, and protection against retaliation for, the whistleblower.

The government can take a variety of different approaches to resolving fraud allegations as evidenced by the recent settlement involving five of the nation's largest orthopedic device manufacturers. These manufacturers of artificial hips and knees were alleged to have used sham consulting agreements and other tactics to induce surgeons to use their products in violation of the AKS. In a new twist, four of the manufacturers entered into Deferred Prosecution Agreements, which allow them to avoid prosecution if they follow new compliance procedures under federal monitoring for 18 months. These four manufacturers also paid a total of $311 million in penalties. One manufacturer avoided criminal charges and civil penalties because it was the first company to cooperate with the federal investigation and instead accepted federal supervision for 18 months. As part of the Deferred Prosecution Agreements, the device manufacturers are required to prominently feature on their Web site the name, city, and state of residence for each of the manufacturer's consultants (defined to include physicians), along with the payments made to each consultant.

In addition, as part of a settlement with the DOJ involving a health care entity, a Corporate Integrity Agreement (CIA) often is required. This is the OIG's contract with the entity with respect to future performance, and reciprocates for the OIG's relinquishment of its option to exclude (debar) the entity from participation in the federal health care programs. Each of the four orthopedic device manufacturers noted above entered into a CIA. These CIAs provide the industry with guidance as to the operational monitoring the OIG would like, or expect, to see from similarly situated entities. For example, the September 2007 CIA with Smith & Nephew, Inc. requires the creation of a database for all of its arrangements, including those with physicians, with eight required categories of information, including the methodology for determining compensation. This CIA also requires tracking of all remuneration to and from parties to these arrangements.

Best Practices

Best practices for device manufacturers to consider to avoid the enforcement trap include, but are not limited to, the following:

- Manufacturers should have an established and effective compliance program, including adequate resources to support it. Some states may require a compliance plan as a condition for doing business in the state (e.g., California's SB 1765). Codes of Ethics (or Conduct) and similar guidance published by trade associations such as the Advanced Medical Technology Association (AdvaMed), PhRMA, the National Electrical Manufacturers Association (NEMA), the American Medical Association, and others, provide basic guidance on contacts with physicians, and should be considered to represent the "industry standard."

- Manufacturers should critically review all existing arrangements with physicians including, but not limited to, the following:
  - Vendor-sponsored product training and education
  - Support for third-party educational conferences
  - Sales and promotional meetings with physician participation
  - Consulting arrangements
  - Gifts, paid entertainment, recreation, and meals
  - Charitable donations
  - Research grants
  - Preceptorship agreements
- Policies and procedures should be designed — and followed — for approval of future arrangements with physicians. It is particularly important to document all terms of such arrangements, including the services to be provided (and proof that they were provided) and the methodology for compensation. "Safe harbors" specified in the regulations may provide protection against AKS allegations if all requisite conditions are met.
- Sales and marketing staff must be trained on the risks associated with basic marketing practices that may be fully acceptable — or even considered key strategies — in non-health care lines of business.

Conclusion

Device manufacturers, following pharmaceutical manufacturers who in turn followed direct health care providers (such as hospitals and nursing facilities), are now the subject of increased government enforcement activity. An initial enforcement focus is the manufacturers' relationships with physician thought leaders. Due care must be taken to assure compliance with all laws and regulations regarding such arrangements.

Compliance With FDA and SEC Disclosure Requirements for Medical Device Makers: Standard Operating Procedures Can Help

Elizabeth P. Gray and Jessica L. Matelis

In 2004, the U.S. Securities and Exchange Commission (SEC) and the U.S. Food and Drug Administration (FDA) announced steps to enhance cooperation between them in order to further protect the investing public from false and misleading statements by public life sciences companies. Given the relationship between the SEC and the FDA, the consistent flow of information between life sciences companies and the FDA, and the frequency with which many such companies utilize the public markets to raise funds, companies in this area are well-advised to establish a robust set of disclosure policies and procedures to ensure that information is being promptly and accurately disclosed.

Although there is no general affirmative duty for a public company to disclose non-public information, SEC rules and regulations may require disclosure of certain information or life sciences companies may voluntarily disclose information. Whenever a disclosure is made, however, it must be complete and accurate to avoid misleading the public. Because of the importance of disclosing accurate information, even small public life sciences companies need to focus on making sure information flows accurately and promptly within the company and then to the public.

One approach is to develop and utilize standard operating procedures that encourage timely and accurate exchange of information. For example, a formal written standard operating procedure (SOP) for dealing with communications from the FDA can help a company identify and disclose pertinent information and may include the following guidelines:

- Written communication with the FDA should be circulated within 24 hours to members of regulatory affairs, clinical trials/development divisions, the general counsel's office, and corporate communications
- Oral communications should be documented in a written summary and circulated to the same group of people
- Specific personnel should be responsible for drafting and distributing these communications, and there should be a procedure for calling meetings on short notice to allow for discussion about the new information throughout the company

Creating SOPs for the drafting, review, and filing of SEC filings also is an important component for disclosure policies and procedures. For each periodic filing on Form 10-K or 10-Q, implementing an SOP that sets forth the timeline for drafting the filing and also includes the necessary sign-offs for each section will help ensure complete and accurate review.

Streamlined SOPs for press releases, Forms 8-K, and registration statements also are useful. Information required to be disclosed on Form 8-K must be filed within four business days of the company

becoming aware of the information. And, although registration statements can integrate prior filings, a company must still ensure that it describes "any and all material changes in the registrant's affairs" that were not previously reported on a Form 10-Q or 8-K.

Finally, because many life sciences companies are regularly communicating with the investing public, particularly institutional investors, developing an SOP that covers Regulation Fair Disclosure may be useful. Under Regulation Fair Disclosure, companies are prohibited from selectively disclosing material nonpublic information to certain parties, such as securities market professionals, institutional investors and investment companies.

Because of the increased level of cooperation between the SEC and the FDA, life sciences companies should take care when disclosing information. Using SOPs, a familiar format of control at life sciences companies, is one way to make disclosure easier and more effective for these dynamic companies.

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