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## Rethinking Enablement in the Predictable Arts - Fully Scoping the New Rule

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# Stanford Law Review

## Rethinking Enablement in the Predictable Arts: Fully Scoping the New Rule

BERNARD CHAO\*

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### ABSTRACT

In exchange for granting inventors a limited monopoly, the patent laws require inventors to “enable” the public to make and use their invention. In *Liebel-Flarsheim Co. v. Medrad, Inc.*, *Automotive Technologies International, Inc. v. BMW of North America, Inc.*, and *Sitrick v. Dreamworks, L.L.C.*, the Federal Circuit made it far easier to show that patents are invalid based on lack of enablement in the predictable arts. These decisions rely on the enablement doctrine to invalidate claims that appear to be far broader in scope than what the written description of the patents suggests.

This Article: (1) explains the rationale underlying the enablement doctrine; (2) traces how the doctrine has evolved into various inconsistent tests; (3) analyzes the three new decisions; and (4) rejects the “full scope” rule that these decisions advance. Specifically, this Article argues that in the predictable arts, the full scope rule is extremely difficult to apply and will cause unnecessary litigation. Moreover, the enablement doctrine is a blunt instrument that rewards unintended beneficiaries and cannot consider all the facts important to an overbreadth analysis. Therefore, the enablement doctrine is not well suited to addressing the problem of generic or overbroad claims.

This Article concludes that the Federal Circuit should take a step back from the full scope rule and return to the principles set forth in its earlier decisions. Finally, this Article suggests that if the Court truly wishes to address overbroad or generic claims, the doctrines of claim construction and the reverse doctrine of equivalents are better vehicles for accomplishing that goal.

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## I. INTRODUCTION

The primary goal of the patent system is to promote innovation without stifling competition.<sup>1</sup> Patents encourage innovation by granting inventors a monopoly to make, use, and sell the patented technology for a limited term.<sup>2</sup> However, when patent rights become too strong, competition can be harmed.

For several years, the predominant view has been that the scales have tipped too far in favor of patent holders.<sup>3</sup> In response, the courts have been reining in patent holders' rights in several different ways. For example, in *KSR International Co. v. Teleflex Inc.*, the Supreme Court clarified the obviousness standard, making it easier to combine references and invalidate patents.<sup>4</sup> In *eBay Inc. v. MercExchange, L.L.C.*, the Supreme Court overruled years of Federal Circuit precedent that granted permanent injunctions to virtually all prevailing plaintiffs.<sup>5</sup> Under the new standard announced in *eBay*, courts must use the same four-factor test that they use for other types of cases. This has resulted in fewer permanent injunctions and reduced the value of patents.<sup>6</sup> The Federal Circuit has also limited patent holders' rights in new ways. For example, in *In re Seagate*, the Federal Circuit made it more difficult for patent holders to prove willful infringement by adopting a recklessness standard to replace the previous standard, which was more akin to negligence.<sup>7</sup>

This anti-patent trend has now touched yet another doctrine. Previously, when confronted with broad or generic claims, defendants raised two primary arguments: 1) the claims should be construed narrowly; and 2) the claims are invalid based on the prior art. Three recent Federal Circuit decisions—*Libel-Flarsheim Co. v. Medrad, Inc.*,<sup>8</sup> *Automotive Technologies International, Inc. v. BMW of North America, Inc.*,<sup>9</sup> and *Sitrick v. Dreamworks, L.L.C.*<sup>10</sup>—have expanded the enablement defense and provided defendants with another tool to challenge claims that have a far broader scope than might be expected from reading the patent's specification.

These decisions rely upon and then extend principles developed in one line of enablement decisions. They ignore, however, another line of cases that has evolved separately. This second line of cases simplified the enablement standard so that a specification that enables *any* embodiment satisfies the enablement requirement notwithstanding the breadth of the claims. *Libel-Flarsheim*, *Automotive Technologies*, and *Sitrick* take the existing split in Federal Circuit law and pry it even further open. The three recent decisions held claims invalid because the descriptions did not enable the *full scope* of the claimed invention. The “full scope” rule, as applied in these decisions, suggests that if a patent fails to enable any embodiment that falls within the scope of the claim, the claim is invalid.

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<sup>1</sup> See FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 1-4 (2003) [hereinafter INNOVATION] (discussing goals of patent policy), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf>.

<sup>2</sup> 35 U.S.C. § 154(a).

<sup>3</sup> See Thomas F. Cotter, *Patent Holdup, Patent Remedies, and Antitrust Responses*, 34 J. CORP. L. (forthcoming 2009) (working paper at 3, available at <http://ssrn.com/abstract=1273293>) (“In recent years, influential scholars, practicing lawyers, government officials, government commissions, enforcement agencies, and courts have all identified the phenomenon of ‘patent holdup’ as a serious problem that may require various reforms to both patent and antitrust law.” (footnotes omitted)); see also Douglas Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 47 n.5 (2007) (“Calls for patent reform have echoed loudly over the past several years, with industry organizations, patent scholars, and government agencies all publicly announcing that the patent system is broken and that the PTO in particular is letting a large number of undeserving patents be issued.”).

<sup>4</sup> 550 U.S. 398 (2007).

<sup>5</sup> 547 U.S. 388 (2006).

<sup>6</sup> See Bernard H. Chao, *After eBay, Inc. v. MercExchange: The Changing Landscape for Patent Remedies*, 9 MINN. J.L. SCI. & TECH. 543 (2008).

<sup>7</sup> *In re Seagate Tech., LLC*, 497 F.3d 1360 (Fed. Cir. 2007).

<sup>8</sup> 481 F.3d 1371 (Fed. Cir. 2007).

<sup>9</sup> 501 F.3d 1274 (Fed. Cir. 2007).

<sup>10</sup> 516 F.3d 993 (Fed. Cir. 2008).

These results would not have been surprising if the patents were found in the unpredictable arts (e.g. chemical or biotechnology). In those fields, the law has long required the specification to provide a higher level of detail to satisfy the enablement requirement.<sup>11</sup> However, the patents in *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* relate to technology that would normally be considered to fall within the predictable arts. These decisions operate under the pretense that they are simply applying existing enablement law. This Article argues that the cases represent a new direction. Before the entire Federal Circuit adopts this approach, it should consider whether applying the full scope rule in the predictable arts is the best course. To aid in that analysis, this Article reevaluates the enablement doctrine and attempts to identify potential problems with the full scope rule.

Part II of this Article reviews the case law that existed prior to *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* and discusses the original split. Part III describes the three recent enablement decisions and how they differ from previous case law. Part IV summarizes the current split. Part V critically analyzes whether the new full scope rule is appropriate. Specifically, this Article explains that the goal of the full scope rule is to address overbroad claims and why the enablement doctrine is not particularly well suited to address that problem. Moreover, because innovation in the predictable arts tends to be incremental, the full scope rule is extremely difficult to apply. This may allow zealous defendants to raise an enablement defense in far too many lawsuits.

Finally, Part VI suggests the following: 1) the Federal Circuit should stop focusing on the full scope of a claim and return to weighing traditional factual considerations; and 2) to the extent that the Federal Circuit is attempting to address overbroad claims, it should consider other doctrines whose remedies are better suited for reining in broad patents.

## II. ENABLEMENT LAW, BACKGROUND

### A. Section 112: Enablement

The statutory basis of the enablement requirement is found in 35 U.S.C. § 112, which states that the specification shall describe “the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the [invention] . . . .”<sup>12</sup>

This requirement is satisfied when a person of ordinary skill in the art, after reading the specification, could practice the claimed invention without undue experimentation.<sup>13</sup> The issue of enablement is “a question of law based on underlying facts.”<sup>14</sup>

### B. The Predictability Issue

Historically, courts have treated inventions involving the predictable arts differently from those in the unpredictable arts. In *In re Fisher*, the Court of Customs and Patent Claims explained the rationale underlying this distinction:

In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such

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<sup>11</sup> See *infra* note 15 and accompanying text.

<sup>12</sup> 35 U.S.C. § 112 (2006).

<sup>13</sup> *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (“Enablement . . . is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive . . .”).

<sup>14</sup> *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1238 (Fed. Cir. 2003) (citing *In re Wands*, 858 F.2d 731, 735 (Fed. Cir. 1988)).

as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.<sup>15</sup>

Importantly, *Fisber* does not describe a different standard for different technologies. Rather, the decision explains why, in practice, a disclosure of a single embodiment in the predictable arts may enable broad claims. In cases where the technology is predictable, disclosing a single embodiment will often allow persons of skill in the art to practice other embodiments. As the technology becomes less predictable, persons of skill in the art may not understand how to practice other embodiments without additional insights.

In *In re Wands*, the Federal Circuit incorporated the issue of “predictability” into its analysis of the enablement standard.<sup>16</sup> Although the term “undue experimentation” does not appear in the statute, “it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation.”<sup>17</sup> The Federal Circuit stated that “[w]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.”<sup>18</sup> The Court then listed a number of factors to be considered:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.<sup>19</sup>

Thus, under *Wands*, the enablement standard is a nuanced test that depends on a number of different factors. As our analysis reveals, many subsequent decisions have simplified that test and focused merely on the issue of predictability.

*In re Vaeck* suggests that, regardless of whether a case falls within the predictable or unpredictable arts, the specific technology must still be examined.<sup>20</sup> In *Vaeck*, the claimed invention was directed to the production of proteins that are toxic to mosquito and black fly larvae.<sup>21</sup> The protein was produced by hosting them in cyanobacteria.<sup>22</sup> Although the claims at issue were directed to cyanobacteria generally, the specification mentioned only nine genera of cyanobacteria and described only one particular species of cyanobacteria in the working example.<sup>23</sup>

The United States Patent and Trademark Office (“Patent Office”) rejected the claims for lack of enablement. On appeal, the Federal Circuit noted that the “molecular biology of [cyanobacteria] has only recently become the subject of intensive investigation and this work is limited to a few genera. Therefore the level of unpredictability . . . is high.”<sup>24</sup> The Federal Circuit went on to affirm the enablement rejection, explaining that “[t]here is no reasonable correlation between the narrow disclosure in appellants’ specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria.”<sup>25</sup>

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<sup>15</sup> 427 F.2d at 839; see also *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1367 (Fed. Cir. 1997) (stating that, in the context of an “unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching”).

<sup>16</sup> 858 F.2d 731, 737 (Fed Cir. 1988).

<sup>17</sup> *Id.* (citing *Hybritech*, 802 F.2d at 1384 and *Atlas Powder Co. v. E. I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984)).

<sup>18</sup> *Id.*

<sup>19</sup> *Id.* (citing *In re Forman*, 230 U.S.P.Q. (BNA) 546, 547 (B.P.A.I. 1986)).

<sup>20</sup> 947 F.2d 488 (Fed. Cir. 1991).

<sup>21</sup> *Id.* at 489.

<sup>22</sup> *Id.*

<sup>23</sup> *Id.* at 495 (stating that there are approximately 150 genera of cyanobacteria).

<sup>24</sup> *Id.* at 493.

<sup>25</sup> *Id.* at 495.

However, the Court cautioned against applying its holding to all patent applications in the “unpredictable” arts:

[W]e do *not* imply that patent applicants in art areas currently denominated as “unpredictable” must never be allowed generic claims encompassing more than the particular species disclosed in their specification. It is well settled that patent applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art.<sup>26</sup>

Thus, although the Federal Circuit found that a specification describing a single embodiment was insufficient to enable the broad claims in *Vaeck*, the decision also suggested that such a disclosure could be sufficient in other circumstances—even in the unpredictable arts.<sup>27</sup>

### C. *In re Wright and the Full Scope of a Claim*

From an analytical perspective, *In re Wright*<sup>28</sup> is not a particularly noteworthy case. It is a decision in the unpredictable arts that uses the same kind of analysis as *Vaeck* to arrive at a similar result. However, from a historical perspective, *Wright* is important because it appears to be the first decision to characterize § 112 as requiring enablement of the “full scope of the claimed invention.”<sup>29</sup>

In *Wright*, the patent application described the production of a recombinant vaccine that confers immunity in chickens against the RNA tumor virus known as Prague Avian Sarcoma Virus. The application contained claims directed to the specific process and vaccine disclosed in the specification.<sup>30</sup> The application, however, also sought claims for a much broader scope of protection, including claims that read “on vaccines against *all* pathogenic RNA viruses.”<sup>31</sup> The Patent Office rejected the broader claims on the grounds that the specification did not enable the full scope of the claims.

In reviewing the Patent Office’s decision, the Federal Circuit described the enablement requirement: “Although not explicitly stated in section 112, to be enabling, the specification of a patent must teach those skilled in the art how to make and use the *full scope* of the claimed invention without ‘undue experimentation.’”<sup>32</sup>

The decision cited *Vaeck*, *Wands*, and *Fisher*. However, none of these decisions use the term “full scope,” nor does *Wright* actually focus on that language in its analysis. Rather the Federal Circuit upheld the enablement rejection based on a straightforward application of the enablement requirement. The decision explained that, “Wright has failed to establish by evidence or arguments that . . . a skilled scientist would have believed reasonably that Wright’s success with a particular strain of an avian RNA virus could be extrapolated with a reasonable expectation of success to other avian RNA viruses.”<sup>33</sup> Predictability was an important factor in the outcome. The Court noted that the claims at issue encompassed AIDS vaccines and that, “because of the high degree of genetic, antigenic variations in such viruses, no one ha[d] yet . . . developed a generally successful

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<sup>26</sup> *Id.* (emphasis in original) (citing *In re Angstadt*, 537 F.2d 498, 502-03 (C.C.P.A. 1976)).

<sup>27</sup> *Id.* See, e.g., *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342 (Fed. Cir. 1998). The claims at issue were drawn to the genus of antibodies that bind to the claimed antigen. The defendant, Cellpro, argued that the specification only disclosed the method of producing the anti-My-10 antibody and thus did not enable the claims that covered the entire genus. *Id.* at 1359. The Court rejected the enablement defense in part based on an expert declaration stating that the expert was able to produce six antibodies using the disclosed method. *Id.* at 1361.

<sup>28</sup> 999 F.2d 1557 (Fed. Cir. 1993).

<sup>29</sup> *Id.* at 1561 (emphasis added).

<sup>30</sup> *Id.* at 1559.

<sup>31</sup> *Id.* at 1560 (emphasis in original).

<sup>32</sup> *Id.* at 1561 (emphasis added) (citing *In re Vaeck*, 947 F.2d 488, 495 (Fed. Cir. 1991); *In re Wands*, 858 F.2d 731, 736 (Fed. Cir. 1988); and *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) ).

<sup>33</sup> *Id.* at 1564.

AIDS virus vaccine.”<sup>34</sup> In sum, the Federal Circuit found that the broad claims of an unpredictable technology were not enabled even though the specification had clearly enabled one embodiment.

This unremarkable decision serves as the foundation of the analysis for *Liebel-Flarsheim*, *Automotive Technologies* and *Sitrick* because of the particular way it characterized the enablement standard. Although many decisions cite *Wright* for the proposition that the “full scope of the claims” must be enabled,<sup>35</sup> those cases do not focus on the phrase in the same manner as *Liebel-Flarsheim*, *Automotive Technologies* and *Sitrick*.

#### *D. The Bright Line Test: Enabling a Single Embodiment is Sufficient*

As shown above, describing one embodiment is often insufficient to enable broad claims in the unpredictable arts. In contrast, decisions in the predictable arts have found that describing one embodiment satisfies the enablement requirement even when the claims are much broader. In contrast to *Fisher*, *Wands*, and *Vaack*, these decisions appear to apply a bright line rule suggesting that describing a single embodiment is always sufficient to satisfy the enablement requirement.

In *Spectra-Physics, Inc. v. Coherent, Inc.*, the ion laser patents stressed the importance of attaching two components that would have to endure repeated heat cycles.<sup>36</sup> That feature was evident in the claims at issue which required a “means for attaching” or essentially the same step of “permanently securing.”<sup>37</sup> The district court found that claims were not enabled because the specification only disclosed pulse soldering and moly-manganese brazing. However, the evidence showed that the patentee actually used a six stage braze cycle that was “necessary to the enjoyment of the invention.”<sup>38</sup> The Federal Circuit reversed the lack of enablement finding and stated:

If an invention pertains to an art where the results are predictable, e.g., mechanical as opposed to chemical arts, a broad claim can be enabled by disclosure of a single embodiment and is not invalid for lack of enablement simply because it reads on another embodiment of the invention which is *inadequately disclosed*.<sup>39</sup>

Thus, *Spectra-Physics* stands for the proposition that in the predictable arts, disclosure of a single embodiment is sufficient to enable a much broader claim that is not taught. That is true even if the claim reads on embodiments that are inadequately disclosed.

In 1991, four years after *Spectra-Physics*, the Federal Circuit began reciting this rule without limiting it to the predictable arts. In *Engel Industries, Inc. v. Lockformer Co.*,<sup>40</sup> the primary issue was whether the patentee properly disclosed the best mode. However, the decision also addressed enablement. In one brief paragraph with no analysis, the *Engel* decision rejected the enablement defense by reciting the following rule: “The enablement requirement is met if the description enables *any mode* of making and using the claimed invention.”<sup>41</sup>

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<sup>34</sup> *Id.* at 1562.

<sup>35</sup> See, e.g., *Chiron Corp. v. Genentech, Inc.*, 363 F.3d 1247, 1253 (Fed. Cir. 2004); *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997).

<sup>36</sup> *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1529 (Fed. Cir. 1987).

<sup>37</sup> *Id.* at 1533.

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

<sup>39</sup> *Id.* (emphasis added) (citations omitted) (citing *Gould v. Mossinghoff*, 711 F.2d 396, 400 (D.C. Cir. 1983) (labeling the rule “settled”)); see also *In re Vickers*, 141 F.2d 522 (C.C.P.A.1944). In *Spectra-Physics*, the Court upheld the district court’s invalidity finding on the alternative ground of failing to disclose the best mode. 827 F.2d at 1537. Arguably, this makes the decision reversing the enablement finding dicta. However, the Court expressly discussed its decision on enablement as a holding. *Id.* at 1538. *But see* Pierre N. Leval, *Judging Under the Constitution: Dicta About Dicta*, 81 N.Y.U. L. REV. 1249, 1257 (2006) (“dictum is not converted into holding by forceful utterance, or by preceding it with the words ‘We hold that . . .’”).

<sup>40</sup> 946 F.2d 1528 (Fed. Cir. 1991).

<sup>41</sup> *Id.* at 1533 (emphasis added) (citing *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 926 (Fed. Cir. 1990)). However, *Chemcast* does not address the issue of whether disclosing a single embodiment can satisfy the enablement requirement.



The technology in *Engel* resided in the predictable arts: connecting duct segments that distribute air through buildings.<sup>42</sup> However, unlike *Spectra-Physics*, *Engel* did not qualify the rule recited above by suggesting that it only applied to the predictable arts. If *Engel* stood by itself, it probably could be overlooked as a poorly considered outlier. However, numerous subsequent Federal Circuit decisions have cited *Engel* for the rule quoted above.<sup>43</sup> These decisions are even found in the unpredictable arts.

For example, in *Invitrogen Corp. v. Clontech Labs, Inc.*, the patents were in the field of molecular biology, which is generally considered to be an unpredictable art.<sup>44</sup> The claims in suit covered genetically engineered reverse transcriptase (RT) and were not limited by how the genes were mutated.<sup>45</sup> Defendant Clontech made at least one accused product by point mutation and argued that the patents' common specification only described how to implement the invention using deletion mutation.<sup>46</sup> Since the claims encompassed point-mutated RT without disclosing that method, Clontech argued that the claims were not enabled.<sup>47</sup>

After recognizing that, "[s]ection 112 requires that the patent specification enable 'those skilled in the art to make and use the *full scope* of the claimed invention,'"<sup>48</sup> the Federal Circuit rejected Clontech's enablement defense. The Federal Circuit repeated the district court's recitation of the *Engel* rule, "[t]he enablement requirement is met if the description enables any mode of making and using the claimed invention,"<sup>49</sup> and explained that the patentee's "teaching regarding deletion mutation is sufficient to satisfy its part of the patent bargain, as it fully teaches a mode of making the claimed invention."<sup>50</sup> The Federal Circuit even went so far as to suggest that Clontech's enablement defense "might have [had] force had Invitrogen limited its claims to modified RT by reference to point mutation."<sup>51</sup> In other words, the specification might not enable one specific embodiment (point mutation), but the broader claim is enabled because the specification taught another embodiment (deletion mutation).

*Invitrogen* represents the furthest extension of *Spectra-Physics*. It is a relatively recent decision, from 2005, in the unpredictable arts that finds the enablement requirement satisfied based on the description of a single embodiment. The decision even suggests that other embodiments that fall within the scope of the claim might not be enabled. Thus, *Invitrogen* represents a bright line rule, not the nuanced multi-factor approach advanced by *In re Wands*. Finally, *Invitrogen* even mentions that the full scope of the claim must be enabled, but interprets that requirement in much different manner than the three recent decisions discussed in the next section.

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<sup>42</sup> *Engel*, 946 F.2d at 1529-30.

<sup>43</sup> See, e.g., *CMFT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338 (Fed. Cir. 1991); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003) ("[T]he law makes clear that the specification need teach only one mode of making and using a claimed composition." (quoting *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 160 (D. Mass. 2001))); *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998) (holding that "CellPro can carry its burden only by showing that all of the disclosed alternative modes are insufficient to enable the claims, because '[t]he enablement requirement is met if the description enables any mode of making and using the invention'").

<sup>44</sup> 429 F.3d 1052, 1058 (Fed. Cir. 2005).

<sup>45</sup> *Id.* at 1070.

<sup>46</sup> *Id.* Apparently, Invitrogen disagreed with Clontech on the facts, but the Court never ruled on whether the specification disclosed point mutation.

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

<sup>48</sup> *Id.* (emphasis added) (citations omitted).

<sup>49</sup> *Id.* at 1071 (quoting *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998)) (citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1335 (Fed. Cir. 2003); *Engel Indus., Inc. v. Lockformer Co.*, 946 F.2d 1528, 1533 (Fed. Cir. 1991)).

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

<sup>51</sup> *Id.*

### III. EMPOWERING THE ENABLEMENT DEFENSE

In 2007 and 2008, the Federal Circuit issued three decisions that are at odds with *Spectra-Physics*, *Engel* and *Invitrogen*: *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick*. These cases made it significantly easier for defendants to raise a lack of enablement defense. As discussed earlier, *Wright* had characterized enablement as requiring a patent to teach the full scope of the claimed invention. That had become part of the standard recitation of enablement, but the three recent enablement decisions brought a new focus on the meaning of “full scope.” They require that different embodiments that fall within the scope of a claim all be enabled and, unlike *Wands*, *Vaeck*, and *Wright*, they require it in the predictable arts.<sup>52</sup>

#### A. *The Prequel*, AK Steel

*Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* trace their doctrinal roots from *In re Wright* via *AK Steel Corp. v. Sollac*.<sup>53</sup> *AK Steel* is not controversial because its outcome is consistent with our sense of justice. The claims at issue were found invalid because they covered subject matter that the patentee expressly disclaimed.

In *AK Steel*, the inventors purported to describe a new way to make hot-dipped aluminum-coated stainless steel.<sup>54</sup> The inventors discovered that maintaining heated steel strips in a hydrogen atmosphere before dipping them in aluminum allowed the aluminum to adhere or “wet” well on the steel.<sup>55</sup> The patent specification discussed the prior art as using aluminum coatings that contained ten percent by weight silicon. It also explained that the invention did not work well with this type of aluminum because it did not wet well. Despite this apparent disclaimer, the independent claim at issue did not limit the type of aluminum coating metal used, and the dependent claims stated that aluminum coating metal contained up to about ten percent by weight silicon.<sup>56</sup> In a Judge Lourie opinion, the Federal Circuit found that a person of ordinary skill would not have been enabled to make the claimed steel strip. Specifically, the decision concluded that “the specification is inadequate as a matter of law in that regard primarily because it expressly teaches against it.”<sup>57</sup>

*AK Steel* is not controversial because its outcome is intuitively correct. Claims that cover material disclaimed in the specification should not be upheld. However, *AK Steel*'s invalidity finding should not have been based on the enablement requirement. The specification discussed aluminum coatings that contain ten percent by weight silicon, albeit as the prior art. Thus, there was a reasonable basis for concluding that the specification did enable a person of ordinary skill to make the claimed steel strips using ten percent by weight silicon. The better basis for an invalidity finding would have been 35 U.S.C. § 112 ¶ 2 which requires that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.”<sup>58</sup> Clearly, the applicant believed that its invention did not

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<sup>52</sup> Typically, mechanical and electrical technology are both classified as falling within the predictable arts while technology involving chemical reactions and physiological activity fall within the unpredictable arts. See, e.g., *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533 (Fed. Cir. 1987); *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970). *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* concerned front loading fluid injectors, side impact sensors for cars, and integrating audio and video images into preexisting content, respectively. The front loading fluid injector involved mechanical components. The side impact sensor involved both mechanical and electrical components. The integration technology involved electrical components and software.

<sup>53</sup> 344 F.3d 1234 (Fed. Cir. 2003).

<sup>54</sup> Aluminum-coated stainless steel resists corrosion and high temperature oxidation. *Id.* at 1236.

<sup>55</sup> *Id.*

<sup>56</sup> *Id.* at 1237 (reciting independent claim 1 and dependent claims 3, 5 and 7).

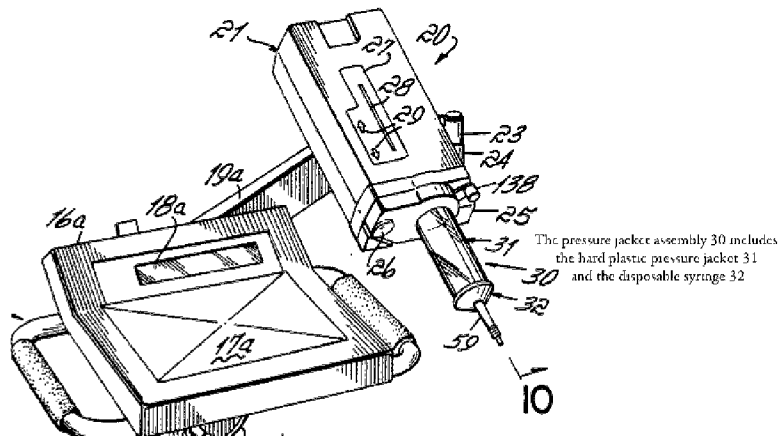
<sup>57</sup> *Id.* at 1244.

<sup>58</sup> See, e.g., *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1349 (Fed. Cir. 2002) (finding claims invalid under § 112 ¶ 2 because “a simple comparison of the claims with the specification” showed that the inventor did not regard the claims to be his

include using aluminum coating metal containing ten percent by weight silicon because that material did not wet well. Since *AK Steel* did not have to rely (and probably should not have relied) on the enablement requirement to invalidate the claims at issue, it could have simply found that claims did not reflect what the inventors regarded as their invention.

### B. Liebel-Flarsheim

In *Liebel-Flarsheim*, the invention was a front-loading fluid injector system with a replaceable syringe capable of withstanding high pressure for delivering a contrast agent to a patient.<sup>59</sup> The specification only described an injector with a pressure jacket but the asserted claims did not mention the pressure jacket. As a result, the Court construed the claims to include an injector with or without a pressure jacket.<sup>60</sup>



However, the breadth of the claim led to a lack of enablement finding. In another Judge Lourie opinion, the Federal Circuit found that there was no enablement of a fluid injector without a pressure jacket. Therefore, the specification failed to enable the full scope of the claim. The decision focused on two facts. First, the specification only described an injector with a pressure jacket and there was no guidance on how to make or use a system without a pressure jacket.<sup>61</sup> The specification even taught away from a pressure-jacketless system by calling it “expensive and therefore impractical” in the context of a disposable syringe.<sup>62</sup> Second, the Court noted that “[t]he inventors admitted that they tried unsuccessfully to produce a pressure-jacketless system and that such a system would have required more extensive experimentation and testing.”<sup>63</sup>

The Court in *Liebel-Flarsheim* distinguished *Spectra-Physics* by arguing that the specification in *Spectra-Physics* somehow enabled a person of skill in the art to make the invention as broadly as it was claimed. It is unclear how the Court arrived at this conclusion. *Spectra-Physics* never discusses whether a person of ordinary skill in the art could use the specification to make and use the undisclosed six-step braze cycle without undue experimentation. Judge Lourie’s characterization of *Spectra-Physics* appears to attempt to reconcile his decision with previous case law, as opposed to directly challenge it. This is somewhat surprising given that Judge Lourie also cited *Engel* without

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invention); *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1377 (Fed. Cir. 2000) (discussing how § 112 ¶ 2 has two requirements: claims must set forth what the inventor regards as his invention and claims must be sufficiently definite).

<sup>59</sup> *Liebel-Flarsheim Co. v. Medrad*, 481 F.3d 1371, 1373 (Fed. Cir. 2007).

<sup>60</sup> *Id.* at 1375. The claim construction was actually the subject of an earlier appeal. *See Liebel-Flarsheim Co. v. Medrad (Liebel I)*, 358 F.3d 898, 901 (Fed. Cir. 2004). Ironically, in *Liebel I*, the plaintiff successfully sought the broad claim construction that resulted in a finding of lack of enablement in the appellate decision. Indeed, Judge Lourie seemed to take some delight in the outcome by reciting the motto “beware of what one asks for.” 481 F.3d at 1380.

<sup>61</sup> *Liebel-Flarsheim*, 481 F.3d at 1379.

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

any discussion.<sup>64</sup> Recall that *Engel* also held that enabling a single embodiment satisfies the enablement requirement.

Judge Lourie concluded that the facts of *Liebel-Flarsheim* were more analogous to *AK Steel* than to *Spectra-Physics*.<sup>65</sup> In both cases, the specifications taught away from subject matter covered by those claims. If *Liebel-Flarsheim* and *AK Steel* stood for the proposition that a claim is invalid when it covers subject matter disclaimed by the patentee, they would have been a footnote in the history of enablement, special cases that lead to just results.<sup>66</sup> However, *Liebel-Flarsheim* relied on *AK Steel* for the proposition that “as part of the *quid pro quo* of the patent bargain, the applicant's specification must enable one of ordinary skill in the art to practice the *full* scope of the claimed invention.”<sup>67</sup> It is the focus on that phrase, “full scope,” that allows *Automotive Technologies* and *Sitrick* to extend the rule to claims that do more than simply cover disclaimed subject matter.

### C. Automotive Technologies

In the next opinion, *Automotive Technologies*, Judge Lourie applied the full scope analysis more generally. The invention was a new type of side impact sensor for use in vehicles. The prior art used a crush sensor for sensing side impacts.<sup>68</sup> The patented side impact sensor used a velocity-based sensor which had the advantage of sensing an impact even when the side was not directly hit.<sup>69</sup> During the prosecution of the patent, the patentee explained that this feature was the “essential concept of the invention” and called it a “breakthrough.”<sup>70</sup>

The specification provided a detailed description of how to make a mechanical side impact sensor and included diagrams of several embodiments. It also noted that an electronic sensor could be used, but only provided a conceptual diagram.<sup>71</sup> The claims at issue were generic and not limited to a mechanical velocity-based sensor. They also covered electronic velocity-based sensors. The Federal Circuit once again found each claim at issue was invalid for failing to enable the full scope of the claim.

In arriving at its decision, the Court focused on one embodiment that fell within the scope of the claims—an electronic velocity-based sensor. The plaintiff, Automotive Technologies International (“ATI”) offered an expert declaration that explained why “one skilled in the art would know how to adapt then-existing technology to create an electronic side impact sensor” and stating “that electronic sensors were commercially available” and could be incorporated into the claims.<sup>72</sup> Although the case law has allowed a patentee to use the knowledge of a person of ordinary skill in the art to help show enablement,<sup>73</sup> Judge Lourie found that this knowledge was not germane to the facts of the case. He reasoned that since “[t]he novel aspect of this invention is using a velocity-type sensor for side impact sensing,” it was insufficient to “merely state that known

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<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 1380.

<sup>66</sup> In light of the three recent enablement cases, Sean B. Seymore warns against disparaging an embodiment that falls within the scope of the claim because these statements can suggest that the “disparaged embodiment was nonenablement at the time of filing.” See Sean B. Seymore, *The Enablement Pendulum Swings Back*, 6 NW. J. TECH. & INTELL. PROP. 278, 290-91 (2008).

<sup>67</sup> *Liebel-Flarsheim*, 481 F.3d at 1380 (citing *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003)) (emphasis added in *Liebel-Flarsheim*).

<sup>68</sup> *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1277 (Fed. Cir. 2007).

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* at 1283.

<sup>71</sup> *Id.* at 1278.

<sup>72</sup> *Id.* at 1284.

<sup>73</sup> See, e.g., *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (“a specification need not disclose what is well known in the art”); *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1234 (Fed. Cir. 2003) (“That is not to say that the specification itself must necessarily describe how to make and use every possible variant of the claimed invention, for the artisan's knowledge of the prior art and routine experimentation can often fill gaps, interpolate between embodiments, and perhaps even extrapolate beyond the disclosed embodiments, depending upon the predictability of the art.”).

technologies can be used to create an electronic sensor.”<sup>74</sup> The Court also rejected that declaration as conclusory.<sup>75</sup> But the Court’s analysis suggests that a better supported declaration would not have changed the outcome.

Interestingly, ATI’s brief cited *Invitrogen* for the proposition that enabling one mode satisfies the enablement requirement.<sup>76</sup> However, the *Automotive Technologies* decision does not mention *Invitrogen*, let alone distinguish it. Rather, Judge Lourie merely alludes to ATI’s argument generally and states that “we addressed and rejected a similar argument made in *Liebel-Flarsheim*.”<sup>77</sup>

In sum, *Automotive Technologies* demonstrates that the full scope requirement is not limited to cases, like *Liebel-Flarsheim* and *AK Steel*, where the patentee has disclaimed subject matter that falls within the scope of claim. Moreover, *Automotive Technologies* takes the rule one step further and states that the patentee cannot rely on what a person of ordinary skill in the art would know to fill in gaps when those gaps relate to the novel aspect of the invention.

#### D. Sitrick

In *Sitrick*, the patents involved integrating a user’s audio signal or visual image into a preexisting video game or movie. The specifications described specific videogame signals and disclosed how an Intercept Adapter Interface System would select, analyze, and identify characters.<sup>78</sup> The specifications also generally discussed how the same techniques would work for movies.<sup>79</sup> The asserted claims covered both video games and movies.<sup>80</sup> Again, the Federal Circuit found that the asserted claims were invalid for lack of enablement because the specification did not enable the full scope of the claimed invention.

In arriving at its decision, the Federal Circuit noted that “[m]ovies do not have easily separable character functions, as video games do” and the specification did not teach how to obtain those functions from a movie.<sup>81</sup> Moreover, the defendants’ expert explained the disclosed analysis techniques were not applicable to movies.<sup>82</sup>

*Sitrick* was authored by Judge Moore and it shows that *Liebel-Flarsheim* and *Automotive Technologies* do not simply represent the personal views of Judge Lourie. Broad claims that are supported by a description of only one embodiment are at risk. Indeed, the *Sitrick* decision said that it did not even need to determine whether the specification was enabled with respect to video games. If the claims were not enabled for movies as well, the broad claims were invalid.<sup>83</sup>

The three recent enablement cases (and *AK Steel*) take a fundamentally different approach than the earlier enablement decisions. Although *Liebel-Flarsheim* and *Automotive Technologies* cited *Wands*, they did not consider the *Wands* factors, much less discuss predictability.<sup>84</sup> By the time it decided *Sitrick*, the Court did not even mention *Wands*. Instead, in each of these cases, the Federal Circuit recited the full scope rule, identified a non-enabled embodiment that fell within the scope of the

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<sup>74</sup> *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1278 (Fed. Cir. 2007).

<sup>75</sup> *Id.* at 1284-85.

<sup>76</sup> See Opening Brief of Plaintiff/Appellant Automotive Technologies International, Inc. at 24, *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274 (Fed. Cir. 2007) (Nos. 2006-1013, 2006-1037).

<sup>77</sup> *Auto. Techs.*, 501 F.3d at 1285 (citations omitted).

<sup>78</sup> *Sitrick v. Dreamworks, L.L.C.*, 516 F.3d 993, 997 (Fed. Cir. 2008).

<sup>79</sup> *Id.* at 997-98.

<sup>80</sup> *Id.* at 1000.

<sup>81</sup> *Id.* (quoting *Sitrick v. Dreamworks, L.L.C.*, 2006 U.S. Dist. LEXIS 97312, at \*82-83 (C.D. Cal. July 20, 2006)).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> The district courts in *Liebel-Flarsheim* and *Automotive Technologies* applied the *Wands* factors, but the Federal Circuit decisions did not analyze them. *Liebel-Flarsheim Co. v. Medrad*, 481 F.3d 1371, 1375 (Fed. Cir. 2007); *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1280 (Fed. Cir. 2007).

claims, and concluded that the claims at issue were invalid. Interestingly, the embodiments that the Federal Circuit relied upon were all mentioned in the specification of the patents at issue.

#### IV. THE SPLIT

Even before *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick*, the Federal Circuit was split. On the one hand, *Spectra-Physics*, *Engel* and *Invitrogen* stated that enabling any embodiment satisfies the enablement requirement regardless of the breadth of the claims. Even those cases were somewhat fractured, however, because *Spectra-Physics* limited the rule to the predictable arts while *Engel* and *Invitrogen* did not.

On the other hand, under *Wands*, *Vaeck*, and *Wright*, describing a single embodiment might not be sufficient to enable broad claims because those cases required a correspondingly more detailed disclosure to show that a person of ordinary skill in the art could use or practice the claimed invention. Enablement was evaluated based on a number of different factors, including predictability. However, these decisions were all found in the unpredictable arts. Thus, even under this line of cases, it was unclear whether disclosing a single embodiment would generally satisfy the enablement requirement in the predictable arts. *AK Steel* suggested the answer was no, but that decision dealt with a special case—claims covering subject matter that the patentee disclaimed.

*Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* rely on the second line of cases and demonstrate that in the predictable arts, disclosing a single embodiment will not automatically satisfy the enablement requirement. *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* require exploring the full scope of a claim and confirming that the specification enables everything found within that scope.

##### A. An Odd Split

Unlike many other splits, this does not appear to be a situation where one set of judges favors one theory and another set favors a second theory. If we examine the panels to determine which judges were responsible for recent opinions that illustrate the conflict, we arrive at some surprising results.

Below, the left-hand column lists three Federal Circuit decisions that state that reciting a single embodiment satisfies the enablement requirement. The list omits *Spectra-Physics* because it was decided in 1987 and only Judge Archer is still sitting on the bench. *Johns Hopkins* demonstrates the strange split. Judge Lourie authored the opinion in *Johns Hopkins*, but he also appears to be the primary proponent of the enablement standard advanced in the conflicting decisions. The right-hand column lists the three recent Federal Circuit decisions that raise the enablement requirement in the predictable arts.

*Engel* (1991)  
Judges Newman\*, Michel, Plager

*Liebel-Flarsheim* (2007)  
Judges Lourie\*, Rader, Bryson

*Johns Hopkins* (1998)  
Judges Lourie\*, Smith, Schall

*Automotive Technologies* (2007)  
Judges Lourie\*, Rader, Prost

*Invitrogen* (2005)  
Judges Gajarsa\*, Michel, Rader

*Sitrick* (2008)  
Judges Moore\*, Michel, Rader

\* indicates the author of the opinion

This table shows that at least three judges—Judges Lourie, Michel, and Rader—have been responsible for decisions on both sides of the split. Interestingly, there have been no dissents in any of the cases listed above.

### B. The Choices

As a threshold matter, the Federal Circuit needs to acknowledge that it has a split in its decisions. *Spectra-Physics*, *Engel*, and *Invitrogen* cannot be reconciled with *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick*. Once the Federal Circuit acknowledges the split, it will have the choice of either following the new rule or taking a step back and selecting one of the older lines of cases. In sum, the Court's choices are:

1. Follow *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick*: enablement requires examining the full scope of the claim to determine whether every embodiment that falls within that scope is enabled. This rule applies regardless of whether the technology is classified as predictable or unpredictable. This article will refer to this as the “full scope rule.”

2. Follow *Wands*: the enablement requirement is evaluated by looking at number of factual considerations, including predictability. Enabling a single embodiment does not necessarily satisfy the enablement requirement. Nor does the patent have to enable every embodiment that falls within the scope of the claim. This article will refer to this as the “*Wands* rule.”

3. Follow *Engel* and *Invitrogen*: the enablement requirement is satisfied if any embodiment is enabled. Again, this rule is not affected by the type of technology involved. This article refers to this as the “single embodiment rule.”

4. Follow *Spectra-Physics*: apply the “full scope rule” in the unpredictable arts and the “single embodiment rule” in the predictable arts.<sup>85</sup> This article refers to this as the “blended rule.” In practice, this is probably the rule that existed before the three recent enablement cases.

## V. EVALUATING THE FULL SCOPE RULE

To evaluate the new full scope rule, we must first understand why the enablement requirement exists. The enablement requirement ensures that an inventor is rewarded with a patent only if he or she describes the invention in sufficient detail to enable a person of ordinary skill in the art to make and use the invention.<sup>86</sup> This serves two purposes. First, it ensures that an inventor actually understands how to make and use the invention and does not simply possess the germ of an idea.<sup>87</sup> Second, it ensures that the inventor fulfills his part of the bargain by teaching the public how to practice the invention in exchange for a limited monopoly.<sup>88</sup> However, the current analysis assumes that the inventor has already satisfied these goals to some limited extent. In other words, by enabling a single embodiment that falls within the scope of the patent's claims, the public is

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<sup>85</sup> This rule should be flexible enough to account for the fact that some technology in the traditionally unpredictable arts can be predictable and some technology in the traditionally predictable arts can be unpredictable.

<sup>86</sup> “To insure adequate and full disclosure so that upon the expiration of the 17-year period ‘the knowledge of the invention enures [sic] to the people, who are thus enabled without restriction to practice it and profit by its use,’ *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 187 (1933), the patent laws require that the patent application shall include a full and clear description of the invention and ‘of the manner and process of making and using it’ so that any person skilled in the art may make and use the invention.” *Keewaneau Oil Co. v. Bicon Corp.*, 416 U.S. 470, 480-81 (1974) (citing 35 U.S.C. § 112).

<sup>87</sup> *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (“Tossing out the mere germ of an idea does not constitute enabling disclosure.”).

<sup>88</sup> *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

assured that the inventor understands how to make and use at least one embodiment and has taught the public to do the same.

The question then becomes how broad the inventor may make her claim.<sup>89</sup> From an economic perspective, an unduly narrow patent may allow competition to undermine the incentive to innovate. However, unduly broad claims may stifle competition.<sup>90</sup> Before *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick*, the FTC concluded that the “current disclosure doctrines” satisfy these goals reasonably well.<sup>91</sup> Specifically, with respect to enablement, the FTC endorsed a standard that analyzes both undue experimentation and predictability:

When considerable experimentation is necessary, follow-on innovation is likely to be costly; the more stringent enablement requirements that follow from greater need to experiment reduce the breadth of the initial innovator’s patent, and expand the rewards potentially available to follow-on innovators. Similarly, less predictability makes follow-on innovation more costly; again the more stringent enablement requirements that follow reduce the breadth of the initial patent and provide opportunities for expanded follow-on rewards.<sup>92</sup>

As discussed earlier, *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* are part of a growing number of decisions that curtail patent holders rights. Obviously, courts should not take the anti-patentee position on every doctrine simply because they perceive that patent holders’ rights have grown too strong. Courts still need to examine each doctrine to see if it is unfairly skewed in favor of one side. The premise underlying *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* is that claims in the predictable arts have become too broad and unfairly stifle competition. The remainder of this article attempts to evaluate the full scope rule and determine how successfully it can address this concern as well as whether the rule creates other problems.

#### *A. Full Scope: Trap for the Unwary*

The goal in *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* was undoubtedly to prevent patentees from claiming their inventions too broadly. However, a good test for determining whether the full scope rule satisfies this goal is to see how it separates valid claims from invalid claims. These three recent decisions applied the full scope rule to the easiest fact pattern—specifications that actually identify the non-enabled embodiment. In each of these decisions, the specifications provided a detailed discussion of one embodiment but mentioned other possible embodiments. In *Liebel-Flarsheim*, the “other” embodiment was a fluid injector without a pressure jacket. In *Automotive Technologies*, it was an electronic sensor, and in *Sitrick*, it was movies.

Given that the claims were plainly drafted with the intent to cover these “other” embodiments, it seems fair to insure that the patent specification actually teaches the public to make and use them. This requirement does force the inventor to expend additional effort in providing a more detailed description. If the inventor is required to fully enable only the embodiments identified in the specification, however, the burden is limited because the task is discrete. Thus, applying the full scope rule to other embodiments that are identified in the specification comports with notions of fairness.<sup>93</sup>

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<sup>89</sup> See INNOVATION, *supra* note 1, at 20 (“Frequently, much will be learned and developed after an initial invention is made: follow-on innovations will occur, and new uses will be found. The question then becomes, how many of these subsequent developments ought to be ascribed to the initial inventor and made subject to his or her patent?”).

<sup>90</sup> See *id.* at 23; Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29 (noting that overbroad patents can also discourage competition in the market for technologies that improve upon the patented invention).

<sup>91</sup> See INNOVATION, *supra* note 1, at 24. This statement described all three disclosure doctrines together: enablement, written description, and best mode.

<sup>92</sup> *Id.*

<sup>93</sup> See Seymore, *supra* note 66, at 289 (suggesting that if a claim covers a range of distinct embodiments, “the written description must sufficiently enable each of the ‘distinctly different’ embodiments”).



However, the rationale underlying the full scope rule suggests that it should apply beyond the fact pattern illustrated by *Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick*. Thus, embodiments not mentioned in the specification must also be enabled if they fall within the scope of the claim. The goal of enabling everything that falls within the scope of a claim does not change depending on whether additional embodiments are identified or not. To do otherwise would provide the perverse incentive for patentees to avoid describing additional embodiments they wish to include within the scope of their claims.<sup>94</sup> But extending the full scope rule to these facts may create a trap for the unwary. Patent prosecutors may not realize they are drafting claims that cover other embodiments.

Imagine if the patent in *Automotive Technologies* did not mention electronic sensors and the claims in dispute generally covered sensors. Should the patentee in *Automotive Technologies* still be required to narrow the claims to cover only mechanical sensors or otherwise have the claim declared invalid for lack of enablement? What if the inventor/patent attorney did not even consider electronic sensors? The full scope rule would still lead to an invalidity finding. Thus, the unintended consequence of the full scope rule might be to invalidate claims that unwittingly cover other non-enabled embodiments. Accordingly, patent attorneys must be extremely wary about drafting overbroad claims.

### *B. Full Scope: Possible Litigation Abuse*

*Liebel-Flarsheim*, *Automotive Technologies*, and *Sitrick* have opened the door for defendants in patent litigation to seek some embodiments that fall within the scope of the claims in dispute but that are not enabled. Assume that the patentee in *Automotive Technologies* had drafted the claim as narrowly as the Court believed it should have. Instead of merely reciting a “side-impact sensor,” the hypothetical claim would recite a “mechanical side-impact sensor.”

Under the full scope rule, this still may not have ended the inquiry. The specification actually described at least three types of mechanical sensors that fell within the scope of the claim: a side impact sensor containing (1) an integral molded hinge, (2) a simple spring mass, and (3) a viscously damped disc sensor.<sup>95</sup> A defendant could still raise an enablement defense by identifying a fourth type of mechanical side impact sensor—say, a sensor based on measuring the change in air pressure.<sup>96</sup> Under the full scope rule, such a showing should invalidate the claim. This is true even if a person of ordinary skill in the art would understand that the air pressure sensor was a reasonable substitute for the three disclosed sensors. According to *Automotive Technologies*, a patentee cannot use the knowledge of a person of ordinary skill in the art to fill in the novel aspect of the patent<sup>97</sup> (i.e., an electronic sensor in the actual *Automotive Technologies* decision, or an air pressure sensor in this hypothetical). If this truly were the rule, only extremely narrow claims that directly reflect disclosed embodiments and their small variations would survive.

This result is at odds with how the law treats patent claims. Decisions discussing both enablement and claim construction repeatedly state that an inventor is entitled to claims that are broader than the embodiments disclosed in the specification. Cases from *Fisher* to *Invitrogen* state that the enablement doctrine was never intended to limit claims to merely their disclosed

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<sup>94</sup> The Federal Circuit has provided a similar incentive with respect to the doctrine of equivalents. Under the public dedication rule announced in *Johnson and Johnson Associates v. R.E. Service Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002), if a claim does not literally cover subject matter disclosed in the specification, the patentee cannot rely on the doctrine of equivalents to recapture that subject matter. This provides a similar incentive to be careful to claim all embodiments disclosed in the specification or to avoid describing them altogether.

<sup>95</sup> These sensors are depicted in Figures 1, 5 and 6 of the patent at issue in *Automotive Technologies*, U.S. Patent No. 5,231,253 (filed Jun. 2, 1992). Figure 7 depicts a safing sensor that appears to be used in conjunction with one of the other sensors. See, e.g., '253 Patent col.11 l.43, col.12 l.43 (claims 15 and 29, claiming the safing sensor with the primary sensor).

<sup>96</sup> Although the air pressure sensor was made up for this hypothetical, the existence of alternative embodiments is not farfetched. In fact, the inventors suggested that there are other possible embodiments using “other geometries, [or] materials . . .” that would fall within the scope of the claims. '253 Patent col.10 l.53.

<sup>97</sup> 501 F.3d at 1283 (holding that “[a]lthough the knowledge of one skilled in the art is indeed relevant, the novel aspect must be enabled *in* the patent”) (emphasis added).

embodiments.<sup>98</sup> This is particularly true when a person of ordinary skill in the art would understand how to make and use alternative embodiments.<sup>99</sup> In *Phillips v. AWH Corp.* the Federal Circuit discussed how it had “repeatedly” warned against interpreting claims to only cover the specific embodiments described in the specification.<sup>100</sup> Moreover, the Court “expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.”<sup>101</sup>

The author does not mean to suggest that the Federal Circuit actually would have invalidated the claims in *Automotive Technologies* if they had been limited to mechanical sensors. That result goes too far and no case to date suggests that the Federal Circuit would apply the new enablement standard to such facts. However, the rules discussed in *Automotive Technologies* dictate that outcome. At a minimum, the *Automotive Technologies* focus on the novel aspect of the invention must be viewed with skepticism. Either the rule or its application proves too much.<sup>102</sup> It appears to make it far too easy to invalidate a claim based on a non-disclosed alternative embodiment. But even if the “novel aspect” of the invention is ignored, the hypothetical shows how patent litigants can create an enablement defense in almost any case.

The reason the full scope rule is subject to abuse in the predictable arts is because innovation in those technologies is often incremental.<sup>103</sup> Thus, in the *Automotive Technologies* example, experts may differ on whether a sensor that measures the difference in air pressure is taught by simply describing other types of mechanical sensors. Similarly, more complex technology inevitably requires some effort to adapt new technology for a particular application. Attorneys will characterize this effort as “undue experimentation.”

We can examine the recent *z4 Technologies, Inc. v. Microsoft Corp.* lawsuit to illustrate this point. The plaintiff, z4 Technologies, was the assignee of two patents directed at preventing the illicit copying and unauthorized use of computer software.<sup>104</sup> z4’s invention controlled the number of copies of authorized software by monitoring registration information and by requiring authorized users to periodically update a password or authorization code provided by a password administrator.<sup>105</sup> z4 accused the “Product Activation” feature in versions of Microsoft’s Office and Windows products of infringing z4’s patents.<sup>106</sup> A review of the district court<sup>107</sup> and Federal Circuit<sup>108</sup> decisions indicates that the primary defenses to liability were non-infringement, anticipation, and obviousness. Enablement was not mentioned in either decision.

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<sup>98</sup> See, e.g., *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) (“It is apparent that such an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are will[sic] within his contribution, since the improvement was made possible by his work.”); see also *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005) (“Enablement does not require the inventor to foresee every means of implementing an invention at pains of losing his patent franchise. Were it otherwise, claimed inventions would not include improved modes of practicing those inventions. Such narrow patent rights would rapidly become worthless as new modes of practicing the invention developed.”).

<sup>99</sup> See *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1244 (Fed. Cir. 2003); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998).

<sup>100</sup> See *Phillips v. AWH*, 415 F.3d 1303, 1323 (Fed. Cir. 2005) (en banc) (citations omitted). Ironically, even *Liebel I* stated that “this court has expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment.” 358 F.3d 898, 906 (Fed. Cir. 2004).

<sup>101</sup> *Phillips*, 415 F.3d at 1323 (citing *Gemstar-TV Guide Int’l, Inc. v. ITC*, 383 F.3d 1352, 1366 (Fed. Cir. 2004)).

<sup>102</sup> The Court viewed the “novel aspect” of the invention as “using a velocity-type sensor for side impact sensing,” not as the velocity-type sensor itself. *Auto. Techs. Int’l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274, 1283 (Fed. Cir. 2007). Thus, even if the Court properly refused to allow a person of ordinary skill to fill in the “novel aspect” of the invention, the Court should have considered the possible existence of velocity-based electronic sensors.

<sup>103</sup> In its 2003 report on innovation, the FTC noted that “technology developed in industries such as semiconductors, computer hardware, and software can contain a large number of incremental innovations.” INNOVATION, *supra* note 1, at 25-26.

<sup>104</sup> *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340 (Fed. Cir. 2007).

<sup>105</sup> *Id.* at 1344.

<sup>106</sup> *Id.* at 1345.

<sup>107</sup> *z4 Techs., Inc. v. Microsoft Corp.*, 434 F. Supp. 2d 437 (E.D. Tex. 2006).

<sup>108</sup> *z4 Techs.*, 507 F.3d at 1340.

However, under the new full scope rule, Microsoft could have raised an enablement defense by arguing that if its products fall within the scope of the claim, z4 was obligated to enable that embodiment. At first blush, this may seem unreasonable. Preventing unauthorized copying appears to be generally applicable to different software products. However, consider the evidence Microsoft could offer. The patents' specifications never mention Office or Windows, much less explain how to incorporate the invention into either product.<sup>109</sup> Microsoft's engineers could testify about the engineering time it took to create the "product activation" feature. Experts could testify that Microsoft's engineers needed to have an intimate knowledge of the workings of both Office and Windows to add this feature. Why isn't this sufficient undue experimentation to render the claims invalid for lack of enablement?

In response, z4 could correctly point out that the test for undue experimentation is not merely quantitative, and that a considerable amount of routine experimentation is permissible.<sup>110</sup> Nevertheless, doesn't Microsoft's argument create a factual dispute?<sup>111</sup> If so, will juries believe that Microsoft's engineering efforts are routine after an expert describes the effort in a manner calculated to emphasize the complexity of the technology? In sum, the full scope rule appears to allow defendants to raise the enablement defense in many cases where the defense is not warranted. To add insult to injury, the rule incentivizes defendants to try to make the disputed technology even more confusing, something that is far too easy to do in patent cases.

### *C. A Blunt Instrument for a Specific Problem*

Another problem with the enablement defense is that it is a blunt instrument. Of course this problem does not reside solely in the predictable arts. It applies regardless of technology. There are at least two aspects to this issue. First, the enablement defense does not discriminate between beneficiaries. Both defendants that practice an embodiment that is enabled by the specification and those that do not can benefit from the enablement defense. Second, since enablement is assessed in view of the state of the art on the filing date, the requirement is not well suited to address overbroad claims that cover future innovations.

#### *1. Non-discriminatory Beneficiaries*

Again, *Automotive Technologies* can be used to illustrate the issue of non-discriminatory beneficiaries. In the actual case, the defendants' side impact sensing systems used electronic sensors<sup>112</sup> and they successfully argued that the claims were invalid because the specification enabled only mechanical, and not electronic, sensors. In contrast, assume that some hypothetical defendants used some form of a mechanical sensor. Even though the hypothetical defendants do not use electronic sensors, there is no reason why they could not argue that the claims at issue were invalid because they did not enable electronic sensors.<sup>113</sup> Such an outcome does not satisfy notions of fairness in the same way that the actual facts of *Automotive Technologies* do.<sup>114</sup>

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<sup>109</sup> See U.S. Patent No. 6,785,825 (filed May 31, 2002); U.S. Patent No. 6,044,471 (filed June 4, 1998).

<sup>110</sup> See *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988); *Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998).

<sup>111</sup> Although enablement is a legal issue, it is based on underlying factual issues. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1238 (Fed. Cir. 2003).

<sup>112</sup> See Brief of Counterclaimant Defendant-Appellee Delphi Automotive Systems and Defendant/Counterclaimant-Appellee General Motors Corp. at 17, *Auto. Techs. Int'l, Inc. v. BMW of N. Am., Inc.*, 501 F.3d 1274 (Fed. Cir. 2007) (Nos. 2006-1013, 2006-1037).

<sup>113</sup> See *Durel Corp. v. Osram Sylvania, Inc.* 256 F.3d 1298 (Fed. Cir. 2001). In *Durel*, the district court found that the only question that the enablement defense raised was whether the plaintiff's patent enabled the accused process. The Federal Circuit reversed, stating that the question of enablement "does not turn on whether the accused product is enabled" but whether the full scope of the claimed invention was enabled. *Id.* at 1306.

<sup>114</sup> This effect is somewhat ameliorated by dependent claims because defendants that practice something akin to the embodiments described in the patent are more likely to infringe the narrower dependent claims. Indeed, dependent claims 6 and

Applying the full scope rule to the actual facts of *Automotive Technologies* is more satisfying, in part, because the plaintiff can be characterized as being greedy for claiming its invention too broadly.<sup>115</sup> However, our concept of fairness is reversed when we look at the hypothetical case. Here, defendants that practice something similar to the preferred embodiment escape liability because the claim happens to cover some unrelated embodiments. Not surprisingly, the defendants in *Liebel-Flarsheim*, and *Sitrick* practice the non-enabled embodiments.<sup>116</sup> In other words, all three recent Federal Circuit cases applied the full scope rule in a manner that is consistent with our notions of fairness.

Contrast this remedy with the results of a claim construction dispute. Typically, a plaintiff argues that a claim should be interpreted broadly while the defendants argue that the claim should be interpreted narrowly, usually in a manner that limits the claim to the disclosed embodiment(s).<sup>117</sup> This defense only benefits defendants who practice an embodiment that falls outside the scope of the claim as defined. Similarly, if the enablement defense were narrowly tailored to address the problem of overbroad claims, it would benefit only defendants who practiced embodiments that were not enabled. But, that is not the case and the doctrine actually aids undeserving beneficiaries.

## 2. Assessing Enablement from the Filing Date

The filing date rule also demonstrates why the enablement defense is not well suited for directly addressing the problem of overly broad claims. Enablement is determined by looking at the state of the art at the time the application was filed.<sup>118</sup> “The law does not expect an applicant to disclose knowledge invented or developed after the filing date. Such disclosure would be impossible.”<sup>119</sup> This rule furthers the purposes of ensuring that inventors understand their invention and teach the public how to practice it.

However, the rule does a disservice to the goal of limiting the breadth of a claim. Returning to *Automotive Technologies*, assume that the air pressure sensor was an innovation that was unknown until after the filing date of the patent.<sup>120</sup> If that were the case, a defendant could not rely on it to argue that plaintiffs failed to enable the full scope of the claim.<sup>121</sup> However, if the air pressure sensor was known by the filing date of the patent, it could serve to invalidate the claim. If the true concern is that a claim is overbroad, the date the alternative embodiment was first known should

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7 of the '253 patent in *Automotive Technologies* do not cover electronic sensors, but do cover the embodiment described in the hypothetical. This suggests that the number of successful enablement defenses brought by such “unsympathetic” defendants may be small because other narrower claims may be the primary focus of the litigation.

<sup>115</sup> That appears to be what Judge Lourie believed when he concluded the *Liebel-Flarsheim* decision with the warning, “beware of what one asks for.” *Liebel-Flarsheim v. Medrad*, 481 F.3d 1371, 1380 (Fed. Cir. 2007).

<sup>116</sup> In *Liebel-Flarsheim*, the defendant, Medrad, had a jacketless injector system. 481 F.3d at 1374. In *Sitrick*, the defendants produced and distributed DVDs of various movies, some of which included the allegedly infringing product. *Sitrick v. Dreamworks L.L.C.*, 516 F.3d 993, 995 (Fed. Cir. 2008).

<sup>117</sup> *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008) (stating that the Federal Circuit “has cautioned against interpreting a claim term in a way that excludes disclosed embodiments, when that term has multiple ordinary meanings consistent with the intrinsic record”).

<sup>118</sup> *In re Hogan*, 559 F.2d 595, 605-06 (C.C.P.A. 1977). In *Hogan*, the Court distinguished “permissible application of later knowledge about art-related facts existing on the filing date and the impermissible application of later knowledge about later art-related facts . . . which did not exist on the filing date.” See also 5B DONALD S. CHISUM, CHISUM ON PATENTS § 18.04(4)(e) (2005) (The enablement requirement “regulates the literal scope of the patent claim in view of the state of the art on the filing date.”).

<sup>119</sup> *Chiron Corp. v. Genentech, Inc.* 363 F.3d 1246, 1254 (Fed. Cir. 2004).

<sup>120</sup> That was not the situation in the actual case; the specification mentioned electronic sensors. *Id.* at 1278.

<sup>121</sup> The filing date rule must be reconciled with cases that reject claims for the failure to enable potential future embodiments. For example, in *Wright*, the Federal Circuit found several claims were not enabled because they broadly covered an entire category of vaccines including vaccines against AIDS viruses that no one has been able to develop. *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993). In practice, it appears that claims should be rejected if *at the time the application was filed* it was clear that claim covered non-enabled potential future embodiments (i.e. claims that predict future innovations).

not matter. The embodiment is either too far afield from the invention described in the patent specification or it is not.

#### *D. Recommendations*

##### *1. Backtrack*

The Federal Circuit should stop focusing on the full scope of the claim. The use of the full scope rule in *Liebel-Flarsheim, Automotive Technologies*, and *Sitrick* suggests that if a defendant can identify any non-enabled embodiment that falls within the scope of a claim, the claim should be invalid. Defendants in the predictable arts will inevitably find some embodiment that satisfies that criteria, and even if they do not, the courts will have to waste considerable resources weeding out those defenses. Broad claims should require a correspondingly more detailed disclosure, but that does not mean that every conceivable embodiment must be enabled.

Instead, the Federal Circuit should return to the *Wands* factors and consider: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. This test should apply to technologies in both the predictable and unpredictable arts.

The *Wands* factors provide a flexible test that can respond to the different circumstances that occur in the real world. Applying the *Wands* factors to the facts of *Automotive Technologies* and one of its variations illustrates the flexibility of the test. In the actual ATI patent, the claim covered electronic and mechanical sensors. That claim may still be invalid under *Wands* because of the breadth of the claim and the fact that those skilled in the art may not be familiar with how to make electronic sensors. However, a claim that simply covers mechanical based sensors would probably be valid despite the possibility of a undisclosed mechanical air pressure sensor. The latter claim is narrower and those skilled in the art are more likely to understand how to make other types of mechanical sensors. Thus, the *Wands* factors provide a better basis for differentiating between non-disclosed embodiments that should and should not invalidate a claim.

In returning to *Wands*, the Federal Circuit should overrule the *Engel-Invitrogen* single embodiment rule. Although enabling a single embodiment may be sufficient to satisfy the enablement requirement, there are plainly cases where such a disclosure would be insufficient. Patentees should not be able to enable a simple embodiment and obtain claims that cover far more complex embodiments that the patentee does not know how to make and use. Such claims improperly implicate future developments but do not teach the invention. Interestingly, the facts of *Sitrick* fall into this category.<sup>122</sup> There will undoubtedly be cases like *Sitrick* that disclose a single embodiment in the predictable arts, but still claim too much.

The Federal Circuit should also overrule *Spectra-Physics*. *Spectra-Physics* goes too far by stating that if a technology is predictable, a single embodiment is *per se* sufficient. The issue of whether a technology falls within the predictable or unpredictable arts should play an important role in determining whether the enablement requirement is satisfied, but *Spectra-Physics*' blended rule is too inflexible. In contrast, the *Wands* factors are flexible enough to consider predictable innovations in the unpredictable arts and vice versa.

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<sup>122</sup> In *Sitrick*, the patent could describe how to integrate a user's audio signal or visual image into preexisting video games because video games have separate preexisting signals. The patent did not attempt to describe the more difficult problem of obtaining those signals from movies which do not have separate preexisting signals. Yet, it claimed both the simple and the non-enabled embodiment. Thus, even applying the *Wands* factors, the claims in *Sitrick* would probably be invalid.

## 2. Consider Relying on Other Doctrines

Although a return to the *Wands* factors can play some role in limiting overbroad patents, the enablement doctrine is not a good choice for addressing this problem. In one sense, the doctrine is overbroad because it benefits undeserving parties—parties that actually practice enabled embodiments. In another sense, the remedy is too narrow because it does not limit how broad claims may be applied against unforeseeable future innovations. If the Federal Circuit feels the need to address these shortcomings in enablement law, it should look to doctrines like claim construction and the reverse doctrine of equivalents. They would be far better vehicles for limiting the breadth of claims because they can directly attack the problem.

### a. Claim Construction

For example, the Federal Circuit could consider what a patent enables as part of the claim construction analysis. Currently, the doctrine of claim construction does not factor that into its analysis.<sup>123</sup> The primary basis for construing claim is intrinsic evidence—specifically, the specification, claims and prosecution history.<sup>124</sup> Interestingly, at least one non-precedential Federal Circuit decision has used enablement analysis to inform its claim construction. In *Medtronic Navigation, Inc. v. Brainlab Medizinische Computersysteme GMBH*, the Federal Circuit affirmed the district court's narrow interpretation of a claim term, in part, because a broader interpretation would have rendered the claim invalid for lack of enablement.<sup>125</sup> By interpreting the claim in a manner that preserved its validity, the Court indirectly relied on enablement analysis. However, the Federal Circuit could directly incorporate that analysis into its claim construction principles. Again, the advantage of this approach is that the remedy is narrowly tailored to address the problem of overbroad claims.

### b. The Reverse Doctrine of Equivalents

The Federal Circuit could also revive the reverse doctrine of equivalents. In *Graver Tank & Manufacturing Co. v. Linde Air Products Co.*, the Supreme Court explained how the doctrine of equivalents could be applied against a patentee (i.e. in reverse):

Thus, where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.<sup>126</sup>

Evaluating whether a device is properly enabled may be one way of determining whether it is so far changed in principle that it should not fall within the scope of the claim, and thereby trigger the reverse doctrine of equivalents. Moreover, the “reverse doctrine of equivalents allows a court to focus on what the appropriate scope of patent protection for an invention should be in light of developments after the filing of the application of the patent.”<sup>127</sup>

However, the Federal Circuit appeared to announce the death of the reverse doctrine of equivalents in *Tate Access Floors Leasing, Inc. v. Interface Architectural Resources, Inc.*:

Not once has this court affirmed a decision finding noninfringement based on the reverse doctrine of equivalents. And with good reason: when Congress enacted 35 U.S.C. § 112, after the decision in *Graver Tank*, it imposed requirements for the written description,

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<sup>123</sup> *Phillips v. AWH*, 415 F.3d 1303, 1327 (Fed. Cir. 2005) (en banc) (“While we have acknowledged the maxim that claims should be construed to preserve their validity, we have not applied that principle broadly, and we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction.”).

<sup>124</sup> *Id.* at 1317.

<sup>125</sup> *Medtronic Navigation Inc. v. BrainLAB Medizinische Comput. GMBH*, 222 F. App'x 952, 956-57 (Fed. Cir. 2007) (reasoning that the ambiguity should be “resolved in a manner that would preserve the patent's validity” even though the patent contained a single sentence that referred to an alternate embodiment that would suggest a broader interpretation) (citing *Phillips*, 415 F.3d at 1327)).

<sup>126</sup> *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-09 (1950).

<sup>127</sup> CHISUM, *supra* note 118.

enablement, definiteness, and means-plus-function claims that are co-extensive with the broadest possible reach of the reverse doctrine of equivalents.<sup>128</sup>

Ironically, *Tate* concluded that the reverse doctrine of equivalents was replaced, in part, by the enablement requirement. However, as discussed above, the reverse of doctrine of equivalents is a better vehicle than the enablement requirement for addressing overbroad claims. Therefore, the Federal Circuit may wish to revive the doctrine.<sup>129</sup>

## VI. CONCLUSION

Although the heightened enablement requirement represented by *Liebel-Flarsheim*, *Automotive Technologies* and *Sitrick* may satisfy some sense of justice by penalizing plaintiffs trying to overreach with broad claims, this Article concludes that the full scope rule does make sense in the predictable arts. In the predictable arts, innovation is incremental, and the full scope rule allows defendants to identify *any* embodiment and try to prove that the patent does not enable it. If this rule becomes settled law, it will probably lead to litigation overuse, if not abuse, and make it difficult to draft patents that do not run afoul of the enablement requirement.

This Article also concludes that the enablement requirement is not well suited for addressing overbroad claims. It is a blunt instrument that aids defendants regardless of whether they practice something that is close to the heart of the invention or something far afield. Moreover, because enablement is determined from knowledge that existed at the patent's filing date, the doctrine cannot weigh future developments in assessing the proper breadth of a claim. As a result, this Article recommends that the Federal Circuit resolve the current split in enablement law and return to the *Wands* factors. To the extent that the Federal Circuit believes that existing doctrines are insufficient to address overbroad claims, it should consider modifying claim construction principles or reviving the reverse doctrine of equivalents.

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<sup>128</sup> *Tate Access Floors Leasing, Inc. v. Interface Arch'l Res., Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002).

<sup>129</sup> It is beyond the scope of this article to fully explore the pros and cons of incorporating enablement issues into claim construction analysis and/or the reverse doctrine of equivalents. Rather, the author is simply suggesting that the enablement defense is not the proper vehicle for addressing overbroad claims, and that there are other doctrines that may be worthy of consideration.

# “And I See Through Your Brain”: Access to Experts, Competency to Consent, and the Impact of Antipsychotic Medications in Neuroimaging Cases in the Criminal Trial Process

MICHAEL L. PERLIN \*

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## INTRODUCTION

¶1 Last fall, I presented a paper at a conference on neuroimaging and the law looking at the way jurors were likely to construe neuroimaging evidence in insanity defense cases.<sup>1</sup> I tried to balance jurors’ likely positive response to the perceived *characteristics* of this evidence—vivid, objective, quantifiable, advanced<sup>2</sup>—with their likely negative response to the *use* of this evidence in such cases (reflecting their prejudice, hostility, and hatred toward insanity pleaders)<sup>3</sup>—and concluded that I was “not at all sure that the pizzazz of neuroimaging testimony—notwithstanding its colorfulness and its propensity to reductionism—will trump these deep-seated attitudes.”<sup>4</sup> In short, I sought to make the point that the *science* of neuroscience has to be assessed in the sociopolitical *context* of the specific question of law that is central to the specific case before the court.

¶2 Again, as I stressed in my earlier article, the reality is that neuroimaging is fraught with uncertainties,<sup>5</sup> that the steps used in the production and presentation of neuroimaging evidence are “[n]ot only not standardized, they are easily manipulated by a person with knowledge of the

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\* © 2009, Michael L. Perlin, Professor of Law, Director of the International Mental Disability Law Reform Project, and Director of the Online Mental Disability Law Program at New York Law School. The author wishes to thank Naomi Weinstein for her (as always) superb research assistance, and Bob Weisberg and Erin Murphy for their thoughtful and helpful comments.

<sup>1</sup> See Michael L. Perlin, “*His Brain Has Been Mismanaged with Great Skill*”: How Will Jurors Respond to Neuroimaging Testimony in Insanity Defense Cases?, 42 AKRON L. REV. 885 (2009).

<sup>2</sup> *Id.* at 890. (“this language jumps off the page”).

<sup>3</sup> See generally MICHAEL L. PERLIN, THE JURISPRUDENCE OF THE INSANITY DEFENSE (1994). See also, e.g., Michael L. Perlin, “*She Breaks Just Like a Little Girl*”: Neonatide, The Insanity Defense, and the Irrelevance of “Ordinary Common Sense,” 10 WM. & MARY J. WOMEN & L. 1, 9 (2003) (discussing the stereotype of persons with mental illness as evil); Michael L. Perlin, “There Was an Evil Messenger”: Blame, Mental Illness, Wickedness, the Insanity Defense and the Pretexts of the Justice System (unpublished manuscript, on file with Stanford Technology Law Review); Michael L. Perlin, *Unpacking the Myths: The Symbolism Mythology of Insanity Defense Jurisprudence*, 40 CASE W. RES. L. REV. 599, 626 (1989-1990) (“[historically], mental illness was tied to notions of religion and traditionally seen as God’s punishment for sin”).

<sup>4</sup> Perlin, *supra* note 1 at 911.

<sup>5</sup> Alexandra Roberts, *Everything New is Old Again: Brain Fingerprinting and Evidentiary Analogy*, 9 YALE J.L. & TECH. 234, 266 (2007).



technology.”<sup>6</sup> Some researchers characterize neuroimaging evidence as “indistinct.”<sup>7</sup> Amanda Pustilnik, by way of example, concludes that “neuroscience cannot provide complete, or even sufficient, explanations of criminal violence by reference primarily to purported neurobiological dysfunctions within isolated parts of offenders’ brains.”<sup>8</sup> Other scholars charge that “researchers, clinicians, and lawyers are seduced into becoming true believers in the merits of [brain imaging] for understanding the relationship between brain and behavior.”<sup>9</sup> Stacey Tovino argues that the fMRI offers only “illusory accuracy and objectivity.”<sup>10</sup> But what is clear is that the *existence* of neuroimaging techniques has changed the contours of the playing field, and no matter which side of the divide we find ourselves on, we must acknowledge that reality.

With this as backdrop, I turn to the topic that I have taken on for this article: what impact neuroimaging evidence will have on a series of “criminal procedure situations,” the resolutions of which are inextricably intertwined with pre-existing socio-political views and attitudes of judges and jurors: (1) the implications of *Ake v. Oklahoma*<sup>11</sup> (an indigent defendant’s access to expert testimony) in cases where neuroimaging tests might be critical; (2) the defendant’s competency in consenting to the imposition of a neuroimaging test or examination; and (3) the impact of medications—specifically, antipsychotic medications—on a defendant’s brain at the time that such a test is performed. I hope that this article spurs some additional hard thinking about this topic.

The criminal procedure and evidence issues that I raise here have all been the subject of extensive consideration in the scholarly literature and in litigated cases over the past three decades (and, in different guises, all have reached the U.S. Supreme Court).<sup>12</sup> All these issues, in these other guises, are (or at least should be) familiar to scholars, practitioners and to judges. Yet each of these “situations” is drastically *underdiscussed* in the neuroimaging literature and in the criminal procedure literature. With the exceptions of one discussion in the law review literature,<sup>13</sup> one in the legal “cross-over” literature<sup>14</sup> and one in the psychiatric “cross-over” literature,<sup>15</sup> there has been no consideration at all of these issues in the context of the papers in this symposium: the admissibility of MRI and related evidence in criminal trials.

This lack of attention is both surprising and not surprising. On one hand, it is surprising because (1) these procedural and constitutional issues *have*, in a range of other topics, been the topic of intense scrutiny and critique,<sup>16</sup> and the resolution of each, in their own way, has been seen as potentially ultimately dispositive of the criminal case before the court,<sup>17</sup> and (2) intuitively, these

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<sup>6</sup> Donald R. Reeves et al., *Limitations of Brain Imaging in Forensic Psychiatry*, 31 J. AM. ACAD. PSYCHIATRY & L. 89, 90 (2003).

<sup>7</sup> Timo Vloet et al., *Structural and Functional MRI-Findings in Children and Adolescents with Antisocial Behavior*, 26 BEHAV. SCI. & L. 99, 99 (2008).

<sup>8</sup> Amanda C. Pustilnik, *Violence on the Brain: A Critique of Neuroscience in Criminal Law* 5, (Harvard Law School Faculty Scholarship Series, Paper No. 14, 2008), available at <http://lsr.nellco.org/harvard/faculty/papers/14/>.

<sup>9</sup> Laurence R. Tancredi & Jonathan D. Brodie, *The Brain and Behavior: Limitations in the Legal Use of Functional Magnetic Resonance Imaging*, 33 AM. J.L. & MED. 271, 289 (2007).

<sup>10</sup> Stacey A. Tovino, *Functional Neuroimaging Information: A Case for Neuro Exceptionalism?*, 34 FLA. ST. U. L. REV. 415, 479 (2006) (quoting Martha J. Farah, *Emerging Ethical Issues in Neuroscience*, 5 NATURE REV. NEUROSCIENCE 1123, 1127 (2002)).

<sup>11</sup> *Ake v. Oklahoma*, 470 U.S. 68, 74 (1985).

<sup>12</sup> See, e.g., *Sell v. United States*, 539 U.S. 166 (2003) (discussed *infra* text accompanying note 102); *Riggins v. Nevada*, 504 U.S. 127 (1992); *Washington v. Harper*, 494 U.S. 210 (1990).

In his commentary on the live presentation of this paper, Bob Weisberg wisely noted the artificial divide that is present in analyses of “criminal procedure questions” and “evidence questions.” Robert Weisberg, Professor of Law, Stanford Law Sch., Commentary at the Stanford Technology Law Review Symposium: Neuroscience and the Courts (Feb. 27, 2009). I hope this article helps to break down that divide.

<sup>13</sup> See Henry Greely, *Neuroscience and Criminal Justice: Not Responsibility but Treatment*, 56 U. KAN. L. REV. 1103 (2008).

<sup>14</sup> See Jennifer Kulynych, *The Regulation of MR Neuroimaging Research: Disentangling the Gordian Knot*, 33 AM. J.L. & MED. 295 (2007).

<sup>15</sup> See Reeves, *supra* note 6.

<sup>16</sup> See generally 2 MICHAEL L. PERLIN, *MENTAL DISABILITY LAW: CIVIL AND CRIMINAL* § 3B (2d ed. 1998), and 4 MICHAEL L. PERLIN, *MENTAL DISABILITY LAW: CIVIL AND CRIMINAL*, § 9A-5.1 (2d ed. 2002).

<sup>17</sup> E.g., *Ake v. Oklahoma*, 470 U.S. 68, 77 (“[A] criminal trial is fundamentally unfair if the State proceeds against an indigent defendant without making certain that he has access to the raw materials integral to the building of an effective defense.”).

issues—access to independent testing, consent to testing, and impact of medical intervention (often *involuntary* intervention) on trial fairness—should all be “high cards” to those who take these issues seriously.<sup>18</sup> On the other hand, it is *not* surprising, because (1) so much of the MRI debate is still so focused on a series of what I elsewhere call “is-it-or-isn’t-it questions”<sup>19</sup> (as to the hardness of the science, as to the ease of juror comprehension, as to the evidence’s potential heuristic power),<sup>20</sup> that it is inevitable that these admittedly less “sexy” issues have gotten almost no attention, and (2) so much of the conversation about MRI has taken place at two ends of the spectrum: at the end of high philosophy or the end of high science.<sup>21</sup> The issues that I discuss here are, concededly, neither. Rather, they deal with the “roll up your sleeves” aspects of criminal procedure, ones that may not, as I have already indicated, have the pizzazz of either the science or the philosophy “takes.” Still, in the long run, they are every bit as important (and perhaps, in “real life,” even more so).

I think that this lack of attention to the issues that I address in this article is, like “the dog that didn’t bark in the night” in the famous Sherlock Holmes story,<sup>22</sup> even more important because of its omission from the scholarly dialogue. As I noted a moment ago, these are important issues—in many cases, *dispositive*—in criminal trials. I raise them here in an effort to bring new attention and focus to them in the hopes that when this evidence becomes more commonplace (especially in what I call “invisible” cases, those that are not the subject of intense publicity because of the nature of the defendant or the victim),<sup>23</sup> courts will regularly assess these issues in their pre-trial and “at trial” decisions.

This article will proceed in the following manner. First, I will briefly restate some of my conclusions from my earlier paper, discussing the tensions inherent in the ways that jurors construe such evidence in insanity defense cases. Then, I will look at each of the three criminal procedure issues at the core of my paper: the right to a neuroimaging expert, the standards of assessing consent to the administration of neuroimaging testing, and the implications of administering antipsychotic, neuroleptic medication for a neuroimaging examiner’s findings. Finally, I will offer some conclusions and speculate on how our answers to these questions might bear on the larger “picture”—neuroimaging-and-the-law.

My title, as I expect many of you know, comes from Bob Dylan’s anthemic masterpiece *Masters of War*.<sup>24</sup> The song is a “blistering indictment of war profiteers,”<sup>25</sup> and as an indictment of the military-industrial complex, it is as vibrant and angry today as it was when it was first recorded in 1963. The lyric that I have chosen comes from this chilling verse: “Like Judas of old/You lie and deceive/A world war can be won/You want me to believe/But I see through your eyes/And I see through your brain/Like I see through the water/That runs down my drain.”<sup>26</sup> Its relevance to this topic should become clear.

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<sup>18</sup> See, e.g., Michael L. Perlin & John Douard, “Equality, I Spoke That Word/As If a Wedding Vow”: *Mental Disability Law and How We Treat Marginalized Persons*, 53 N.Y.L. SCH. L. REV. 9, 23-24 (2008/2009) (discussing the “high cards of mental disability law: the balance between autonomy and social control, the extent to which a person in the community can still be subject to social control, and the right of a person with a mental disability to refuse the imposition of antipsychotic medications.”).

<sup>19</sup> See Perlin, *supra* note 1, 915 (“Neuroimaging is (or isn’t) hard science. It is (or isn’t) relatively easy for jurors to interpret. It is (or isn’t) immune to falsification efforts. It is (or isn’t) objective. It will (or won’t) lead jurors to ‘better’ verdicts in insanity cases. It will (or won’t) be used disproportionately in news-friendly cases. It will (or won’t) ‘trump’ jurors’ inherent suspicion of the insanity defense.”).

<sup>20</sup> Michael L. Perlin, *Fatal Assumption: A Critical Evaluation of the Role of Counsel in Mental Disability Cases*, 16 LAW & HUM. BEHAV. 39, 57 n.115 (1992) (Heuristics are “cognitive-simplifying devices that frequently lead to systematically erroneous decisions through ignoring or misusing rationally useful information.”).

<sup>21</sup> See generally Perlin, *supra* note 1 (discussing multiple approaches).

<sup>22</sup> See SIR ARTHUR CONAN DOYLE, *Silver Blaze*, in *THE COMPLETE SHERLOCK HOLMES* 335, 349 (1927).

<sup>23</sup> See Perlin, *supra* note 1 895-898. (discussing use of neuroimaging in cases of John Hinckley and Vincent Gigante).

<sup>24</sup> BOB DYLAN, *Masters of War*, on *THE FREEWHEELIN’ BOB DYLAN* (Columbia Records 1963).

<sup>25</sup> ROBERT SHELTON, *NO DIRECTION HOME: THE LIFE AND MUSIC OF BOB DYLAN* 155 (1997).

<sup>26</sup> Bob Dylan: *Masters of War*, <http://www.bobdylan.com/#/songs/masters-war> (last visited Apr. 9, 2009).

## I. THE AMBIGUITIES AND AMBIVALENCES OF NEUROIMAGING EVIDENCE

Although commentators bravely assert that neuroscience seems “advanced enough to enter forensic psychiatry,”<sup>27</sup> that “[a]dvances in neurobiological research methods allow one to address the nature and biological basis of human behavior,”<sup>28</sup> and that jurors can be counted on to critically evaluate such evidence,<sup>29</sup> a cluster of other factors forces us to think seriously about how factfinders will construe neuroimaging evidence. In a recent article, I identified these factors as “visualization, reductionism, the attribution heuristic, and the impact of a belief in ‘the CSI effect.’”<sup>30</sup> Regarding “visualization,” I referred to the ways that the “visual allure”<sup>31</sup> can “dazzl[e]” and “seduc[e]” jurors<sup>32</sup> in ways that are “inappropriately persuasive.”<sup>33</sup> Regarding “reductionism,” I referred to the ways that neuroimaging testimony has the meretricious capacity to “[reduce] . . . psychosocial complexity.”<sup>34</sup>

By “the attribution heuristic,” I referred to the way that we seek to attribute human behavior, in the words of Laura Khoshbin and Shahram Khoshbin, “to a physical source in the head.”<sup>35</sup> And by the “CSI effect,” I referred to the way that we *believe* that jurors demand the “money shot” of hard forensic evidence in all trials, even though valid and reliable evidence as to the reality of that belief “is scant.”<sup>36</sup>

This remains, in the end, an area fraught with ambiguity and contradiction.<sup>37</sup>

## II. THE CRIMINAL PROCEDURE QUESTIONS

### A. Introduction

Concerns that (1) jurors may accept some scientific thinking uncritically, and (2) lawyers may not be sufficiently adept at cross-examining certain sorts of expert witnesses are not new in the evidence/trial practice scholarship.<sup>38</sup> By raising the issues that are the focal point of this paper, I hope to rearticulate these concerns in a new context: that of neuroimaging evidence.

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<sup>27</sup> Joachim Witzel et al., *Neurophilosophical Perspectives of Neuroimaging in Forensic Psychiatry—Giving Way to a Paradigm Shift?*, 26 BEHAV. SCI. & L. 113, 115 (2008).

<sup>28</sup> Jurgen Müller et al., *Disturbed Prefrontal and Temporal Brain Function During Emotion and Cognition Interaction in Criminal Psychopathy*, 26 BEHAV. SCI. & L. 131, 131 (2008).

<sup>29</sup> Dov Fox, *Brain Imaging and the Bill of Rights: Memory Detection Technologies and American Criminal Justice*, 8 AM. J. BIOETHICS 34, 36 (2008).

<sup>30</sup> See Perlin, *supra* note 1 at 893-4.

<sup>31</sup> Laura Stephens Khoshbin & Shahram Khoshbin, *Imaging the Mind, Minding the Image: An Historical Introduction to Brain Imaging and the Law*, 33 AM. J.L. & MED. 171, 182 (2007).

<sup>32</sup> *Id.* at 183 n.98, 185; see also Tancredi & Brodie, *supra* note 9, at 289. See generally Deena Skolnick Weisberg et al., *The Seductive Allure of Neuroscience Explanations*, 20 J. COGNITIVE NEUROSCIENCE 470 (2008).

<sup>33</sup> Neil Feigenson, *Brain Imaging and Courtroom Evidence: On the Admissibility and Persuasiveness of fMRI*, 2 INT’L J.L. CONTEXT 233, 247 (2006).

<sup>34</sup> *Id.* at 248.

<sup>35</sup> Khoshbin & Khoshbin, *supra* note 31 at 171. On “heuristics” in general, see Perlin, *supra* note 20. *But see* Weisberg et al., *supra* note 32, at 476 (suggesting that the “seductive details effect” is a more likely explanation for juror behavior than use of heuristic reasoning devices).

<sup>36</sup> Donald Shelton et al., *A Study of Juror Expectations and Demands Concerning Scientific Evidence: Does the “CSI Effect” Exist?*, 9 VAND. J. ENT. & TECH. L. 331 (2006); see also, Wendy Brickell, *Is It the CSI Effect or Do We Just Distrust Juries?* 23 CRIM. JUST. 10 (Summer 2008).

<sup>37</sup> For recent experimental research, concluding that neuroscience evidence led “novices” (non-experts) to judge “bad explanations” of behavior more favorably, see Weisberg et al., *supra* note 32, at 475, urging that there are “more reasons for caution” when applying such evidence to “social issues.” *Id.* at 477.

<sup>38</sup> E.g., Shari Seidman Diamond, *How Jurors Deal With Expert Testimony and How Judges Can Help*, 16 J.L. & POL’Y 47, 48 (2007); Steven Wilkins, *Know Thine Expert: Expert Witnesses in Medical Malpractice Cases: Supplementing Disclosure with Online Investigation*, 76 N.Y. ST. B.A.J. 31 (2004).

Michael L. Perlin: "And I See Through Your Brain": Access to Experts, Competency to Consent, and the Impact of Antipsychotic Medications in Neuroimaging Cases in the Criminal Trial Process

*B. Right to an Expert*

The vast majority of criminal defendants are indigent.<sup>39</sup> Neuroimaging testing is expensive, and is more expensive in cases in which the examined defendant is in jail awaiting trial.<sup>40</sup> The question before us here is relatively simple: does the defendant have a right to an independent neuroimaging expert in either (1) insanity cases, or (2) other criminal trial matters, including, but not limited to, incompetency to stand trial proceedings,<sup>41</sup> sentencing hearings,<sup>42</sup> and inquiries into mental status in instances where the difference in gradations of a crime may be of great significance as a correlation of exposure to a specific punishment?<sup>43</sup>

Nearly twenty-five years ago, the U.S. Supreme Court addressed the question of a defendant's right to an expert in a criminal trial. In *Ake v. Oklahoma*, a death penalty case, the Supreme Court ruled that an indigent criminal defendant who makes a threshold showing that insanity is likely to be a significant factor at trial is constitutionally entitled to a psychiatrist's assistance.<sup>44</sup> The Court observed that it had "long recognized that when a State brings its judicial power to bear on an indigent defendant in a criminal proceeding, it must take steps to insure that the defendant has a fair opportunity to present his defense."<sup>45</sup> This principle, grounded in the due process clause's guarantee of "fundamental fairness," derives from the belief "that justice cannot be equal when, simply as a result of his poverty, a defendant is denied the opportunity to participate meaningfully in a judicial proceeding in which his liberty is at stake."<sup>46</sup>

"Meaningful access to justice" is the theme of the relevant cases, the Court found,<sup>47</sup> noting that "mere access to the courthouse doors does not by itself assure a proper functioning of the adversary process."<sup>48</sup> A criminal trial is "fundamentally unfair if the State proceeds against an indigent defendant without making certain that he has access to the raw materials integral to the building of an effective defense."<sup>49</sup>

In determining whether access to a psychiatrist is one of the "basic tools of an adequate defense,"<sup>50</sup> the Court set out three relevant factors:

The first is the private interest that will be affected by the action of the State. The second is the governmental interest that will be affected if the safeguard is to be provided. The third is the probable value of the additional or substitute procedural safeguards that are sought, and the risk of an erroneous deprivation of the affected interest if those safeguards are not provided . . .<sup>51</sup>

The Court quickly disposed of the first prong, characterizing the private interest in accuracy of a criminal proceeding as "almost uniquely compelling."<sup>52</sup> In the same way, it summarily rejected the

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<sup>39</sup> Publicly financed counsel represented about 66% of Federal felony defendants in 1998 and 82% of felony defendants in the 75 most populous counties in 1996. U.S. Department of Justice, Bureau of Justice Statistics Indigent Defense Statistics, <http://www.ojp.usdoj.gov/bjs/id.htm> (last visited April 17, 2009); Press Release, U.S. Department of Justice, Bureau of Justice Statistics, Two of Three Felony Defendants Represented by Publicly-Financed Counsel (Nov. 29, 2000), <http://www.ojp.usdoj.gov/bjs/pub/press/iddcpr.htm> (last visited April 17, 2009).

<sup>40</sup> For sample fee scales, see, for example, New Hampshire Insurance Department, NH Health Cost, [http://www.nhhealthcost.org/uninsuredWizardUserInput.aspx?procedure=16&procedureName=MRI+-+Brain+\(outpatient\)](http://www.nhhealthcost.org/uninsuredWizardUserInput.aspx?procedure=16&procedureName=MRI+-+Brain+(outpatient)) (last visited April 17, 2009). See generally, Steve Silberman, *Don't Even Think About Lying: How Brain Scans Are Reinventing the Science of Lie Detection*, WIRED, Jan. 2006, at 147, available at <http://www.wired.com/wired/archive/14.01/lying.html>.

<sup>41</sup> See e.g., *United States v. Gigante*, 982 F. Supp. 140, 147 (E.D.N.Y. 1997).

<sup>42</sup> This issue is discussed extensively in Greely, *supra* note 13.

<sup>43</sup> See e.g., *People v. Weinstein*, 591 N.Y.S.2d 715 (1992).

<sup>44</sup> 470 U.S. 68, 74 (1985). See generally 4 PERLIN, *supra* note 16, § 9A-5.1, at 217-27.

<sup>45</sup> *Ake*, 470 U.S. at 76.

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

<sup>47</sup> *Id.* at 77.

<sup>48</sup> *Id.*

<sup>49</sup> *Id.* While such a defendant does not have a right to all the assistance that a wealthier defendant might be able to purchase, he is nonetheless entitled to "an adequate opportunity to present [his] claims fairly within the adversary system." *Ross v. Moffitt*, 417 U.S. 600, 612 (1974).

<sup>50</sup> *Britt v. North Carolina*, 404 U.S. 226, 227 (1971).

<sup>51</sup> *Ake*, 470 U.S. at 77 (citing *Little v. Streater*, 452 U.S. 1 (1981) (indigent's right to blood grouping tests in paternity action); *Mathews v. Eldridge*, 424 U.S. 319 (1976)).

<sup>52</sup> *Ake*, 470 U.S. at 78.

argument that a reversal would “result in a staggering burden to the State,”<sup>53</sup> noting that at least forty states and the federal government already made such services available.<sup>54</sup> The Court also found it “difficult to identify *any* interest of the state, other than in its economy, that weighs against recognition of this right.”<sup>55</sup> Finally, it considered the “pivotal role” psychiatry has come to play in criminal proceedings,<sup>56</sup> reflecting the “reality that when the State has made the defendant’s mental condition relevant to his criminal culpability and to the punishment he might suffer, the assistance of a psychiatrist may well be crucial to the defendant’s ability to marshal his defense.”<sup>57</sup>

The Court set out what it perceived as the role of the psychiatrist in such cases:

[P]sychiatrists gather facts, both through professional examination, interviews, and elsewhere, that they will share with the judge or jury; they analyze the information gathered and from it draw plausible conclusions about the defendant’s mental condition, and about the effects of any disorder on behavior; and they offer opinions about the defendant’s mental condition might have affected his behavior at the time in question. They know the probative questions to ask of the opposing party’s psychiatrists and how to interpret their answers. Unlike lay witnesses, who can merely describe symptoms they believe might be relevant to the defendant’s mental state, psychiatrists can identify the “elusive and often deceptive” symptoms of insanity, *Solesbee v. Balkcom*, 339 U.S. 9, 12 (1950), and tell the jury why their observations are relevant. Further, where permitted by evidentiary rules, psychiatrists can translate a medical diagnosis into language that will assist the trier of fact, and therefore offer evidence in a form that has meaning for the task at hand. Through this process of investigation, interpretation, and testimony, psychiatrists ideally assist lay jurors, who generally have no training in psychiatric matters, to make a sensible and educated determination about the medical condition of the defendant at the time of the offense.<sup>58</sup>

Because psychiatry is not an exact science, however, and because of frequent psychiatric disagreement on the classification and diagnosis of mental illness and the likelihood of future dangerousness, it is often necessary for juries to resolve differences in opinion.<sup>59</sup> On such a determination, “the testimony of psychiatrists can be crucial and ‘a virtual necessity if an insanity plea is to have any chance of success.’”<sup>60</sup> This finding led the Court “inexorably” to conclude that:

[W]ithout the assistance of a psychiatrist to conduct a professional examination on issues relevant to the defense, to help determine whether the insanity defense is viable, to present testimony, and to assist in preparing the cross-examination of a State’s psychiatric witnesses, the risk of an inaccurate resolution of sanity issues is extremely high. With such assistance, the defendant is fairly able to present at least enough information to the jury, in a meaningful manner, as to permit it to make a sensible determination.<sup>61</sup>

As the risk of error from denial of such assistance is highest “when the defendant’s mental condition is seriously in question,”<sup>62</sup> the defendant would thus qualify for such assistance when he is able to make an “*ex parte* threshold showing that his sanity is likely to be a significant factor in his defense.”<sup>63</sup> The Court thus held that, when a defendant is able to demonstrate that

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<sup>53</sup> *Id.*

<sup>54</sup> *Id.* at 79-80 & nn.4-6; see, e.g., 18 U.S.C. § 3006A(e) (2006).

<sup>55</sup> *Ake*, 470 U.S. at 79 (emphasis added).

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 80.

<sup>58</sup> *Ake*, 470 U.S. at 80-81.

<sup>59</sup> *Id.* at 81.

<sup>60</sup> *Id.* (quoting Martin R. Gardner, *The Myth of the Impartial Psychiatric Expert—Some Comments Concerning Criminal Responsibility and the Decline of the Age of Therapy*, 2 LAW & PSYCHOL. REV. 99, 113-14 (1976)).

<sup>61</sup> *Ake*, 470 U.S. at 82. On the ethical issues involved in the relationship between the lawyer and the mental health expert, see W. Lawrence Fitch et al., *Legal Ethics and the Use of Mental Health Experts in Criminal Cases*, 5 BEHAV. SCI. & L. 105, 109-16 (1987).

<sup>62</sup> *Ake*, 470 U.S. at 82.

<sup>63</sup> *Id.* at 82-83 (“It is in such cases that a defense may be devastated by the absence of a psychiatric examination and testimony; with such assistance, the defendant might have a reasonable chance of success. In such a circumstance, where the potential accuracy of the jury’s determination is so dramatically enhanced, and where the interests of the individual and the State in an accurate proceeding are substantial, the State’s interest in its fisc must yield.”) (footnote omitted).

On the question of what is a “significant factor,” see, for example, *Volant v. Lynaugh*, 874 F.2d 243 (5th Cir. 1989), *cert. denied*, 493 U.S. 955 (1989) (defendant’s bare assertion that he was heroin addict insufficient basis for *Ake* appointment); *Mendoza v. Leapley*, 5 F.3d 341 (8th Cir. 1993) (habeas corpus relief denied; failure to appoint expert psychologist did not deprive petitioner of fair trial); *Perkins v. State*, 450 S.E.2d 324 (Ga. Ct. App. 1994) (refusal to appoint psychiatrist at trial not error where psychiatrist

his sanity was such a "significant factor," the state must "assure the defendant access to a competent psychiatrist who will conduct an appropriate examination and assist in evaluation, preparation, and presentation of the defense."<sup>64</sup>

Finally, the Court held that a defendant was similarly entitled to psychiatric expert assistance to rebut the state's evidence of future dangerousness at the penalty phase of a death penalty trial.<sup>65</sup> Where the consequence of error is so great, the relevance so evident, and the burden to the state so slim, due process requires "access to a psychiatric examination" for assistance in the preparation of the sentencing phase.<sup>66</sup>

The courts have generally read *Ake* narrowly, and have refused to require appointment of an expert unless it is "absolutely essential to the defense."<sup>67</sup> By way of examples, courts have split on whether there is a right to an expert *psychologist* to perform psychological testing under *Ake*,<sup>68</sup> and have also, without citing *Ake*, rejected an application for the right to the appointment of a social psychologist to aid in jury selection.<sup>69</sup> *Ake*, on the other hand, was relied on so as to require the appointment of a pathologist in a criminal case.<sup>70</sup> On the perhaps-closer question of the requirement of the appointment of a DNA expert, after an intermediate appellate court in Virginia relied on *Ake* to require the appointment of such an expert, that decision was subsequently vacated, with no discussion of *Ake* in the subsequent opinion.<sup>71</sup>

In his exhaustive survey article about the implementation of *Ake*, Professor Paul Giannelli points out, in a slightly different context, that, "in 1985, the *Ake* Court could not have anticipated how the advent of DNA evidence would revolutionize forensic science."<sup>72</sup> Nor, of course, could it have anticipated the new significance of neuroimaging evidence. To this point in time, however, lower courts have been generally reluctant to extend *Ake* to requests for funding for neuroimaging tests.<sup>73</sup> In *Bates v. State*,<sup>74</sup> no *Ake* violation was found where a defendant sought additional expert assistance in establishing functional organic brain damage, and in *Smith v. Kearney*,<sup>75</sup> there was no *Ake* error where defendant sought funds for a PET scan.<sup>76</sup> Although the court in *Walker v. Oklahoma*<sup>77</sup> found

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who had done pretrial evaluation of defendant concluded that he was sane).

<sup>64</sup> *Ake*, 470 U.S. at 83. The Court emphasized that this did not give the defendant the right to "choose a psychiatrist of his personal liking." *Id.* Its concern was simply that an indigent defendant "have access to a competent psychiatrist." *Id.* Cf. *In re Gannon*, 301 A.2d 493 (N.J. Ct. Ct. 1973) (indigent in civil commitment case has no right "to shop around for a psychiatrist who agrees with him"). See generally PERLIN, *supra* note 16, § 2B-16.

<sup>65</sup> *Ake*, 470 U.S. at 83-84.

<sup>66</sup> *Id.* at 84.

<sup>67</sup> STEPHEN A. SALTZBURG & DANIEL J. CAPRA, AMERICAN CRIMINAL PROCEDURE 802 (6th ed. 2000); see also David A. Harris, *Ake Revisited: Expert Psychiatric Witnesses Remain Beyond Reach for the Indigent*, 68 N.C. L. REV. 763, 783 (1990) ("Lower courts often have interpreted *Ake* less than generously, unduly constricting the availability of the right."); Comment, *Nonpsychiatric Expert Assistance and the Reg requisite Showing of Need: A Catch-22 in the Post-Ake Criminal Justice System*, 37 EMORY L.J. 995 (1988) (arguing *Ake* should be read to encompass nonpsychiatric expert assistance).

<sup>68</sup> Compare *Jones v. State*, 375 S.E.2d 648 (Ga. Ct. App. 1988) (rejecting defendant's request for additional psychological evaluation; limiting *Ake* to *psychiatrists*) and *Hough v. State*, 524 N.E.2d 1287 (Ind. 1988) (no right under *Ake* to appointment of social psychologist to help in jury selection), with *Funk v. Commonwealth*, 379 S.E.2d 371 (Va. Ct. App. 1989) (rejecting defendant's argument that psychiatric assistance is mandated under *Ake*; no error to appoint clinical *psychologist*), and *King v. State*, 877 S.W.2d 583 (Ark. 1994) (appointment of psychologist sufficient under state statute).

<sup>69</sup> *Wallace v. State*, 553 N.E.2d 456 (Ind. 1990), *cert. denied*, 500 U.S. 948 (1991).

<sup>70</sup> *Rey v. State*, 897 S.W.2d 333 (Tex. Crim. App. 1995).

<sup>71</sup> See e.g., *Husske v. Commonwealth*, 448 S.E.2d 331 (Va. Ct. App. 1994) (state required to appoint DNA expert under *Ake*), *vacated*, 462 S.E.2d 120 (Va. Ct. App. 1995) (*Ake* issue not discussed), *aff'd*, 476 S.E.2d 920 (Va. 1996), *cert. denied*, 519 U.S. 1154 (1997). For a more recent consideration of the application of *Ake* to DNA and other non-psychiatric evidence, see Paul Giannelli, *Ake v. Oklahoma: The Right to Expert Assistance in a Post-Daubert, Post-DNA World*, 89 CORNELL L. REV. 1305, 1418-19 (2004), concluding that "*Ake*'s rationale extends to nonpsychiatric experts."

Beyond the scope of this paper is a related, important question: is neuroimaging evidence—for purposes of assessing validity and reliability of testimony—more like DNA evidence or more like other more traditional forensic evidence (e.g., bitemarks, hair comparisons, etc.). See e.g., Dawn McQuiston-Surrett & Michael Saks, *Communicating Opinion Evidence in the Forensic Identification Sciences: Accuracy and Impact*, 59 HASTINGS L.J. 1159 (2008).

<sup>72</sup> Giannelli, *supra* note 71, at 1418.

<sup>73</sup> *Jones* is discussed in this context in Jennifer Kulynych, *Psychiatric Neuroimaging Evidence: A High-Tech Crystal Ball?*, 49 STAN. L. REV. 1249, 1254 (1997), and Mark Pettit, *fMRI and BF Meet FRE: Brain Imaging and the Federal Rules of Evidence*, 33 AM. J.L. & MED. 319, 335 (2007).

For an array of recent post-*Ake* decisions, see MICHAEL L. PERLIN & HEATHER ELLIS CUCOLO, MENTAL DISABILITY LAW: CIVIL AND CRIMINAL, § 9A-5.1, at 76-77 (2007 Cum. Supp.).

<sup>74</sup> 750 So. 2d 6, 16-17 (Fla. 1999).

<sup>75</sup> No. 2 CA-SA 2008-0019, 2008 WL 2721155 (Ariz. Ct. App. July 22, 2008).

<sup>76</sup> *Smith* was a challenge based on *Atkins v. Virginia*, 536 U.S. 304 (2002), arguing that the defendant's mental retardation

that it was *Ake* error to fail to provide funds for additional neurological testing “to flesh out the etiology of [the defendant’s] mental illness,”<sup>78</sup> it deemed that error harmless.<sup>79</sup> On the other hand, *People v. Jones*<sup>80</sup> did reverse a conviction because of the lower court’s refusal to fund brain scans.

The constitutional analysis here cannot be undertaken without serious consideration of likely juror response to the glitter of neuroimaging evidence, what Dean Mobbs has called the “Christmas tree phenomenon”<sup>81</sup> in writing about the *seductiveness* of this evidence.<sup>82</sup> Certainly, this analysis argues persuasively for an expansive reading of *Ake* and its progeny.<sup>83</sup>

The need for this expansive reading is heightened because insanity defense cases are so often so utterly dissonant with jurors’ flawed “ordinary common sense” (OCS).<sup>84</sup> How well can lawyers cross-examine experts on these sophisticated questions of science where the “dazzle” of the proffered evidence makes the expression of skepticism about such evidence equally dissonant from juror OCS? Also, the neuroimaging-mental status cases (here, I am combining insanity and incompetency cohorts) that have received the most attention were the subject of saturation publicity, such as *Hinckley* and *Gigante*.<sup>85</sup> This reflects the vividness heuristic, a cognitive-simplifying device through which a “single vivid, memorable case overwhelms mountains of abstract, colorless data upon which rational choices should be made,” and further accentuates a mis-perception of reality.<sup>86</sup> Until neuroimaging evidence is used more frequently in what I have elsewhere called “invisible cases,”<sup>87</sup> the distortion effect of famous cases will require our speculations to remain tentative.<sup>88</sup>

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barred the imposition of the death penalty. The Court concluded on this issue:

Thus, while we do not dispute Thompson’s testimony that frontal lobe damage can be a cause of mental retardation, Smith has not demonstrated on the facts before us how a current PET scan would be useful in assessing the pivotal question presented in this case—whether his mental functioning was significantly more deficient thirty years ago than today. *Id.*, at \*4.

<sup>77</sup> 167 F.3d 1339, 1348-49 (10th Cir.), cert. denied, 528 U.S. 987 (1999).

<sup>78</sup> See *Allen v. Mullin*, 368 F.3d 1220, 1236 (10th Cir. 2004) (discussing *Walker*).

<sup>79</sup> *Walker*, 167 F.3d at 1348-49.

<sup>80</sup> 620 N.Y.S.2d 656, 657 (N.Y. App. Div. 1994).

<sup>81</sup> See Neil Feigenson & Richard Sherwin, *Thinking Beyond the Shown: Implicit Inferences in Evidence and Argument*, 6 LAW, PROBABILITY & RISK 295, 299-300 (2007) (citing Dean Mobbs et al., *Law, Responsibility, and the Brain*, 5 PLOS BIOLOGY 693 (2007)).

<sup>82</sup> See also Richard Henson, *What Can Functional Neuroimaging Tell the Experimental Psychologist?*, A58 Q. J. EXPERIMENTAL PSYCHOL. 193 (2005) (“There is a real danger that pictures of blobs on brains seduce one into thinking that we can now directly observe psychological constructs.”); Tancredi & Brodie, *supra* note 9, at 289. Cf. Robert Granacher, *Commentary: Applications of Functional Neuroimaging to Civil Litigation of Mild Traumatic Brain Injury*, 36 J. AM. ACAD. PSYCHIATRY & L. 323, 323 (2008) (“The overselling of [neuroimaging evidence] by lawyers is a serious potential evidentiary concern in . . . civil litigation.”).

<sup>83</sup> On the dangers of showing “undue deference” to expert witnesses, see, for example, Elaine Sutherland, *Undue Deference to Experts Syndrome?* 16 IND. INT’L & COMP. L. REV. 375 (2006). On the dangers of “anecdotal forensics,” see, for example, David Faigman, *Anecdotal Forensics, Phrenology And Other Abject Lessons from the History of Science*, 59 HASTINGS L.J. 979 (2008).

Beyond the scope of this paper is a consideration of the implications of the *Daubert* doctrine on these questions. We do know, however, that courts generally “lower the bar” on the resolution of *Daubert* issues in criminal cases. See e.g., Paul Giannelli, *Forensic Science Under the Microscope*, 34 OHIO N.U.L. REV. 315, 317 & n.22 (2008); see generally, Deirdre Dwyer, *(Why) Are Civil and Criminal Expert Evidence Different?*, 43 TULSA L. REV. 381, 382-84 (2007). On the question addressed here, see James Merckangas, *Commentary: Functional MRI Lie Detection*, 36 J. AMER. ACAD. PSYCHIATRY & L. 499 (2008) (fMRI evidence, for purposes of lie detection, does not meet *Daubert* standards).

<sup>84</sup> OCS is self-referential and non-reflective: “I see it that way, therefore everyone sees it that way; I see it that way, therefore that’s the way it is.” In criminal procedure, by way of example, “OCS presupposes two self-evident truths: 1) everyone knows how to assess an individual’s behavior, and 2) everyone knows when to blame someone for doing wrong.” Perlm, *Neonaticide*, *supra* note 3, at 8, quoting Michael L. Perlm, *Psychodynamics and the Insanity Defense: Ordinary Common Sense and Heuristic Reasoning*, 69 NEB. L. REV. 3, 22-33 (1990).

<sup>85</sup> See also, e.g., *United States v. Mezzvinsky*, 206 F. Supp. 2d 661 (E.D. Pa. 2002) (multi-million dollar fraud case; defendant was former Congressman); *People v. Goldstein*, 786 N.Y.S.2d 428 (App. Div. 2004), *rev’d on other grounds*, 843 N.E.2d 727 (N.Y. 2005) (murder case in which victim was Kendra Webdale, after whom New York’s assisted outpatient treatment law was named).

<sup>86</sup> Michael L. Perlm, *“The Borderline Which Separated You From Me”: The Insanity Defense, the Authoritarian Spirit, the Fear of Faking, and the Culture of Punishment*, 82 IOWA L. REV. 1375, 1417 (1997).

<sup>87</sup> See Michael L. Perlm, *A Law of Healing*, 68 U. CIN. L. REV. 407, 425 (2000) (“[T]he overwhelming number of cases involving mental disability law issues are litigated” in pitch darkness. Involuntary civil commitment cases are routinely disposed of in minutes behind closed courtroom doors.”)

<sup>88</sup> On this phenomenon in the universe of *civil* mental disability cases, see *id.* at 424-25 (“Civil cases are rarely the focus of so much interest, but court decisions in a handful of cases involving potential professional liability—*Tarasoff v. Regents of the University of California* is, by far, the most famous—are disseminated widely to professional audiences. Their holdings—and concomitant significance for practitioners—are regularly over-exaggerated and distorted.”).

Beyond the scope of this paper is the interplay between the Supreme Court’s pallid “effectiveness of counsel” standard set out in *Strickland v. Washington*, 466 U.S. 668, 688 (1984) (“whether counsel’s conduct so undermined the proper function of the adversarial process that the trial court cannot be relied on as having produced a just result”) and the responsibilities on counsel to understand and contextualize neuroimaging evidence. (My thanks to Erin Murphy for raising this issue to me).

C. Competency to Consent

The question of “competency” has been a core issue in the criminal law for hundreds of years.<sup>89</sup> For most of this time, the focus has been solely on questions of competency to stand trial. In 1960 and 1966, the Supreme Court constitutionalized the prevailing common law standards in this area in the context of both substantive and procedural due process, establishing a lenient test for assessing a defendant’s trial competency.<sup>90</sup>

More recently, the Court ruled—in what I think was a hopelessly misguided opinion<sup>91</sup>—that the same minimalist standard articulated in *Dusky v. United States* as to matters of trial competency also applied in inquiries regarding defendants’ competency to plead guilty and/or to waive counsel.<sup>92</sup> However, in its most recent term, the Court backed off this position a bit, finding in *Indiana v. Edwards* that the Constitution permits states to insist upon representation by counsel for those who are competent enough to stand trial but who are sufficiently ill to be incompetent to conduct trial proceedings by themselves.<sup>93</sup>

Other courts have considered questions of criminal competency in a host of other pretrial (confessions, search and seizures, line-ups), trial (jury waivers, evidentiary objections, impact of incompetency finding on ability to enter insanity plea) and post-trial settings (motion for new trial, sentencing, parole or probation hearing), but these cases all seem to have been decided without reference to or consideration of what other courts had decided in analogous (or even identical) areas of the law.<sup>94</sup>

The question of “competency” has also been a core issue in civil, constitutional and private mental disability law,<sup>95</sup> especially in the context of a patient’s right to refuse the involuntary imposition of antipsychotic medications.<sup>96</sup> The Supreme Court has considered this issue directly in three criminal cases involving different forensic populations (defendants who had been convicted of crimes,<sup>97</sup> those who were proffering the insanity defense at trial,<sup>98</sup> and those who were awaiting trial on “serious” criminal offenses<sup>99</sup>) and indirectly in a civil case.<sup>100</sup> Multiple federal appellate courts and state high courts have also weighed this issue, mostly in the civil context.<sup>101</sup>

On the criminal side of the ledger, the Supreme Court’s most recent case, *Sell v. United States*, sets out an elaborate formulation:

[T]he Constitution permits the government involuntarily to administer antipsychotic drugs to a mentally ill defendant facing serious criminal charges in order to render that defendant competent to stand trial, but only if the treatment is medically appropriate, is substantially unlikely to have side effects that may undermine the fairness of the trial, and, taking account

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<sup>89</sup> 4 PERLIN, *supra* note 16, § 9A-2.1 at 3 (doctrine traditionally traced to mid-seventeenth century England); *But see* RONALD ROESCH & STEVEN GOLDING, COMPETENCY TO STAND TRIAL 19 (1980) (suggesting its roots are in legal developments of the thirteenth century).

<sup>90</sup> *See Dusky v. United States*, 362 U.S. 402 (1960) (test is whether the defendant “has sufficient present ability to consult with his lawyer with a reasonable degree of rational understanding” and whether he has a “rational as well as factual understanding of the proceedings against him.”); *Pate v. Robinson*, 383 U.S. 375 (1966) (conviction of mentally incompetent defendant violates due process).

<sup>91</sup> *See* Michael L. Perlin, “Dignity Was the First to Leave”: *Godinez v. Moran*, *Colin Ferguson*, and the Trial of Mentally Disabled Criminal Defendants, 14 BEHAV. SCI. & L. 61 (1996) (critiquing the use of a unitary standard in such cases).

<sup>92</sup> *Godinez v. Moran*, 509 U.S. 389 (1993).

<sup>93</sup> 128 S. Ct. 2379 (2008).

<sup>94</sup> Michael L. Perlin, *Beyond Dusky & Godinez: Competency Before and After Trial*, 21 BEHAV. SCI. & L. 297, 309-10 (2003) (“The failure of most of the cases to consider carefully the relevant precedents (and analogous developments in other jurisdictions) is . . . surprising.”).

<sup>95</sup> *See generally* MICHAEL L. PERLIN ET AL., COMPETENCE IN THE LAW: FROM LEGAL THEORY TO CLINICAL APPLICATION (2008).

<sup>96</sup> 2 PERLIN, *supra* note 16, chapter 5B. *See generally* Michael L. Perlin, “And My Best Friend, My Doctor/Won’t Even Say What It Is I’ve Got”: The Role and Significance of Counsel in Right to Refuse Treatment Cases, 42 SAN DIEGO L. REV. 735 (2005).

<sup>97</sup> *Washington v. Harper*, 494 U.S. 210 (1990).

<sup>98</sup> *Riggins v. Nevada*, 504 U.S. 127 (1992).

<sup>99</sup> *Sell v. United States*, 539 U.S. 166 (2003).

<sup>100</sup> *Mills v. Rogers*, 457 U.S. 291 (1982).

<sup>101</sup> *See* 2 PERLIN, *supra*, note 16, § 3B-7 to 7.2f.



of less intrusive alternatives, is necessary significantly to further important governmental trial-related interests.<sup>102</sup>

On the civil side, two models have emerged: the “expanded due process model” and the “limited due process model.” Under the expanded due process model, mental health patients are often provided with procedural due process protections such as notice, counsel, the right to cross-examine witnesses, the right to present evidence (including expert testimony), and the right to appeal. Under the limited due process model, mental health patients are provided with only minimal due process protections: narrower administrative review is provided, and broad readings of the Fourteenth Amendment’s Due Process Clause are rejected.<sup>103</sup>

Analysis of the intersection between the right to refuse treatment and the criminal trial process takes on even more importance when considered in the context of the findings by the MacArthur Research Network that mental health patients are not always incompetent to make rational decisions and are not inherently more incompetent than nonmentally ill medical patients.<sup>104</sup> This research suggests that a criminal defendant’s autonomy in medication refusal decisionmaking should be more privileged and less subordinated than it typically is.<sup>105</sup>

Mostly lost to the pages of history are the “barely remembered case[s]”<sup>106</sup> of *Mackey v. Procnier*<sup>107</sup> and *Knecht v. Gillman*.<sup>108</sup> These forerunner cases set the stage<sup>109</sup> for the civil and criminal cases just discussed, but I think it is more important to think about them in the context of this inquiry.

*Mackey* and *Knecht* dealt with the use of medication as a tool of negative behavior modification/operant conditioning purposes,<sup>110</sup> and also raised issues under the First and Eighth Amendments.<sup>111</sup> I seek to resurrect these opinions here, because I think they may potentially illuminate some of the issues we need to consider when we weigh what I see as a critical (but virtually never discussed) criminal procedure question: what are the criteria for assessing whether a criminal defendant is competent to consent to neuroimaging testing?<sup>112</sup>

Although such tests are not physically invasive in the same way as injectible antipsychotic medication or nausea-inducing drugs,<sup>113</sup> a strong parallel argument can be made, I think, that such testing, involving measurement of brain functioning, *is* invasive for purposes of constitutional analysis. It can lead—directly and inexorably—to negative outcomes for the person being tested, and, as such, inevitably raises the substantive cluster of competency questions implicated by involuntary

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<sup>102</sup> *Sell*, 539 U.S. at 179.

<sup>103</sup> Michael L. Perlin & Deborah A. Dorfman, *Is It More Than “Dodging Lions and Wastin’ Time”? Adequacy of Counsel, Questions of Competence, and the Judicial Process in Individual Right to Refuse Treatment Cases*, 2 PSYCHOL. PUB. POL’Y & L. 114, 122-23 (1996).

<sup>104</sup> Perlin, *supra* note 96, at 746-47 (discussing Thomas Grisso & Paul S. Appelbaum, *The MacArthur Treatment Competence Study. III: Abilities of Patients to Consent to Psychiatric and Medical Treatments*, 19 LAW & HUM. BEHAV. 149 (1995)).

<sup>105</sup> Grant Morris, *Judging Judgment: Assessing the Competence of Mental Patients to Refuse Treatment*, 32 SAN DIEGO L. REV. 343 (1995).

<sup>106</sup> Michael L. Perlin, *“There’s No Success like Failure/and Failure’s No Success at All”: Exposing the Pretextuality of Kansas v. Hendricks*, 92 NW. U. L. REV. 1247, 1271 (1998). *But see* Greely, *supra* note 13, at 1110 (discussing *Knecht* and *Mackey*).

<sup>107</sup> 477 F.2d 877 (9th Cir. 1973).

<sup>108</sup> 488 F.2d 1136 (8th Cir. 1973).

<sup>109</sup> Thomas Hafemeister & John Petrla, *Treating The Mentally Disordered Offender: Society’s Uncertain, Conflicted, And Changing Views*, 21 FLA. ST. U. L. REV. 731, 788-89 (1994).

<sup>110</sup> *See* Bruce Winick, *Ambiguities in the Legal Meaning and Significance of Mental Illness*, 1 PSYCHOL. PUB. POL’Y & L. 534, 590 n. 230 (1995) (*Knecht* involved the use of apomorphine, a vomit-inducing drug, in a security hospital aversive conditioning program, and *Mackey*, the use of succinylcholine, a paralyzing drug, in a California prison aversive conditioning program).

<sup>111</sup> 2 PERLIN, *supra* note 16, §§ 3B-4.1 to 4.2, at 171-79.

<sup>112</sup> Commentators have argued that, for certain purposes, neuroimaging tests may run afoul of the privilege against self-incrimination and substantive due process. *See, e.g.*, Sarah E. Stoller & Paul Root Wolpe, *Emerging Neurotechnologies for Lie Detection and the Fifth Amendment*, 33 AM. J.L. & MED. 359, 371 (2007); Jody C. Barillare, *As Its Next Witness, the State Calls . . . the Defendant: Brain Fingerprinting as “Testimonial” Under the Fifth Amendment*, 79 TEMP. L. REV. 971, 1003 (2006); Sean Kevin Thompson, *A Brave New World of Interrogation Jurisprudence?*, 33 AM. J.L. & MED. 341, 357 (2007); John New, *If You Could Read My Mind*, 29 J. LEGAL MED. 179, 193-95 (2008).

On the possible application of the Fourth Amendment, compare *id.* at 195-98 (concluding that Amendment is inapplicable), with Richard Boire, *Searching the Brain: The Fourth Amendment Implications of Brain-Based Deception Detection Devices*, 5 AM. J. BIOETHICS 62 (2005) (suggesting possible application of that Amendment).

<sup>113</sup> On the relationship between these questions and the doctrine of *Schmerber v. California*, 384 U.S. 757 (1966) (discussing physiological intrusivity and the criminal trial process, and finding extraction of blood sample constitutional), *see* Stoller & Wolpe, *supra* note 112, at 368-69.

medication practices.<sup>114</sup> We know that there is no unitary standard of competency<sup>115</sup> and that the body of case law and commentary that has evolved in criminal, mental disability and private civil law is maddeningly inconsistent.<sup>116</sup> I am not suggesting that I can resolve these multiple dilemmas in this context; rather, I simply want to call our attention to this issue as one that must be “on the table” for future discussions.

In a recent article, Jennifer Kulynych raises the important—but as of yet, rarely discussed—issue of the need to determine whether a defendant is competent to consent to the administration of neuroimaging tests,<sup>117</sup> noting that there is currently “no federal regulatory bar to enrolling adults in an MRI study.”<sup>118</sup> Robert Michels has also noted that the National Bioethics Advisory Commission considers the present system for evaluating a patient’s capacity to consent to dangerous treatment “inadequate even to assess the capacity to consent to MRI for research purposes.”<sup>119</sup>

The question of competency to consent to treatment and testing has become the focus of great attention in the past thirty years.<sup>120</sup> As I have indicated, it is a question that the US Supreme Court has considered several times in the context of the administration of antipsychotic medication in both civil and criminal cases,<sup>121</sup> concluding that “a qualified right to refuse medication is located in the Fourteenth Amendment’s Due Process Clause.”<sup>122</sup> Yet there has been no reported litigation on this specific issue that I raise here, although attention to it has been paid by leading bioethicists.<sup>123</sup> It is certainly reasonable to suggest that this is something we should be alert for in the coming years.

#### D. *The Impact of Medication*

Five years ago, in an article about brain imaging and the law, Dr. Donald Reeves and his associates stressed that “psychotropic drugs affect functional imaging of the brain,” and that the effects of such drugs “are not always short-lived.”<sup>124</sup> Given the fact that the Supreme Court, in establishing the right-to-refuse-psychotropic-drug-treatment, has stressed that “the pervasiveness of side effects is a key factor in the determination of the scope of the right,”<sup>125</sup> it comes as a surprise that this insight has not, as of yet, been discussed elsewhere in the legal literature.<sup>126</sup> Again, especially

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<sup>114</sup> Cf. Judy Illes & Eric Racine, *Imaging or Imagining? A Neuroethics Challenge Informed by Genetics*, 5 AM. J. BIOETHICS 5, 12 (2005) (“Even while neuroimaging cannot establish moral culpability . . . of where, when, or how a crime occurred, nor individual guilt . . . the constant stream of innovative scientific approaches is aimed at deriving biologic correlates for behaviors committed in the past . . . is unrelenting. As we seek to understand responsibility of others through their biology, it is incumbent upon us to contemplate, yet again, our own responsibilities in interpreting such information, and in protecting access and appropriate use.”) On how the use of neuroimaging evidence can compromise “cognitive liberty,” see Boire, *supra* note 112, at 62-63.

<sup>115</sup> Michael L. Perlin, *Pretexts and Mental Disability Law: The Case of Competency*, 47 U. MIAMI L. REV. 625, 673 (1993) (the search for a single test is akin to a “search for the Holy Grail” (quoting Loren H. Roth et al., *Tests of Competency to Consent to Treatment*, 134 AM. J. PSYCHIATRY 279, 283 (1977))); *see also*, PERLIN ET AL., *supra* note 95.

<sup>116</sup> By way of example, courts routinely find mentally disabled women incompetent to engage in sexual intercourse (i.e., to lack sufficient competence to engage knowingly and voluntarily in such behavior), but just as routinely find such individuals competent to consent to give their children up for adoption. In one startling case, a court made both of these findings simultaneously about the same woman. *See* Michael L. Perlin, *Hospitalized Patients and the Right to Sexual Interaction: Beyond the Last Frontier?* 20 N.Y.U. REV. L. & SOC’L CHANGE 517, 538 (1993-94) (discussing research reported in Susan Stefan, *Silencing the Different Voice: Feminist Theory and Competence*, 47 U. MIAMI L. REV. 763, 805 (1993)); *State v. Soura*, 796 P.2d 109, 113-15 (Idaho 1990); Michael L. Perlin, *Competence to Have Sex* (unpublished manuscript), at 37-38 (discussing *State v. Ortega-Martinez*, 881 P.2d 231, 237 (Wash. 1994) (holding, in statutory rape case involving a woman with a mental disability, that the complainant (whom the court found incompetent to consent to having sex) was *married* at the time)).

<sup>117</sup> Kulynych, *supra* note 14, at 312-13.

<sup>118</sup> *Id.* at 313. Kulynych’s work is characterized as “entirely persuasive” in George Annas, *Imagining a New Era of Neuroimaging, Neuroethics, and Neurolaw*, 33 AM. J.L. & MED. 163, 168 (2007).

<sup>119</sup> Robert Michels, *Are Research Ethics Bad for Our Mental Health?*, 340 NEW ENG. J. MED. 1427, 1428 (1999).

<sup>120</sup> *See, e.g.*, PERLIN ET AL., *supra* note 95.

<sup>121</sup> *See, e.g.*, *Washington v. Harper*, 494 U.S. 210 (1990) (discussing the right to refuse treatment in prisons); *Riggins v. Nevada*, 504 U.S. 127 (1992) (discussing the right to refuse treatment at insanity defense trial); *Sell v. United States*, 539 U.S. 166 (2003) (discussing the right to refuse treatment in determination of defendant’s competency to stand trial); *Mills v. Rogers*, 457 U.S. 291 (1982) (state may recognize greater liberty interests for persons with mental illness than U.S. Constitution).

<sup>122</sup> Perlin, *supra* note 96, at 736.

<sup>123</sup> *See, e.g.*, Susan Wolf et al., *Managing Incidental Findings in Human Subjects Research: Analysis and Recommendations*, 36 J.L. MED. & ETHICS 219 (2008).

<sup>124</sup> Reeves, *supra* note 6, at 92.

<sup>125</sup> Perlin, *supra* note 96, at 736. *See also, e.g.*, *Sell*, 539 U.S. 166, 179 (2003) (discussed in *supra* text accompanying note 102).

<sup>126</sup> Reeves’s article is cited in O. Carter Snead, *Neuroimaging and the ‘Complexity’ of Capital Punishment*, 82 N.Y.U. L. REV. 1265 (2007), Richard Redding, *The Brain-Disordered Defendant: Neuroscience and Legal Insanity in the 21<sup>st</sup> Century*, 56 AM. U. L. REV. 51 (2006), and Tancredi & Brode, *supra* note 9, but on other points.

in cases that involve individuals institutionalized against their will in matters that involve the criminal trial process, it is reasonable to predict that this will be the subject of important future consideration.

The final criminal procedure issue that I wish to discuss relates also—although from an entirely different perspective—to a question involving antipsychotic medication: what substantive impacts can that medication have on the findings of neuroimaging testing?<sup>127</sup> The answer to this question is self-evidently critical to this entire area of law and policy, because of the alleged (or at least, *perceived*) “objectivity” of such evidence, and its expected acceptance by jurors.<sup>128</sup> If antipsychotic drugging affects brain functioning—as it is *supposed* to do<sup>129</sup>—then neuroimaging tests performed on drugged defendants need to be reconsidered.<sup>130</sup> This is especially troubling, given the way that the use of neuroimaging testimony “reduces the psychosocial complexities” of the matter before the court, and “conflate[s] representation with reality.”<sup>131</sup> If the use of medication—*involuntary* medication—distorts the “pretty pictures,” jurors perceptions of “scientific reality” will be even more distorted.

I can identify at least three questions that need to be thought about in this context:

- (1) Does such drugging distort the results of neuroimaging tests, as Professor Reeves suggests?
- (2) If so, should such tests be performed *at all* on this cohort of defendants (or, should they only be performed after a more elaborate form of informed consent is obtained)?<sup>132</sup>
- (3) In either case, what should jurors be told about this?<sup>133</sup>

Again, juror beliefs in the infallibility of neuroimaging<sup>134</sup> has to be factored into any analysis of the issues at hand. If jurors are inappropriately “seduced” by “Christmas tree phenomenon” evidence, and the pictures that are shown are not an accurate depiction or representation of the defendant’s brain at the time of the alleged crime—but rather, depict it in the aftermath of forced antipsychotic drugging—the entire enterprise becomes even more perilous.

## CONCLUSION

The issues that I have discussed in the heart of this paper—access to experts, competence to consent, and impact of antipsychotic medications—have all been the subject of intense academic and clinical interest. The debate has not been without some vitriol.<sup>135</sup> Yet, again, there has been virtually no consideration of these issues in the context of the type of testimony that is at the core of the articles in this symposium.

Given the warning signals that have been raised by commentators as to the potentiality of juror misuse and misinterpretation of neuroimaging testimony, it is, I think, all the more critical that we take seriously the issues I have raised here. I have sought to argue in this paper that there are

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<sup>127</sup> The issue of mandatory treatment with antipsychotic drugs is raised in this context in Greely, *supra* note 13, at 1109-10.

<sup>128</sup> See, e.g., Jessica Gurley & David Marcus, The Effects of Neuroimaging and Brain Injury on Insanity Defenses, 26 BEHAV. SCI. & L. 85, 94 (2008) (“The neuroimages of readily apparent brain damage give the jurors *tangible proof* of the disorder.”) (emphasis added).

<sup>129</sup> *In re the Guardianship of Roe*, 421 N.E.2d 40, 53-55 (Mass. 1981) (comparing the administration of psychotropic medications to the use of electroconvulsive therapy, emphasizing the possible adverse side effects and potential effects on brain functioning that are attendant to the use of psychotropic drugs) (discussed in Kathleen Knepper, *The Importance of Establishing Competence in Cases Involving the Involuntary Administration of Psychotropic Medications*, 20 LAW & PSYCHOL. REV. 97, 134 n.141 (1996)). See generally, Katherine Brown & Erin Murphy, *Falling Through the Cracks: The Quebec Mental Health System*, 45 MCGILL L.J. 1037 (2000).

<sup>130</sup> Beyond the scope of this paper is an inquiry as to whether there should be any difference in the law if the aim of the drugging in question was based on the defendant’s alleged dangerousness or the desire to restore him to competence to stand trial.

<sup>131</sup> Feigenson & Sherwin, *supra* note 81, at 300.

<sup>132</sup> See Kulynych, *supra* note 14; Greely, *supra* note 13.

<sup>133</sup> *Cf.* Riggins, 504 U.S. at 130 (defendant argued that he had right to have jurors see him *not* under the influence of antipsychotic medication in his “true mental state”). The Supreme Court, in a related area, has been unsympathetic to defendants’ arguments that jurors needed more information with regards to the disposition of cases in which mental status defenses are raised. *E.g.*, Shannon v. United States, 512 U.S. 573 (1994). Elsewhere, I characterize Shannon’s reasoning as “bizarre.” 4 PERLIN, *supra* note 16, § 9A-4.4b, at 197.

<sup>134</sup> *Cf.* Barefoot v. Estelle, 463 U.S. 880, 926 (1983) (Blackmun, J., dissenting) (expressing fear that testimony in death penalty case as to defendant’s likely future dangerousness lends “an aura of scientific infallibility [that] may shroud the evidence and thus lead the jury to accept it without critical scrutiny.”). *But see* Brickell, *supra* note 36 (questioning the empirical evidence for the proposition that jurors inappropriately defer to forensic experts).

<sup>135</sup> See, e.g., Paul S. Appelbaum & Thomas G. Gutheil, “Rotting With Their Rights On”: Constitutional Theory and Clinical Reality in Drug Refusal by Psychiatric Patients, 7 BULL. AM. ACAD. PSYCHIATRY & L. 306 (1979); Darold A. Treffert, *Dying with Their Rights On*, 130 AM. J. PSYCHIATRY 1041 (1973).

landmines inevitably present when we think about the use of neuroimaging in criminal trials—landmines that can infect the fairness of the trial process itself.

If an indigent criminal defendant is refused access to an independent expert in an area where juror OCS<sup>136</sup> may lead to uncritical acceptance of neuroimaging testimony (because of its visual appeal and its apparent lack of falsifiability), the fairness of the entire trial remains, to me, in question. If no attention is paid to the difficult and complex ethical issues that should surface if the question of the defendant’s competency to consent to being tested is not raised, trial fairness is a concern. And finally, if we ignore the reality that the neuroimaging evidence shown to jurors may not be an accurate depiction of the defendant’s brain at the time of the offense—but rather, a depiction of his brain at a later time when his brain biochemistry has been altered by the imposition of medication—we willfully blind ourselves to the possibility (I might say “likelihood”) that the data presented to the jury is potentially fatally flawed.

Let me pause for a second to assure you that I am not a Luddite or a nihilist. Do not interpret this as an anti-science screed, pining for the good-old-days of crime detection (perhaps based on phrenology). That is not the image that I want to leave with you. Rather, I raise these issues because I sense the power of the evidence in question, and because of my fears that its seductive dazzle may hold jurors in thrall, leading to outcomes that are both factually and legally inaccurate and constitutionally flawed. My hope is that a consideration of the issues that I am raising here will lead all of us to think a little harder about the road ahead.

I end with a return to the Bob Dylan line that serves as my title. Dylan angrily sneered at the “Masters of War,” telling us—accurately, I think, if the events of the last 45 years are to be acknowledged—that he could tell what was *really going on* in the minds of war-makers and war-profiteers.<sup>137</sup> The line—“and I see through your brain”—is an ominous one, especially in the context of the blood and death imagery that permeates the song. I use it here, because it seems to me that uncritical acceptance of neuroimaging testimony in the criminal trial process will lead jurors to *believe* that they can do what Bob said he was able to do. The difference is this: Bob was right, and the jurors are wrong.

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<sup>136</sup> See *supra* note 84.

<sup>137</sup> BOB DYLAN, *Masters of War*, on THE FREEWHEELIN’ BOB DYLAN (Columbia Records 1963) (“Let me ask you one question/Is your money that good/Will it buy you forgiveness/Do you think that it could/I think you will find/When your death takes its toll/All the money you made/Will never buy back your soul.”).