A TRAP FOR THE WARY: HOW COMPLIANCE WITH FDA MEDICAL DEVICE REGULATIONS CAN JEOPARDIZE PATENT RIGHTS

ERIC P. RACITI AND JAMES D. CLEMENTS *

ABSTRACT

The medical device industry is unique in its highly regulated nature, generally short R&D cycles, and growing financial incentives. Patent protection, both in the USA and abroad, is critical for medical device companies to survive competition, protect its market space, and attract investment. Medical device companies are also subject to FDA regulations, which place conditions on the sale of medical devices. In certain circumstances, the interplay of the patent and medical regulatory systems in the USA can serve to destroy the patent rights of a compliant, but unwary, medical device company.

I. INTRODUCTION

The medical device industry is unique in several respects. One major distinction is its highly regulated nature, especially in lucrative technologies related to invasive surgical procedures. While it might appear that the medical device industry shares an analogous regulatory framework (and the same regulatory agency, the U.S. Food and Drug Administration (hereinafter "FDA")) with the pharmaceutical industry, the complexity, clinical burden, and time for regulatory permission[1] to enter the market are usually far less onerous for medical devices. This translates to much shorter product times-to-market, and a more

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 © 2005. Mr. Raciti is an attorney and Mr. Clements a student associate at Finnegan, Henderson, Farabow, Garrett & Dunner, LLP. The opinions expressed herein are those of the authors and do not necessarily reflect those of Finnegan Henderson.

[1] The term "permission" as used here is intended to encompass both "approval" under the Premarket Approval (PMA) process and "clearance" under the Premarket Notification (510(k)) process.

kinetic competitive environment. The added financial incentives in this industry, which show no signs of abating, place a premium on the market exclusivity that a patent estate can provide.

The regulatory function of the FDA is to ensure the welfare of the public by requiring that the safety and efficacy of medical devices are, to the largest extent possible, documented and scientifically established before a device enters the stream of commerce. A corollary function of the FDA is to ensure that the public is made aware of any dangers or risks that accompany the use of a particular device already on the market. While the filings made by a company for premarket regulatory purposes are held in confidence until permission is granted, the same is not true for obligatory reports made to the FDA about adverse events involving a device's safety or efficacy. As an additional matter, the duty to report adverse events is sometimes incumbent on entities or persons not directly under the control of the company.

The patent laws are a separate regulatory framework that results for the successful applicant, in limited monopoly rights for inventions. Inventions are, by definition, both novel and non-obvious over what is already known ("prior art"). Generally speaking, an applicant for a patent is under pains to avoid making an invention known, through public disclosures or other acts, before filing a patent application. Otherwise, these disclosures threaten the patentability of an invention. The U.S. patent laws provide a one-year grace period for inventors to file a patent application after making a public disclosure implicating an invention,[2] but outside the United States (OUS), this grace period does not exist.[3] Notwithstanding this difference, all patent systems share the aim of promoting public disclosure of technology through publication of inventions in exchange for the possibility of market exclusivity.

Most medical device companies are mindful of the distinction between the U.S. patent system and OUS systems, and most companies are diligent in making sure that public disclosures are not made until patent applications have been filed in order to preserve OUS rights. However, under the right set of circumstances, the FDA's public disclosure procedures can pose a genuine threat to the patentability of a new device by revealing a critical feature. This paper will attempt to illuminate the circumstances in which events, mostly out of the control of the otherwise diligent and compliant device company, could conspire to deprive the company of valuable patent rights OUS.

The interface of FDA regulation with domestic and foreign patent law and practice is jagged and complicated, and these functions are most often left

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2 35 U.S.C. § 102(b) (2005).

3 *See e.g.*, The European Patent Convention. Art. 54 [hereinafter EPC].

to separate, independent, counsel that rarely interact substantively. Medical device companies often have regulatory counsel, U.S. patent counsel, and foreign patent counsel, the latter usually serving under the direction of U.S. patent counsel. In a large majority of the cases, the parallel and independent paths that regulatory and patent counsel follow are in harmony and create no problems. The vulnerability that this paper addresses is, however rare, quite possible, and the consequences are real. Fortunately, any risk can be mitigated by involving patent counsel in adverse event episodes reported to the FDA.

This paper begins with a brief overview of the applicable law, and will then describe the interplay of events which could lead to the loss of OUS patent rights by a device company through a sequence of seemingly unrelated events.

II. WHAT TYPE OF DEVICES ARE VULNERABLE?

The illustration of the issues discussed in this paper is well served through the use of a hypothetical. Assume that American manufacturer NQR, Inc., develops a new medical device it intends to market. As mentioned earlier, NQR must obtain FDA permission before the device can be placed on the market. NQR must, as a competitive reality, file patent applications directed to its new device before making public disclosures, including market release of the device, if NQR is to preserve its OUS patent rights. These two processes are addressed in turn.

A. FDA Regulatory Matters

1. Classification

The first step toward obtaining FDA permission to market a device is its classification. NQR must first ensure that their new product satisfies the FDA's definition of a medical device, and then choose the appropriate FDA class for the device. The class of the device will in turn dictate the level of premarketing scrutiny that the FDA will expend before granting permission to market.[4] A

[4] The FDA defines a medical device broadly as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is: (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is

device is classified in one of three classes according to the potential risk it poses to a patient. Class I devices are low risk and require only the general controls required for all medical devices.[5] Because of broad exemptions, a Premarket Notification (510(k)) is rarely needed for a Class I device.[6] Intermediate risk devices, categorized as Class II, are governed by so-called "special controls" and typically require a 510(k) submission in order to show "substantial equivalence" to previously-cleared devices, known as "predicates."[7] There are exceptions to the 510(k) requirements for Class II devices, such as when the device (1) is not available in finished form for purchase, (2) is not offered through labeling or advertising, and (3) is intended for use only by a physician or dentist or by a patient specified in the order of a physician or dentist.[8] Class III is reserved for devices that are life-supporting, life-sustaining, or of substantial importance in preventing impairment, or present an unreasonable risk of illness or injury.[9] Class III devices, which usually represent breakthrough devices or introduce a modality paradigm shift, require premarket approval (PMA).[10] The PMA pathway is far more comprehensive, detailed, time-consuming, and expensive than the 510(k) pathway.

As a matter of form, the FDA refers to marketing permission granted to a device under a PMA as "approval." Marketing permission granted to a device under a 510(k) is known as "clearance." For readers with acquaintance with the FDA's drug approval processes, the PMA is the device analog of the new drug application (NDA); the 510(k) the analog of the Abbreviated New Drug Application (ANDA). Device companies prefer the 510(k) pathway because data showing equivalence to a predicate device is fairly easy to obtain. Consequently, it presents a shorter timeline to regulatory permission, fewer issues and concomitant risk, and less expense. These observations are borne out by the FDA's filing statistics. Each year, the FDA receives approximately 50-70 PMAs and over four thousand 510(k)s.[11]

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not dependent upon being metabolized for the achievement of any of its primary intended purposes." http://www.fda.gov/cdrh/devadvice/312.html (accessed on 11/19/2005).

5 21 U.S.C. § 360(c)(A).

6 Approximately 74% of the Class I devices are exempt from the pre-market notification process. http://www.fda.gov/cdrh/devadvice/313.html (accessed on 11/19/2005).

7 21 U.S.C. § 360(c)(B); 21 C.F.R. § 807.92(a) (2004).

8 21 C.F.R. § 807.85.

9 21 U.S.C. § 360(c)(C)(ii)(I) – 360(c)(C)(II).

10 21 C.F.R. § 814.1(c)(2).

11 http://www.advamed.org/newsroom/regulatory/fdaapprovalprocess.htm (accessed on 11/19/2005).

2. The 510(k) Process

Using our hypothetical, we will assume for ease of illustration that NQR initiates the 510(k) process for its device. NQR begins by filing a 510(k) Notification of Intent to Market a New Device with the FDA. A 510(k) summary must be included with the submission.[12] The summary must be in sufficient detail to provide a basis for determination of substantial equivalence with a legally marketed product.[13] A legally marketed product, referred to as a "predicate device," is one that (1) was marketed prior to 28 May 1976, or (2) was reclassified from III to I or II, or (3) was found to be substantially equivalent through the 510(k) process.[14] Furthermore, if the device has undergone a "significant change or modification" that could significantly affect the safety or effectiveness of the device, then the 510(k) submission must include supporting data to show what the effects of the modification might be.[15] The FDA will acknowledge substantial equivalence once NQR has effectively shown that (1) the device has the same intended use as the predicated device, (2) the data submitted demonstrates that the device is as safe and effective as a legally marketed device, and (3) the device does not raise different questions of safety and effectiveness than the predicate device.[16] Clinical data may be required by the Commissioner for purposes of satisfying (2).[17]

The flowchart appearing in Appendix A illustrates the 510(k) process.[18] NQR's device will be assumed to qualify for the Traditional 510(k) pathway.[19] If the FDA, following assessment of the application, determines that the device is substantially equivalent to the named predicate devices for the labeled indications, it will clear the device for market. A letter is sent to NQR indicating that the device may be marketed and setting forth any additional restrictions, such as labeling.[20]

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12 21 C.F.R. § 807.87(h).

13 *Id.* at § 807.92.

14 *Id.* at § 807.92(a)(3).

15 *Id.* at § 807.87(g).

16 *Id.* at § 807.100(b).

17 *Id.* at § 807.100(b)(2)(ii)(B).

18 http://www.fda.gov/cdrh/devadvice/314.html (accessed on 11/19/2005).

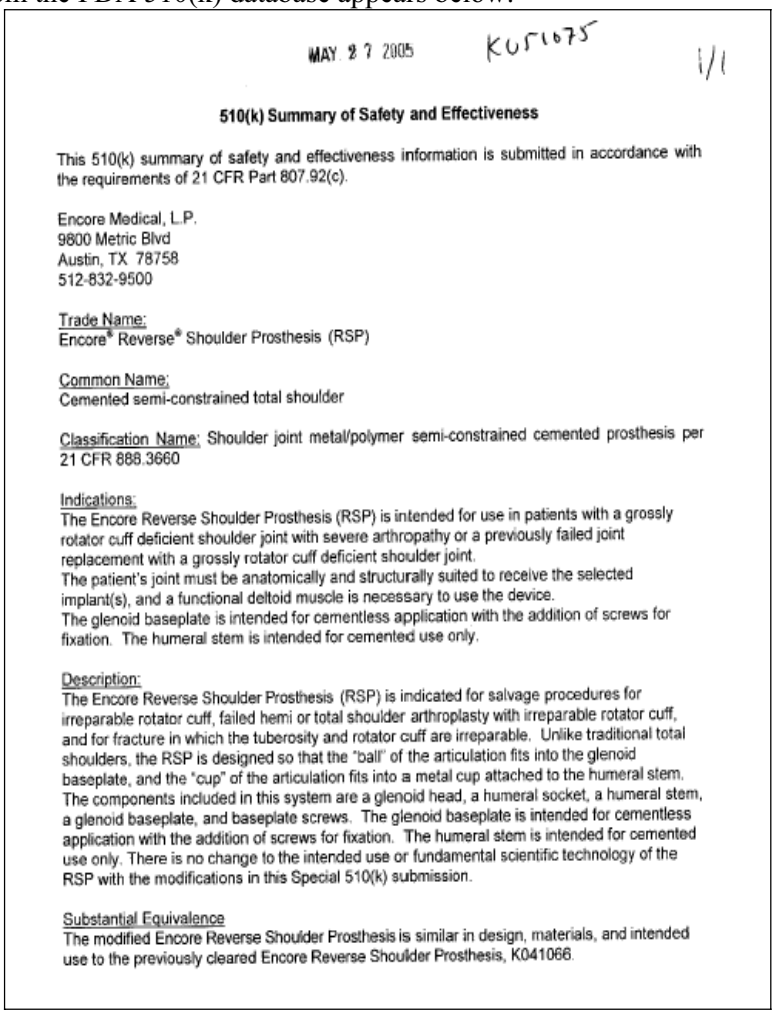
19 The FDA provides three pathways for 510(k) submissions: Traditional, Special, and Abbreviated. http://www.fda.gov/cdrh/ode/parad510.html (accessed on 11/19/2005).

20 http://www.fda.gov/cdrh/devadvice/31435.html#link_8 (accessed on 11/19/2005).

3. Availability of 510(k) Information to the Public

a. The 510(k) Summary

When the 510(k) application is cleared, the FDA publishes the decision on their website. A 510(k) summary is usually available by the fifth of the month for decisions made the previous month.[21] A representative summary page from the FDA 510(k) database appears below:



MAY 27 2005 K051675 1/1

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

Encore Medical, L.P.
9800 Metric Blvd
Austin, TX 78758
512-832-9500

Trade Name:
Encore® Reverse® Shoulder Prosthesis (RSP)

Common Name:
Cemented semi-constrained total shoulder

Classification Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis per 21 CFR 888.3660

Indications:
The Encore Reverse Shoulder Prosthesis (RSP) is intended for use in patients with a grossly rotator cuff deficient shoulder joint with severe arthropathy or a previously failed joint replacement with a grossly rotator cuff deficient shoulder joint.
The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.
The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only.

Description:
The Encore Reverse Shoulder Prosthesis (RSP) is indicated for salvage procedures for irreparable rotator cuff, failed hemi or total shoulder arthroplasty with irreparable rotator cuff, and for fracture in which the tuberosity and rotator cuff are irreparable. Unlike traditional total shoulders, the RSP is designed so that the "ball" of the articulation fits into the glenoid baseplate, and the "cup" of the articulation fits into a metal cup attached to the humeral stem. The components included in this system are a glenoid head, a humeral socket, a humeral stem, a glenoid baseplate, and baseplate screws. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is intended for cemented use only. There is no change to the intended use or fundamental scientific technology of the RSP with the modifications in this Special 510(k) submission.

Substantial Equivalence
The modified Encore Reverse Shoulder Prosthesis is similar in design, materials, and intended use to the previously cleared Encore Reverse Shoulder Prosthesis, K041066.

[21] http://www.fda.gov/cdrh/510khome.html (accessed on 11/19/2005).

The above summary was available on the FDA's website in early June 2005. The decision date on the application was May 27, 2005. Availability, therefore, is nearly immediate. As can be readily appreciated, the Description provides technical details regarding an improvement to a prior-art device in fairly specific terms. As will be discussed further below, the absence of a patent application filing priority date before the publication of this 510(k) summary by the FDA could create potential issues to obtaining patent protection on the described feature modifications (after one year in the United States, immediately OUS).

In some cases, the Description does not rise to the level of technicality seen here. Sometimes the 510(k) summary describes the new device only generally, but almost all 510(k) summaries list the predicate device over which the product was cleared.[22] In a saturated market with many products, the predicate device might be chosen judiciously to avoid disclosing too much information about the new device. But occasionally, the best predicate device for regulatory purposes is closely related in technology, and the patentable distinction between the new device and the predicate device might be marginal. Furthermore, the best, or perhaps only, predicate device available may be the manufacturer's own previously cleared product, upon which improvements (possibly patentable) have been made.

b. The 510(k) File Availability under FOIA

Once the decision to clear the new device has been taken by the FDA, the 510(k) submission is subject to disclosure to the public in accordance with the Freedom of Information Act (FOIA)[23], along with any data or information that was submitted in support of the 510(k).[24] The FDA also requires that NQR disclose this information upon request by a member of the public.[25] These disclosures are intended to exclude all trade secret and confidential commercial information that is exempted under the Freedom of Information Act (FOIA).[26] The onus lies with NQR to identify and designate all such information when the 510(k) is submitted to the FDA.[27] If they fail to do so, safety nets exist. NQR

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22 21 C.F.R. § 807.92(a)(3).

23 *See infra* II (c).

24 21 C.F.R. at § 807.95(e).

25 *Id.* at § 807.93(a)(1).

26 *Id.* at §§ 807.93(a), 807.95(e); 5 U.S.C. § 552(b)(4).

27 21 C.F.R. § 20.61(d).

may still designate the info within a "reasonable time" thereafter.[28] The FDA may also decide, of its own initiative, that the information is exempt from disclosure.[29]

Although subject to redaction, the 510(k) file can consist of several hundred pages of information above and beyond that available in the 510(k) summary. Packaging inserts are typically included in the 510(k) application and can be very informative regarding the intended use of the newly-cleared product.[30] Testing data and detailed comparison to the predicate devices are also commonly included.[31] Consequently, standard disclaimers are often written in the 510(k) application stating that the comparison of the new device to the predicate device is not intended to raise any patent issues. But resemblance to the predicate device must be compelling enough to convince the FDA that the new device is safe for human use. Such a high standard of equivalence could forge a stubborn correspondence between the devices in the mind of a fact finder (such as a jury or a patent examiner).

Of course, if redacting companies were given absolute discretion to determine what information is confidential, the final disclosure could be a blank sheet of paper. FDA regulations provide the necessary guidance on what qualifies as either a trade secret or as privileged or confidential commercial and financial information.[32] Potentially patentable technology probably falls into the second category as being the type of "valuable data or information" that is "customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs."[33] Consequently, if the FDA receives a request for records that have been designated as confidential by NQR, the FDA will attempt to notify NQR of the request.[34] NQR then has five working days to object to the disclosure of any part of the records, and must specify all bases for their objections.[35] Notwithstanding the objections, if the FDA then decides to disclose the records, NQR will have five additional working days to obtain an injunction from the appropriate U.S. District Court.[36] Likewise, if the FDA rejects any part of a request for disclosure, the requester

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28 *Id.*

29 *Id.* at § 20.61(e).

30 *See id.* at § 807.87.

31 *See id.*

32 *Id.* at § 20.61(a)-(b).

33 *Id.* at § 20.61(b).

34 *Id.* at § 20.61(e)(1).

35 *Id.* at § 20.61(e)(2).

36 *Id.* at § 20.61(e)(3).

then has five days to file suit under the Freedom of Information Act (FOIA) in the U.S. District Court to enjoin release of the records.[37]

Regardless of what information is ultimately disclosed, the obtaining of data via an FOIA request can be time consuming. Although the intent of the FOIA is to make information available (and the information is eventually made available), the delay between the filing of a FOIA request and the receipt of the information can be months or even years.[38] Most companies are compelled by the realities of the market to perfect their patent filings well within this timeframe, but there are instances in which a 510(k) can be made available almost immediately. It remains, however, unlikely that the 510(k) file itself would become available during the timeframe necessary to wreak havoc on a patent portfolio, which is perhaps the reason why FDA submissions are not viewed as a major threat.

B. Patent Matters

In order to encourage investment in research and development, the United States, as well as most other nations, offers something of a quid pro quo to prospective inventors. In exchange for full public disclosure of a new idea, an inventor (or assignee) is awarded a limited monopoly, or a patent, on the invention. The invention must be both novel and non-obvious, lest the invention be of no public benefit.

The novelty requirement for U.S. patents is set forth in 35 U.S.C. § 102. Simply put, the patent applicant must have invented the subject matter before anyone else.[39] If the subject matter was already known prior to the patent application, the invention is considered "anticipated" by pre-existing technology, known as the "prior art." An anticipation requires that the inventor's claim be disclosed by a reference which encompasses every element of the claim within its "four corners."[40]

While the United States attempts to honor an inventor's presumed right to a patent, the inventor must file his patent application within one year of the discovery.[41] This one-year grace period strikes a balance between the interests

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37 *Id.* at §§ 20.48, 20.61(e)(4).

38 Anecdotally, the timeframe for the FDA to respond to a FOIA request for a 510(k) application is eighteen to twenty-four months. *See* http://www.foiservices.com/brochure/devicedocs.cfm (accessed on 11/19/2005).

39 35 U.S.C. § 102.

40 *See e.g. Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999); *In re Paulsen*, 30 F.3d 1475, 1479 (Fed. Cir. 1994).

41 *See* 35 U.S.C. § 102.

of the inventor and the promotion of science.[42] Without such a provision, inventors might be encouraged to delay filing a patent application in order to extend the effective term of their patents.[43]

Additionally, even if an invention is novel, patent laws require that an invention be non-obvious in light of the prior art:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.[44]

The prima facie case of obviousness consists of three elements.[45] First, there must exist a motivation to modify or combine references:[46]

> [T]he relevant inquiry is whether there is a reason, suggestion, or motivation in the prior art that would lead one of ordinary skill in the art to combine the references, and that would also suggest a reasonable likelihood of success.[47]

A patent can be obtained for an invention that is completely contained within the prior art as long as the combination of prior art is not readily apparent. The Federal Circuit has noted that "[t]he genius of invention is often a combination of known elements which in hindsight seems preordained."[48]

Second, there must be a reasonable expectation of success.[49] "The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art."[50] Finally, the prior art references must teach all the elements of the claim.[51]

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42 Robert A. Matthews, Jr., *Annotated Patent Digest: An Annotated Digest and Compendium of Legal Principles and Authority for Patent-Related Matters*, §17:28 (2005).

43 *Id.*

44 35 U.S.C. § 103(a).

45 Manual of Patent Examining Procedures § 706.02(j) (8th ed. 2004) [hereinafter MPEP].

46 *Id.*

47 *Smiths Indus. Medical Sys., Inc. v. Vital Signs, Inc*., 183 F.3d 1347, 1356 (Fed. Cir. 1999).

48 *McGinley v. Franklin Sports, Inc*., 262 F.3d 1339, 1351 (Fed. Cir. 2001).

49 MPEP § 706.02(j).

50 *In re Dow Chem*., 837 F.2d 469, 473 (Fed. Cir. 1988).

51 MPEP § 706.02(j).

In contrast to the American first-to-invent system, most countries OUS ascribe to a first-to-file patent scheme. These countries require absolute novelty of new patent claims. In other words, *any* prior public disclosure of the subject matter invalidates its patentability, regardless of the means of disclosure. Some narrow exceptions apply. The European Patent Office, for example, provides a six-month grace period if the invention was displayed at an international exhibition or if there was evident abuse in relation to the applicant.[52] But in most instances, public disclosure by a company in any form (*e.g.*, by publication, oral disclosure, presentation exhibit) before a patent filing will be available as prior art against any subsequently filed OUS patent application.

C. Adverse Event Reporting and Disclosure to the FDA

Medical Device Reporting (MDR) is the U.S. Food and Drug Administration's mechanism to quickly detect and correct serious device problems, and is by its nature reactive. Before discussing the mechanics of MDA reporting, the reader is asked to bear in mind that when an adverse event occurs, the luxury of measured and thoroughly contemplated action is not available. Accordingly, medical device manufacturers are well advised to have contingency plans in place, and a regular review process to be sure that adverse events are promptly reported without detriment to a company's intellectual property.

Manufacturers and importers of medical devices have been required to report all device-related deaths, serious injuries, and certain malfunctions to the FDA since 1984. However, due to widespread underreporting, the Safe Devices Medical Act (SMDA) of 1990 was enacted, which requires device user facilities to report device-related serious injuries to both the FDA and the manufacturer. The Food and Drug Administration Modernization Act (FDAMA), which became effective in 1998, removed the responsibility of domestic distributors to file MDR reports.[53] An exception to the MDR reporting requirement exists if the device is "intended for use in humans solely for [such] person's use in research or teaching and not for sale."[54]

If death ultimately results from the accident, the user facility (*e.g.,* hospital) must submit a report to both the manufacturer and the FDA within ten days of the event. If only serious injury has occurred, the user facility is only

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52 EPC at art. 55(1).

53 U.S. Food and Drug Administration, *Medical Device Reporting (MDR),* http://www.fda.gov/cdrh/mdr/mdr-general.html (last updated Sept. 22, 2002).

54 21 C.F.R. § 803.19(a)(2).

obliged to report to the manufacturer.[55] In either case, the manufacturer must report to the FDA within thirty days of becoming aware of the event.[56] Mandatory MDR reports are submitted on a FDA Form 3500A.[57] The user facility is required to complete Sections A-F, which includes a description of the event or problem and relevant tests performed. When the user facility submits Form 3500A to the manufacturer, the manufacturer is required to complete the form (Sections G and H) before forwarding it to the FDA.[58] Of particular interest to the manufacturer is that the scope of the disclosure made by the user facility by this mechanism is largely outside of its control.

Once the MDR report is submitted to the FDA, the report is made publicly available on the FDA's website in accordance with the Freedom of Information Act (FOIA).[59] Briefly, the FOIA was enacted in 1966 to correct any presumption against disclosure present in the Administrative Procedure Act (APA).[60] At the time of its adoption, the Administrative Procedure Act provided that: "Except as otherwise required by statute, matters of official record shall be made available, in accordance with published rule, to persons properly and directly concerned, except information held confidential for good cause found."[61] In effect, the APA gave agencies absolute discretion over public disclosure.[62] The Freedom of Information Act (FOIA) now gives private persons previously unprecedented access to government information, and remains a curiosity to citizens in countries with little or no access to such information.[63]

Nonetheless, the FOIA does protect some types of information from disclosure.[64] Specifically, exemption b(4) exempts commercial and financial information and trade secrets from disclosure.[65] This exemption is reflected in the FDA's guidelines for public disclosure of records.[66] 21 C.F.R. § 20.61(d) provides that "[a] person who submits records to the Government may designate

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55 *Id.* at § 803.20(b)(1)(ii).

56 *Id.* at § 803.20(b)(3)(i).

57 *See* U.S. Food and Drug Administration, http://www.fda.gov/cdrh/mdr/mdr-forms.html (last updated Nov. 21, 2005).

58 21 C.F.R. at § 803.20(a)(2).

59 *Id.* at § 803.9(a); *see generally* 5 U.S.C. § 552.

60 William F. Fox, Jr., *Understanding Administrative Law* § 85, 278 (1st ed., Bender 1986).

61 *Id.* (citations omitted).

62 *Id.*

63 *Id.* at § 85, 278-79.

64 *Id.* at § 85, 281.

65 5 U.S.C. § 552(b)(4).

66 21 C.F.R. § 20.61.

part or all of the information in such records as exempt from disclosure under exemption 4 of the Freedom of Information Act. The person may make this designation either at the time the records are submitted to the Government or within a reasonable time thereafter."[67] However, while this language may appear to give manufacturers significant control over disclosure, the FDA's specific procedures for preventing disclosure of confidential material included in MDR reports is not so auspicious. Before public disclosure of a report, the *FDA will delete* from the report: "(1) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61 of this chapter."[68]

There appears to exist, therefore, a question regarding whether the manufacturer or the FDA is responsible for a MDR redaction. In an effort to answer this question, the authors inquired directly of the FDA whether manufacturers could redact confidential information from MDR reports, keeping in mind that MDR's may be filed by user facilities out of control of the manufacturer. The FDA promptly responded:

> There is no method by which a manufacturer can redact confidential information submitted (either by a user facility/importer or inadvertently by the manufacturer) in an MDR report. Once the FDA receives reports either from manufacturers, user facilities, etc. the report is redacted by the FDA in accordance with the Freedom of Information Act.[69]

In other words, the manufacturer must rely upon the FDA to recognize and delete all confidential information from the MDR report before it is made available to the public.

The FDA has separate disclosure guidelines governing voluntary reports.[70] If the voluntary report is submitted by a third party (physician, hospital, etc.), the FDA will publicly disclose the information after deleting names and information that might reveal either the person using the device or any third party involved with the report.[71] But the regulation makes no mention of confidential, commercial, and financial information or trade secrets. To complicate matters further, the FDA provides an exception to the voluntary submission

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67 *Id.* at § 20.61(d).

68 *Id.* § 803.9(b)(1).

69 E-mail from Connie Daly, Public Health Advisor, Division of Small Manufacturers, International and Consumer Assistance (DSMICA), Office of Communication, Education, and Radiation Programs (Formerly OHIP), Center for Devices and Radiological Health, U.S. Food and Drug Administration, to James Clements, Finnegan Henderson, Farabow, Garrett & Dunner, L.L.P., *Redacting Confidential Information from MDR Reports* (June 17, 2005, 12:27 EST) (on file with author).

70 21 C.F.R. § 20.111(c).

71 *Id.* at § 20.111(c)(3)(iii).

regulation if the information "may be required to be submitted . . . ."[72] In that case, the information will be treated as if it was required to be submitted.[73] Whether "may", as used in 21 C.F.R. § 20.111(a), means "possibility or probability" or is simply used as a substitute for "might" is unclear[74], but the former interpretation seems more consistent with the remainder of the regulations. Manufacturers should realize that MDR reporting is intended to disclose information to the public on an immediate basis, and that the protection of confidential information is secondary.

III. ANALYSIS OF A "WORST CASE" HYPOTHETICAL

Returning to our hypothetical, we have already established that NQR must receive both FDA permission and file a patent application prior to introducing the device on the market to preserve OUS patent rights. But suppose NQR decides, for whatever reason, to delay applying for a patent for a particular feature while seeking FDA clearance. After all, even the Supreme Court has recognized that a delay in patent prosecution may be "requisite . . . for a test of [the invention's] value or success by a series of sufficient and practical experiments."[75] Such a delay may even be "highly advantageous, as tending to the perfecting [sic] the invention . . . ."[76]

Presuming that FDA approval is already obtained, assume that, prior to full market release, NQR wishes to perform some pre-market testing for marketing release or physician education purposes. Normally such testing does not jeopardize the patentability of the new design in the United States, because the term "public use" has been interpreted, for purposes of §102(b), to not include experimental or confidential use.[77] Moreover, such testing does not require an investigational device exemption (IDE), since the device has already been cleared for market release.[78]

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72 *Id.* at § 20.111(a).

73 *Id.*

74 *Merriam-Webster OnLine,* http://www.m-w.com; (accessed Nov. 21, 2005).

75 *Kendall v. Winsor*, 62 U.S. 322, 328 (1858).

76 *Id.* at 329.

77 *See TP Laboratories, Inc. v. Prof. Positioners, Inc.*, 724 F.2d 965, 971-72 (Fed. Cir. 1984).

78 21 C.F.R. § 812.2(c)(2). Pre-market testing of a medical device on humans normally requires an investigational device exemption (IDE). Investigational device exemptions (IDE) were created to promote clinical safety and effectiveness evaluations, consistent with public health, on medical devices that do not yet have FDA permission to market. An approved investigational device exemption (IDE) permits a device that otherwise would be required to comply with a performance standard or to have premarket approval (PMA) to be shipped

Further, suppose that during pre-market testing, an adverse event occurs. The injury is serious, perhaps even life-threatening, and the event was related to a particular feature on the device NQR is testing. The user facility[79] that was involved with the tests for NQR is required to submit a Medical Device Reporting (MDR) report.[80]

A problem emerges when a user facility includes information in Section B (Adverse Event or Product Problem) that reveals a patentable feature of the device. Such an outcome is quite possible if the new feature is directly related to the malfunction. Even if the user facility submits the report only to NQR, NQR is forbidden from making alterations to the completed sections of the report before submitting the final report to the FDA.[81] Of course, NQR can request a variance from the FDA to modify the data elements required in the MDR report.[82] But the FDA provides little guidance as to what type of information will qualify for a variance, and, in any case, the variance would provide little comfort since NQR would still be unable to remove any damning information provided by the user facility. The issue is even more alarming if the MDR report was submitted voluntarily.[83] This situation is much more likely to occur if the user facility is uncertain about whether an MDR report is required and conservatively chooses to err on the side of safety.

Our analysis doesn't end with the possibility of disclosure. The crux is whether a public disclosure of an innovative device feature by the FDA would jeopardize future patentability of that device. 35 U.S.C. § 102 provides: "A person shall be entitled to a patent unless . . . (b) the invention was patented or *described in a printed publication* in this or a foreign country or in public use or on sale in this country, *more than one year prior to the date of the application*

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lawfully for the purpose of conducting investigations of that device. IDEs are exempt from the Medical Device Reporting (MDR) scheme normally used to document and address adverse device-related events. *See* 21 C.F.R. §§ 812.46, 812.150(a)(1).

79 *Id.* at § 803.3(2) (providing examples of user facilities as hospitals and nursing homes).

80 *Id.* at § 803.3. Although a literal interpretation of FDA regulation suggests that NQR's research might qualify for an exemption (since the device isn't currently on the market), FDA probably intended that this exception only apply to premarket approval (PMA) research, which would fall within the scope of an investigational device exemption (IDE) replete with its own requirements. *See supra* n. 78.

81 21 C.F.R. § 803.20(a)(2); U.S. Food and Drug Administration, *Medical Device Reporting for Manufacturers,* http://www.fda.gov/cdrh/manual/mdrman.html#exempt (last updated May 25, 2004).

82 21 C.F.R. § 803.19(b); *Medical Device Reporting*, *supra* n. 81, at http://www.fda.gov/cdrh/manual/mdrman.html#exempt.

83 *See supra* nn. 70-74 and accompanying text.

for patent in the United States."[84] This printed publication prohibition is intended to prevent an inventor from removing from the public domain that which is already available as proven by the publication.[85]

The first step in our analysis is to determine whether the MDR report qualifies as a "printed publication" for the purposes of 35 U.S.C. § 102. According to the Manual of Patent Examining Procedure (MPEP), "[a] reference is proven to be a 'printed publication' 'upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.'"[86] So although treatment of an MDR report as a "printed publication" would only marginally promote the policy objective of § 102(b), an MDR report unambiguously satisfies a literal interpretation of the MPEP's definition of "printed publication". Additionally, the medium for publication is irrelevant, i.e., an electronic publication is a "printed publication" within the meaning of § 102(a) and (b).[87] Not surprisingly, there is no binding case law answering this question, but *In re Klopfenstein*, does provide some insight as to how the courts might address the issue:

> Whether a party has a reasonable expectation that the information it displays to the public will not be copied aids our § 102(b) inquiry. Where professional and behavioral norms entitle a party to a reasonable expectation that the information displayed will not be copied, we are more reluctant to find something a printed publication.[88]

While In re *Klopfenstein* related specifically to academic disclosures, the case demonstrates that courts are willing to approach the question with an eye on the purpose of the statute.

Notwithstanding the likelihood that U.S. courts and the U.S. Patent and Trademark Office (PTO) would regard MDR reports as "printed publications", we acknowledge that most device companies would not wait a year before filing a patent application in the ordinary course of events. But the issue is far from moot in countries which require absolute novelty. The European Patent Convention provides:

> (1) An invention shall be considered to be new if it does not form part of the state of the art.

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84 35 U.S.C. § 102(b) (emphasis added).

85 Matthews, *supra* n. 42, at § 17:14.

86 MPEP § 2128.

87 *Id.*

88 380 F.3d 1345, 1351 (Fed. Cir. 2004).

> (2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.[89]

Analogous to the one-year grace period in the United States, the EPC provides a six-month grace period, but only if the public disclosure was "an evident abuse in relation to the applicant or his legal predecessor."[90] "Evident abuse" is a term of art that has been interpreted in several cases before the Boards of Appeal of the European Patent Office. In order to fall within this exception, the patentee (or applicable party) must demonstrate that the abusing party obtained the information from the patentee, that the information was confidential, and that the patentee was harmed.[91] However, the patentee need not prove that there was an intention to harm:

> Within the meaning of Article 55(1)(a) EPC, there would be evident abuse if it emerged clearly and unquestionably that a third party had not been authorised [sic] to communicate to other persons the information received. [In the Board's opinion, there would be] . . . . abuse not only when there is the intention to harm, but also when a third party, [knowing full well that it is not permitted to do so,] acts in such a way as to risk causing harm to the inventor, or when this third party fails to honour [sic] the declaration of mutual trust linking him to the inventor.[92]

Nonetheless, the offending party must have actual knowledge that harm could result:

> [A] disclosure, made . . . with actual knowledge (cf. constructive knowledge) that some such harm would or could reasonably be expected to result from it, would amount to an abuse . . . . [But d]ifferent criteria apply to a disclosure by a recipient of information who does not stand in any personal or specific contractual relationship to the discloser but merely owes to the public a general duty to prevent disclosure. Such a disclosure made by dint of mere inadvertence or a genuine mistake, however unfortunate and detrimental its results may turn out to be, is not tainted with the necessary amount of actual or constructive knowledge and therefore guilty inadvertence so as to turn it into an evident abuse. . . .[93]

The Board in *T 585/92* held that even though a government agency had infringed Brazilian law by publishing the patent application, such an act was not "evident abuse" within the meaning of Article 55(1)(a) EPC.[94] Likewise, in *T*

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89 EPC at art. 54.

90 *Id.* at art. 55(1)(a).

91 T 575/95, Hydrangea plants/Eveleens.

92 T 173/83, Polymer compositions/Telecommunications, OJ EPO 1987, 465.

93 T 585/92, Deodorant detergent/UNILEVER PLC, OJ EPO 1996, 129.

94 *See id.*

575/95, the Board found no evident abuse when a civil servant violated his obligation to secrecy as set forth in the General Rules for Civil Servants. Thus, European case law suggests that inadvertent or even reckless disclosure of confidential information by a government agency like the FDA would not invoke the exception to absolute novelty.

IV. CLOSING REMARKS

As a final note, the United States could soon move to a first-to-file patent scheme. The Patent Reform Act of 2005 is currently pending in Congress.[95] The new legislation, at first glance, does not appear to have much practical effect on the current one-year grace period. H.R. 2795 § 102 provides in part: (a) Novelty: Prior Art - A patent for a claimed invention may not be obtained if -- (1) the claimed invention was patented, *described in a printed publication*, or otherwise publicly known -- (A) *more than one year before* the effective filing date of the claimed invention. . . ."[96] However, the one-year grace period would become an exception to absolute novelty instead of a fundamental principle (as it is in the present U.S. patent scheme), and would apply only in cases where the disclosure was "made by the inventor [] or by others who obtained the subject matter disclosed directly or indirectly from the inventor."[97] Our analysis in light of this new legislation turns on whether courts ascribe sufficient breadth to the meaning of the phrase "obtained . . . indirectly from the inventor" so as to include mandatory reports submitted to government agencies."[98]

Although we presented the NQR hypothetical in order to address the question of whether a specific chain of events in the development of a new medical device could extinguish any patent rights pertaining to the device, we won't attempt to disguise our conjecture in a cloak of credibility. The authors are unaware of any case where the events described here have actually played out. Yet all medical device companies know that they are asked to walk a difficult line between the PTO and the FDA in order to enter the market with a new product. At one agency, the FDA, the company must argue strenuously that their product is the same as the prior art. At the other, the PTO, the company must argue strenuously that their product is completely different than the prior

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95 *See* H.R. 2795, 109th Cong. (June 8, 2005).

96 35 U.S.C. § 102(a)(1)(A) (emphasis added).

97 *Id.* at § 102(a)(1)(B); *See* Symposium, *The Future of Patent Law: Rethinking the United States' First-to-Invent Principle from a Comparative Law Perspective: A Proposal to Restructure § 102 Novelty and Priority Provisions*, 39 Hous. L. Rev. 621, 630 (2002).

98 H.R. 2795 at § 102(a)(1)(B).

art. To date, the authors are unaware of any legislative movement to address this tension, possibly because the risk of ensnarement appears remote, and possibly because bigger issues confront legislators and trade groups. So while these ambiguities persist, the surest means for medical device companies to preserve the patentability of innovative products, and the value of their IP assets, is to demand close and frequent intercourse between their regulatory and patent counsel.