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## In Cyclobenzaprine, an Objective Failure to Reach a Long-Felt Need in Secondary Considerations Jurisprudence

C. Dylan Turner

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**In *Cyclobenzaprine*, an Objective Failure to Reach a Long-Felt Need in Secondary Considerations Jurisprudence**

*C. Dylan Turner*



# **In Cyclobenzaprine, an Objective Failure to Reach a Long-Felt Need in Secondary Considerations Jurisprudence**

**By C. Dylan Turner\***

## ABSTRACT

*Over the tenure of the Court of Appeals for the Federal Circuit, secondary considerations have become increasingly important in the analysis of nonobviousness. However, a close examination of the analytical framework behind these factors tells a cautionary tale. Courts often interpret evidentiary details of disputable import to indicate multiple secondary factors. In particular, the courts' handling of the secondary consideration of long-felt need has allowed courts to spin mountains from evidentiary molehills. Analysis of the opinions in *In re Cyclobenzaprine* will demonstrate this proclivity. This Note proposes a solution: a thorough analytical method for each factor, to ensure the independence, and persuasiveness, of each. A framework for careful analysis of the secondary consideration of a long-felt need is provided.*

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\* J.D., Northwestern University School of Law, 2015; Ph.D, University of British Columbia, 2012; B.S., Cal Poly, San Luis Obispo, 2005. The author thanks Prof. Dr. Laura Pedraza-Fariña for her invaluable encouragement and feedback throughout the writing process, Prof. Nadav Shoked for considerable helpful commentary, and the current and former staff of the *Northwestern Journal of Technology & Intellectual Property*.

## TABLE OF CONTENTS

INTRODUCTION .....	361
I. OBVIOUSNESS AND SECONDARY CONSIDERATIONS THEREOF .....	363
A. Prima Facie Obviousness Doctrine.....	364
B. Secondary Considerations.....	365
C. Implementing the Standard.....	366
D. The Nexus Requirement .....	368
II. ANALYSIS OF CYCLOBENZAPRINE.....	368
A. Summary .....	368
B. Analysis of the Courts' Reasoning .....	372
1. Long-felt need and failure of others.....	373
2. Did the invention merely achieve predictable results? .....	375
3. The CAFC's choice of language.....	376
III. WEAKNESS IN THE SECONDARY CONSIDERATIONS .....	376
A. Long-felt Need .....	376
B. Failure of Others .....	379
C. Long-felt Need vs. Motivation to Combine Doctrine.....	379
IV. POLICY PRESCRIPTIONS .....	381
A. Analyze Inferences.....	381
B. Bona Fide Long-felt Need .....	381
V. CONCLUSION.....	383

## INTRODUCTION

¶1 The process of determining what inventions are deserving of a patent has been fraught with difficulty since the idea of awarding exclusive rights to an invention was implemented. In order to determine which inventions are important enough to deserve patent protection, the patent system, in the United States and elsewhere, requires a judge to examine the invention in light of what came before. Analyzing a patent for inventiveness requires a judge to quickly absorb technical information, often in a conceptually challenging or cutting edge field. Judges have long been wary of this process.<sup>1</sup> Five decades ago, Judge Learned Hand, an important figure in patent law jurisprudence, remarked that the obviousness test was “as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts”<sup>2</sup>; ten years later he simply muttered it was “misty enough.”<sup>3</sup>

¶2 Such discomfort as that expressed by Judge Hand highlights the reasons for the popularity of non-technical evidence on the issue of obviousness. Non-technical evidence is categorized under various names: secondary considerations, secondary factors, objective evidence, or objective indicia. This evidence shows how the public, the inventor’s competitors, and other experts in the field regard the invention or the product(s) embodying it.<sup>4</sup> Such evidence sidesteps the need for technical education or specialized training. Thus, judges are often more comfortable analyzing such evidence, rather than parsing technical jargon provided by experts and published works in the field.

¶3 Courts disagree about what to call such non-technical evidence. A rift appears in the language used: some courts refer to “secondary considerations,”<sup>5</sup> while some invoke “objective indicia.”<sup>6</sup> This rift is reflected in the weight afforded such evidence by different courts. While the Supreme Court has referred to “secondary considerations,”<sup>7</sup> or “secondary factors”<sup>8</sup> and, in *KSR*, dismissed them in a single sentence,<sup>9</sup> the Court of Appeals for the Federal Circuit (CAFC) has held that such factors are an important and mandatory part of the obviousness analysis.<sup>10</sup>

¶4 With the rise of the CAFC, the specialized court handling all patent law appeals in the United States, secondary considerations have become weighty evidence in obviousness determinations. However, such evidence can be troublesome in its own right, and the CAFC has arguably taken its use of this evidence too far. This Note endeavors to explain how, in at least one instance, the CAFC has misused secondary considerations evidence.<sup>11</sup>

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<sup>1</sup> Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 36 (1992); see generally Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 5 (2010).

<sup>2</sup> *Harries v. Air King Prods. Co.*, 183 F.2d 158, 162 (2d Cir. 1950).

<sup>3</sup> *Reiner v. I. Leon Co.*, 285 F.2d 501, 503 (2d Cir. 1960).

<sup>4</sup> *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997).

<sup>5</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

<sup>6</sup> E.g., *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig. (Cyclobenzaprine II)*, 676 F.3d 1063, 1083 (Fed. Cir. 2012).

<sup>7</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

<sup>8</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 426 (2007).

<sup>9</sup> *Id.*

<sup>10</sup> *Cyclobenzaprine II*, 676 F.3d at 1076-78.

<sup>11</sup> Although the analysis here argues that the reasoning relied on by the CAFC is weak, the arguments should not be read to indicate a disagreement with the court’s treatment of the prima facie case or its overall conclusion of nonobviousness.

¶5 This Note provides an analysis of the law of secondary considerations of nonobviousness, as applied in the recent opinion of the CAFC in *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*.<sup>12</sup> In *Cyclobenzaprine*, the CAFC found a patented extended-release formulation of the known skeletal muscle relaxant cyclobenzaprine nonobvious.<sup>13</sup> The court interpreted a limited pool of evidence to find a long-felt need, a failure of prior would-be inventors, and hinted at unexpected results of a combination of known elements.<sup>14</sup> The CAFC's method allows the court to uncritically expand modest evidence into several different factors. The end result is that the court buttressed its determination over the prior art without necessity or cause.

¶6 In view of the reasoning on display in the *Cyclobenzaprine* decision, this Note argues that courts should carefully focus their inquiries into each category of objective evidence for the following three reasons: first, the secondary considerations doctrine as currently practiced often relies on evidence that is only weakly indicative of the nonobviousness of the invention. Second, the evidence relied on may only be relevant if some condition, which the court does not analyze or inquire into, is met. In this vein, courts, as demonstrated by the *Cyclobenzaprine* decision, make implicit inferences that are not necessarily valid. These inferences undercut the probativity of the secondary considerations. Third, courts rely on narrow evidence, such as a single past event of questionable relevance, to find the presence of multiple secondary considerations. Because of this jurisprudential problem, different factors, especially long-felt need and failure of others, overlap to a great degree.

¶7 In particular, the *Cyclobenzaprine* court's analysis of the secondary consideration of long-felt need is troubling. A long felt need indicates that a solution to a particular problem was sought after for an extended period of time before the patentee provided it. In *Cyclobenzaprine*, the CAFC based its finding of long felt need on two types of evidence. First, expert testimony (1) offered only after the patenting of the invention, in the litigation context, and (2) claiming only that the invention provided a benefit over the prior art. Second, a claimed prior failure by a would-be inventor that did not clearly target the invention claimed by the patentee.

¶8 The analysis leads to a set of recommendations for long-felt need in particular. This paper argues that a bona fide long-felt need can be found following a seven-question query. Such a procedure would ensure the evidence in a particular case pointed to a bona fide long-felt need for a particular invention.

¶9 Part I provides a brief overview of obviousness determination in the courts, along with statutory and policy underpinnings. Part II takes a look at the *Cyclobenzaprine* decision and provides an analysis of the treatment of obviousness, and secondary considerations thereof, in the district and appeals courts. Part III examines secondary considerations in light of the unexamined inferences they invoke, focusing on long-felt need. Part IV advances recommendations for treatment of an expanded nexus requirement and determination of a *bona fide* long-felt need for an invention.

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<sup>12</sup> The litigation discussed in this Note arose when six district court suits were joined. *See In re: Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 657 F. Supp. 2d 1375 (U.S. J.P.M.L. 2009).

<sup>13</sup> *Cyclobenzaprine II*, 676 F.3d at 1066.

<sup>14</sup> *See infra* Part II.

## I. OBVIOUSNESS AND SECONDARY CONSIDERATIONS THEREOF

¶10 Obviousness is the “ultimate condition of patentability” because it is a patentee’s most difficult hurdle to clear.<sup>15</sup> Nonobviousness ensures that the subject invention represents a sufficiently significant advance to warrant government protection.<sup>16</sup> Thus, the analogous inquiry in the EU is called “inventive step,”<sup>17</sup> and prior to the 1952 Patent Act, the Supreme Court looked for evidence of genuine “invention.”<sup>18</sup> “Obviousness is a question of law based on underlying factual findings.”<sup>19</sup> The inquiry is highly specific to each case, so determinations made in one case should not be universal.<sup>20</sup>

¶11 The obviousness doctrine’s predecessor was the inventiveness doctrine introduced by the Supreme Court in *Hotchkiss v. Greenwood*.<sup>21</sup> Congress enacted the statutory obviousness requirement as part of the 1952 Patent Act.<sup>22</sup> This statutory nonobviousness requirement, of Title 35 of the United States Code, read as follows:

¶12 A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.<sup>23</sup>

¶13 The America Invents Act (“AIA”) made subtle changes to the statutory obviousness requirement. The current § 103 refers to “claimed invention as a whole” rather than “subject matter as a whole.”<sup>24</sup> It also establishes the filing date for the patent application as the date for analysis, in keeping with the first-inventor-to-file system.<sup>25</sup> The AIA clarifies the current law through the use of precise definitions but is unlikely to have drastic effect.<sup>26</sup> At time of writing, the Supreme Court had not heard a case related to obviousness analysis under the AIA.

¶14 In the seminal decision *Graham v. John Deere Co. of Kansas City*, the Supreme Court set out a framework for analysis in determining obviousness under the Patent Act of 1952. The Court gave factors to be considered: the scope and content of the prior art, the differences between the claimed invention and the prior art, and the level of ordinary skill in the art.<sup>27</sup> The Court did not recite a specific standard to be met by an inventor, but instead held that Congress, in passing the 1952 Act, merely intended a “codification of judicial

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<sup>15</sup> Mark D. Janis, *Tuning the Obviousness Inquiry After KSR*, 7 Wash. J.L. Tech. & Arts 335, 340 (2012).

<sup>16</sup> John H. Barton, *Non-Obviousness*, 43 IDEA 475, 476 (2003).

<sup>17</sup> *Id.* at 475.

<sup>18</sup> *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850).

<sup>19</sup> *Cyclobenzaprine II*, 676 F.3d at 1068.

<sup>20</sup> *Newell Companies, Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 779 (Fed. Cir. 1988) (citing *In re Durden*, 763 F.2d 1406, 1410 (Fed. Cir. 1985)).

<sup>21</sup> 52 U.S. 248.

<sup>22</sup> 35 U.S.C. § 103(a) (2006).

<sup>23</sup> *Id.*

<sup>24</sup> 35 U.S.C. § 103 (2012).

<sup>25</sup> *Id.*

<sup>26</sup> See Robert A. Armitage, *Understanding the America Invents Act and its Implications for Patenting*, 40 AIPLA Q.J. 1, 24 (2012).

<sup>27</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

precedents.”<sup>28</sup> In addition, the Court mentioned “secondary considerations” that might illuminate the nonobviousness determination. It named three: commercial success, long felt but unsolved need, and failure of others.<sup>29</sup> These secondary considerations have grown in number and importance since the decision in *Graham*.

¶15 In practice, the Court’s obviousness inquiry comprises two parts: first, a prima facie case of obviousness is determined, in which a patent challenger presents the elements of the patent claims as found in the prior art and makes an argument that the invention would have been obvious over those elements.<sup>30</sup> A court tests for prima facie obviousness based on the framework laid out in *Graham*, as interpreted in the Court’s subsequent opinion in *KSR*, discussed below. Second, the patentee provides any evidence of secondary considerations of nonobviousness—generally, evidence found outside the technical materials in the prior art—available to it.<sup>31</sup>

#### A. *Prima Facie Obviousness Doctrine*

¶16 The Court provided its most recent guidance on the nonobviousness requirement in *KSR International Co. v. Teleflex, Inc.*<sup>32</sup> In *KSR*, the Court found the combination of an electronic sensor and a moveable pedal assembly obvious.<sup>33</sup> The patentee did not dispute that each element of the claimed invention had been disclosed in the prior art, but argued that the combination of elements was not obvious.<sup>34</sup> The CAFC agreed, finding no specific motivation to combine an adjustable pedal with a pivot-mounted sensor in the published art, and the patentee was trying to solve a distinct problem from that addressed in the relevant art.<sup>35</sup> The CAFC relied on its teaching, suggestion, motivation test, which held that a “movant must also establish some ‘suggestion, teaching, or motivation’ that would have led a person of ordinary skill in the art to combine the relevant prior art teachings in the manner claimed.”<sup>36</sup>

¶17 The Supreme Court’s central holding was that “[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”<sup>37</sup> This results in a three part inquiry: whether one of skill in the art “would have seen a benefit” in combining known elements,<sup>38</sup> whether the method of combination would be within ordinary skill,<sup>39</sup> and whether the result of the combination would be predictable.<sup>40</sup> The Court chastised the CAFC for focusing too narrowly on

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<sup>28</sup> *Id.*

<sup>29</sup> *Id.* at 17-18.

<sup>30</sup> *Minnesota Min. & Mfg. Co. v. Research Med., Inc.*, 679 F. Supp. 1037, 1051 (D. Utah 1987) (“The test in determining whether a claimed invention would have been obvious is what the combined teachings of the references would have suggested to one of ordinary skill in the art.” (citing *In re Keller*, 642 F.2d 413, 425 (C.C.P.A.1981))).

<sup>31</sup> *Graham*, 383 U.S. at 17.

<sup>32</sup> *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

<sup>33</sup> *Id.* at 407.

<sup>34</sup> *Id.* at 424, 427.

<sup>35</sup> *Teleflex, Inc. v. KSR Int’l Co.*, 119 F. App’x 282 (Fed. Cir. 2005), *rev’d*, 550 U.S. 398 (2007).

<sup>36</sup> *Id.* at 285.

<sup>37</sup> 550 U.S. at 416.

<sup>38</sup> *Id.* at 424.

<sup>39</sup> *Id.*

<sup>40</sup> *Id.* at 416.

finding an express motive to combine elements at issue and instead instructed courts to search for more general reasons or motivations.<sup>41</sup> The sources of such motivation might include the teachings of various patents, recognized needs in the field, marketplace demands, and the background knowledge of a person of skill in the art.<sup>42</sup>

¶18 The claim at issue in *KSR* was to an adjustable pedal assembly with a fixed pivot point and a throttle position sensor at the pivot.<sup>43</sup> The elements of the invention were described in three prior references, authored by Asano, Smith, and Rixon. A single reference by Asano taught all claimed elements except the electronic position sensor. This final element was first disclosed in Rixon’s patent while a subsequent reference by Smith located the sensor on a fixed part of the pedal assembly.<sup>44</sup>

¶19 The Court overruled the CAFC’s reasoning. It found the claim at issue encompassed obvious subject matter, upholding the district court’s finding that the design of Asano’s pedal was suitable for adaption for use with an electronic sensor.<sup>45</sup> Critically, the Court found a motivation within the field of pedal design to combine Asano with a pivot-mounted sensor.<sup>46</sup> First, in light of disclosures by Smith and Rixon, one of skill in the art would have been motivated to avoid wire chafing by mounting the sensor at the pivot;<sup>47</sup> second, and more generally, market forces in the field of pedal design were leading to the use of electronic sensors.<sup>48</sup> The Court also found that the prior art did not teach away from the combination, implying that a successful result would have been predictable.<sup>49</sup> Notably, the Court did not expressly analyze secondary considerations, but merely stated that those presented by the patentee were insufficient to overcome the *prima facie* case.<sup>50</sup>

### B. Secondary Considerations

¶20 The consideration of evidence outside the *prima facie* inquiry of nonobviousness is well-entrenched in the obviousness analysis.<sup>51</sup> The prominence of objective evidence may be due to the fact that judges find such evidence “relatively easy to ascertain.”<sup>52</sup>

¶21 Factors considered include commercial success, long-felt but unsolved need, licensing, industry praise, copying, expert skepticism, and failure (or success) of other

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<sup>41</sup> *Id.* at 415.

<sup>42</sup> *Id.* at 418.

<sup>43</sup> *Id.* at 410-11.

<sup>44</sup> *Id.* at 409.

<sup>45</sup> *KSR*, 550 U.S. at 423-24. This amounts to a finding that the prior art disclosed each element in the claim at issue.

<sup>46</sup> *Id.* at 424.

<sup>47</sup> *Id.* at 425.

<sup>48</sup> *Id.* at 424. Moreover, the accused infringer took the route of adding a sensor to a known design.

<sup>49</sup> *Id.* at 425-26.

<sup>50</sup> *Id.* at 426.

<sup>51</sup> The CAFC has repeatedly required judges to consider such evidence as part of the obviousness inquiry. *See, e.g., Cyclobenzaprine II*, 676 F.3d at 1076.. For a historical example of analysis, see Dorothy Whelan, *A Critique of the Use of Secondary Considerations in Applying the Section 103 Nonobviousness Test for Patentability*, 28 B.C. L. REV. 357, 363-74 (1987).

<sup>52</sup> Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 36 (1992); *see generally* Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 5 (2010). The present work will focus on the factors mentioned in *Graham*, although some courts include secondary considerations, such as unexpected results, arising from technical evidence in the prior art. *See, e.g., Syntex (U.S.A.) LLC v. Apotex, Inc.*, 407 F.3d 1371, 1378 (Fed. Cir. 2005).

would-be inventors.<sup>53</sup> Some courts consider the factors named in the *Graham* decision—commercial success, long-felt need, and failure of others—to carry more weight.<sup>54</sup> Commercial success has traditionally been considered to be the most persuasive,<sup>55</sup> although it has more recently been subject to intense criticism.<sup>56</sup> It is noteworthy that each factor weighs almost exclusively in favor of the patentee,<sup>57</sup> though simultaneous invention by another has been used as evidence of obviousness.<sup>58</sup>

¶22 The secondary considerations of long-felt need and failure of others are most relevant to the analysis here. The idea of a long-felt need is that an invention that was long desired, but not delivered, is more likely nonobvious.<sup>59</sup> If the invention were known to be valuable, someone would have developed it to try and reap the reward.<sup>60</sup> Failure of past inventors who attempted to conceive of the invention (or perhaps a similar one) but failed to complete it similarly indicates that the invention was more likely nonobvious because the invention must have presented some obstacle to would-be inventors.<sup>61</sup> The two factors are tied together; theorists generally infer a failure of others from a long-felt need for an invention,<sup>62</sup> while courts analogously infer long-felt need from a failure of others.<sup>63</sup> In particular, courts have recognized long-felt need as historically important to the obviousness, or inventive step, analysis.<sup>64</sup>

¶23 The value of objective evidence is vitiated if the evidence of nonobviousness presented to the court is not attributable to novel features of the claimed invention.<sup>65</sup> Thus, courts analyze objective evidence under a nexus requirement, discussed below, without which the evidence is discredited.

¶24

### C. Implementing the Standard

¶25 The nonobviousness standard requires that a judge take the perspective of a person working in the art at the time the invention was made. This approach causes problems because it requires reconstruction of the state of knowledge in a technical field at a particular point in time. This is a notoriously difficult task, and courts have long expressed

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<sup>53</sup> See, e.g., *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349-54 (Fed. Cir. 2012).

<sup>54</sup> E.g., *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1380 (Fed. Cir. 2000).

<sup>55</sup> Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CALIF. L. REV. 803, 817 (1988).

<sup>56</sup> See, e.g., Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J. 1590, 1674 (2011).

<sup>57</sup> See Whelan, *supra* note 51.

<sup>58</sup> *Ecolochem*, 227 F.3d at 1379.

<sup>59</sup> Joseph Scott Miller, *Level of Skill and Long-Felt Need: Notes on A Forgotten Future*, 12 LEWIS & CLARK L. REV. 579, 584-85 (2008).

<sup>60</sup> See, e.g., *id.*

<sup>61</sup> See, e.g., *id.*

<sup>62</sup> E.g., Merges, *supra* note 55, at 829-30.

<sup>63</sup> See *infra* Part III.

<sup>64</sup> Miller, *supra* note 59, at 583.

<sup>65</sup> E.g., *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1327 (Fed. Cir. 2008); *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006) (noting that evidence of commercial success and failure of others presented by the patentee were not shown to be related to the claimed features of the patented invention).

a fear that judges, after being presented with simplified explanations of the invention and the art that preceded it, will make an unwarranted finding that an invention was only a trivial advance over what had been known in the field.<sup>66</sup>

¶26 Hindsight bias is implicated when a judge or other factfinder, having all relevant prior art references before him and knowing that the invention was indeed conceived, makes an unwarranted finding that a past invention would have been obvious. Early in its tenure, the CAFC warned against the “insidious attraction of the siren hindsight.”<sup>67</sup> The CAFC’s concern with this type of hindsight bias informs its obviousness jurisprudence to the present day.<sup>68</sup> The fear of hindsight is important because an issued patent is presumed valid, as confirmed by a recent Supreme Court decision.<sup>69</sup> The evidentiary standard for invalidating an issued patent is “clear and convincing.”<sup>70</sup>

¶27 Although Supreme Court precedent holds that a person having ordinary skill in the art has “ordinary creativity,”<sup>71</sup> he is, by definition, not an expert. A judge, relying on expert opinions on events well past, might find a particular line of reasoning more likely than an ordinary artisan would at the time of invention. For example, in *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, the CAFC found that one part of the district court’s analysis amounted to “merely retrac[ing] the inventor’s steps.”<sup>72</sup> This sort of reasoning might be exacerbated because judges can resort to playing hunches in the context of technology they do not understand well.<sup>73</sup> The fact that hindsight affects decision making on obviousness has been empirically studied.<sup>74</sup> The problem is perhaps attributable in part to the lack of obviousness standard provided by the *Graham* Court.<sup>75</sup>

¶28 The secondary considerations are argued to act as a hedge against hindsight bias because they do not permit a technically untrained factfinder to reason backward from a hunch.<sup>76</sup> Even if a judge regards a combination of elements to be trivial, a judge who keeps perspective of the circumstances surrounding the development of the invention should make a more objective analysis. However, some commentators have criticized the CAFC’s invocation of hindsight bias as being a mere rhetorical tool.<sup>77</sup>

<sup>66</sup> *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983).

<sup>67</sup> *Id.* The court noted that objective evidence acts as insurance against said siren.

<sup>68</sup> *See, e.g., Plantronics, Inc. v. Aliph, Inc.*, 724 F.3d 1343, 1354-55 (Fed. Cir. 2013).

<sup>69</sup> *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238, 2242 (2011).

<sup>70</sup> *Id.*

<sup>71</sup> *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

<sup>72</sup> *Cyclobenzaprine II*, 676 F.3d at 1073.

<sup>73</sup> *E.g., Richard L. Robbins, Subtests of “Nonobviousness”: A Nontechnical Approach to Patent Validity*, 112 U. PA. L. REV. 1169, 1170 (1964).

<sup>74</sup> Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1393 (2006); but see Glynn S. Lunney, Jr. & Christian T. Johnson, *Not So Obvious After All: Patent Law’s Nonobviousness Requirement, KSR, and the Fear of Hindsight Bias*, 47 GA. L. REV. 41, 51 (2012) (criticizing Professor Mandel’s study as conclusory).

<sup>75</sup> After *Graham*, judges were left to answer a subjective question: whether an invention represented a “truly significant advance.” Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 9 (1989). *See, e.g., SSIH Equip. S.A. v. U.S. Int’l Trade Comm’n*, 718 F.2d 365, 375 (Fed. Cir. 1983) (rejecting a patent for having only an “insubstantial difference” compared to the prior art). More recently, the *KSR* Court was skeptical of the kind of hindsight oft-mentioned by the CAFC. As a counter example, the Court noted that if one views the prior art as being unpredictably inefficient in light of the current state of the art, then one engages in hindsight. *KSR*, 550 U.S. at 425-26.

<sup>76</sup> *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966); *see also* Dreyfuss, *supra* note 75, at 9-10 (arguing that the CAFC’s objective evidence law acts as a hedge against the hindsight bias of nontechnical judges).

<sup>77</sup> Lunney & Johnson, *supra* note 74, at 46-47. Indeed, the inconsistency of the CAFC’s analysis of

### D. The Nexus Requirement

¶29 As applied by the CAFC, secondary considerations are evidence of how the public regards the invention or the product(s) embodying it.<sup>78</sup> Since this is not direct evidence of nonobviousness, courts apply a nexus requirement to this evidence in order to ensure that it reflects the characteristics of the novel features of the invention.<sup>79</sup> In practice, this inquiry is often applied to evidence of commercial success.<sup>80</sup> Applying the nexus to commercial success requires a careful analysis, as courts have advanced a burden-shifting framework within this one factor.<sup>81</sup> However, courts apply the nexus requirement to other factors as well.<sup>82</sup>

¶30 One case exemplifying the nexus requirement is *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*<sup>83</sup> There, the key inventive feature of the claimed oil rig was a dual-activity capability. The CAFC pointed out how testimony presented tended to link commercial success, expert skepticism and later praise, and long-felt need to the claimed dual activity feature and the efficiency thereof.<sup>84</sup>

¶31 The nexus requirement as currently implemented is an incomplete doctrinal vehicle for linking evidence to the nonobviousness of an invention. While it is important for courts to link the success of a commercial embodiment of an invention to its claimed features, a number of possible circumstances can limit the value of secondary considerations evidence. Some such circumstances are discussed in Parts II and III, below.

¶32

## II. ANALYSIS OF CYCLOBENZAPRINE

### A. Summary

¶33 In *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*<sup>85</sup> claims of two patents directed to an extended-release formulation of the skeletal muscle relaxant cyclobenzaprine, U.S. Patent Nos. 7,387,793 (the '793 patent) and 7,544,372 (the '372 patent), were at issue. The challenged claims related to a new extended-release formulation of the skeletal muscle relaxant cyclobenzaprine, marketed under the trademark AMRIX®. Defendant generic manufacturers were accused of infringing the patents by filing for Abbreviated New Drug Applications (ANDAs) to introduce products embodying patentee Eurand's claimed formulation. Dosage form and method claims with essentially

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commercial success with its oft-repeated justification therefor is apparent. Commercial success is necessarily collected after a product embodying the invention and protected by market exclusivity appears.

<sup>78</sup> *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997).

<sup>79</sup> *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1539 (Fed. Cir. 1983) (adopting the law of *Solder Removal Co. v. USITC*, 582 F.2d 628, 637 (C.C.P.A. 1978)).

<sup>80</sup> *See, e.g., Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311-12 (Fed. Cir. 2006).

<sup>81</sup> Gregory E. Upchurch, 2 IP Litigation Guide: Patents & Trade Secrets § 15:31 (2013).

<sup>82</sup> *See, e.g., PerkinElmer, Inc. v. Intema Ltd.*, CIV.A. 09-10176-FDS, 2011 WL 10756712, at \*21 (D. Mass. Aug. 12, 2011) *aff'd in part, rev'd in part*, 496 F. App'x 65 (Fed. Cir. 2012).

<sup>83</sup> *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340 (Fed. Cir. 2012).

<sup>84</sup> *Id.* at 1349-54.

<sup>85</sup> *In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig. (Cyclobenzaprine I)*, 794 F. Supp. 2d 517 (D. Del. 2011).

identical limitations were challenged as being invalid as obvious over the prior art. Claim 1 of the '793 patent is representative:

1. A multi-particulate pharmaceutical dosage form of a skeletal muscle relaxant providing a modified release profile comprising a population of extended release beads, wherein said extended release beads comprise an active-containing core particle comprising a skeletal muscle relaxant selected from the group consisting of cyclobenzaprine, pharmaceutically acceptable salts or derivatives thereof and mixtures thereof; and an extended release coating comprising a water insoluble polymer membrane surrounding said core, wherein said dosage form when dissolution tested using United States Pharmacopoeia Apparatus 2 (paddles @ 50 rpm) in 900 mL of 0.1 N HCl at 37° C exhibits a drug release profile substantially corresponding to the following pattern: after 2 hours, no more than about 40% of the total active is released; after 4 hours, from about 40–65% of the total active is released; after 8 hours, from about 60–85% of the total active is released; wherein said dosage form provides therapeutically effective plasma concentration over a period of 24 hours to treat muscle spasm associated with painful musculoskeletal conditions when administered to a patient in need thereof; and wherein said water insoluble polymer membrane comprises a water insoluble polymer selected from [the provided molecules].

¶34 The district court found the challenged claims obvious in that they entailed a “mere substitution” of elements that yielded predictable results.<sup>86</sup> The district court found that the active principal had itself been FDA-approved for human use for decades, but only in immediate-release form,<sup>87</sup> while the drug-release technology was described in the prior art.<sup>88</sup> In the reasoning of the district court, since the combination of known formulation and known pharmaceutical gave merely predictable results, the combination was obvious.<sup>89</sup>

¶35 The CAFC reversed, ruling that the district court erred in its analysis. The CAFC held that the district court erred in two ways: first, the lower court improperly found that the invention was obvious over the prior art before examining secondary considerations of nonobviousness presented by the patentee. Second, the CAFC disagreed with the substance of the district court’s obviousness determination, including its analysis of secondary considerations.

¶36 With regard to the technology at issue, the CAFC explained,

Pharmacokinetics is the study of what a person's body does to a drug after administration. The pharmacokinetic (“PK”) values recited in claim 3 [of the '793 patent] measure various characteristics about the drug's behavior in a patient's blood plasma.  $C_{max}$ , as claim 3 alludes, represents the maximum concentration of the drug in a person's blood plasma.  $AUC_{0-168}$  represents

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<sup>86</sup> *Cyclobenzaprine I*, 794 F. Supp. 2d at 537.

<sup>87</sup> *See id.* at 523-24.

<sup>88</sup> *Id.* at 534-35.

<sup>89</sup> *Id.* at 537.

the area under the blood plasma concentration curve, or, in other words, the body's total exposure to the drug . . . .

To formulate a therapeutically effective, extended-release version of cyclobenzaprine hydrochloride, the inventors had to ascertain the correct pharmacokinetic/pharmacodynamics (“PK/PD”) profile. The PK side of the relationship—what a person's body does to the drug—includes the  $C_{\max}$ , AUC, and  $T_{\max}$ , as identified in claim 3. The PD side of the relationship describes the effect that a drug renders on a person's body. The PD of cyclobenzaprine hydrochloride is the relief of muscle spasms.

The determination of a PK profile is a quantitative exercise. The determination of PD, or therapeutic effectiveness, however, is a qualitative exercise . . . [A] therapeutically effective plasma concentration is “a concentration that the formulation provides when the formulation works . . . .”<sup>90</sup>

¶37 The district court noted that the prior art revealed the blood levels resulting from multiples dosages of immediate-release cyclobenzaprine, and that its PK profile was linear.<sup>91</sup> The court credited the testimony of a named inventor, who stated that blood levels of the drug similar to those from immediate-release administration would lead to therapeutic effect.<sup>92</sup> Because of these findings, the court ruled that all claimed elements were available to one of skill in the art, even if not expressly disclosed in the prior art.

¶38 The court found a motivation to combine the claimed elements. FDA guidance provided motivation to try extended-release formulations having the same PK parameters (specifically, AUC<sup>93</sup> and  $C_{\max}$ <sup>94</sup>) as an approved immediate-release formulation.<sup>95</sup> This is because the FDA recommended that a new extended-release formulation of a known drug match these values with respect to a series of doses of an immediate-release formulation of the same drug.<sup>96</sup>

¶39 Finally, the court held that the combination of known elements would have given a reasonable probability of success. The court found that “a person of ordinary skill in the art can generally expect that the extended release formulation will have approximately the same effect in the body as the immediate release formulation.”<sup>97</sup> The court took note of a prior-art extended-release formulation of a drug having similar properties.<sup>98</sup>

<sup>90</sup> *Cyclobenzaprine II*, 676 F.3d at 1067.

<sup>91</sup> *Cyclobenzaprine I*, 794 F. Supp. 2d at 536. The court cited a CAFC decision supporting its finding that a known PK profile and blood levels of a drug could be sufficient for one of skill in the art to formulate an extended-release form of a drug. *See* *Purdue Pharma Prods. v. Par Pharm., Inc.*, 642 F. Supp. 2d, 329, 373 (D. Del. 2009), *aff'd*, 377 F. App'x 978 (Fed.Cir. 2010).

<sup>92</sup> *Cyclobenzaprine I*, 794 F. Supp. 2d at 536. The court cited a CAFC decision supporting its finding.

<sup>93</sup> AUC, or area under the curve, measures the total amount of drug administered.

<sup>94</sup>  $C_{\max}$  represents the peak plasma concentration of a drug after administration.

<sup>95</sup> *Cyclobenzaprine I*, 794 F. Supp. 2d at 537.

<sup>96</sup> *Id.*

<sup>97</sup> *Id.* at 536-37.

<sup>98</sup> *Id.* at 536.

¶40 Regarding the secondary considerations, the plaintiffs argued that a previous instance of an attempt, by third party ALZA,<sup>99</sup> to modify the effects of cyclobenzaprine constituted an objective failure of others to create the claimed invention.<sup>100</sup> The district court dismissed this factor because the plaintiff and the prior art undertook this invention with different goals: the prior art aimed to reduce side effects, while the plaintiffs sought to improve patient compliance by reducing dose frequency.<sup>101</sup> As for commercial success, the court found that “any commercial success of [the invention] was linked to a powerful and expansive marketing campaign, rather than its patented features.”<sup>102</sup> Similarly, the court did not find a long-felt need for the invention since other products “filled the niche.”<sup>103</sup> Moreover, the court noted that a prior-art extended-release formulation drug had similar properties to that claimed in the patent-at-issue.<sup>104</sup>

¶41 On appeal, the CAFC reversed. According to the CAFC, the key question in the prima facie obviousness inquiry was whether the lack of prior art reference for a therapeutic effectiveness limitation for cyclobenzaprine should lead to a finding of nonobviousness.<sup>105</sup> Therapeutic effectiveness depended on deriving the desired effect of the drug following administration of a given dose.<sup>106</sup> According to the CAFC, if the inventors could not expect success in choosing to administer a particular amount of the drug over a particular period of time, their invention would not be expected to provide therapeutic effectiveness, and would be nonobvious.<sup>107</sup> Nonobviousness turned on whether the inventors could expect therapeutic effectiveness by choosing a drug-release profile similar to that provided by multiple administrations of the immediate-release formulation of cyclobenzaprine. The CAFC noted that the prior art did not disclose a PK/PD relationship<sup>108</sup> for the drug. Thus, the lack of this element meant that the inventors could not expect therapeutic effectiveness in formulating an extended-release form of the drug.<sup>109</sup>

¶42 The CAFC was convinced that a formulation of extended-release cyclobenzaprine claiming “therapeutic effectiveness” was nonobvious.<sup>110</sup> Moreover, it held that the lack of a prior art PK/PD relationship meant that a person of skill in the art would not have a reasonable expectation of success.<sup>111</sup> The court reasoned that the lack of a PK/PD relationship was the deciding factor since therapeutic effectiveness depends on PD; thus, one skilled in the art had “no way to match the dosage for the extended-release formulation

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<sup>99</sup> The district court refers to “ALIZA.” *Id.* at 537.

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> *Id.* at 538. The nexus requirement was not in dispute since the parties agreed that the patent described the product.

<sup>103</sup> *Id.*

<sup>104</sup> *Id.* at 536-37.

<sup>105</sup> *Cyclobenzaprine II*, 676 F.3d at 1070.

<sup>106</sup> *Id.* at 1069.

<sup>107</sup> *Id.*

<sup>108</sup> The pharmacokinetics (PK) of a drug refers to its disappearance from the body through metabolism or excretion. Pharmacodynamics (PD) refers to the drug’s effect on the body after the drug is administered. The PK/PD relationship links the change in drug concentration over time to the intensity of the patient response. Hartmut Derendorf & Bernd Meibohm, *Modeling of Pharmacokinetic/Pharmacodynamic (PK/PD) Relationships: Concepts and Perspectives*, 16 PHARMACEUTICAL RES. 176 (1999).

<sup>109</sup> *Cyclobenzaprine II*, 676 F.3d at 1071.

<sup>110</sup> *Id.* at 1069-70.

<sup>111</sup> *Id.* at 1071.

to achieve a known therapeutic effect.”<sup>112</sup> Although the opinion cited cases where such a relationship was assumed to be present, the court was hesitant to take such a step when therapeutic effectiveness was a claim limitation.<sup>113</sup> The CAFC disagreed with the lower court’s interpretation of expert testimony and FDA guidance with regard to the probability of success of the invention.<sup>114</sup>

¶43 Perhaps unsurprisingly, the CAFC also disagreed with the district court’s analysis of the secondary considerations evidence, ruling the lower court’s factual findings to be clearly erroneous.<sup>115</sup> First, the CAFC credited the previous attempt to formulate an extended release formulation of cyclobenzaprine.<sup>116</sup> The court explained the methodological differences of the plaintiffs and the previous attempt at invention. The court argued that the previous attempt at formulation had an additional goal, rather than a distinct goal, for its research. Both the plaintiffs and ALZA desired to make a “therapeutically effective product,” the CAFC concluded.<sup>117</sup>

¶44 The CAFC found evidence of a long-felt need for the invention. For one, improved patient compliance when taking extended-release medications was an advantage presented by one of the plaintiffs’ expert witnesses.<sup>118</sup> The court buttressed its analysis by citing cases arguing that a failure of others indicated a long-felt need for the invention.<sup>119</sup>

¶45 The court also implied that the previous failure at formulation served as evidence of unexpected results of the plaintiff’s invention by holding that one with skill in the art would not reasonably expect success knowing of the previous failed attempt.<sup>120</sup>

### B. Analysis of the Courts’ Reasoning

¶46 The disagreement between the district and appeals courts demonstrates two things about secondary considerations. First, the courts’ overlapping conception of the various factors allows the underlying biases or pre-decision of a fact-finder to direct the analysis. A close examination of the reasoning relied on by the district court and the CAFC reveals the fraught nature of seemingly-reliable categories of secondary considerations. For instance, courts—such as the *Cyclobenzaprine* court—often group together long-felt need and failure of others despite the fact that they can be readily distinguished.<sup>121</sup> This allows

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<sup>112</sup> *Id.* at 1070.

<sup>113</sup> *Id.* at 1084.

<sup>114</sup> *Id.* at 1073.

<sup>115</sup> *Id.* at 1082.

<sup>116</sup> *Id.* at 1081-82.

<sup>117</sup> *Id.* at 1081.

<sup>118</sup> The CAFC also noted that the immediate-release form of cyclobenzaprine suffered from poor patient compliance; however, this is in tension with the district court’s findings, which noted that no expert testimony had been presented on the topic of long-felt need. See *Cyclobenzaprine I*, 794 F.Supp.2d at 538.

<sup>119</sup> *Cyclobenzaprine II*, 676 F.3d at 1082-83.

<sup>120</sup> *Id.* at 1083. For an analysis showing that a determination of unexpected results on account of this evidence is questionable, see Laura G. Pedraza-Fariña, *Patent Law and the Sociology of Innovation*, 2013 WIS. L.REV. 813, 867-73 (2013).

<sup>121</sup> See, e.g., *Mformation Techs., Inc. v. Research in Motion Ltd.*, 2012 WL 1142537 (N.D. Cal.); *Rambus Inc. v. Hynix Semiconductor Inc.*, 254 F.R.D. 597, 603 (N.D. Cal. 2008); *Tex. Instruments v. U.S. Int’l Trade Comm’n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993) (“[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem.”); *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983) (holding that the lack of previous attempts to achieve the results of the invention indicated a lack of long-felt need).

courts to find two factors present on account of even a single perceived failure. When a court finds multiple factors indicating nonobviousness from limited evidence, it risks allowing the opinion to become an echo chamber. If the evidence is to be truly objective, the interdependence between elements of the invention and the secondary considerations, and that between the various factors, must be severed. This can be accomplished by providing a framework to analyze the persuasiveness of each factor.<sup>122</sup>

¶47 Second, untested inferences and implicit assumptions undercut the persuasiveness of the secondary considerations analysis. Specifically, the CAFC’s reasoning uncritically expands the meaning and legal effect of testimony concerning past events.

#### 1. Long-felt need and failure of others

¶48 With regard to failure of others, the district court found that a previous failure of others was not indicative of nonobviousness, while the CAFC disagreed. The district court noted that the previous, unsuccessful attempt to formulate an extended-release cyclobenzaprine drug had the dual goals of reducing sedation and side-effects, while that of patentee was to improve patient compliance by reducing the dosing frequency.<sup>123</sup> This analysis implies that the previous attempt may have been halted for reasons that were not sufficiently relevant to the patentee’s invention. Hence, the district court refused to infer that the previous attempt made it more likely that the patentee had made an inventive step, but instead that the patentee had different criteria for success.

¶49 On the other hand, the CAFC credited the previous attempt at formulation of cyclobenzaprine as evidence of nonobviousness, stating that ALZA, like the patentee, had the “central common goal” of “mak[ing] a therapeutically effective product.”<sup>124</sup> The court noted that ALZA used a different PK profile in its formulation and that the resulting product was not therapeutically effective.<sup>125</sup> The CAFC was not convinced by the fact that ALZA chose its PK profile based on a desire to limit side effects, while the patentee did not.<sup>126</sup> Instead, the CAFC interpreted the prior failure as a poor choice of PK profile.<sup>127</sup> However, if ALZA had indeed targeted lowered side effects, one could find this point to be indicative that the prior failure did not weigh in favor of nonobviousness.

¶50 At least two reasons for ALZA’s abandonment are possible. First, if ALZA believed that consumers would only buy the formulation if it limited side effects, its failure would be one of market evaluation rather than inventiveness. Under Federal Circuit doctrine, a court should not find this to be evidence of nonobviousness if it inferred that a prior attempt was abandoned due to a market analysis for a potential product.<sup>128</sup> Second, ALZA’s failure could be attributable to choosing to pursue a more difficult invention than the patentee. Previous work on a different invention would not necessarily reflect on the obviousness of the patentee’s invention.

<sup>122</sup> See *infra* Part IV.

<sup>123</sup> *Cyclobenzaprine I*, 794 F.Supp.2d at 537.

<sup>124</sup> *Cyclobenzaprine II*, 676 F.3d at 1082.

<sup>125</sup> *Id.* at 1081-82.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> *DyStar Textilfarben GMBH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1371-72 (Fed. Cir. 2006) (finding that a “calculated business judgment” not to pursue an innovation was not evidence of nonobviousness).

¶51 More factors could explain the failure of ALZA to formulate the invention five years prior. The CAFC did not consider, at least expressly, if the formulation technology relied on by the patentee had appeared before ALZA's attempt (it had). The court did not consider that ALZA's attempt at formulation might have been halted for pure business reasons—for instance, if the company had decided that \$10 million was the most they were willing to spend on research into the potential product. Further, the court did not compare the \$10 million spent by the prior researches relative to other successful research ventures in pharmaceutical formulation to give context to the attempt. Nor did it compare this amount to the expenditure of the patentee. Of course, the onus is on an adversary to gather evidence of and present such arguments, but the implicit inference by the court is that no such circumstance was present.

¶52 The CAFC also hinted that the previous failed attempt at formulation was indicative of a lowered expectation of success.<sup>129</sup> Consequently, the CAFC drew another inference from the failure of others' evidence. The district court's observation that ALZA had different objectives than the patentee seems particularly pertinent to this point.<sup>130</sup>

¶53 The courts again disagreed on the question of long-felt need. Perhaps unsurprisingly, the district court found no pertinent evidence of long-felt need, while the CAFC saw a long-felt need for an extended release formulation of cyclobenzaprine. The district court examined the patentee's arguments that such need was evidenced by the commercial success of the product.<sup>131</sup> That court was unconvinced, stating that any commercial success was due to marketing.<sup>132</sup> Additionally, the district court found that alternative products on the market meant that no need existed.<sup>133</sup>

¶54 The CAFC disagreed on two points. First, it noted that, under case law, long-felt need existed where others attempted to satisfy a demand for a product but failed.<sup>134</sup> However, the CAFC's doctrine unabashedly conflates long-felt need and failure of others. Furthermore, the evidence of failure of others the CAFC relied on was questionable for the reasons discussed above.

¶55 Second, the CAFC credited expert testimony of a physician who testified that extended-release drugs in general help to improve patient compliance.<sup>135</sup> The CAFC did not consider the district court's argument that the presence of other products in the same market meant no need existed. This point is particularly important because it shows the lack of persuasiveness of this evidence. If alternative products existed, the financial incentive to develop an extended-release formulation of cyclobenzaprine would be reduced.<sup>136</sup> Without such incentive, a would-be inventor would be dissuaded from pursuing such an invention for financial reasons, rather than actual or perceived technical difficulty. Thus, such an invention cannot be considered more nonobvious in the traditional sense.

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<sup>129</sup> See *Cyclobenzaprine II*, 676 F.3d at 1083.

<sup>130</sup> See *Merges*, *supra* note 55, at 863 ("If two runners are on tracks of differing length or terrain, they will not be in a true race.").

<sup>131</sup> *Cyclobenzaprine I*, 794 F.Supp.2d at 537.

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* at 538.

<sup>134</sup> *Cyclobenzaprine II*, 676 F.3d at 1082-83.

<sup>135</sup> *Id.* at 1083.

<sup>136</sup> It is also noteworthy that no special characteristics of cyclobenzaprine were expounded, and no demand for a new formulation of cyclobenzaprine in particular was noted.

¶56 Additionally, the expert testimony relied on by the CAFC in finding a long-felt need was not rooted in a time before invention by the patentee. Rather, the statement reflected *ex post* rationalization—the invention was long-desired merely because it had a desirable characteristic and was an improvement over predicate prior art. Even if true, these facts do not prove that an extended-release formulation of this drug, or one like it, was long-needed. Neither court required evidence of *ex ante* statements of experts indicating that such a formulation was actually needed or desirable.

## 2. Did the invention merely achieve predictable results?

¶57 First, the CAFC commented on the district court’s treatment of evidence of routine experimentation. Regarding the lack of PK data in the prior art, the district court stated “plaintiffs were able to meet their target profiles on the first or second try.”<sup>137</sup> The higher court chastised the district court for hindsight bias because expert testimony indicated only the therapeutic effect would “hopefully” be the same in the extended release formulation as the immediate release prior art.<sup>138</sup>

¶58 Second, the CAFC did not accept the district court’s finding that extended-release cyclobenzaprine could be reasonably expected to have a therapeutic effect. The CAFC noted that the drug lacked a published PK/PD relationship.<sup>139</sup> Since the extended-release technology was a known element, the defendants needed only to show a reasonable expectation of success under *KSR*. However, one of skill in the art would have known that the generic drug industry relies heavily on the assumption that therapeutic effect follows bioequivalence, as evidenced by FDA guidelines and Hatch-Waxman law.<sup>140</sup> Thus, an inventor would have little choice but to mirror the PK profile. More persuasive was the CAFC’s argument that the claimed C<sub>max</sub> was not revealed in the prior art.<sup>141</sup>

¶59 The CAFC also stated that the previous failed attempt at formulation was indicative of a lowered expectation of success.<sup>142</sup> Consequently, the CAFC draws another inference from this evidence. The district court’s observation that ALZA had different objectives than the patentee seems particularly pertinent to this point.<sup>143</sup> For example, if a previous inventor tried to improve the power output and fuel efficiency of a combustion engine that had been used for generations, a subsequent inventor who merely tried to improve the power output while maintaining efficiency relative to power output might well expect success if he implemented known strategies to achieve this one objective. By this logic, the critical question is whether the previous attempt failed for the objectives sought by the patentee or due to the pursuit of a further objective. That is, did the previous inventor seek the same invention or a different one?

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<sup>137</sup> *Cyclobenzaprine I*, 794 F.Supp.2d at 536.

<sup>138</sup> *Cyclobenzaprine II*, 676 F.3d at 1073.

<sup>139</sup> *Id.* at 1071.

<sup>140</sup> Elizabeth Stotland Weiswasser & Scott D. Danzis, *The Hatch-Waxman Act: History, Structure, and Legacy*, 71 ANTITRUST L.J. 585 (2003-2004) (Hatch-Waxman allows “establishing the safety and efficacy of [generic] drugs and to obtain FDA approval merely by showing their drugs to be the ‘same’ as, and ‘bioequivalent’ to, the listed drug”). This constitutes “background knowledge” possessed by skilled artisans. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007).

<sup>141</sup> *Cyclobenzaprine II*, 676 F.3d at 1071-72.

<sup>142</sup> *Id.* at 1071.

<sup>143</sup> See *Merges*, *supra* note 55, at 863 (“If two runners are on tracks of differing length or terrain, they will not be in a true race.”).

### 3. The CAFC's choice of language

¶60 The CAFC in *Cyclobenzaprine* argued that the Supreme Court in *Deere* did not relegate the secondary considerations to secondary status.<sup>144</sup> Although the *Cyclobenzaprine* court did pointedly refer to objective indicia, the Supreme Court has consistently referred to this evidence as “secondary,” beginning with its seminal opinion on obviousness.<sup>145</sup>

¶61 Furthermore, the Court was clearly permissive in merely indicating that such factors “may have relevancy.”<sup>146</sup> Later, the Court instructed that lower courts “look at any secondary considerations *that would prove instructive*.”<sup>147</sup> Indeed, the district court itself quoted the Supreme Court’s permissive language in *KSR*: “secondary considerations . . . *might be* utilized to give light to the circumstances surrounding the origin of the subject matter.”<sup>148</sup> These Supreme Court directives hardly support the Federal Circuit’s assertions that such evidence must be considered along with the *prima facie* case, and suggest that such evidence is indeed secondary to evidence of obviousness over the prior art.

### III. WEAKNESS IN THE SECONDARY CONSIDERATIONS

¶62 The *Cyclobenzaprine* decision reveals a number of troubling aspects of secondary considerations jurisprudence. The factor of long-felt need best illustrates the problems with the court’s treatment of secondary considerations. Two aspects of the CAFC’s decision in particular demonstrate the weakness. First, the court’s tendency to look at such evidence from the standpoint of whether the evidence provides any support for the particular factor at issue, rather than whether it is evidence of nonobviousness itself. Second, many courts, as the *Cyclobenzaprine* decision exemplifies, group together long-felt need and failure of others, despite the fact that they can be readily distinguished. This allowed the CAFC in *Cyclobenzaprine* to find two factors present on account of a single perceived failure. In this way, the ultimate goal of the inquiry is lost, and courts can buttress their decisions by recycling weak evidence through each factor. More precise analysis would limit these problems and allow courts to enact policies that incentivize efficient innovation. The following section is intended to address this weakness in detail.

#### A. Long-felt Need

¶63 The circumstances in which courts perceive a long-felt need do not always suggest that the invention was nonobvious. Instead, courts have found long-felt need when merely presented with evidence that the invention was desirable, or where the invention improved on previous technologies.<sup>149</sup>

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<sup>144</sup> *Cyclobenzaprine II*, 676 F.3d at 1078.

<sup>145</sup> *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

<sup>146</sup> *Id.* at 17-18.

<sup>147</sup> *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007) (emphasis added).

<sup>148</sup> *Cyclobenzaprine I*, 794 F.Supp.2d at 533 (emphasis added), (citing *KSR*, 550 U.S. at 406).

<sup>149</sup> The purpose of the nonobviousness requirement is to determine the increment of improvement, not that the invention represented any improvement at all. *See, e.g.*, George M. Sirilla & Honorable Giles S. Rich, 35 *U.S.C. ... 103: From Hotchkiss to Hand to Rich, the Obvious Patent Law Hall-of-Famers*, 32 *J. MARSHALL L. REV.* 437, 447 (1999).

¶164 Long-felt need is particularly susceptible to being derived from evidence more properly falling under a different category. In *Cyclobenzaprine*, the CAFC pointed to precedent holding that a previous failure to invent was evidence of a long-felt need. Commercial success can also be used as evidence of a fulfilled need in a market.<sup>150</sup>

¶165 What courts have found to be a long-felt need might merely show that the inventor improved an existing technology. In *Cyclobenzaprine*, the CAFC reasoned that because patient compliance was desirable and the extended-release form of a drug improved compliance, there was a long-felt need for an extended-release formulation of cyclobenzaprine.<sup>151</sup> However, the district court's holding, that any such need was met by existing products, is more persuasive. By the CAFC's reasoning, any improvement of a technology is evidence of nonobviousness, if the inventor can find an expert to testify that the new product would be better than its direct antecedents. Such an invention might only weakly meet the policy goals of patent law in a general sense, because social benefit is minimal where more than one near substitute is already available.<sup>152</sup> The fundamental purpose of nonobviousness analysis is to determine the increment of improvement, not whether an improvement took place.<sup>153</sup>

¶166 A contrasting example is provided by the reasoning in *Transocean v. Maersk*, where the claimed "dual-activity" oil rig design measurably improved deepwater drilling efficiency over *any other* oil rig available.<sup>154</sup> Deepwater drilling, expert testimony revealed, had been taking place since the 1970s.<sup>155</sup> This was more persuasive evidence of nonobviousness than that claimed in *Cyclobenzaprine*.<sup>156</sup> At the least, such a gain in efficiency evidenced that the invention presented a measurable social benefit that might well be befitting of patent protection.

¶167 Finally, a more particular standard of long-felt need was explained in *Rambus Inc. v. Hynix Semiconductor Inc.*:

A long-felt need implies the existence of an articulated and identified problem in the art calling out for a solution. The existence of a long-felt need for a solution to the problem suggests that others of skill in the art tried to solve the problem, but did not develop the claimed invention (which

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<sup>150</sup> See 2 D. CHISUM, PATENTS § 5.05[1][d] at 5–579 ("Finally, it must appear that the inventor's solution in fact satisfied the long-felt need, that is, reached a result superior to prior solutions. For this reason, it is common for supporters of patent claims to combine evidence of long-felt need with evidence of the commercial success of the invention.") (citing *Caldwell v. United States*, 481 F.2d 898 (1973), *cert. denied*, 416 U.S. 938, 94 S.Ct. 1938 (1974)).

<sup>151</sup> *Cyclobenzaprine II*, 676 F.3d at 1082-83.

<sup>152</sup> Where only one substitute product is on the market, the policy question is less clear since a competitor would presumably have to entice price competition, though this is not always the case. Additionally, parallel behavior in the market with only two competitors might mean that price competition is absent.

<sup>153</sup> See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 9 (1966).

<sup>154</sup> 699 F.3d 1340, 1354 (2012). It is worth noting that percentage improvements in efficiencies of oil rigs allowed direct comparison with existing technologies.

<sup>155</sup> *Id.*

<sup>156</sup> The evidence of long-felt need found in *Transocean* is questionable under the obviousness doctrine of *KSR*. See discussion in subsection c., *infra*.

must, of course, solve the problem). In turn, this suggests that the claimed invention is not obvious.<sup>157</sup>

Revealingly, the *Rambus* court's reasoning ties long-felt need evidence to the obviousness standard, something that the *Cyclobenzaprine* courts did not do, at least explicitly.<sup>158</sup>

¶168 The preceding discussion exposes three questions, which were not satisfactorily answered by the courts in the preceding examples: (1) was there a known problem in the art that needed solving? (2) what was the specific nature of the unmet need? and (3) when did it arise?<sup>159</sup> *AstraZeneca Pharm. LP v. Anchen Pharm., Inc.*<sup>160</sup> provides a good example of a specific technological need. There, the court found "a recognized but unmet medical need for an effective drug therapy for the treatment of bipolar depression," a need which arose prior to the time of invention in May 1997.<sup>161</sup> The key distinction between the invention in *AstraZeneca* and the previous examples provided here is that in the latter cases, no product provided a substantial solution to the problem addressed by the patented invention. In *Cyclobenzaprine*, the district court identified other substitute products and showed the art lacked a problem to solve, while in *Transocean*, the CAFC noted only an increase in efficiency, not that deepwater drilling was impossible or substantially impossible before the invention of a dual-activity rig. The presence of substantial substitute products capable of deepwater drilling again shows a lack of a specific problem solved.

This analysis points to three separate categories of inventions courts have credited as meeting a long-felt need. First, an invention with improved characteristics over direct antecedents, but one which is not clearly an improvement over existing substitutes, as demonstrated in the CAFC's ruling in *Cyclobenzaprine*. Second, an invention that is an unequivocal improvement over any substitute technology at the time of invention. This category requires direct comparison between products of an index that is backed by the consensus of experts, as found in *Transocean*. Third, an invention that fills a niche that no previous technology could fill, as was the case in *AstraZeneca*. This third category of invention represents the purest form of long-felt need. However, even the third category requires supporting evidence, since a court should identify *ex ante* expert disclosures in a field expressing desire for a product with specific characteristics, and that the invention's closest existing substitutes did not substantially meet the need.

¶169 Even the third, and strongest, category of long-felt need could be mooted due to intervening causes. For example, when a necessary material with particular properties appears, long-felt need might be solved by a recent disclosure by other researchers relied on by the inventor and making the invention obvious given the new technology. New regulations could spur the invention.<sup>162</sup> A spike in market demand might incentivize researchers to produce the invention.<sup>163</sup> Finally, a delay in the appearance of the invention could be due to ethical concerns.<sup>164</sup> Such issues raise concerns about the inference of

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<sup>157</sup> *Rambus Inc. v. Hynix Semiconductor Inc.*, 254 F.R.D. 597, 607 (N.D. Cal. 2008) (citations omitted).

<sup>158</sup> However, the *Rambus* court's reasoning once again conflates long-felt need and failure of others.

<sup>159</sup> *Perfect Web Technologies, Inc. v. InfoUSA, Inc.*, 587 F.3d 1324, 1332 (Fed. Cir. 2009) (citing *Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1178 (Fed. Cir. 1993)).

<sup>160</sup> 2012 WL 1065458 (D.N.J. Mar. 29, 2012) *aff'd*, 498 F.App'x 999 (Fed. Cir. 2013).

<sup>161</sup> *Id.*; see also *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369 (Fed. Cir. 2006).

<sup>162</sup> *E.g.*, *Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1377 (Fed. Cir. 2000).

<sup>163</sup> *Abramowicz & Duffy*, *supra* note 56, at 1677.

<sup>164</sup> See *PerkinElmer, Inc. v. Intema Ltd.*, 2011 WL 10756712, at \*21 (D. Mass. Aug. 12, 2011) *aff'd in*

nonobviousness. Litigants would be well-advised to seek evidence of such intervening causes.

¶70 Finally, the preceding analysis exposes an important time index. As noted by the *Rambus* court, a long-felt need should arise at a particular time; specifically, whether the need arose *ex ante* or *ex post* of the patented invention is critical. To reflect that the invention was nonobvious, the testimony or public statement of need should reflect that the invention was desired at the time of invention but was not forthcoming. An *ex ante* need could be reflected in statements or publications appearing prior to the invention, or could be testified to by a witness during litigation; the former type is clearly more persuasive. An *ex post* need, as was credited in *Cyclobenzaprine*, might reflect nothing more than the opinion of an interested expert who has an incentive to argue that an invention was patentable.

### B. Failure of Others

¶71 Failure of others is a deceptively attractive secondary consideration. The inference is that someone else tried and failed to make the invention, and so the invention could not have been easy to make. However, this evidence, like other secondary considerations, raises a number of questions. In addition to the concerns given in the discussion of the *Cyclobenzaprine* decision, one could imagine other problems that, under the current system, would severely stress a court's ability to connect the inferential chain.

¶72 For example, the previous would-be inventors may have ceased research due to the cost of producing the resulting product rather than due to a lack of insight. The would-be inventors may have lacked access to critical information from the prior art because they were not aware of key references.<sup>165</sup> They may have suffered from an inferior brand image that would make introduction of a new product risky. Their capital may have disappeared or become prohibitively expensive. A key employee might have left due to a disagreement. Evidence of failure of others may be mooted when an inventor relies on technology that appeared in the prior art *after* the claimed failure.<sup>166</sup> As shown by the *Cyclobenzaprine* decision, a past failure could be multiplied into long-felt need, unexpected results, expert skepticism, and an expectation of failure in combining known elements with little or no corroborating evidence.

### C. Long-felt Need vs. Motivation to Combine Doctrine

¶73 The *Cyclobenzaprine* court's careless treatment of long-felt need is particularly problematic in light of the *KSR* doctrine of motivation to combine. The *KSR* Court looked for "any need or problem known in the field of endeavor" to provide motivation to combine known elements.<sup>167</sup> A marketplace incentive is one such motivation, as market demand can

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*part, rev'd in part*, 496 F. App'x 65 (Fed. Cir. 2012), *cert. denied*, 2013 WL 2155734 (U.S. Oct. 7, 2013) (arguing that expert skepticism due to ethical concerns was not evidence of nonobviousness).

<sup>165</sup> Intuitively, costs of researching the prior art are lower than those incurred in pursuing a duplicative research program. *See* Abramowicz & Duffy, *supra* note 56, at 1615-16 (arguing for an economic standard of personhood in obviousness determination).

<sup>166</sup> *See* John F. Duffy, *A Timing Approach to Patentability*, 12 LEWIS & CLARK L. REV. 343 (2008).

<sup>167</sup> *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 420 (2007).

drive design decisions.<sup>168</sup> In *KSR*, the Court noted that “[t]here then existed a marketplace that created a strong incentive to convert mechanical pedals to electronic pedals, and the prior art taught a number of methods for achieving this advance.”<sup>169</sup> The prior element need not be directed at solving the same problem the patentee seeks to solve.<sup>170</sup>

¶74 A broad conception of “long-felt need,” as exemplified by the CAFC’s reasoning in *Cyclobenzaprine*, is dangerously commensurate with a market incentive. The two overlap, since a demand for a product could be a source of such need.<sup>171</sup> In *KSR*, the market demanded electronic gas pedals to allow more careful tuning to improve fuel economy and lower emissions, but the Court saw the demand for electronic pedals as weighing towards obviousness.<sup>172</sup>

¶75 Long-felt need probes the limits of the motivation to combine reasoning of *KSR*. If a notably long period of time elapses after a need arose, an inference that the invention was nonobvious is warranted. Thus, the presence of *ex ante* evidence of need indicates that the invention presented particular challenges. An inventor who overcomes these challenges deserves to be rewarded; this is the essence of long-felt need.

¶76 The Supreme Court’s treatment of an incentive to combine elements is inconsistent with the *Cyclobenzaprine* court’s conception of a long-felt need.<sup>173</sup> In *Cyclobenzaprine*, the CAFC found that a long-felt need, emanating in part from the desire of doctors to have muscle relaxants with good patient compliance, was objective evidence of nonobviousness.<sup>174</sup> However, the analogy with *KSR* suggests a different view, that old inventions modified to fit new, market-demanded, categories are more likely obvious. In *KSR*, the category was pedals with electronic sensors; in *Cyclobenzaprine*, the category was formulations using extended-release technology. Hence, doctors’ demand for pharmaceuticals with improved patient compliance noted by the CAFC<sup>175</sup> indicates, by *KSR*’s reasoning, the obviousness of the combination. Importantly, the CAFC, in relying on *ex post* evidence, did not probe the length of time the invention was supposedly needed.

¶77 In its overreliance on, and over-generality in, secondary considerations, the CAFC ignores the principle underlying *KSR*. Where the claimed elements of the invention are found in the prior art, a need for a particular category of product provides an incentive to combine elements; it does not indicate a longstanding need for something new.

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<sup>168</sup> See *id.* at 419.

<sup>169</sup> *Id.* at 424.

<sup>170</sup> *Id.* at 420.

<sup>171</sup> See *Shuffle Master, Inc. v. MP Games LLC*, 553 F. Supp. 2d 1202, 1225 (D. Nev. 2008) (“The evidence of long-felt need can cut two ways: On the one hand, long-felt need might be considered evidence of non-obviousness, but on the other hand, to the extent that other factors support obviousness, the existence of ‘market pressure to solve a problem’ can support a finding of obviousness where there are a finite number of possible solutions.”).

<sup>172</sup> *KSR*, 550 U.S. at 424.

<sup>173</sup> Long-felt need is a secondary consideration recited by the Court, however the Court’s opinions give no indication it has considered the implications of this factor since *KSR*. One district court has recognized the tension between the two doctrines. See *Shuffle Master*, 553 F. Supp.2d at 1224 (finding “a motivation to try the limited possibilities for utilizing image processing” in the face of an argument for a long-felt need for casino surveillance technology).

<sup>174</sup> *Cyclobenzaprine II*, 676 F.3d at 1083.

<sup>175</sup> See *id.*

#### IV. POLICY PRESCRIPTIONS

##### A. Analyze Inferences

¶78 The *Cyclobenzaprine* decision shows this troubling aspect of secondary considerations jurisprudence: courts can buttress their decisions by recycling weak evidence through each factor. This Note proposes that courts verify that the evidence before the court derives from the nonobviousness of the invention rather than from other forces. In order to meet this goal, two outcomes are desirable. First, courts should be more skeptical in connecting the inferential chain from evidence to nonobviousness; second, each secondary consideration should be a narrowly-defined, discrete factor. A carefully-wrought framework for each factor would allow courts to meet these requirements.<sup>176</sup> Ideally, courts would develop the framework for each factor would be developed based on practical and theoretical considerations. This could be framed as a doctrinal expansion of the nexus inquiry.

¶79 The final goal of this Note is to create a framework to ensure the persuasiveness of long-felt need evidence. In the following section, I propose by way of example a series of questions for determining whether evidence that a court might accept as long-felt need is *bona fide* evidence that an invention was long desired.

##### B. Bona Fide Long-felt Need

¶80 Evidence that an invention is an improvement over its antecedents does not provide evidence of a long-felt need. Furthermore, evidence that the invention improves efficiency over any available product should not be weighed as long-felt need. Such evidence is more properly considered as expert praise for the invention.

¶81 When one examines the policy behind long-felt need, it is clear that a mere improvement, in the absence of *ex ante* evidence of its importance, should not be sufficient to indicate a long-felt need. I do not argue that a significant improvement over substitutes such as shown in *Transocean* should not be evidence of nonobviousness, but only that it is not evidence of a long-felt need. When courts rule a long-felt need present because experts testify that the invention improves its predecessors, they impute long-felt need to something else, perhaps expert praise.

¶82 The third category of long-felt need discussed in Part III above, is more convincing as evidence of nonobviousness. If experts in a field called for an invention having specific characteristic such that no existing invention provided a substantial substitute, then a *bona fide* need is evident. *Ex ante* expert statements pointing out a need for an invention with particular properties allow the court to infer that the problem to be solved was widely known and important, and that no solution was forthcoming, even to the expert. This may or may not imply that the invention would be commercially valuable. In the most persuasive case, the expert statements will call for an invention that fills a niche for which no existing product provides a satisfactory substitute, or perform a function that no existing product can perform adequately. Expert statements might call for improvements of inventions that already substantially perform a particular function. This type of statement

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<sup>176</sup> For a previous contribution on this topic, see Jonathan J. Darrow, *Secondary Considerations: A Structured Framework for Patent Analysis*, 74 ALB. L. REV. 47, \*54, \*71 (2011).

evidences that the problem needing to be solved, or the improvement desired, was an important one for which a solution was not obvious.

¶183 This change would go some length towards mitigating the doctrinal conflict with the Supreme Court's *KSR* decision. A general market need does not reflect nonobviousness given the policy considerations underlying the *KSR* Court's reasoning. The Court states that patent law need not protect inventions which would arise without the incentive of a patent.<sup>177</sup> Under the Court's reasoning, a market need, such as the need for pedal with electronic sensors in *KSR*, or the general need for improved efficiency as in *Transocean*, provides such an incentive. Thus, long-felt need as evidence of nonobviousness should arise only when a specific, articulated need has been identified by experts in the field of art, and a significant period of time has elapsed since the need arose.

¶184 Courts should not require evidence that others attempted a solution to find a long-felt need present in a field of art. Some courts have attached such a requirement,<sup>178</sup> while others, such as the *Cyclobenzaprine* court, imply that failure alone is sufficient.<sup>179</sup> On the one hand, this makes some sense because a desire for a particular invention can be derived from attempts to make it, and such attempts might show the invention is challenging. However, the absence of previous attempts to solve the problem does not indicate that the desired invention is more obvious. This is because one aspect of invention might involve a re-framing of the question posed by a particular inventive possibility. For example, if the dogma in a field of art holds that two elements cannot be combined, an innovator might imagine a new method for their combination, or might draw on knowledge from a nonanalogous art.<sup>180</sup> The lack of previous inventive activity towards a long-desired invention should give courts pause, and direct them to look for intervening causes that might break the inferential chain to nonobviousness, though.

¶185 In the same vein, previous attempts to develop an invention or product should not be sufficient for a finding of long-felt need. Such failure is a discrete factor that should remain so. Keeping these two factors separate gives courts the best opportunity to weigh the evidence presented to them and make an objective determination. A bona fide failure of others is persuasive evidence in its own right.

¶186 In sum, I would propose that courts ask seven questions in determining if a long-felt need for a particular invention was present: (1) was there a problem in the art that needed solving? (2) what was the specific nature of the problem? (3) when did the need arise or when was the problem first identified? (4) was the problem a public one, and one that was accepted by experts in the field? (5) did sufficient time pass since the need was identified to allow others to consider the problem? (6) were others successful in meeting the need? (7) what intervening causes might have made the invention more obvious or more feasible since the articulated need arose?<sup>181</sup>

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<sup>177</sup> *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 11 (1966).

<sup>178</sup> *See, e.g., Mformation Techs., Inc. v. Research in Motion Ltd.*, No. C 08-04990 JW, 2012 WL 1142537, at \*5, \*9 (N.D. Cal. Mar. 29, 2012).

<sup>179</sup> *See supra* Part III.

<sup>180</sup> *See Pedraza-Fariña, supra* note 120, at 841.

<sup>181</sup> The obviousness requirement should prevent patenting of invention that is valuable only because of "exogenous developments." John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 12-13 (2007) (arguing that Amazon.com's one-click patent, and the patent on the automobile, fit in this category).

## V. CONCLUSION

¶87 Secondary considerations of nonobviousness, though well-suited to counter the lack of expertise of the courts when technical matters are central to a case, must be wielded with care. Secondary considerations, as currently practiced, are subject to serious criticism on a number of fronts: due to their troubling interconnectedness, they are heavily influenced by the biases of the factfinder, they implicate questionable inferences, and they are in tension with *KSR* nonobviousness doctrine. Theoretical analysis of when to take into account secondary considerations in obviousness determinations, along with empirical studies of their impact, would provide grist for further policy prescriptions.

¶88 Analysis of the *Cyclobenzaprine* decisions reveals how the CAFC's use of secondary considerations plays out in practice. The state of the larger doctrine is reflected in the unexamined inferences underlying long-felt need and failure of others. A number of concerns limit the real-world objectivity and persuasiveness of these seemingly-reliable factors. To meet these concerns, this Note provided a framework for analysis of long-felt need that aims to be comprehensive in asking whether the evidence provided is truly probative of the named factor.

¶89 Until Congress or the Supreme Court take action to reign in the CAFC in their application, courts would be well-advised to apply the secondary considerations only with vigilance and careful circumspection.





