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# The Interplay between FDA and Patent Law: Infusing Organizational Knowledge for Medical Device Companies

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**THE INTERPLAY BETWEEN FDA AND PATENT LAW:  
INFUSING ORGANIZATIONAL KNOWLEDGE FOR  
MEDICAL DEVICE COMPANIES**

Suneel Arora, Timothy J. Christman, Ashley N. Mays, PhD,  
and Andrew Schmidt<sup>†</sup>

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I. INTRODUCTION

The United States Food and Drug Administration (FDA) is a federal regulatory agency granted authority under the Federal Food, Drug, and Cosmetic Act (FDCA) to oversee and promote the safety of food, drugs, and cosmetics manufactured or sold in the

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United States.<sup>1</sup> Under the FDCA, the FDA is also responsible for approval or clearance of medical devices to be marketed or sold within the United States.<sup>2</sup> Navigating the FDA regulatory approval process is a challenge faced by well-established medical device manufacturers and startups alike. Generally, such organizations either hire or routinely consult with experts in preparing submissions related to product approval or clearance and in developing and maintaining compliance with FDA-enforced requirements. In parallel with these regulatory efforts, medical device developers also routinely work vigorously to establish intellectual property (IP) rights, such as patents.

Regulatory compliance is often treated as wholly independent from development or enforcement of IP rights. Even sophisticated organizations prepare and file regulatory submissions but fail to consider the impact that those submissions may have on their IP portfolio. For example, statements made in such regulatory submissions may detrimentally impact patent validity or enforceability. Information related to clinical efficacy or competitor devices may later be considered to have been material to patentability. Delays associated with the regulatory approval process may provide an opportunity to beneficially extend a patent's enforceable term. In this paper, we explore this interplay between patent law and the FDA regulatory process.

## II. CLEARANCE OR APPROVAL—510(K) NOTIFICATION VERSUS PMA

Under the FDCA and its implementing regulations, the FDA considers medical devices to fall into one of three classifications.<sup>3</sup> Class I is reserved for devices requiring only “general controls” to ensure safety and effectiveness.<sup>4</sup> For example, a device that “(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and (II) does not present a potential unreasonable risk of illness or injury” would fall into class I.<sup>5</sup>

Class II is reserved for devices presenting an intermediate level of risk. According to the FDCA, such devices fall into class II

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1. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ch. 9 (2006).
  2. *See* 21 U.S.C. § 360c (“Classification of devices intended for human use”).
  3. *Id.* § 360c(a)(1).
  4. *Id.* § 360c(a)(1)(A).
  5. *Id.*

because “general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness,” and special controls can be established “to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions . . . ).”<sup>6</sup>

Class III is reserved for devices posing the highest level of risk, such as a device for use in supporting or sustaining human life or for use in preventing impairment of human health, or a device presenting a potentially unreasonable risk of illness or injury.<sup>7</sup>

The FDA’s medical device classification scheme may seem somewhat arbitrary, but a particular device’s classification can be determinative with respect to the cost, timing, and certainty surrounding FDA approval or clearance of the device. If a device falls into class III and is not subject to an exemption for certain older devices marketed prior to 1976, then the device must be submitted to the FDA under the premarket approval (PMA) process specified in FDCA section 515.<sup>8</sup> In contrast, if a device falls into class I or II, the device may be marketed and sold once the device is “cleared” via the process specified in FDCA section 510(k).<sup>9</sup>

PMA is far more cumbersome than the 510(k) clearance process and can be both costly and time-consuming. The PMA route generally involves the submission of a device description and indications, marketing and manufacturing information, reference to pertinent performance standards, preclinical investigatory studies, and proposed labeling.<sup>10</sup> For example, for PMA, 21 U.S.C. § 360e requires “full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective.”<sup>11</sup> The FDA may require additional supplemental submissions as well.<sup>12</sup> Once all of the relevant information is provided to the FDA, the process may still take years.

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6. *Id.* § 360c(a)(1)(B).

7. *Id.* § 360c(a)(1)(C).

8. *Id.* §§ 360e(a)–(b), 360j(g).

9. *Id.* § 360.

10. *See, e.g., id.* § 360e(f) (“Product development protocol”).

11. *Id.* § 360e(c)(1)(A).

12. *Id.* § 360e(c)(1)(H).

In comparison, the 510(k) clearance process, referred to as “premarket notification,” is abbreviated and uses somewhat different terminology. In the PMA process, the applicant “submits” the device for approval, and the FDA “approves” the device. In the 510(k) process, the applicant “notifies” the FDA, and the FDA “clears” the device for sale.

A 510(k) notification generally must be made at least ninety days prior to launch;<sup>13</sup> in comparison, the delay for PMA review by the FDA should be no longer than 180 days, by statute, yet actual delays are frequently longer.<sup>14</sup> Under the 510(k) clearance process, an applicant notifies the FDA of a new device and asserts substantial equivalence to a predicate device.<sup>15</sup> The applicant then, hopefully, receives a letter from the FDA, finding the new device is substantially equivalent to the predicate device.<sup>16</sup> The applicant can then market and offer the device for sale in the United States.

### III. SUBSTANTIAL EQUIVALENCE TO A PREDICATE DEVICE UNDER 510(K) NOTIFICATION

When notifying the FDA of an applicant’s intent to market a new device under the 510(k) process, the applicant identifies a “predicate device,” that is, a legally marketed equivalent device, and then must provide details showing that the new device is “substantially equivalent” to the predicate device.<sup>17</sup> Such a predicate device may be one of the applicant’s own devices or a competitor’s device.

Additionally, the applicant must include a statement of intended use, including a general description of “diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended.”<sup>18</sup> If these factors differ between the new device and the identified predicate device, an explanation is required as to why the differences do not affect

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13. *Id.* § 360(k).

14. *Id.* § 360e(d)(1)(a). Further specific requirements are outlined in 21 C.F.R. § 807.81–.100 (2012).

15. 21 U.S.C. § 360(o).

16. *See id.* § 360(n) (requiring the FDA to make a determination of substantial equivalence within ninety days).

17. *See* 21 C.F.R. § 807.92 for information regarding the content and format of the 510(k) summary.

18. 21 C.F.R. § 807.92(a)(5).

the safety and effectiveness of the new device.<sup>19</sup> From the FDA's perspective, the touchstone of "substantial equivalence" is demonstration of safety and efficacy via a showing that the applicant's new device is at least as safe and effective as an existing marketed device.<sup>20</sup>

According to the FDA, a device is substantially equivalent if, in comparison to a predicate device, the new device either: (a) has the same intended use as the predicate device and has the same technological characteristics as the predicate device; or (b) the new device has the same intended use as the predicate device and has different technological characteristics, and the information submitted to the FDA does not raise new questions of safety and effectiveness and demonstrates that the device is at least as safe and effective as the legally marketed device.<sup>21</sup>

In the substantial equivalence determination, "technological characteristics" can include such aspects as design, material selection, chemical composition, or energy source, for example. If the device has the same technological characteristics, a summary of the technological characteristics of the new device in comparison to those of the predicate device is included in the 510(k) summary submitted by the applicant.<sup>22</sup> If the device has different technological characteristics than the selected predicate device, the summary must show how the technological characteristics of the device compare to the legally marketed predicate device.<sup>23</sup>

#### IV. PATENT LAW'S INTERSECTION WITH 510(K) NOTIFICATION

At least two aspects of patent law may intersect with a medical device developer's 510(k) strategy. First, the developer should consider the impact of regulatory submissions on patentability, as well as on the validity of any resulting patents. For example, equivalence assertions made in the context of safety and efficacy may indirectly implicate equivalence from a perspective of novelty or obviousness under patent law. Secondly, the developer should

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19. *Id.*

20. *Id.* § 807.92(b).

21. *Id.* § 807.100(b); see also *Premarket Notification (510k)*, U.S. FOOD & DRUG ADMIN. (FDA), <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm> (last visited Jan. 16, 2013).

22. 21 C.F.R. § 807.92(a)(6).

23. *Id.*

consider whether such submissions include factual averments that may point the way for a competitor to allege infringement by the applicant, or for a competitor to evade infringement using the applicant's own admissions.

#### V. PATENTABILITY

In order to obtain a patent in the United States, an invention must be new, useful, and non-obvious.<sup>24</sup> A patent application must generally be filed with the cooperation of the inventor, and the application must properly list all of the inventors.<sup>25</sup> The usefulness or "utility" requirement is a relatively low bar to meet; presumably, most medical devices would satisfy this requirement, leaving novelty and non-obviousness to be shown.

Regarding novelty, the portions of 35 U.S.C. § 102 pertinent to patent applications filed before March 16, 2013 include a "statutory bar" to filing in certain circumstances.<sup>26</sup> Under § 102(b), a person shall be entitled to a patent unless "the invention was patented or described in a printed publication in this or a foreign country . . . more than one year prior to the date of the application for patent in the United States."<sup>27</sup> The novelty requirement ensures that patents are only issued for new inventions. An invention lacks novelty if anticipated, or described, by a previously published reference, termed "prior art."<sup>28</sup> According to the *Manual of Patent Examining Procedure* (MPEP) section 2131, "[a] claim is anticipated

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24. 35 U.S.C. §§ 101, 103 (Supp. V 2011).

25. 35 U.S.C. § 115. Sweeping reforms to patent law were recently enacted by Congress in the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 284-341 (2011) (codified as amended at 35 U.S.C. §§ 1-390). For applications including an effective filing date after September 16, 2012, it is now possible for an assignee or other applicant having a "proprietary interest" in the patent application to proceed without the cooperation of the inventors, though under this procedure "sufficient" notice must still be provided to the inventors before the patent is granted to a real party in interest. 35 U.S.C. § 118.

26. 35 U.S.C. § 102 (2006) (pre-AIA). The passage of the AIA has substantially altered § 102 as applied to patents having an effective filing date after March 16, 2013. Leahy-Smith America Invents Act § 3. Among other changes, the AIA's amendment of § 102 broadens the scope of what activities constitute public disclosure, and places less restriction on where such activities must take place in order to be considered prior art. *Id.* However, the considerations discussed in relation to 510(k) notification in view of § 102 prior to amendment are believed generally applicable to § 102 as amended by the AIA. *See generally* 35 U.S.C. § 102(a)(1), (b)(1)(A) (Supp. V 2011).

27. 35 U.S.C. § 102(b) (2006) (pre-AIA).

28. *See* 35 U.S.C. § 102(a) (Supp. V 2011).

only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference” and that “identical invention must be shown in as complete detail as is contained in the . . . claim.”<sup>29</sup>

Under § 102(b), a prospective patent applicant who has also submitted a 510(k) summary may have a grace period of up to one year to file a utility patent application concerning the subject matter of the 510(k) summary from the date of public access to the substance of the 510(k) notification. This assumes no other public disclosure, offers for sale, or other events that themselves may start the clock ticking. For example, lack of FDA clearance does not protect the prospective patent applicant from the on-sale bar.<sup>30</sup> For prospective patent applicants considering a global patent strategy, not all jurisdictions offer a grace period, so publication of the 510(k) summary before any patents have been filed can destroy foreign patent filing rights.<sup>31</sup>

Accordingly, the prospective patent applicant should file any patent applications related to the 510(k) submission well in advance of the submission, or at least in advance of the publication of the submission. Presently, decisions and 510(k) summaries are published on the FDA website by the fifth of the month following clearance, and further supporting information is available via a Freedom of Information Act (FOIA) request.<sup>32</sup>

Novelty and statutory bars are not the only concerns. A patent must also be non-obvious. 35 U.S.C. § 103 recites that a patent may not be obtained “if the differences between the subject matter

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29. U.S. PATENT & TRADEMARK OFFICE, U.S. DEP’T OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 2131 (8th ed., rev. 8, Aug. 2012) [hereinafter MPEP] (quoting *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1987); *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989)), available at <http://www.uspto.gov/web/offices/pac/mpep/index.html>.

30. The “on-sale bar” prevents the patenting of an invention that has been on sale for more than one year. 35 U.S.C. § 102(b) (2006) (pre-AIA). However, “FDA approval is not required before a sale can bar patent rights.” *CR Bard, Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1376 (Fed. Cir. 1998).

31. This does not imply that applicants must file in all jurisdictions of interest prior to public availability of a 510(k) notification. The prospective patent applicant should consider whether a priority filing in a country that is a signatory of the Paris Convention or other international agreement may be sufficient to establish rights, in advance of publication of the 510(k) submission. For example, a provisional patent filing in the United States may be sufficient to preserve rights in many—but not all—jurisdictions.

32. The website for 510(k) notifications at the FDA can be found at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm#main>.

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.”<sup>33</sup>

Unlike “anticipation” under § 102, obviousness is a nebulous and somewhat subjective inquiry. *Graham v. John Deere Co. of Kansas City* established that an obviousness determination requires a series of factual inquiries, including determining:

1. the scope and the content of the prior art;
2. the differences between the claimed invention and the prior art; and
3. the level of ordinary skill in the pertinent art.<sup>34</sup>

The *Graham* inquiries underpin a legal determination of obviousness and were recently revisited and reaffirmed in *KSR International Co. v. Teleflex Inc.*<sup>35</sup> Unlike anticipation, in which a single reference must show each and every limitation in an applicant’s patent claims, obviousness involves finding the pieces of the puzzle in various references.<sup>36</sup>

Often, all that is lacking is a motivation to combine the various references and a teaching of how such a combination might be made. An applicant’s own 510(k) notification materials might inadvertently provide such a motivation or may provide evidence of expectation of success. To avoid these issues, an applicant might be tempted to disclose only what is necessary to demonstrate equivalence from a safety and efficacy perspective. But the applicant has an obligation of candor to the FDA.<sup>37</sup> The applicant may be faced with dilemmas involving whether to omit patentable features from the FDA materials or to construct arguments as to

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33. 35 U.S.C. § 103(a) (2006) (pre-AIA). As amended by the AIA, § 103 remains similar in spirit to the pre-AIA statute. The primary difference is the replacement of the phrase “obvious at the time the invention was made” with the phrase “obvious before the effective filing date of the claimed invention,” illustrating the shift in emphasis from date of invention in the old law to the concept of the “effective” filing date under the new law, thereby further incentivizing prospective patent applicants to file as early as possible. *See* 35 U.S.C. § 103(a) (Supp. V 2011). The new § 103 applies to patent applications having an effective filing date after March 16, 2013. *Id.*

34. 383 U.S. 1, 17 (1966).

35. 550 U.S. 398 (2007).

36. *See id.* at 418–419.

37. 21 C.F.R. § 807.93 (2012). Such an obligation to the FDA is independent of the applicant’s “duty to disclose information material to patentability” to the United States Patent and Trademark Office. 37 C.F.R. § 1.56.

why particular features can be omitted because they are believed not to relate to safety or efficacy.

Again, the best approach is to file any patents before submitting the 510(k) summary. The 510(k) summary can then be constructed to avoid overbroad statements of equivalence that extend beyond safety and efficacy. For example, one wearing a regulatory hat may be tempted to use phrases such as “identical” for persuasive weight. Such assertions may impact novelty or non-obviousness if construed broadly and out of context.<sup>38</sup>

Prospective patentees may find themselves in a position where their 510(k) asserts that a device is substantially equivalent to a family of different predicate devices, and such predicate devices may include all of the patentee’s claim elements in combination. Remember that the applicant only needs one predicate device.<sup>39</sup> In fact, claiming substantial equivalence to multiple predicate devices may create unnecessary IP risks without obtaining any concomitant regulatory benefit. Accordingly, it is important to choose the predicate device(s) carefully, with patentability and infringement in mind, as well as “substantial equivalence” considerations. Case law shows that the requisite statement of substantial equivalence in terms of safety and efficacy is less likely to affect patentability or infringement than the accompanying factual summary of technological characteristics, which can hurt or help.

In *Sunrise Medical HHG, Inc. v. AirSep Corp.*,<sup>40</sup> Sunrise sued AirSep for patent infringement. AirSep challenged validity based on Sunrise’s 510(k) assertion of substantial equivalence between Sunrise’s patented EX 2000 device and the prior art.<sup>41</sup> Specifically, the Sunrise 510(k) notification stated:

The PulseDose series devices are *fundamentally repackaged* versions of the OMS 20 and 50, DeVilbiss current oxygen management system. There are no *significant* changes in the materials or features. Therefore, based on the above-mentioned similarities, *especially the dosage methodology*, the PulseDose Series devices and the OMS 20 and 50 are

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38. An applicant might also consider including a disclaimer in their 510(k) summary defining “substantial equivalence” in accordance with the FDCA and disclaiming definition according to the patent statute (e.g., “this document uses the term ‘substantial equivalence’ as defined in 21 C.F.R. § 807.87 and not as considered in 35 U.S.C. § 112”).

39. 27 C.F.R. § 807.92; *see supra* text accompanying notes 17–22.

40. 95 F. Supp. 2d 348 (W.D. Pa. 2000).

41. *Id.* at 405–06.

substantially equivalent devices. . . . The gas dose methodology oxygen delivery specifications and performance of the device in the PulseDose series are *identical* to those of the OMS 20 and 50. . . . Previous designs of the DeVilbiss OMS 50 and 20 had similar components except for the integral regulator and pressure relief.<sup>42</sup>

The *Sunrise* court disregarded the 510(k) notification, stating that its sole purpose was to demonstrate to the FDA that the EX 2000 was as safe and effective as the predicate device.<sup>43</sup> The substantial equivalence assertion focused on the gas dose methodology, which was not the subject matter of the patent claim, and other patented differences were omitted from the 510(k) notification because they were not essential to safety and effectiveness.<sup>44</sup>

*Sunrise* shows the importance of carefully wording a substantial equivalence assertion to limit its scope to safety and efficacy. But the accompanying factual assertions can help or hurt patentability or infringement, depending on whether the assertions are focused toward or away from the patent claims. Here, it helped, because the factual assertions focused the basis of the FDA substantial equivalence away from the subject matter of the patent claims.

#### VI. PATENT INFRINGEMENT AND THE LINGERING 510(K) NOTIFICATION

The 510(k) notification can remain a latent issue long after FDA clearance and the grant of a patent. For example, the 510(k) notification may be factually relevant to a variety of infringement situations including direct or indirect (e.g., induced<sup>45</sup> or contributory<sup>46</sup>) infringement.<sup>47</sup> The 510(k) notification may also implicate infringement under the doctrine of equivalents or willful infringement.<sup>48</sup>

The test for infringement of a patent claim is determined on an element-by-element basis. Direct infringement requires literal identity between the claims and an infringer's device and is in some

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42. *Id.* (emphasis added) (quoting plaintiff's exhibits 154 and 155) (internal quotation marks omitted).

43. *Id.* at 406.

44. *Id.* at 405.

45. 35 U.S.C. § 271(b) (2006).

46. *Id.* § 271(c).

47. *See id.* § 271.

48. *See infra* text accompanying notes 66–67.

ways a mirror image of determining anticipation.<sup>49</sup> For direct infringement, every claimed element in the patent must be found in the accused infringer's device.<sup>50</sup> In addition to a theory of direct infringement, a theory of indirect infringement also exists.<sup>51</sup> Indirect infringement can have two forms: contributory infringement or induced infringement. Contributory infringement involves a defendant providing a component, a material, or an apparatus for the purpose of infringement.<sup>52</sup> In contrast, induced infringement involves the defendant inducing another party to infringe.<sup>53</sup>

Similar to patentability, substantial equivalence, by itself, does not admit patent infringement because substantial equivalence and patent infringement are fundamentally different inquiries. For substantial equivalence, a comparison of a product to a predicate device is performed.<sup>54</sup> For patent infringement an element-by-element comparison of the patent's claims to the accused product is performed.<sup>55</sup>

Courts have been wary of the risk of confusing the jury with the 510(k) substantial equivalence assertion to the FDA. In *Medtronic Navigation, Inc. v. BrainLAB Medizinische Computersysteme GMBH*, the court called counsel's statement to the jury that BrainLAB had admitted equivalence in its FDA submission an abuse of advocacy.<sup>56</sup> Additionally, in *Cardiovention, Inc. v. Medtronic, Inc.*, the court stated that admitting 510(k) evidence would be misleading and unfairly prejudicial to Medtronic.<sup>57</sup> There have been many cases that note these problems and make somewhat sweeping statements regarding the admissibility of FDA submission data.

However, it is best to be wary of statements in the case law implying that 510(k) notifications are somehow generally inadmissible in infringement proceedings. Supporting statements to the FDA may still be used to help establish or defeat

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49. 35 U.S.C. § 271; *see also supra* text accompanying notes 27–29.

50. 35 U.S.C. § 271(a); *see also supra* text accompanying notes 27–29.

51. 35 U.S.C. § 271(b), (c).

52. *Id.* at § 271(c).

53. *Id.* at § 271(b).

54. 21 U.S.C. § 360(o)(1).

55. *See Johns Hopkins Univ. v. Datascope Corp.*, 543 F.3d 1342 (Fed. Cir. 2008).

56. 417 F. Supp. 2d 1188, 1201 (D. Colo. 2006).

57. 483 F. Supp. 2d 830, 840 (D. Minn. 2007).

infringement. “Technological characteristics” and other specific information in the FDA submission may be used to develop a patent infringement case. For example, in *U.S. Surgical Corp. v. Hospital Products International Pty. Ltd.*, the court noted that, beyond a generalized “substantial equivalence” assertion, the defendant also stated that “[b]oth devices utilize the same type of disposable cartridges . . . [which] utilize similar staples, similar anvils, similar staple line configurations, and the same tissue-joining methods.”<sup>58</sup> Such a series of statements can provide a road map that the patentee can use to establish factual predicates in support of a patent infringement claim.

Also, in *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, the court held as admissible statements

made by Abbott in its letters to the FDA and [USPTO] regarding whether Baxter’s proposed product as described in its [Abbreviated New Drug Application] contain[ed] an effective amount of Lewis acid inhibitor and statements made in those letters indicating that a water content of 300 ppm is required to effectively prevent degradation regardless of the container.<sup>59</sup>

Again, factual statements made to the FDA are not immune from being used against an accused infringer and are often used for that very purpose.

All is not lost, however. “Technological characteristics” and other specific information in the FDA submission may also be used to refute an infringement case. In *University of Florida v. Orthovita, Inc.*, the court considered a technical chart that was in the 510(k) notification.<sup>60</sup> The chart noted marked differences between the cleared product and the predicate device with regard to patented particle size.<sup>61</sup> Thus, because the contents of an FDA submission can be used to hurt or help a patent infringement defense, it may be helpful to keep such potential considerations in mind when preparing the FDA submission.

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58. 701 F. Supp. 314, 347 (D. Conn. 1988) (alteration in original).

59. No. 01-C-1867, 2004 WL 2496459, at \*5 (N.D. Ill. Nov. 3, 2004). An abbreviated new drug application (ANDA) submission for a pharmaceutical is somewhat analogous to a 510(k) notification for a medical device, providing an abbreviated pathway to marketability of a drug based upon a scientific showing of “bioequivalence” to an “innovator” drug in the same sort of way that “substantial equivalence” must be shown to a predicate device in the medical device context.

60. No. 1:96-CV-82-MMP, 1998 WL 34007129 (N.D. Fla. Apr. 20, 2008).

61. *Id.* at \*23 n.23.

Other issues related to patent infringement can be raised by the 510(k) notification. For example, the 510(k) notification can provide statements to support (or refute) a doctrine of equivalents analysis, such as by establishing similarity of “function/way/result”<sup>62</sup> or “insubstantial differences,”<sup>63</sup> two common tests used for determining patent infringement under the doctrine of equivalents. For example, in *Abbott Laboratories v. Sandoz, Inc.*, the court acknowledged that a bioequivalency statement to the FDA, by itself, does not constitute an admission of patent infringement, but noted that it may be relevant to the “function” prong of the “function-way-result” test for infringement under the doctrine of equivalents.<sup>64</sup>

In *Mahurkar v. C.R. Bard, Inc.*, the court questioned the relevance of the actual 510(k) filing, because it is controlled by a different regulatory scheme.<sup>65</sup> However, the *Mahurkar* court then went on to note that Bard’s 510(k) filing showed that Bard did not retest the accused infringing Hickman II catheter and then used that fact as probative of functional equivalence in determining patent infringement under the doctrine of equivalents.<sup>66</sup> In sum, factual and other statements in a 510(k) filing, other than the mere assertion of “substantial equivalence,” can create latent issues that can spring to light many years later during a patent infringement lawsuit.

Willful patent infringement can also potentially be implicated by a 510(k) filing. Willful infringement, which can lead to up to tripled damages and an award of attorney’s fees, is determined using a “totality of circumstances” test.<sup>67</sup> One might imagine that a

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62. This test asks whether the allegedly infringing device performs substantially the same function, substantially the same way, to perform substantially the same result as the limitations recited in the patent claim. *See Graver Tank & Mfg. Co. v. Linde Air Prods. Inc.*, 339 U.S. 605, 608 (1950).

63. This test asks whether “[a]n element in the accused device is equivalent to a claim limitation if the only differences between the two are insubstantial.” *Honeywell Int’l Inc. v. Hamilton Sundstrand Corp.*, 370 F.3d 1131, 1139 (Fed. Cir. 2004) (citing *Eagle Comtronics, Inc. v. Arrow Commc’n Labs., Inc.*, 305 F.3d 1303, 1315 (Fed. Cir. 2002)).

64. 566 F.3d 1282, 1298 (Fed. Cir. 2009).

65. No. 92-C-4803, 1993 WL 259446 (N.D. Ill. July 6, 1993).

66. *Id.* at \*9. Infringement can be found under the doctrine of equivalents when a device falls outside the literal scope of a claim, but the differences are insubstantial. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997).

67. Under this standard, a plaintiff must prove “by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its

510(k) filing could be viewed as an admission used to establish knowledge of the predicate device, which may be patented. It may be worth considering whether such a “circumstance” can be used in the “totality of circumstances” test for willful infringement to establish knowledge of the patent rights associated with the predicate device.

Other illustrative holdings help further explain the relationship between FDA submissions and patent infringement. In *American Medical Systems, Inc. v. Laser Peripherals, LLC*, the court found that material issues of fact remained on a summary judgment motion regarding patent infringement because “a reasonable jury could find that the accused devices do not meet the [claim] limitations regardless of [the defendant’s] representations to the FDA.”<sup>68</sup> In *Cardiovention, Inc. v. Medtronic, Inc.*, the court found that an admission of substantial equivalence in a 510(k) notification does not, by itself, constitute an admission of patent infringement because substantial equivalence has a different meaning in the FDA context than in the patent context.<sup>69</sup>

#### VII. CANDOR TO BOTH THE FDA AND THE USPTO

There is an obligation to disclose any information “material to patentability” to the United States Patent and Trademark Office (PTO) during the patent application process.<sup>70</sup> Failure to comply with this obligation can result in a finding of unenforceability of a patent or even unenforceability of an entire patent family (e.g., a parent patent, to which priority is claimed, and divisional or continuation patents, which claim priority from the patent raising the unenforceability issue). Such an “inequitable conduct” defense is often raised during patent litigation, and can implicate inventors and patent counsel alike.

As an initial note, patent attorneys and others involved in the patent process sometimes assume that they are obligated only to provide material “prior art,” such as prior patents or academic papers predating the patent applicant’s filing date. However, it is important to recognize that patents and other prior art are not the only forms of information material to patentability. It is not

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actions constituted infringement of a valid patent.” *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007), .

68. 712 F. Supp. 2d 885, 905 (D. Minn. 2010).

69. 483 F. Supp. 2d 830, 840 (D. Minn. 2007).

70. 37 C.F.R. § 1.56 (2012).

inconceivable that such material information may potentially include, for example, regulatory submissions, clinical data (either positive or adverse), or adverse event reports.

There are two elements of inequitable conduct: materiality and intent. Regarding materiality, the Federal Circuit recently ruled that, “as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art.”<sup>71</sup>

Regarding intent, prior court rulings demonstrate that “[i]ntent need not be proven by direct evidence; it is most often proven by a showing of acts, the natural consequence of which are presumably intended by the actor.”<sup>72</sup> There had been a recent trend that high materiality may weigh heavily in favor of an inference of intent.<sup>73</sup> However, in *Therasense v. Becton, Dickinson & Co.*, the Federal Circuit unequivocally stated that “[i]ntent to mislead and materiality must be separately proved. There is no ‘sliding scale’ under which the degree of intent that must be proved depends on the strength of the showing as to the materiality of the information at issue.”<sup>74</sup>

Failure to disclose a particular piece of information does not obviate the need to prove specific intent by clear and convincing evidence. For example, intent to deceive cannot be “inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent.”<sup>75</sup> Proof that non-disclosed information was highly material and that the patent applicant knew or should have known of that materiality makes it “difficult to show good faith to overcome an inference of intent to mislead.”<sup>76</sup>

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71. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1291 (Fed. Cir. 2011) (en banc).

72. *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995).

73. *See, e.g., Pharmacia Corp. v. Par Pharm., Inc.*, 417 F.3d 1369, 1373 (Fed. Cir. 2005) (“Given the highly material nature of these misleading statements and the failure to submit a directly conflicting article co-authored by the declarant himself, the district court did not clearly err in inferring an intent to deceive.” (citing *Molins PLC v. Textron, Inc.*, 48 F.3d at 1180)).

74. *Therasense*, 649 F.3d at 1304.

75. *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1116 (Fed. Cir. 1996).

76. *Semiconductor Energy Lab. Co. v. Samsung Elecs. Co.*, 204 F.3d 1368, 1375 (Fed. Cir. 2000).

Similar to the obligation of candor to the PTO, there is also an obligation not to engage in puffery or mislead the FDA. Applicants must be honest in relation to their disclosures to the FDA, including any substantial equivalence assertion made in a 510(k) filing. In fact, the 510(k) filing must be certified by the submitter (not an external consultant).<sup>77</sup>

There are strict and severe consequences of non-compliance with such obligations to the FDA. The FDA has the power to take enforcement actions that can include removal of the product from market, seizure, and personal financial liability for company officers.<sup>78</sup> There can even be criminal liability imposed for fraud upon the FDA. For example, fraud upon the FDA could expose conspirators to federal prosecution for a federal conspiracy offense under 18 U.S.C. § 371.<sup>79</sup>

On the other hand, there are possible mitigating factors to an allegation of breach of the duty of candor to the PTO. Immateriality of information to the PTO, or its cumulative nature with respect to other previously submitted information may help mitigate the consequences of non-compliance.<sup>80</sup> Additional mitigating factors may include: organizational structure, regulatory group or 510(k) submitter separate from patent counsel, R&D

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77. 21 C.F.R. § 807.93(a)(1) (2012) (“A 510(k) statement submitted as part of a premarket notification shall state as follows: I certify that, in my capacity as (the position held in company by person required to submit the premarket notification, *preferably the official correspondent* in the firm), of (company name), I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, *including any adverse safety and effectiveness information*, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR [sic] 20.61.” (emphasis added)).

78. *See, e.g.,* Orthokinetics, Inc. v. Safety Travel Chairs, Inc., 806 F.2d 1565, 1578–79 (Fed. Cir. 1986) (illustrating an example of liability for officers).

79. For example, Micro Interventional Systems, Inc submitted 510(k) filings that contained materially false and fraudulent documents. The director of Regulatory Affairs and Quality Assurance was sentenced to 10 months in prison for her role in submitting fraudulent 510(k) notifications. *See Former Medical Company Official Sentenced to 10 Months Charged with Fraud Against the United States*, U.S. DEPARTMENT JUST. (Sept. 4, 2001), <http://www.justice.gov/opa/pr/2001/September/445civ.htm>.

80. *See, e.g.,* Christopher A. Cotropia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 762 (2009) (highlighting solutions to the current inequitable conduct doctrine’s emphasis on over-compliance—submitting of excess immaterial information).

personnel working on patent application, size of organization, or good faith.

#### VIII. THE BREADTH OF THE DISCLOSURE OBLIGATION EXTENDS BEYOND PRIOR ART

Case law illustrates scenarios in which information not considered to be prior art may still constitute information material to patentability. In *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, Rhone-Poulenc obtained a U.S. patent based on semi-synthesis of the chemotherapy drug Taxol.<sup>81</sup> The U.S. matter claimed priority to an earlier-filed French patent, and the French patent itself was based on a draft submission for a scholarly journal.<sup>82</sup> The final journal article stated that the method of making Taxol could only be successful by use of certain protecting groups, such as methoxymethyl protecting group at C-2', which could not be removed following esterification and unique reaction conditions.<sup>83</sup>

The journal article was not disclosed to the PTO, nor were the technical limitations of the article discussed in the U.S. patent.<sup>84</sup> In fact, the U.S. patent seemed to suggest that the technical limitations did not even exist.<sup>85</sup> The journal article was held to be material, even though it was not prior art since its publication date was after the filing date of the patent.<sup>86</sup> The journal article was still deemed to be material because it concerned issues of enablement and contradicted positions taken in the patent application.<sup>87</sup>

With this as a guidepost, it may be worth considering sharing pre-filing and post-filing information with a patent attorney for review to evaluate such information for possible disclosure to the PTO. Even if such post-filing information does not outright contradict a position taken in the patent application, it still may be worth considering for disclosure to inoculate the patent application against contrived assertions along such lines. Such post-filing information may arise from the FDA submissions, including from the duty of candor to the FDA that may necessitate submitting negative information or data to the FDA that contradicts the

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81. 326 F.3d 1226, 1229 (Fed. Cir. 2003).

82. *Id.* at 1231.

83. *Id.* at 1230.

84. *Id.* at 1236.

85. *Id.* at 1234–35.

86. *Id.* at 1234–38.

87. *Id.*

earlier-filed patent. Similarly, while drafting a patent application, it may be wise to be circumspect with respect to positions taken that may potentially later be contradicted in data submitted to the FDA, such as by data being gathered during preclinical or clinical studies that are ongoing or in the future at the time the patent application is filed.

*Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd.*, is a representative guidepost case regarding candor to the PTO.<sup>88</sup> Bruno sued Acorn on its patented stairlift for the elderly.<sup>89</sup> Acorn produced numerous prior art stairlifts and, in defense, accused Bruno of having intentionally withheld material prior art on the “Wecolator” stairlift from the PTO.<sup>90</sup> Bruno had submitted information on several prior art stairlifts to the FDA in its 510(k).<sup>91</sup> Bruno argued “that its claim of ‘substantial equivalence’ between” its SRE-1500 and the Wecolator (which was not disclosed to the PTO) “was relevant only for the purpose of securing FDA approval.”<sup>92</sup> Bruno also argued that despite its awareness of the prior art stairlifts, it did not appreciate the Wecolator’s materiality.<sup>93</sup>

Bruno’s non-materiality arguments were unpersuasive in both the district court<sup>94</sup> and the Federal Circuit.<sup>95</sup> The patent examination history suggested that had the examiner been made aware of the Wecolator, Bruno’s amendments would have been insufficient to achieve allowance.<sup>96</sup> Bruno’s argument of unawareness of materiality was deemed “disingenuous” because “the FDA submission was prepared by William Belson”—the same individual “who was also involved in prosecution of” the Bruno patent being asserted against Acorn.<sup>97</sup> Regarding intent, the

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88. 394 F.3d 1348, 1350–51 (Fed. Cir. 2005).

89. *Id.* at 1350.

90. *Id.* at 1350.

91. *Id.* at 1350–51.

92. *Id.* at 1352.

93. *Id.* at 1351.

94. *Id.* at 1350–51 (citing *Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, No. 02-C-0391-C, 2003 WL 23095743 (W.D. Wis. Nov. 6, 2003)).

95. *Id.* at 1355.

96. *Id.* at 1353. Incidentally, such a finding would meet the present “but-for” materiality requirement established under *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011).

97. *Bruno Indep. Living Aids, Inc.*, 394 F.3d at 1352 (citing *Black v. Cutter Labs.*, 351 U.S. 292, 297 (1956); *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540 (Fed. Cir. 1983)).

Federal Circuit found that “[w]hile the district court indeed provided little explicit support for its finding of intent, it is well established that, as an appellate tribunal, we review judgments, not opinions.”<sup>98</sup> The review focused on the evidence of record.<sup>99</sup> Bruno failed to offer a “credible” explanation for the nondisclosure.<sup>100</sup>

Given that the same individual was involved in preparing the FDA submission and the prosecution of the patent application in *Bruno*, the question naturally arises: is there “plausible deniability” in a large organization in which these different functions are performed by different individuals? In *Ranbaxy Laboratories Ltd. v. Abbot Laboratories*, the court briefly touched upon this very issue with respect to “taste perversion” results that were disclosed to the FDA, but not the PTO, stating,

Abbott’s argument appears to be that it is a very large corporation with many employees performing disparate tasks in separate facilities who cannot all be required to know what each of the others is doing. In short, Abbott appears to be arguing that because it has many employees who do not all communicate with each other as well as they might, this Court should find no more than negligence on Abbott’s part in its failure to disclose the material results of the clinical studies. . . . [H]owever, this Court *preliminarily* finds that Abbott fails to provide a credible explanation for the failure to disclose the taste perversion results to the PTO. The results were highly material, but Abbott selectively disclosed only the gastrointestinal results despite claiming reduced taste perversion . . . .<sup>101</sup>

In *Abbott*, it was the same inventors named on the patent that also approved and signed off on clinical study reports and authored a journal article.<sup>102</sup> Thus, there may be risk in having a named inventor on the patent also certify the 510(k) submission because such a certification may impute knowledge of the regulatory process to the inventor or, additionally or alternatively, may impute the inventor’s knowledge of adverse or contradictory information

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98. *Bruno Indep. Living Aids, Inc.*, 394 F.3d at 1354.

99. *Id.*

100. *Id.*

101. No. 04-C-8079, 2005 WL 3050608, at \*9 (N.D. Ill. Nov. 10, 2005) (emphasis added).

102. *Id.*

to those preparing regulatory filings.

Given these holdings, one might assume that FDA filings must be scoured, and everything from the FDA file must be resubmitted to the PTO. But consider *Pfizer Inc. v. Ranbaxy Laboratories Ltd.*,<sup>103</sup> which reached a different result than *Bruno*. *Bruno* involved non-disclosure of prior art.<sup>104</sup> *Pfizer* involved data submitted to the FDA for seeking *Lipitor* approval.<sup>105</sup> No inequitable conduct was found in *Pfizer* for failure to submit similar data to the PTO.<sup>106</sup> This finding was based on (1) a credible assertion that the data was unreliable and thus immaterial and (2) that the submitter of the data to the FDA was not the same as the inventor, Dr. Roth.<sup>107</sup> With this contrary result to *Bruno* in mind, the question is again raised: Is there an unnecessary risk that is created in having a named inventor on the patent also certify the 510(k) submission?

In another noteworthy example, *Abbott Laboratories v. Sandoz, Inc.* involved a drug-related patent involving Abbott's Biaxin<sup>®</sup>XL antibiotic.<sup>108</sup> Here, studies submitted to the FDA indicated a lack of supporting evidence for the patent's claimed method of reducing gastrointestinal (GI) side effects.<sup>109</sup> The district court found, however, that the information was "not material to patentability" because various other tables of information demonstrating no change in GI side effects had already been submitted (meaning that the submission of the additional studies would have been cumulative).<sup>110</sup>

Viewing the preceding two cases in isolation, one may be lulled into a false sense of security that no inequitable conduct will be found for failure to cite data to the PTO that had been cited in the FDA submissions. This is likely not a safe assumption. *Pfizer* and *Abbott* both relied on specific factual considerations involving the un-submitted data. In *Pfizer*, the data was deemed questionable. In *Abbott*, the data was deemed cumulative. In sum, it may be best to err on the side of caution and submit to the PTO any notably

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103. 405 F. Supp. 2d 495, 523–24 (D. Del. 2005) (distinguishing *Bruno Indep. Living Aids, Inc.*, 394 F.3d 1328), *aff'd in part, rev'd in part, remanded by* 457 F.3d 1284 (Fed. Cir. 2006).

104. *Id.* at 523.

105. *Id.* at 501.

106. *Id.* at 525.

107. *Id.* at 522–23.

108. 544 F.3d 1341, 1343 (Fed. Cir. 2008).

109. *Id.* at 1357.

110. *Id.*

different information submitted to the FDA or to be certain that an objectively credible explanation exists for not submitting such information.

#### IX. EXEMPTION FROM INFRINGEMENT UNDER 35 U.S.C. § 271(E)(1)

The interplay between FDA and patent law is also evident in the limited exemption from patent infringement under 35 U.S.C. § 271(e)(1).

In 1984, a pharmaceutical company was sued for use of a patented chemical in bioequivalence testing for a generic drug.<sup>111</sup> At trial, the company argued that the use did not constitute patent infringement because it was experimental.<sup>112</sup> The Federal Circuit found the use to constitute patent infringement and focused on the purpose of the experiments, which was to prepare for competition with the patented product after patent expiration.<sup>113</sup> It was widely recognized that this decision would effectively force pharmaceutical companies to delay bioequivalence testing until after expiration of a competitive patent. That, in turn, would delay market launch of a generic drug until well after the patent expiration, due to the time required to carry out such bioequivalence testing, and would effectively provide a *de jure* extension of the term of the patent.

In response, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984.<sup>114</sup> This included the 35 U.S.C. § 271(e)(1) provision, which established a safe harbor for an experimental use related to a regulatory approval submission, thereby addressing the issue of artificial extension of effective patent life.

The statute states:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological

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111. Roche Prod., Inc. v. Bolar Pharm. Co., 733 F.2d 858, 860 (Fed. Cir. 1984).

112. *Id.* at 861–62.

113. *Id.* at 863.

114. Pub. L. No. 98-417, 98 Stat. 1585.

products.<sup>115</sup>

This regulatory submission exemption from patent infringement of § 271(e)(1) provides yet another example of the interplay between the FDA regulatory process and patent law. It is worth exploring several potential questions that it raises. First, what is its applicability to medical devices? Second, how broad is the language “solely for uses reasonably related”? Third, what are the practical implications of the § 271(e)(1) exemption in business strategy planning for a medical device?

In *Eli Lilly & Co. v. Medtronic, Inc.*,<sup>116</sup> the Supreme Court recognized that § 271(e)(1) applies to a “patented invention.”<sup>117</sup> The Court further concluded that “a patented invention” under § 271(e)(1) includes all inventions subject to FDA approval and not simply drug-related inventions alone.<sup>118</sup> Therefore, the Court decided that medical devices must be included in the research exemption under § 271(e)(1).<sup>119</sup> The Federal Circuit later further clarified this in *Abtox, Inc. v. Exitron Corp.*, finding that the § 271(e)(1) exemption applies to all medical devices regardless of FDA classification and is not limited to the class III medical device at issue in *Eli Lilly*.<sup>120</sup>

After *Eli Lilly* and *Abtox*, the scope of the exemption, which is “solely for uses reasonably related”<sup>121</sup> to the FDA approval process, was further clarified. In *Intermedics, Inc. v. Ventritex, Inc.*,<sup>122</sup> a district court noted that the inquiry is not focused on whether the alleged infringer has engaged in conduct that has purposes beyond presenting data to the FDA.<sup>123</sup> Instead, one relying on the § 271(e)(1) exemption need only believe there was a “decent prospect” that the use would contribute information relevant to an FDA submission.<sup>124</sup> The activities at issue in *Intermedics* were the manufacture of several hundred Cadence defibrillators, sales of

115. 35 U.S.C. § 271(e)(1) (2006).

116. 496 U.S. 661 (1990).

117. *Id.* at 665.

118. *Id.*

119. *Id.* at 667–69.

120. *See Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1028–30 (Fed. Cir. 1997) (“Section 271(e)(1) makes no distinctions based upon the different FDA classes of medical devices or drugs.”).

121. 35 U.S.C. § 271(e)(1) (2006).

122. 775 F. Supp. 1269, 1278 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993).

123. *Id.* at 1280.

124. *Id.*

Cadence to hospitals in the United States, sales of Cadence to international distributors, testing of Cadence (including certain testing done in Germany), and demonstrations of Cadence at “trade shows.”<sup>125</sup> The district court found that these commercial activities, which were ancillary to testing needed for an FDA regulatory submission, fell within the § 271(e)(1) exemption from patent infringement, and the Federal Circuit affirmed in an unpublished opinion.<sup>126</sup>

In *Telectronics Pacing Systems, Inc. v. Ventritex, Inc.*, the Federal Circuit applied the § 271(e)(1) exemption when the accused infringer, Ventritex, demonstrated an infringing device at a medical conference.<sup>127</sup> The *Ventritex* court found that dissemination of data initially collected for the purposes of FDA approval is not an act of infringement under § 271(e)(1), even when the data is then used for collateral fundraising activities.<sup>128</sup> The court reasoned that an accused infringer should be permitted to search for qualified investigators to conduct clinical trials and that such use of data did not constitute a sale or an offer to sell.<sup>129</sup>

Later, in *Merck KGaA v. Integra Lifesciences I, Ltd.*,<sup>130</sup> the United States Supreme Court weighed in declaring that the § 271(e)(1) safe harbor is applicable to “all uses of patented inventions that are reasonably related to the . . . submission of *any* information under the FDCA.”<sup>131</sup> The § 271(e)(1) exemption was found by the *Merck* Court to include both clinical trials and preclinical studies appropriate for FDA submission; however, consummating the FDA regulatory submission is not required for the § 271(e)(1) exemption to apply.<sup>132</sup> Although the Court gave a wide berth to activities related to FDA submissions, the Court stated that the exemption “does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval

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125. *Id.* at 1282.

126. *Id.* at 1282–89. The court viewed this as dissemination of data developed for FDA approval. *Id.* Because the data was initially gathered for FDA approval, the exemption remained, despite use of the data for collateral fundraising activities. *Id.*

127. *See* 982 F.2d 1520, 1524–25 (Fed. Cir. 1992), *aff'g*, 19 U.S.P.Q.2d (BNA) 1960 (N.D. Cal. 1991) (“[Section 271(e)(1) is not] revoked when the resulting data is later used for non-FDA reporting purposes.”).

128. *Id.* at 1525.

129. *Id.* at 1523.

130. 545 U.S. 193 (2005).

131. *Id.* at 202.

132. *Id.* at 207–08.

process.”<sup>133</sup> Thus, the scope of the § 271(e)(1) exemption is not so broad as to exempt from infringement basic scientific research unrelated to an FDA regulatory approval submission.<sup>134</sup> To have found otherwise would eviscerate any value on a patent directed toward a research tool device or method.<sup>135</sup>

This issue was squarely addressed in *Proveris Scientific Corp. v. Innovasystems, Inc.*, in which the defendant sold a patented optical spray analyzer (OSA) only to pharmaceutical companies and the FDA for use to measure parameters of aerosol sprays of nasal drug delivery systems.<sup>136</sup> The *Proveris* court noted that in *Eli Lilly & Co. v. Medtronic, Inc.*,<sup>137</sup> the Supreme Court stated that those products listed in 35 U.S.C. § 156(f) were entitled to safe harbor under § 271(e)(1).<sup>138</sup> Therefore, the court ruled that the § 271(e)(1) exemption did not apply since the OSA is not subject to a required FDCA approval process under 35 U.S.C. § 156(f).<sup>139</sup> The court stated that the patented invention itself must be subject to FDA approval because Congress only intended to exempt those products that are adversely affected by the unintended extension of patent life caused by the FDA approval delay.<sup>140</sup>

In *Classen Immunotherapies, Inc. v. Biogen IDEC*,<sup>141</sup> the Federal Circuit carved out post-approval activities from the § 271(e)(1) exemption by holding that it “does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained.”<sup>142</sup> The court cited legislative history to emphasize that the purpose of § 271(e)(1) is simply to allow generic manufacturers to experiment and prepare for regulatory approval so as to be able to engage in commercial activity promptly after patent expiration.<sup>143</sup> The court further stated that explicit purpose of the exemption is to remedy the delay in market entry due to the regulatory approval process suffered by would-be

133. *Id.* at 205 (quoting *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2005)).

134. *Id.* at 205–06.

135. *Id.* at 205 n.7.

136. 536 F.3d 1256, 1265–66 (Fed. Cir. 2008).

137. 496 U.S. 661 (1990).

138. *Proveris*, 536 F.3d at 1262.

139. *Id.* at 1265.

140. *Id.*

141. 659 F.3d 1057 (Fed. Cir. 2011), *cert. denied*, 133 S. Ct. 973 (2013).

142. *Id.* at 1070.

143. *Id.* at 1071.

competitors.<sup>144</sup> The court also noted that previous cases had exempted preclinical research whether eventually included in an actual FDA submission or not, but explicitly declined to enlarge the scope of the exemption to post-approval uses.<sup>145</sup>

The bright-line rule of *Classen* was qualified somewhat by the Federal Circuit in *Momenta Pharm., Inc. v. Amphastar Pharm., Inc.*, which held that post-ANDA approval activities fit within the scope of § 271(e)(1).<sup>146</sup> The *Momenta* court held that the plain language of the statute was broad enough to cover any submission to the FDA.<sup>147</sup> The court distinguished *Classen* on the grounds that the information submitted in *Momenta* was not merely “routine” but necessary for continued approval and ability to market the generic drug.<sup>148</sup> The court pointed out that in *Classen* the information was not required by the FDA.<sup>149</sup>

Although these recent cases focused on pharmaceuticals, not medical devices, the history of applying § 271(e)(1) jurisprudence to medical devices may warrant using these cases as guidance for analogous situations surrounding medical device regulatory submissions to the FDA, at least to the extent that such activities are necessary for continued approval and ability to market the medical device. Nonetheless, since these questions have not been squarely addressed in the context of medical devices, some risk may exist in relying on such cases in the medical device context.

The § 271(e)(1) exemption raises a number of practical considerations for a business strategy surrounding the design, regulatory submission, and marketing of a medical device. First, one should keep the issue of patent infringement and the § 271(e)(1) exemption from patent infringement in mind when selecting a predicate device for use in a 510(k) submission. Ideally, a patent Freedom-to-Operate (FTO) investigation<sup>150</sup> should be

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144. *Id.*

145. *Id.* at 1071–72. A petition for writ of certiorari was filed in this case, with the major issue being whether the phrase “solely for uses reasonably related” is by definition limited to preapproval use of information required by FDA law or whether the phrase refers to the type of use rather than to the time period during which it was conducted. That petition was denied. *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, 133 S. Ct. 973 (2013).

146. 686 F.3d 1348, 1359 (Fed. Cir. 2012).

147. *Id.* at 1358–59.

148. *Id.* at 1357–58.

149. *Id.* at 1368.

150. An FTO investigation can help ascertain whether a product or method can be practiced without infringing potentially valid patent rights of another.

carried out well in advance of clinical investigations, with monitoring and updating occurring during the clinical investigations and other activities leading up to an FDA approval regulatory submission, such as a 510(k). This can help choose a predicate device wisely, such as to avoid patent infringement, while keeping the § 271(e)(1) exemption in mind.

Second, more specifically, one should be mindful that the inappropriate choice of a predicate device relying on § 271(e)(1) may inadvertently lock one into a position of patent infringement of a patent covering the predicate device, unless that patent under § 271(e)(1) generally expires (at latest) upon FDA approval, with *Classen* and *Momenta* leaving post-approval activities, at the very least, extremely vulnerable to being excluded from the § 271(e)(1) exemption. Simply put, if a patent at issue on a selected predicate device has not expired, then upon FDA approval the approved medical device may now be infringing that patent, since § 271(e)(1)'s safe-harbor provision no longer applies. Moreover, the medical device maker may be unable to modify the medical device without re-submitting the modified product to the FDA, thereby effectively locking the medical device into a position of patent infringement until expiration of the patent. Parties should exercise care to avoid this outcome.

Third, if there is intent to rely on the § 271(e)(1) exemption for preclinical, clinical, or other regulatory approval activities, it is worth asking whether the clinical study can be designed (or whether the clinical study protocol or 510(k) submission can be written) in such a way as to document the § 271(e)(1) safe harbor. This might include clearly stating that the study is being carried out for the purpose of FDA regulatory submission, and that the FDA regulatory touchstones of "safety" and "efficacy" are being addressed by the clinical study, if in fact that is indeed the case.

Fourth, it is worth being at least somewhat wary of the statements in the case law emphasizing the breadth of the safe harbor of § 271(e)(1) as applicable to certain forms of arguably commercial activity ancillary to regulatory-approval submission activity. If the § 271(e)(1) exemption is being relied upon, then personnel throughout the medical device manufacturer's organization should be cognizant of that fact and its limited nature.

In sum, with these considerations regarding the § 271(e)(1) exemption in mind, coordination between regulatory and intellectual property personnel is key in avoiding any problems.

## X. PATENT TERM EXTENSION FOR REGULATORY APPROVAL DELAY

The interplay between FDA and patent law is even more directly evident in the availability of patent term extension for FDA regulatory approval delay, which, as explained below, is extremely limited since it is available only to products approved under the PMA route,<sup>151</sup> and not the 510(k) route, and is limited to extension of the term of a single patent.<sup>152</sup>

A patent gives the owner of the patent a right to exclude others from practicing the claimed invention for a specified period of time (referred to as the patent's "term"). In the United States, a patent's term is generally twenty years<sup>153</sup> from the earliest priority date.<sup>154</sup> Once a patent is granted, the patented product may still require FDA approval before the product can be marketed. The time consumed in obtaining such approval decreases the time available to the patentee to act as the exclusive provider of the patented product. Under 35 U.S.C. § 156, a patent term can be extended for PMA regulatory approval delay.<sup>155</sup> Section 156(a) states that, "[t]he term of a patent which claims a product, a method of using a product, or method of manufacturing a product shall be extended . . . if . . . (4) the product has been subject to a regulatory review period before its commercial marketing or use."<sup>156</sup>

In order to qualify for the § 156 patent term extension, an application must be submitted by the patentee to the PTO. The patent term extension application must be submitted within sixty days of the date on which the product received FDA permission for commercial use.<sup>157</sup>

The § 156 patent term extension is available for pharmaceuticals and for medical devices. Through April 4, 2012, there have been 617 patents extended under § 156. Of the 617

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151. 35 U.S.C. § 156(g)(3)(B)(i) (2006 & Supp. V 2011).

152. *Id.* § 156(c)(4).

153. *Id.* § 154(a)(2).

154. A provisional application shall not be taken into account in determining the term of a patent. *Id.* § 154(a)(3). Take note that patents filed before January 1, 1995 have a term of seventeen years from the patent grant. Patents that were in force on June 8, 1995, or that issued on an application that was filed before June 8, 1995, have a term that is the greater of the twenty-year term or seventeen years from the patent grant. *Id.* § 154(c)(1).

155. *Id.* § 156.

156. *Id.* § 156(a)(4) (2006).

157. *Id.* § 156(d)(1); MPEP, *supra* note 29, § 2754.

patents that were extended, 570 were for pharmaceuticals and 47 were for medical devices.<sup>158</sup> This may reflect the higher value placed on the latter part of the patent term in the pharmaceutical industry than in the medical device industry. Alternatively, this may simply indicate that FDA regulatory approval is more likely to be sought via a new drug application, which is the equivalent of a PMA for pharmaceuticals, than for medical devices, for which the 510(k) route is a more common path to FDA regulatory approval.

The application for a § 156 patent term extension generally includes several parts. First, the application should include the identity of the product and the relevant federal statute for regulatory review.<sup>159</sup> Second, the identity of the relevant patent and the identity of each relevant claim should be included.<sup>160</sup> Further, the applicant should include a statement showing how the claims of the patent for which extension is sought map to the approved product.<sup>161</sup> Third, the application should include information for the PTO to determine eligibility for patent extension.<sup>162</sup> Fourth, the dates and description of activities performed during the regulatory review period should be included.<sup>163</sup> Fifth, any other information the PTO may require should be included.<sup>164</sup>

There are limitations placed on what can be extended and how much time can be added with the extension. The length of an extension depends on several factors. The length of extension is set forth in § 156, and extensions for medical devices are specifically set forth in § 156(g)(3).<sup>165</sup> There are three important dates: (1) when clinical investigations on humans began; (2) when the PMA application was initially submitted for the device; and (3) when the PMA application was approved.<sup>166</sup> The length of the extension equals half of the number of days between the date when clinical investigations on humans began and the date when the PMA application was initially submitted for the device, in addition to the number of days between the date when the PMA application

158. *Patent Term Extensions*, U.S. PAT. & TRADEMARK OFF. (Apr. 4, 2012, 3:57 PM), <http://www.uspto.gov/patents/resources/terms/156.jsp>.

159. 35 U.S.C. § 156(d)(1)(A).

160. *Id.* § 156(d)(1)(B).

161. *Id.*

162. *Id.* § 156(d)(1)(C).

163. *Id.* § 156(d)(1)(D).

164. *Id.* § 156(d)(1); 37 C.F.R. § 1.740 (2012); MPEP, *supra* note 29, § 2753.

165. 35 U.S.C. § 156.

166. *Id.* § 156(g)(3).

was initially submitted for the device and the date when the PMA application was approved.<sup>167</sup>

There are, however, some limitations to the length of the § 156 extension. The extension cannot be longer than five years.<sup>168</sup> Additionally, the patent's expiration date (including the extension) cannot be more than fourteen years from the date of regulatory approval.<sup>169</sup> Finally, and significantly, no more than one patent can be extended for the same regulatory review period for any product.<sup>170</sup>

An applicant's diligence can also affect the § 156 patent term extension. "[E]ach period of the regulatory review period shall be reduced by any period determined under subsection (d)(2)(B) during which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period."<sup>171</sup> The diligence required for the extension is diligence with the FDA, not with the PTO.<sup>172</sup> A third party can petition the § 156 patent term extension, by asserting applicant's lack of diligence.<sup>173</sup>

Notably, a patent can be eligible for a patent term adjustment (PTA) for PTO delay, in addition to an FDA delay extension under § 156.<sup>174</sup> If a patent is eligible for both a PTA for PTO delay and an extension under § 156 for FDA regulatory approval delay, the § 156 extension extends from the date of the PTA.<sup>175</sup> In sum, the PTO and FDA delay extensions are additive, not concurrent.

A patent that has been terminally disclaimed<sup>176</sup> is still eligible for § 156 extension.<sup>177</sup> A patentee can terminally disclaim<sup>178</sup> a

167. *Id.*

168. *Id.* § 156(g)(6)(A).

169. *Id.* § 156(c)(3).

170. *Id.* § 156(c)(4).

171. *Id.* § 156(c)(1).

172. 21 C.F.R. § 60.36 (2012).

173. *Id.* § 60.30.

174. 35 U.S.C. § 154(b) (2006 & Supp. V 2011).

175. "A patent term extension generally extends the patent from its 'original expiration date,' as defined by 35 U.S.C. § 154 to include extension under 35 U.S.C. § 154 (b)." MPEP, *supra* note 29, § 2758.

176. When a patentee has terminally disclaimed a portion of a second patent, the second patent and the first patent will normally have the same expiration date. *See* 35 U.S.C. § 253.

177. MPEP, *supra* note 29, § 2751.

178. Generally, when a patentee terminally disclaims a portion of a patent's term, such a disclaimer constrains the term of the patent so that it will expire at the same time as an earlier-issued patent. 35 U.S.C. § 253.

portion of a patent's term if the patent is deemed obvious in view of a different previously filed patent owned by the patentee.<sup>179</sup> The second patent is still eligible for an extension under § 156, even though it was terminally disclaimed.<sup>180</sup>

There are many things that should be considered when applying for an extension under § 156. The possibility of a § 156 extension can be considered when deciding between which FDA regulatory approval route to take: 510(k) or PMA. Although the PMA route is likely lengthier and more onerous, it may be possible to recover some of the delay in terms of § 156 patent term extension, albeit only for a single patent. It seems unlikely, however, that this would ever outweigh the additional delay to market given the increased uncertainty of the PMA route, before both the FDA and the PTO, since the § 156 patent term extension benefit ultimately depends on what coverage can be obtained in a single patent for which the § 156 extension can be sought.

For products that are undergoing PMA, it may be advantageous to map patents to such products in order to get the most value out of any patent that might be eligible for § 156 extension. Since only one patent can be extended under § 156, a patentee would have to choose the "best" patent on which to apply for the § 156 extension. The patentee will have to decide which patent is "best," which may be based on, among other things: actual infringement, patent strength (infringement, validity, enforceability), and the amount of extended term available.

Within a medical device company, regulatory personnel responsible for the FDA approval should communicate the appropriate docket deadline to the patent personnel, so there is no question of diligence or missed deadlines. It should also be remembered that a third party can challenge the diligence of the patentee during the FDA regulatory approval investigation and submissions, and the § 156 extension can be adjusted. In sum, these decisions will require coordination between regulatory and intellectual property personnel.

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179. *Id.*

180. *Merck & Co. v. Hi-Tech Pharmacal Co.*, 482 F.3d 1317, 1322–24 (Fed. Cir. 2007). But, in contrast to patent term *extension* under 35 U.S.C. § 156, patent term *adjustment* under 35 U.S.C. § 154 cannot extend a patent's term beyond the term of the earlier-expiring patent if a terminal disclaimer has been filed. 35 U.S.C. § 154(b)(2)(B).

## XI. CONCLUSIONS

For medical devices, the patent and FDA regulatory processes have considerable interplay. Simply put, commercializing a medical device is unlike developing other products. As explained above, it can involve significant clinical research, a clinical trial to demonstrate safety and effectiveness, and regulatory approval from the FDA. How a company handles these tasks will impact its patent portfolio. The people focused on these tasks are likely oblivious to patent consequences—they are simply diligently working toward other goals and have other business needs.

Medical device patent attorneys should beware: you may live and breathe patents, but you likely lead a solitary existence. Most people in your company are probably blissfully unaware of how their everyday activities can impact your company's patent portfolio. You may never know the consequences of what they are doing until uncovered much later during patent litigation, which is common in the medical device industry. Infusing knowledge of the interplay between the patent and FDA processes can help ensure coordination between regulatory and intellectual property personnel, increase opportunities, and avoid pitfalls with the patent portfolio and accompanying business strategy.