

## Federal Courts Debate Safe Harbor Exemption for Patent Infringement Under 35 U.S.C. § 271(e) Following *Merck v. Integra*

**By Patrick G. Gattari and Nicole E. Grimm**

Patent protection is a critical driver of value for the biotech industry. One of the unique aspects of biotech patents, however, is that many otherwise infringing activities are exempt from claims of patent infringement when those activities are “reasonably related to the development and submission of information” to the Food and Drug Administration (FDA).<sup>1</sup> The scope of this exemption has been hotly contested since the passage of the Hatch-Waxman Act in 1985 (the Act).<sup>2</sup> The Supreme Court has weighed in on this exemption twice, the last time being in *Merck KGaA v. Integra LifeSciences I, Ltd.*<sup>3</sup> In that case, the Supreme Court expressly side-stepped the question of whether research tools are exempt from infringement.<sup>4</sup> Since *Merck*, there have been a number of Federal Circuit and district court decisions that interpret the Act.<sup>5</sup> The Supreme Court just recently refused to review another important Federal Circuit decision regarding the question of whether activities engaged in after FDA approval fall within the scope of the Act. Each case is noteworthy for being factually intensive and having difficult to predict outcomes. The following review of the post-*Merck* decisions is intended to guide patent holders and would be infringers in analyzing whether the use of research tools and other activities are exempt from infringement under the Act.

The exemption under 35 U.S.C. § 271(e)(1) (“safe harbor” or “exemption”) was first codified in the U.S. patent laws with the passage of the Hatch-Waxman Act in 1985:

It shall not be an act of infringement to make, use, offer to sell, or sell... or import... 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...<sup>6</sup>

The Act is an attempt to balance the demand for low cost generic pharmaceuticals with the rights of patent owners. The Act allows activities that would otherwise infringe a U.S. patent before the expiration of the patent if those activities are “solely for uses reasonably related to the development and submission of information” to the FDA.<sup>7</sup> The statute has spurred an abundance of litigation and, over the years, the federal courts have regularly interpreted the language of the statute in broad terms. For example, though the statute explicitly refers to “the use and sale of drugs,” the Supreme Court has interpreted the statute to include medical devices.<sup>8</sup> Moreover, the courts have essentially eviscerated the term “solely” from the statute, as there is now no dispute that the infringing activities may be for reasons other than those “solely” related to FDA approval.<sup>9</sup>

In *Merck*, the Supreme Court continued the practice of liberally interpreting the safe harbor of § 271(e)(1). This case involved patents on short peptides that Merck supplied to Scripps Research Institute in order for Scripps to test the peptides as potential angiogenesis inhibitors.<sup>10</sup> Integra LifeSciences I, Ltd. owned a patent covering the peptides, and sued Merck

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and Scripps for patent infringement.<sup>11</sup> As a defense, Merck and Scripps asserted that their activities associated with the use of the peptides were exempt from patent infringement under § 271(e)(1) because their testing of the peptides was reasonably related to the development and submission of information about the peptides to the FDA.<sup>12</sup>

The federal trial court and the appeals court found that the exemption did not apply because the testing of a number of the patented peptide compounds, prior to the selection of any particular compound as a potential drug candidate, was not sufficiently directly related to the submission of information to the FDA.<sup>13</sup> The trial and appeal courts found that Scripps was simply conducting biomedical research, which had no relation to FDA approval of any of the peptides.<sup>14</sup>

The Supreme Court reversed the lower courts and held that the exemption can apply to activities involving a drug compound that infringes a patent even though approval is not sought for that compound as long as the activities are reasonably related to the approval of some other compound.<sup>15</sup> The Supreme Court, however, explicitly left open the question of whether a patented research tool can be used without a license.<sup>16</sup>

Since *Merck*, a number of courts have reviewed the use of research tools under § 271(e)(1). The Supreme Court's express intention to avoid addressing the research tool question has left several open questions about the scope of the safe harbor. So far, only one court has found in favor of a research tool exemption.<sup>17</sup> In addition, the Federal Circuit has twice reviewed whether post-FDA approval activities are exempt.<sup>18</sup>

## Research Tools Exempt under § 271(e)(1) post-*Merck*

In *Classen Immunotherapies, Inc. v. King Pharms., Inc.*, Classen owned patents covering methods for identifying and commercializing new uses of existing drugs.<sup>19</sup> Elan produced a muscle relaxant drug called Skelaxin.<sup>20</sup> Elan conducted studies on the bioavailability of Skelaxin, and found that food significantly impacted absorption rate.<sup>21</sup> Elan then submitted a Citizen Petition to the FDA containing the results of the bioavailability study, and requested that the FDA require manufacturers seeking approval for generic Skelaxin to submit fed and fasted studies along with an Abbreviated New Drug Application (ANDA).<sup>22</sup> Elan also submitted to the FDA a label supplement that contained the results of its study.<sup>23</sup>

Classen sued Elan for infringement of its patented process when Elan: 1) conducted the bioavailability of Skelaxin study; 2) identified a new use of the drug; and 3) commercialized the new use.<sup>24</sup> Elan claimed that even if its activities were considered infringement, the activities fell under the safe harbor of § 271(e)(1) because the results of the bioavailability study were submitted to the FDA.<sup>25</sup>

The district court agreed with Elan, and held that Elan's use of Classen's patented process was reasonably related to the submission of information to the FDA and was protected under § 271(e)(1).<sup>26</sup> In so holding, the district court acknowledged that the Supreme Court in *Merck* specifically declined to rule on whether the use of "research tools" was protected under § 271(e)(1). Although the Classen process could be considered a "research tool," the district court found that the extension of the safe harbor to cover the use of these

tools was warranted by the language of *Merck* and a plain reading of the statute.<sup>27</sup>

## Research Tools Not Exempt under § 271(e)(1) post-*Merck*

In *Proveris Scientific Corp. v. InnovaSystems, Inc.*, the patent at issue covered a system and apparatus for identifying different aerosol sprays that are used in drug delivery devices, such as nasal sprays.<sup>28</sup> The patent also disclosed that the characterization of aerosol sprays is a part of the FDA regulatory approval process.<sup>29</sup> The defendant, Innova, marketed an Optical Spray Analyzer (OSA) that, although not itself subject to FDA approval, can be used in connection with FDA submissions related to aerosol sprays.<sup>30</sup> When Proveris sued Innova for infringement of its patent, Innova claimed that its actions fell within the safe harbor of § 271(e)(1) because the OSA device was used by others for the purpose of generating information to submit to the FDA.<sup>31</sup>

The Federal Circuit focused its analysis on the terms "patented invention" and "reasonably related" from the statutory language of § 271(e)(1).<sup>32</sup> While deciding that the OSA was a medical device that would be covered by § 271(e)(1), the court found that the use of the device was not exempt from infringement because **§ 271(e)(1) is not designed to protect parties who are not themselves seeking FDA approval of a product.**<sup>33</sup> As a result, the court concluded that Innova was "not within the category of entities for whom the safe harbor provision was designed to provide relief."<sup>34</sup>

In *PSN Illinois, LLC v. Abbott Labs.*, the district court found that Abbot's use of PSN's patented invention as a research tool to identify potential drug candidates did not fall under the safe harbor of

§ 271(e)(1).<sup>35</sup> PSN owned patents covering the SIP2 receptor, which is a member of a family of protein receptors involved in vasculature and immune system regulation.<sup>36</sup> Abbott's research focused on identifying drug candidates that might interact with SIP receptors and have therapeutic properties.<sup>37</sup> The research revealed three possible drug candidates. Abbott had not offered these candidates for sale, but had submitted information to the FDA.<sup>38</sup>

In the face of a PSN's infringement allegation, Abbott argued that the use of the patented SIP2 receptor was included under § 271(e)(1), and turned to *Merck* for support. The district court disagreed and stated that *Merck* stands for the proposition that an alleged infringer may still be protected under § 271(e)(1), even if the alleged infringer fails to submit data to the FDA.<sup>39</sup> However, the court stated that *Merck* does not support the broad principle that "any use of a patented invention to gather information to submit to the FDA is protected."<sup>40</sup> The court noted that "*Proveris* excluded research tools from the purview of the safe harbor exemption."<sup>41</sup> Furthermore, the court looked to the legislative history of the Hatch-Waxman Act, which stated that the "only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute."<sup>42</sup> The court concluded that Abbott was not protected because it was infringing the patented SIP2 receptors to develop its own patented product, as opposed to seeking FDA approval of a generic receptor to enter into the marketplace.<sup>43</sup> The court noted that the holding in *Proveris* forbids this kind of activity from exemption, and that the SIP2 receptors were not considered "patented inventions" under § 271(e)(1) as they did not require regulatory approval.<sup>44</sup>

### **Post Approval Activities May be Exempt under § 271(e)(1)**

Since *Merck*, the Federal Circuit has twice considered and reached differing conclusions regarding whether post-FDA approval activities involving patented methods for testing approved compounds are exempt activities under § 271(e)(1). In *Classen Immunotherapies, Inc. v. Biogen IDEC*, the Federal Circuit held that the § 271(e)(1) safe harbor does not apply to infringing activities that generate information "routinely reported to the FDA, long after marketing approval has been obtained."<sup>45</sup> Here, Biogen and GlaxoSmithKline utilized Classen's patented invention to conduct risk assessment studies for childhood vaccines. Classen argued that, by participating in these studies, Biogen and GlaxoSmithKline directly infringed its patent for methods of immunization.<sup>46</sup>

Biogen argued that reporting vaccine relationships and recommendations are actions in conformity with FDA regulations, and should therefore fall under the safe harbor of § 271(e)(1).<sup>47</sup> The Federal Circuit, however, did not agree and found that Biogen's interpretation was beyond the statutory purpose of § 271(e)(1) because information on vaccine relationships post-approval does not relate to the submission of information for the purpose of obtaining FDA approval of a generic drug.<sup>48</sup> The Federal Circuit agreed with Classen, noting that "[e]xtensive precedent recites the purpose of § 271(e)(1) to facilitate market entry upon patent expiration."<sup>49</sup>

In *Momenta Pharma., Inc. v. Amphastar Pharma., Inc.*, the Federal Circuit held, contrary to its earlier opinion in *Classen*, that post-approval studies can fall within the safe harbor of § 271(e)(1).<sup>50</sup> Momenta was the licensee of a patent relating to "methods for analyzing heterogeneous

populations of sulfated polysaccharides," such as enoxaparin. Amphastar was the first to submit an ANDA for generic enoxaparin, but Momenta's ANDA was approved first.<sup>51</sup> Once Amphastar was approved, Momenta sued Amphastar for patent infringement when Amphastar tested its commercial batches of generic product using Momenta's test methods.

In response to Momenta's allegations, Amphastar argued that its quality control testing of each commercial batch of enoxaparin fell within the scope of § 271(e)(1).<sup>52</sup> Momenta, on the other hand, maintained that § 271(e)(1) does not apply to information routinely reported to the FDA during post-market approval, according to the Federal Circuit's holding in *Classen*.<sup>53</sup>

In determining whether Amphastar's quality control test submissions fell within the safe harbor, the Federal Circuit distinguished this case from the facts of *Classen* by noting that, in *Classen*, the studies submitted to the FDA were not required by the FDA for the continued approval of the ANDA.<sup>54</sup> Unlike the information submitted in *Classen*, the data Amphastar submitted to the FDA were not "routine submissions," rather these submissions were required in order to maintain FDA approval.<sup>55</sup> The Federal Circuit also noted that Amphastar was legally required under FDA requirements to submit the quality control data, whereas in *Classen*, the information submitted was largely for non-FDA purposes.<sup>56</sup>

Additionally, in response to Momenta's argument that there were other quality control testing methods available to Amphastar, making Amphastar's use of the patented method not required by the FDA, the Federal Circuit stated that the Act "does not mandate the use of a

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noninfringing alternative when one exists.”<sup>57</sup>

The Supreme Court recently refused to review the Federal Circuit’s opinion in *Classen v. Biogen IDEC*.<sup>58</sup> Therefore, the Federal Circuit’s differentiation of “routine submissions” from those “required” to be submitted to the FDA will be the central tenant for post-approval submissions.

## Summary

While factually intensive, the foregoing cases offer some guidance about the use of research tools and post-approval submissions to the FDA. *Merck* suggests that using a patented compound in research that will be submitted to the FDA is exempt activity, even if the compound is not the product for which approval is sought. Caution is advised, however, since the district court in *Abbott* found that the use of a patent receptor in the search for potential therapeutics that bind the receptor is not a safe harbor activity. The district court in *Abbott* distinguished *Merck* and followed the Federal Circuit’s precedent in *Proveris* that holds that the safe harbor does not cover using a patented device in research, even if the results of the research will be submitted to the FDA. Finally, the Federal Circuit provided guidance through its *Classen* and *Momenta* opinions that post-approval activities are protected under the safe harbor as long as those activities are required by the FDA.

## Endnotes

1 35 U.S.C. § 271(e)(1) (2006).

2 21 U.S.C. § 355(j) (2006).

3 545 U.S. 193 (2005).

4 *Id.* at 205 n.7.

5 *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, No. 11-1078, 2013 WL 141405 (U.S. Jan. 14, 2013).

6 35 U.S.C. § 271(e)(1).

7 *Id.*

8 See *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 673-74 (1990).

9 See, e.g., *Merck*, 545 U.S. at 202 n.6 (interpreting the statutory language of § 271(e)(1) broadly without regard to the meaning of the term “solely” in the statute).

10 *Id.* at 200.

11 *Id.* at 197, 200.

12 *Id.* at 200.

13 See *Integra LifeSciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 867-68 (Fed. Cir. 2003).

14 See *id.* at 872.

15 *Merck*, 545 U.S. at 207-08.

16 *Id.* at 205 n.7.

17 See *Classen Immunotherapies, Inc. v. King Pharms., Inc.*, 466 F.Supp.2d 621 (N.D. Md. 2006).

18 *Proveris Scientific Corp. v. InnovaSystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008); *PSN Illinois, LLC v. Abbott Labs*, No. 09cv5879, 2011 U.S. Dist. LEXIS 108055 (N.D. Ill. Sept. 20, 2011).

19 466 F.Supp.2d at 623.

20 *Id.*

21 *Id.* at 624.

22 *Id.*

23 *Id.*

24 *Id.*

25 *Id.* at 624-25.

26 *Id.* at 625.

27 *Id.* at n.2. (internal citations omitted).

28 *Proveris*, 536 F.3d at 1258.

29 *Id.*

30 *Id.* at 1259.

31 *Id.* at 1260.

32 *Id.* at 1261.

33 *Id.* at 1265.

34 *Id.*

35 *PSN Illinois*, 2011 U.S. Dist. LEXIS 108055, at \*18.

36 *Id.* at \*3.

37 *Id.*

38 *Id.* at \*6.

39 *Id.* at \*17-18.

40 *Id.* at \*18 (emphasis in original).

41 *Id.* at \*14.

42 *Id.* at \*15 (quoting H.R. Rep. No. 98-857, pt.2, at 8 (1984)).

43 *Id.* at \*18.

44 *Id.*

45 659 F.3d 1057, 1070 (Fed. Cir. 2011).

46 *Id.*

47 *Id.*

48 *Id.*

49 *Id.* at 1072.

50 686 F.3d 1348, 1359 (Fed. Cir. 2012).

51 *Id.* at 1351.

52 *Id.* at 1353.

53 *Id.*

54 *Id.* at 1358.

55 *Id.*

56 *Id.*

57 *Id.* at 1359.

58 *GlaxoSmithKline*, 2013 WL 141405.

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# If I Prioritize Examination of My Application, Should the Patent Office?

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Applications under the US Patent and Trademark Office's (USPTO) prioritized examination program are given "special status" and examined out-of-turn until a final disposition is reached.<sup>1</sup> This program has considerably reduced delay incurred during prosecution for such applications. Notably, the average application pendency remains about 32 months.<sup>2</sup> In this context, the stated goal to achieve final disposition within 12 months for prioritized examination applications initially seemed ambitious, but so far the USPTO has considerably over-performed even that benchmark. Applications under prioritized examination have reached final disposition in an average of 5.4 months after special status is granted.<sup>3</sup>

This article reviews the requirements for requesting prioritized examination, discusses whether to request prioritized examination, and considers strategies for using prioritized examination effectively.

## What is Prioritized Examination?

Prioritized examination is available both for newly filed, original or continuing applications, and for applications in which a request for continued examination (RCE) was previously or will be filed. The procedures for newly filed applications, also referred to as Track 1, were officially put into place on September 26, 2011 pursuant to the Leahy-Smith America Invents Act.<sup>4</sup> The program was then extended to provide procedures for requesting prioritized examination of an application with a previously or concurrently filed RCE, referred to as PE-RCE, on December 19, 2011.<sup>5</sup> In general, prioritized examination under either program considerably mitigates prosecution delay.

## Requirements for Prioritized Examination

Applications are granted prioritized examination special status upon filing a request and paying additional fees. For Track 1 applications: the request must be made at the time of application filing,<sup>6</sup> the application must be filed via the USPTO's electronic filing system (EFS),<sup>7</sup> must be "complete" at time of filing,<sup>8</sup> must comply with prioritized examination claim requirements,<sup>9</sup> and must include the fees summarized below.<sup>10</sup> An information disclosure statement (IDS) is not required at the time of filing, but should be filed promptly in view of the short pendency to a first action on the merits for prioritized examination applications.

Prioritized PE-RCE requests can be made in an application with a previously filed RCE, or can be made concurrently with an RCE.<sup>11</sup> The rules for PE-RCE requests do not specify that the application must be complete at the time of making the request, but we encourage any application with an unsigned declaration to be filed alongside a petition under 37 C.F.R. § 1.47, if such a petition was not previously filed.<sup>12</sup>

When requesting prioritized examination, applicants are required to pay a prioritized examination fee of \$4800 (\$2400 for a small entity) and a processing fee of \$130.<sup>13</sup> In addition, applicants must pay all fees that would ordinarily be due and pre-pay the \$300 publication fee. However, the publication fee will be refunded if the applicant requests non-publication and then submits a request for refund.<sup>14</sup> Failure to include any of the required fees with a request will be grounds for denying the request, and so applicants should strongly consider including an authorization to charge any additional required fees with their request.<sup>15</sup>

If the requirements and conditions have been met, and the appropriate fees have been paid, the USPTO will grant the request for prioritized examination. Otherwise, the USPTO may dismiss the request, in which case, the prioritized examination fee will be refunded automatically.<sup>16</sup> However, the processing fee is retained to cover the cost of processing the request. In accordance with 37 C.F.R. § 1.26, the application fees, including the basic filing fee, search fee, examination fee, and any required application size or excess claim fees cannot be refunded, unless paid by mistake.<sup>17</sup>

## Your Request Is "GRANTED," Now What?

A granted request places the application on the Examiner's special docket until final disposition is reached.<sup>18</sup> However, "special status" will be terminated during the course of prosecution if certain triggers occur. Upon termination of special status, the application is placed on the Examiner's regular docket in accordance with its stage of prosecution.<sup>19</sup> The triggers to avoid during prosecution to prevent termination of the applications "special status" are summarized below.

Special status is terminated upon the USPTO mailing: a notice of incomplete application; a notice to file missing parts; a notice to file corrected application papers; a notice of omitted items; or a notice of informal application.

Special status is terminated upon an applicant filing: a petition for an extension of time to file a reply; a request for a suspension of action; an amendment that results in more than 4 independent claims, more than 30 total claims, or any multiple dependent claims; an RCE following

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a notice of final rejection; or a notice of appeal.

Accordingly, applicants should take care to respond to office actions within the shortened statutory period for response without taking an extension of time (prioritized examination provides for typical 3-month time periods for filing replies to office actions<sup>20</sup>). In addition, applicants should take care when preparing amendments to remain within the limited number of pending claims. The same caution applies to preliminary or voluntary amendments, which are permissible under the prioritized examination program.<sup>21</sup>

## Tips on Effective Prosecution of Prioritized Examination Cases from MBHB's Experience

Applicants should consider conducting an examiner interview to build rapport with the Examiner. MBHB professionals' experience reflects an increase in Examiner cooperation in expedited applications, at least in some cases. While there is surely variability among Examiners, experience suggests that at least some Examiners treat applications on their special docket with an increased willingness to find allowable subject matter.<sup>22</sup> We note, however, that the effect is largely Examiner-dependent, and contrary examples can be found.<sup>23</sup>

Applicants may consider an amendment that violates the claim limitations of the prioritized examination program if it puts the application in condition for allowance. For example, an amendment that casts dependent claims identified as allowable in independent form, or that adds new dependent claims to allowable independent claims may be considered. Even if the amendment causes prioritized examination to be terminated, the application will

still be acted on relatively quickly if the amendments put the application in condition for allowance.<sup>24</sup> This may be particularly attractive in a response to a final office action, because such an action terminates prioritized examination anyway.

## Strategic Concerns When Deciding Whether to Pursue Prioritized Examination

Requesting Track 1 and/or PE-RCE will naturally depend on the particular goals and interests of individual applicants. In simplest terms, applicants should pursue expedited examination for applications in which they desire fast prosecution.

An early indication of patentability and/or allowability may be useful for applications directed to rapidly developing technologies. Expedited examination may allow for enforceable rights to mature sooner rather than later, which is particularly desirable if the industry is developing rapidly enough that within 12 months an applicant's competitors will foreseeably be engaging in potentially infringing activity.

The early feedback afforded by prioritized examination may also help applicants determine whether and where to pursue additional protection (a prioritized examination allows for US prosecution to be completed within the 12-month window in which foreign filing determinations must be made). For example, the outcome of prioritized examination may help applicants gauge the allowability and/or patentability of their application before pursuing protection in other jurisdictions, or perhaps before deciding to abandon their application and preserve their invention as a trade secret. If the trade secret approach is desired, a non-publication request must be included at the time of filing.

Prioritized examination may also serve as an early indication of allowable subject matter and a chance to build rapport with the Examiner for an application with additional current or anticipated family members. Applicants may also consider filing a continuation or divisional under the prioritized examination procedure upon receiving a restriction requirement or an office action. The prioritized application will quickly catch up to the original, and both applications can be prosecuted in parallel, likely before the same Examiner. This may be preferable to waiting to prosecute the continuation before a new Examiner, particularly if a good relationship is already established with the current Examiner.

In addition to increased filing fees, applicants utilizing prioritized examination will incur the expenses of patent prosecution much sooner and in an expedited manner than if the application were prosecuted under a typical track. For applicants concerned about conserving resources while the market for their technology develops, prioritized examination may not be a good option. Although, learning that an application is unlikely to receive favorable treatment may persuade applicants to pursue protection in fewer jurisdictions, and thereby reduce total expenses.

The USPTO currently limits the number of Track 1 and PE-RCE cases to 10,000 per fiscal year.<sup>25</sup> Requests for prioritized examination submitted early in the fiscal year, which begins October 1, are therefore more likely to be granted.<sup>26</sup> Applicants may want to check the number of requests already received before filing a request late in the fiscal year.<sup>27</sup>

**But, is Prioritized Examination Really the Best Way to Expedite Prosecution?** Prioritized examination can effectively

expedite examination of a new or pending application. The request can be efficiently prepared, and so far the USPTO has been processing these applications faster than advertised.<sup>28</sup> However, it is worthwhile to consider available alternatives to expedite examination, particularly those that require less official fees. For example, special status is given to applications with an inventor over age 65 upon filing a simple form-based petition with no separate fee required.<sup>29</sup> Applications may also be expedited upon a petition showing the relevancy of the application to particular technology areas deemed to have national importance,<sup>30</sup> or where the claimed technology is subject to a competitor's prospective manufacture or actual infringement.<sup>31</sup> For eligible applications, the patent prosecution highway program can expedite examination.<sup>32</sup> The accelerated examination program also allows for expedited examination, but requires preparing and filing a pre-examination search statement and examination support document.<sup>33</sup>

Even though the official fees are generally much less for the alternative means of expediting examination noted above, savvy applicants should carefully consider both the full costs associated with preparation and the potential for undesirable estoppel effects. In other words, some applicants may elect to simply pay the prioritized examination fee rather than pursue an alternative petition that requires assertions in their patent prosecution history on the applicability of their technology to particular technology areas, the existence of actual infringement, etc.<sup>34</sup> Moreover, the strategic costs associated with expediting alternatives are reinforced when combined with the generally higher preparation expenses required for such petitions.<sup>35</sup>

## Conclusion

The prioritized examination program offers a path to expediting examination that is as simple as a form-based request and some extra fees. Applicants interested in expediting prosecution should weigh the official fees for prioritized examination against the full costs for any available alternatives. Individual determinations will naturally turn on an analysis of those concerns, but we believe that most applicants are well served by electing to request prioritized examination even where alternative methods of expedited examination are available.

## Endnotes

- 1 See Changes to Implement the Prioritized Examination Track (Track I) of the Enhanced Examination Timing Control Procedures under Leahy-Smith America Invents Act, 76 Fed. Reg. 59050-55, (Sept. 23, 2011) [hereinafter Track 1]; see also 37 C.F.R. § 1.102(e) (2012).
- 2 USPTO, Data Visualization Center: Your Window to the USPTO, <http://www.uspto.gov/dashboards/patents/main.dashxml> (last visited Jan. 17, 2013) [hereinafter Patents Dashboard].
- 3 *Id.* at Track One-Related Measures.
- 4 Pub. L. No. 112-29, §11(h) (to be codified at 35 U.S.C. § 41); see also Track 1, *supra* note 1.
- 5 Changes to Implement the Prioritized Examination for Requests for Continued Examination, 76 Fed. Reg. 78566-69, (Dec.19,2011) [hereinafter PE-RCE].Track 1 procedures will apply to any newly filed application filed on or after September 26, 2011, and PE-RCE procedures will apply to any application in which a proper RCE has been filed before, on, or after December 19, 2011.
- 6 Form PTO/SB/424 is strongly recommended. While not required, the USPTO cautions that not using the form may result in a failure to recognize an otherwise proper request. USPTO, USPTO's Prioritized Examination Program

FAQs, Question PE3, [http://www.uspto.gov/patents/init\\_events/track1\\_FAQS.jsp](http://www.uspto.gov/patents/init_events/track1_FAQS.jsp) (last visited Jan. 17, 2013) [hereinafter FAQs].

- 7 However, requests for prioritized examination in a plant application must be filed in paper. Track 1, *supra* note 1, at 59052; PE-RCE, *supra* note 5, at 78567.
- 8 A complete application must include: (1) specification; (2) oath or declaration; (3) drawings, when necessary; and (4) all fees, including: filing fee, search fee, examination fee, and, if applicable, excess claims and application size fees. See 37 C.F.R. § 1.51(b).
- 9 A prioritized examination application can include: no more than 4 independent claims, no more than 30 total claims, and no multiple-dependent claims. Track 1, *supra* note 1, at 59052; PE-RCE, *supra* note 5, at 78567.
- 10 M.P.E.P. 708.02(b); see also Accelerated Examination v. Prioritized Examination, Snippets v. 10, issue 1, Winter 2012, available at <http://www.mhbb.com/files/FirmService/ec735e40-7528-4e97-8998-5adaf51db15f/Presentation/ceSnippetIssue/Snippets%20Vol%2010%20Issue%201-030712-FINAL.pdf> [hereinafter AE v. PE].
- 11 For PE-RCE, a request must be filed by EFS, claims must comply with prioritized examination requirements, an RCE must have been previously or concurrently filed, and all fees must be paid. M.P.E.P. 708.02(b); see also AE v. PE, *supra* note 10.
- 12 We are mindful that some applications may reach a late stage of prosecution before having a signed oath/declaration on file in view of the new rules that allow an oath/declaration to be filed at any time prior to issuance. See Changes to Implement the Inventor's Oath or Declaration Provisions of the Leahy-Smith America Invents Act, 77 Fed. Reg. 48776-825 (Aug. 14, 2012).
- 13 FAQs, *supra* note 6, Questions PE-TI3, PE-RCE5.
- 14 *Id.*, Question PE-TI12.
- 15 *Id.*, Question PE-TI3.
- 16 *Id.*, Questions PE-TI15 and PE-RCE12.

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# If I Prioritize Examination of My Application, Should the Patent Office?

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17 For abandoned applications, an applicant may, however, request a refund of the search fee and any excess claims fees by filing a petition for express abandonment of the application in accordance with 37 C.F.R. § 1.138(d). Furthermore, an applicant may request a refund of the publication fee in accordance with MPEP 1126 if the application is not published under 35 U.S.C. § 122(b).

18 Final disposition includes the following: mailing a notice of allowance; mailing of a final office action; filing a notice of appeal; completion of examination as defined in 37 C.F.R. § 41.102; filing a RCE; and abandonment of the application. M.P.E.P. 708.02(b), heading II. An application reverts to regular status at final disposition. So, special status is not retained during appeal, for example.

19 For example, an application that receives a first office action and that is thereafter amended to include 5 independent claims is placed on the Examiner's regular docket for applications having one office action. See Track 1, *supra* note 1, at 59051; PE-RCE, *supra* note 6, at 78566.

20 M.P.E.P. 708.02(b), heading II.

21 Track 1, *supra* note 1, at 59051; PE-RCE, *supra* note 6, at 78567.

22 Perhaps this effect is due to Examiners' increased motivation to find allowable subject matter to resolve the case or an increased respect for the subject applications when applicants are willing to pursue expedited examination. It is also possible that increased Examiner cooperation results from a cross-pollination of the accelerated examination procedures, which are commonly referred to together with the prioritized examination procedures by the USPTO. Whatever the reason, statistics from the USPTO suggest that prioritized examination applications receive, on average, less office actions than average during prosecution. The statistics show that typical applications receive an average of 2.54 office actions and spend 7.1 months during prosecution pendency waiting on a response from an applicant, which roughly corresponds to typical 3 month response times. The USPTO does not separately report the number of office

actions in prioritized examination cases, but does show that prioritized examination applications spend an average 3.5 months during prosecution pendency waiting on an applicant response, less than half the amount for a non-prioritized application. See Patent Dashboard, *supra* note 2, Office Time and Applicant Time – Traditional Total Pendency; Average Actions Per Disposal.

23 We have observed that one way the USPTO facilitates the expedited processing of prioritized examination cases is by assigning those applications to its most astute and experienced Examiners, which, of course, can go either direction in terms of Examiner cooperation.

24 See M.P.E.P. 708.01, heading (G).

25 In fiscal years 2011 and 2012 the number of requests did not come close to the cap; in those years the USPTO received 855 and 5027 requests, respectively. So far in FY2013, which began October 1, 2012, the USPTO has received 1327 requests as of December 20, 2012. At this rate, the USPTO will receive fewer than 6,000 requests in FY2013. The USPTO has also indicated the 10,000 limit may be reevaluated. Track 1, *supra* note 1, at 59052.

26 The USPTO also claims that the ability to request prioritized examination will be automatically deactivated in EFS once the limit is reached. FAQs, *supra* note 9, Question PE4.

27 USPTO, USPTO's Prioritized Patent Examination Program, [http://www.uspto.gov/patents/init\\_events/Track\\_One.jsp](http://www.uspto.gov/patents/init_events/Track_One.jsp) (last visited Jan. 15, 2013).

28 Patents Dashboard, *supra* note 2.

29 See 37 CFR 1.102(c)(1) and MPEP 708.02 (IV).

30 Technology areas include environmental quality, energy, recombinant DNA, superconductivity, counter-terrorism, and treatments for HIV/AIDS or cancer. A list of the technology areas and a discussion of the requirements for such petitions can be found in M.P.E.P. 708.02.

31 M.P.E.P. 708.02.

32 Applications with a corresponding case that received an indication that at least one claim is patentable may be eligible

for the PPH program. See USPTO, Patent Prosecution Highway (PPH) – Fast Track Examination of Applications, [http://www.uspto.gov/patents/init\\_events/pph/index.jsp](http://www.uspto.gov/patents/init_events/pph/index.jsp) (last visited Jan. 22, 2013).

33 The requirements for filing an accelerated examination application can be found at M.P.E.P. 708.02(a). A more thorough comparison of prioritized examination and accelerated examination has also previously appeared in these pages. See *AE v. PE*, *supra* note 10.

34 A notable exception would be petitions to expedite on the basis of inventor's age or health. These petitions would rarely, if ever, implicate estoppel concerns.

35 For a detailed comparison of means to expedite examination, including a cost comparison, see Dennis Crouch and Jason Rantanen, *Expediting Prosecution: Comparing Track 1 Prioritized Examination, Patently-O*, Dec. 27, 2012, <http://www.patentlyo.com/patent/2012/12/expediting-prosecution.html>. (Last visited Jan. 15, 2013).

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# InterDigital Communications v. ITC: (Some) Non-Practicing Entities are Welcome

**By Alison Baldwin and Jordan Pringle**

On January 10, 2013, the Federal Circuit in *InterDigital Communications v. ITC* denied a combined petition for panel rehearing and for rehearing en banc, holding that InterDigital's patent licensing alone met the domestic industry requirement of § 337 of the Tariff Act of 1930, 19 U.S.C. §§ 1337(a)(2) and 1337 (a)(3).<sup>1</sup> On its face, this decision seems to open the floodgates for non-practicing entities (NPEs) to file lawsuits in the International Trade Commission (ITC). However, a close reading of the Court's opinion and the legislative history of § 337 indicates that this is not the case.

## ***InterDigital v. ITC***

To initiate a proceeding before the ITC, the patent owner must establish the existence of a domestic industry "relating to the articles protected by the patent..."<sup>2</sup> Evidence of domestic industry may be satisfied by (A) significant investment in plant and equipment; (B) significant employment of labor or capital; or (C) substantial investment in its exploitation, including engineering, research and development, or licensing.<sup>3</sup> The issue before the Federal Circuit was whether InterDigital's licensing activities fell within the scope of § 337(a)(3)(C).

Nokia argued that the ITC and the Federal Circuit panel misconstrued the statutory language "relating to the articles protected by the patent" in § 337(a)(2) and "with respect to the articles protected by the patent" in § 337(a)(3).<sup>4</sup> Nokia contended that this statutory language meant that the only licensing activity that matters, for purposes of establishing domestic industry, is activity "with respect to the articles protected by the patent." Nokia further argued that this licensing activity must be tethered to a tangible good and

that the technology covered by the patent must be put into practical use.<sup>5</sup>

The Federal Circuit panel, in its August 1, 2012 opinion,<sup>6</sup> ruled 2-1 against Nokia, explaining that the 1988 amendment to § 337 allowed InterDigital's domestic licensing activities to give the company standing to file a complaint with the ITC.<sup>7</sup> The Court held that it is not necessary that the party manufacture the product that is protected by the patent, nor is it necessary that any other domestic party manufacture the protected article.<sup>8</sup> As long as the patent covers the article that is the subject of the exclusion proceeding and as long as the party seeking relief can show that it has a sufficiently substantial investment in the exploitation of the intellectual property to satisfy the domestic industry requirement of the statute, that party is entitled to seek relief under section 337.<sup>9</sup>

## **"Substantial Investment" Requirement**

The key phrase in the Federal Circuit's analysis of § 337(a)(3)(C) is "substantial investment."<sup>10</sup> In this case, InterDigital invested a total of approximately \$7.6 million in salaries and benefits for employees engaged in its licensing activities, had 24 revenue producing licensees, and received almost \$1 billion in revenues from portfolio licenses (including the patents in suit). This clearly showed a "substantial investment." However, this begs the question: where is the line for "substantial investment" drawn?

Unsurprisingly, the answer is not a bright-line rule. In performing the "substantial investment" analysis, the ITC has adopted a flexible approach. The type of efforts that are considered a "substantial investment" under § 337(a)(3)(C) will vary depending on the nature of the industry and the resources of the complainant.<sup>11</sup> Some factors that might be relevant in determining whether

or not a complainant's investment is substantial are (1) the existence of other types of "exploitation" of the asserted patent such as research, development, or engineering, (2) the existence of license-related ancillary activities such as ensuring compliance with license agreements and providing training or technical support to its licensees, (3) whether complainant's licensing activities are continuing, and (4) whether complainant's licensing activities are those that are referenced favorably in the legislative history of §337(a)(3)(C).<sup>12</sup>

## **Does this Decision Open the Floodgates for NPEs?**

If substantial investment in licensing meets the domestic industry requirement, has the Federal Circuit opened the floodgates for NPEs to obtain relief at the ITC? While there is no commonly held definition of an NPE, the ITC has attempted to separate NPEs into two categories.<sup>13</sup>

### *Category 1 NPE:*

- Manufacturers whose products do not practice the asserted patent
- Inventors who may have done research and development, but do not make a product covered by the asserted patents
- Research institutions, such as universities and laboratories
- Start-ups that possess IP rights but do not yet manufacture a product that practices the patent

### *Category 2 NPE:*

- Companies whose business model primarily focuses on purchasing and asserting patents

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# InterDigital Communications v. ITC: (Some) Non-Practicing Entities are Welcome

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The Federal Circuit's decision in *InterDigital v. ITC* centered on Congress' intent to make relief in the ITC available only to Category 1 NPEs.

Prior to 1988, § 337 of the Tariff Act of 1930 required proof of the existence (or prospect) of a domestic industry manufacturing the articles protected by intellectual property before the ITC could bar the import of infringing products.<sup>14</sup> Objections were raised that § 337 "did not provide protection for innovators who did not actually produce goods in this country, but who were injured by the importation of goods that incorporated the technology that they had invented or sought to license."<sup>15</sup> Congress proposed to expand the coverage of § 337 to protect American industries "that did not manufacture products but were engaged in engineering, research and development, or licensing of the technology that others used to make products."<sup>16</sup> Those proposals resulted in the current language of § 337(a)(3)(C), which makes relief in the ITC available to a patent owner despite not actually producing goods relating to the patent, provided there has been a "substantial investment in its exploitation, including engineering, research and development, or licensing."<sup>17</sup>

Congress' intent to open up the ITC to the Category 1 NPEs listed above is specifically reflected in the comments of Representative Kastenmeir who noted that the change to § 337 will "enable universities and small businesses who do not have the capital to actually make the good in the United States to still have access to the ITC forum for the protection of their rights."<sup>18</sup> In contrast, Congress specifically drafted the current language of § 337(a)(3)(C) to avoid the use of the ITC by "foreign patent holders" to exclude foreign or American competitors

from obtaining access to the U.S. market.<sup>19</sup> Only those foreign patent holders who had made a substantial investment in facilities or activities including research and development, licensing, sales, and marketing would fall within the scope of the statute.<sup>20</sup> While the legislative history does not directly mention the Category 2 NPEs listed above, an analogy can be drawn between those Category 2 NPEs and the "foreign patent holders" specifically excluded from § 337(a)(3)(C). This analogy is reflected in the ITC's application of § 337(a)(3)(C).

snippets.

On its face, this decision seems to open the floodgates for non-practicing entities (NPEs) to file lawsuits in the International Trade Commission (ITC). However, a close reading of the Court's opinion and the legislative history of §337 indicates that this is not the case.

The ITC has held that revenue-driven licensing activities should be given less weight in the "substantial investment" analysis than production-driven licensing activities.<sup>21</sup> The ITC defined production-

driven licensing activity as activity "which encourages adoption and use of the patented technology to create new products and/or industries,"<sup>22</sup> and revenue-driven licensing activity as activity "which takes advantage of the patent right solely to derive revenue by targeting existing production."<sup>23</sup> This is known as the "production/revenue dichotomy."

The "production/revenue dichotomy" weighs against Category 2 NPEs. The business model of Category 2 NPEs suggests that the entity will typically assert patents against existing industry and products.<sup>24</sup> This is especially so at the ITC, given that the ITC cannot award money damages directly.<sup>25</sup> At the ITC, a Category 2 NPE's best chance to recoup their investment in the lawsuit would be to target mature products with which the respondents have the most to lose, and then extract settlement payment with the imminent threat of an exclusion order.<sup>26</sup> The ITC's "production/revenue dichotomy" will continue to have a deterrent effect on such rent-seeking activities.<sup>27</sup>

## Conclusion

For Category 1 NPEs, like *InterDigital*, the Federal Circuit's decision has affirmed that the ITC is an open and available forum. For Category 2 NPEs, the Court has firmly held the door shut.

## Endnotes

- 1 *InterDigital Commc'n., LLC v. Int'l Trade Comm'n.*, No. 2010-1093, 2013 WL 124064 (Fed. Cir. Jan, 10, 2013).
- 2 19 U.S.C. § 1337(a)(2).
- 3 19 U.S.C. § 1337(a)(3).
- 4 *InterDigital Commc'n., LLC*, 2013 WL 124064, at \*3.
- 5 *Id.*
- 6 *InterDigital Commc'n., LLC v. Int'l Trade Comm'n.*, 690 F.3d 1318 (Fed. Cir. 2012).

- 7 *InterDigital Commc'n., LLC*, 2013 WL 124064, at \*6.
- 8 *Id.*
- 9 *Id.*
- 10 *Id.* at \*2.
- 11 *Certain Multimedia Display and Navigation Devices and Systems, Components Thereof, and Products Containing Same ("Multimedia Display and Navigation Devices")*, Inv. No. 337-TA-694, USITC Pub.4292, Comm'n Op., at 15(Nov. 2011).
- 12 *Id.* at 16.
- 13 FACTS AND TRENDS REGARDING USITC SECTION 337 INVESTIGATIONS 2 (2012), available at [http://www.usitc.gov/press\\_room/documents/featured\\_news/337facts.pdf](http://www.usitc.gov/press_room/documents/featured_news/337facts.pdf).
- 14 See, e.g., *Certain Miniature, Battery-Operated, All-Terrain, Wheeled Vehicles*, Inv.No. 337-TA-122, USITC Pub. 1300 (Oct. 1982), *aff'd*, *Schaper Mfg. Co. v. U.S. Int'l Trade Comm'n*, 717 F.2d 1368 (Fed. Cir. 1983).
- 15 *InterDigital Commc'n., LLC*, 2013 WL 124064, at \*3.
- 16 *Id.*
- 17 19 U.S.C. § 1337(a)(3)(C).
- 18 *InterDigital Commc'n., LLC*, 2013 WL 124064, at \*4.
- 19 *Id.*
- 20 *Id.*
- 21 *Multimedia Display and Navigation Devices* at 25.
- 22 *Id.* at 25 n.20.
- 23 *Id.*
- 24 *Wei Wang, Non-Practicing Complainants at the ITC: Domestic Industry or Not?*, 27 *BERKELEY TECH. L.J.* 409, 439 (2012).
- 25 *Id.*
- 26 *Id.*
- 27 *Id.*

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## MBHB to Exhibit at 2013 BIO International Convention in Chicago

April 22-25, 2013

McDonnell Boehnen Hulbert & Berghoff LLP will be participating as an exhibitor at the 2013 BIO International Convention ("BIO") set for April 22-25 in Chicago. We invite you to visit us at Booth #3684 in the exhibit hall to meet our attorneys, learn more about our services and enter our raffle. Billed as the largest global event for the biotechnology industry, 2013 BIO is organized by the Biotechnology Industry Organization. The organization represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products.

2013 BIO covers the wide spectrum of life science innovations and application areas. Drug discovery, biomanufacturing, genomics, biofuels, nanotechnology, and cell therapy are just a few of the industries represented at the BIO International Convention. More than 15,000 leaders from over 65 countries are expected to attend 2013 BIO. The key elements of the event are education, networking, partnering and the 1,800 companies showcasing the latest technologies, products and services in the BIO Exhibition. View complete details at <http://convention.bio.org/>.



# Conducting Efficient Patent Litigation Discovery, Part 2

**By Kurt Rohde**

The costs associated with discovery, and particularly electronic document discovery, in patent litigation can be effectively controlled with upfront planning, preparation, and coordination between in-house and outside counsel. Presented in this second part of a two-part article are some practical considerations for conducting efficient document collection and review. In the first part of this article, published in the Fall 2012 issue of *snippets*, early collection activities and agreements with opposing counsel were discussed. In this second part, developing and implementing a collection plan and reviewing documents will be discussed.

## **Developing and Implementing a Collection Plan**

Once you have accomplished your pre-collection activities and made a start at reaching stipulation agreements with opposing counsel, as discussed in the first part of this article, it is time to develop a collection scheme. By focusing on a few key items early, the collection can be as efficient as possible and you may avoid having to retrace steps later down the road. Defining the “who,” “where,” and “what” of collection can keep everyone on the same page and set a clear path, preventing inefficient expenditure of labor and electronic resources.

### *Who?*

It is important to maintain a “living” list of document custodians from whom collection is required, not required, and/or completed. An excellent source of initial custodian names is a litigation hold memo. Additional names of potential custodians may be discovered during employee interviews and initial document review. The list of document custodians should identify the full names, current titles, and

geographic location (if there are multiple corporate locations) of each custodian.

If possible, consider conducting an interview with each key person on the list. If you are outside counsel, ask in-house counsel to join you in the interview and to explain why you are contacting the interviewee and why it is important to the company. Explain the litigation in general terms, as well as a summary of the document requests. Ask the interviewee whether they might have responsive documents, where they store such documents (whether in hardcopy and/or electronic format), who else might have responsive documents, and if there is anyone else you should talk to regarding the subject matter of the litigation. Ask if the interviewee ever takes documents home. It's better to get them to think about such things at the start of discovery, rather than the day before their deposition preparation.

Take copious notes during each interview and save those notes at least until discovery is complete. As new information is discovered during document review, you may want to revisit (or rule out) certain custodians for repeat interviews based on that later-discovered information.

Also, as early as practical, develop a list of all current and former attorneys that worked on documents (such as prosecution dockets or agreements) you might be collecting. This will be extremely important during the earliest document review sessions when the reviewers are trying to identify privileged communications.

Finally, determine who will collect hardcopy documents and electronic documents. Will it be outside attorneys, in-house counsel, IT staff, dedicated in-house e-discovery staff, or an outside service? Try to obtain contact information for all involved personnel

and arrange planning meetings between outside counsel, in-house counsel, and the collecting persons to identify what is important during collection (e.g., retained metadata, custodian data, physical location data, etc.).

### *Where?*

It is useful to develop a standardized nomenclature for collection locations. This consistent nomenclature can be used during all collection efforts and later during review efforts. For example, if a highly responsive group of documents are identified during review, it may be necessary to revisit their source location later to determine whether additional documents are present. Collection locations can be geo-physical locations (e.g., “Archive Center”) or virtual locations (e.g., Network Server\Project Share Drive).

It is also advisable to determine the existence and operational capabilities of any internal or external archiving system. Are old documents stored in boxes in a warehouse? Is there a paper or electronic subject matter index? Is there an archive database system that can be searched with keywords or personnel names or project names? Similarly, through custodian interviews and/or discussions with IT staff, you should determine whether there are network shares or other electronic repositories that are dedicated to particular projects or individuals. These can be a rich resource for targeted document collections.

Further, try to develop a working knowledge of how the electronic collection scheme will work. For instance, it may be useful to know whether collecting personnel will need to remove a custodian's laptop for a period of time, or if the hard drive can be cloned through the network. This is a common question during employee



interviews. It is also beneficial to know details such as whether the collecting personnel can restrict email searches to specific folders on the email server and whether they can remotely access offline mail folders, such as PST files.

#### *What?*

When collecting documents, two very important things to remember are to record the collection information (or metadata) and to maintain familial relationships (as maintained in the ordinary course of business). As to the former, it saves many headaches down the road if every group of hardcopy documents collected is adequately identified as to what date it was collected, where it was stored, who collected it, and who the custodian was. For electronic documents, care must be taken to identify the proper custodian (which may be a network share or archiving system as opposed to a person) and to preserve metadata. Even if metadata is not ultimately produced, it is still useful during document review and searching.

Additionally, care should be taken so that physical documents are collected and transported in a manner that does not disturb any folder or binder arrangements, or other collating methods. For electronic data, family data should always be preserved. Every modern document review system can display document family hierarchies and there is nothing more frustrating than reviewing an email that points to an attached critical document and finding that the document is not there due to collection issues. This can lead to significant spoliation allegations and must be avoided.

#### **Reviewing Documents**

Once collection is progressing in earnest, and review is about to begin, a few early

considerations can aid in an efficient review and forestall time-consuming complaints following production.



Always proceed with an eye toward developing a defensible history of good faith preservation, collection, and review efforts when collecting and reviewing documents.

#### *Document Coding*

If you plan to code your documents during the review process (e.g., for subject matter content or legal issues), try to plan your process well in advance. The goal is to touch a document only once (or twice in a two-tier review process) and to never have to return to it again for review. By initially identifying your codes carefully, your reviewers will not have to return to previously reviewed documents to recode with amended codes.

Additionally, you should make an informed decision about the quantity and granularity of codes used by reviewers. Highly granular coding, if done effectively, can make later work on specific legal issues much easier. However, it is rarely done effectively, and it can exponentially increase the review time for each document. Further, if codes are

not well defined as discrete, and smartly limited, subject matter areas or legal issues, they can have substantial overlap. The consequence is that when you're later searching for documents based on codes, the results of a search are not always useful without another round of review.

#### *Review Order*

Consider identifying key custodians and having each reviewer proceed logically and completely through the documents collected from a single custodian before moving onto the next. A common alternative is to search the entirety of unreviewed documents (or some subset of those documents) for key documents or document groups, and then review those. However, this can interrupt familial relationships and interfere with a contextual understanding of the documents that are being reviewed. Sometimes it can't be helped and you have to focus on certain categories of documents, but in general, a custodian-by-custodian review may be best.

#### *Production Order*

Always try to produce logical sets of documents. Whether or not you perform a custodian-by-custodian review, try to produce the complete set of each custodian's documents in a single batch. The produced documents should be Bates-ordered based on the custodian and document-family relationships. This is the most logical manner and satisfies the "as kept in the ordinary course" requirement.

It is also important to resolve all responsiveness or privilege questions prior to producing a logical set of documents. It is not uncommon that certain reviewed documents will be segregated and held back because they are questionable. However, if their family members are produced, and those segregated documents are

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## Conducting Efficient Patent Litigation Discovery, Part 2

continued from p. 13

later determined to be responsive and non-privileged, they will be produced out of order. This is a situation that is best avoided as it causes confusion, potentially violates the “ordinary course” rule, and can cast a spot light on those documents.

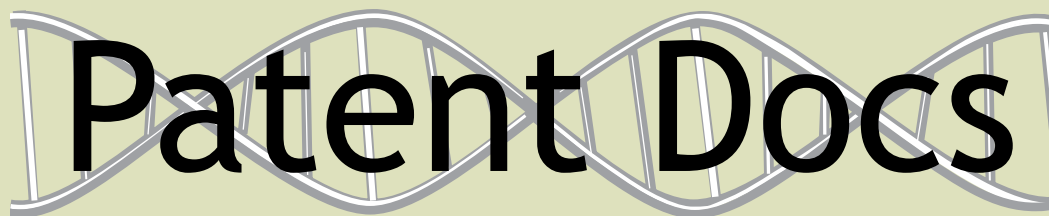
### Conclusion

As a final note, always proceed with an eye toward developing a defensible history of good faith preservation, collection, and review efforts when collecting and reviewing documents. Maintain

a written record (including summary logs) of all collection efforts, intra-party communications, interview notes, collection notes, and documents received outside of the ordinary collection methods. Good documentation throughout the collection and review process can help answer later questions of whether certain documents exist, what efforts you made to find them, and why opposing counsel doesn’t have a reasonable argument when he or she alleges that documents are missing.

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**McDonnell Boehnen Hulbert & Berghoff LLP** recognizes the ever-increasing importance of intellectual property. Our mission is to enhance the value of our clients' businesses by creating and defending their intellectual property assets. We have built our reputation by guiding our clients through the complex web of legal and technical issues that profoundly affect these assets. We are keenly aware of the trust placed in us by our clients—*Fortune* 100 corporations, universities, individuals, and start-up companies—and we always remain focused on their ultimate business goals.

With offices in Chicago and North Carolina, MBHB provides comprehensive legal services to obtain and enforce our clients' intellectual property rights, from navigating the U.S. Patent and Trademark Office procedures to litigating complex infringement actions. We don't merely procure rights and litigate cases; we craft winning strategies that achieve our clients' business objectives.

Our entrepreneurial spirit, combined with the wealth of our legal experience and technological expertise, gives McDonnell Boehnen Hulbert & Berghoff LLP the power to achieve success for our clients.

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