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Article

**DUMB INVENTORS REJOICE: HOW DAIICHI SANKYO V. APOTEX VIOLATED THE FEDERAL PATENT STATUTE**

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**I. Introduction**

“Nonprecedential Opinion Issued: July 11, 2007.

Precedential Opinion Issued: Sept. 12, 2007.”<sup>1</sup>

With those two lines, the Federal Circuit Court of Appeals quietly reissued its opinion in *Daiichi Sankyo Co. v. Apotex, Inc.* last autumn. At the time the opinion did not cause much of a stir in the patent community, but it should have had practitioners up in arms. *Daiichi* not only adds another twist to the existing tangle of case law within the Federal Circuit regarding its test to determine the level of ordinary skill in the art, it also violates § 103(a) of the Patent Act.<sup>2</sup>

Congress enacted § 103(a) in 1952 to codify a one hundred year-old common law concept known as the nonobviousness requirement.<sup>3</sup> The provision required, in addition to satisfaction of the previously codified requirements for patentability, \*82 that an invention would not have been obvious to an average person in the field at the time it was made.<sup>4</sup>

A little more than a decade later, the Supreme Court in *Graham v. John Deere Co.* elaborated on this provision by holding that a court must determine if an invention is obvious in light of the factual background consisting of: (1) the “scope and content of the prior art,” (2) the “differences between the prior art and the claims at issue,” and (3) the “level of ordinary skill in the pertinent art.”<sup>5</sup>

More recently, the Supreme Court reaffirmed this approach in *KSR International Co. v. Teleflex Inc.*<sup>6</sup> In *KSR*, the Court specifically addressed the Federal Circuit’s test for determining whether an invention is obvious or not.<sup>7</sup> Generally, under the Federal Circuit’s nonobviousness test, an invention was only obvious if some motivation or suggestion to create the invention

was “found in the prior art, the nature of the problem [to be solved], or the knowledge of a person having ordinary skill in the art.”<sup>8</sup> The Supreme Court in KSR, however, found that the Federal Circuit had applied the test too narrowly—that it had unduly limited its analysis by only considering the problem the inventor wished to solve and by assuming that the person of ordinary skill in the art would only look to prior art elements designed to solve that same problem.<sup>9</sup>

After KSR, the Federal Circuit followed the Supreme Court’s instruction and issued a string of opinions where it applied its nonobviousness test more broadly.<sup>10</sup> In doing so, the court often found that the patents at issue were obvious because a person having ordinary skill in the art would have been motivated to make the invention based on his own creativity and knowledge.<sup>11</sup>

With this post-KSR increase in the court’s focus on the creativity and knowledge of the person having ordinary skill in the art, the resolution of the level of ordinary skill necessarily becomes much more important to the ultimate nonobviousness determination. Where the level of ordinary skill in the art is high, the average worker in the field will be more creative and knowledgeable, and a \*83 given invention will more likely be obvious to that average worker.<sup>12</sup> Unfortunately, the Federal Circuit has provided very little guidance for determining the level of ordinary skill and has only exacerbated the problem with its recent decision in Daiichi.

In 1983, the Federal Circuit first articulated a five-factor test for determining the level of ordinary skill in the art.<sup>13</sup> Shortly thereafter the court issued the first of what would become a string of inconsistent cases<sup>14</sup> when it appeared to add an additional factor—the inventor’s education level—to its level of ordinary skill test.<sup>15</sup> Most recently, the Federal Circuit continued this trend of confusing decisions when it focused exclusively on the inventor’s skill level in its determination of the level of ordinary skill in the art in Daiichi.<sup>16</sup>

This article argues that the Federal Circuit’s test for determining the level of ordinary skill in the art, as applied in Daiichi, is contrary to § 103(a) of the Patent Act, and that the Federal Circuit should return to its original five-factor test, removing the inventor’s level of skill as a sixth factor, to prevent any future violations of 35 U.S.C. § 103(a). By focusing solely on that sixth factor, the test in Daiichi conflicts with the first sentence of § 103(a),<sup>17</sup> because it changed the nonobviousness inquiry from a question of whether an invention would have been obvious to a person having the ordinary level of skill in the art to a question of whether an invention would have been obvious to a person having the inventor’s level of skill in the art. The test also conflicts with the second sentence of § 103(a),<sup>18</sup> which prohibits limiting the patentability of an invention by the way in \*84 which it was made because it made an invention’s potential nonobviousness dependent upon its inventor.

Returning to its original five-factor test for determining the level of ordinary skill in the art and completely excluding the inventor’s skill level from the analysis will not only bring the test back in line with both sentences of 35 U.S.C. § 103(a), but it will also allow the Federal Circuit to establish some consistency within the current disarray of case law surrounding the level of ordinary skill in the art.<sup>19</sup>

Part II of this article will discuss the developments in nonobviousness jurisprudence that have increased the emphasis on the level of ordinary skill in the art. First, Part II will trace the development of the nonobviousness requirement for patentability, beginning with its initial articulation by the Supreme Court in *Hotchkiss v. Greenwood* in 1850,<sup>20</sup> through its codification by Congress in the 1952 Patent Act,<sup>21</sup> its subsequent interpretation by the Supreme Court in *Graham* in 1966,<sup>22</sup> and its reiteration and clarification by the Supreme Court in KSR in 2007.<sup>23</sup> Then, Part II will discuss how KSR and the Federal Circuit’s post-KSR nonobviousness decisions have placed an increased emphasis on the level of ordinary skill in the art<sup>24</sup> and why this is problematic in light of the Federal Circuit’s poorly defined test for determining the level of ordinary skill.

Part III of this article will trace the evolution of the Federal Circuit’s test for determining the level of ordinary skill in the art from its adoption to its application in Daiichi. First, Part III will discuss the initial adoption of the test by the Federal Circuit in 1983<sup>25</sup> and its early changes in that same year.<sup>26</sup> Then, Part III will discuss the inconsistent line of cases that developed within the Federal Circuit with respect to the inclusion of the skill level of the inventor as a factor over the ensuing \*85 two decades.<sup>27</sup> Finally, Part III will address the Federal Circuit’s decision in Daiichi and how it diverged from the already inconsistent Federal Circuit case law by focusing exclusively on the inventor’s skill level in determining the level of ordinary skill in the art.

Part IV of this article will discuss why the Federal Circuit’s test, as applied in Daiichi, is not only inconsistent with previous Federal Circuit case law,<sup>28</sup> but also in conflict with § 103(a) of the Patent Act. Specifically, Part IV will show that the current test is inconsistent with both sentences of § 103(a) and thus must be changed.

Finally, Part V of this article will recommend the changes that should be made to the Federal Circuit's test for determining the level of ordinary skill in the art. In particular, Part V will suggest that the Federal Circuit return to its original five-factor test and expressly remove the inventor's level of skill from the analysis. Addressing the current tangle of Federal Circuit case law surrounding the determination of the level of ordinary skill in the art in this way will ensure that the test remains in harmony with § 103(a) of the Patent Act in the future.

## **II. Nonobviousness Through the Years: The Level of Ordinary Skill in the Art's Increasing Importance to the Ultimate Analysis**

The nonobviousness requirement for patentability first began to take shape in *Hotchkiss v. Greenwood*, an 1850 Supreme Court opinion.<sup>29</sup> The invention in Hotchkiss was a knob for use on a cabinet or door, for example, made from potter's clay rather than the previously used metal or wood.<sup>30</sup> In the lower court, the patent holder argued for an instruction that if the knob's construction had the required skill and invention, then the patent was valid.<sup>31</sup> The Circuit Court for the District of Ohio rejected this request and instead charged the jury with instructions that the patent was invalid if "no more ingenuity or skill [was] required to construct the knob in this way than that possessed by an ordinary mechanic acquainted with the \*86 business."<sup>32</sup> On appeal, the Supreme Court upheld this instruction reasoning that it was correct because, for an invention to be patentable, it had to exhibit a minimum degree of skill and ingenuity beyond that of a skillful mechanic.<sup>33</sup> This additional requirement for patentability, that an otherwise new and useful invention must be more than just the work of an ordinary mechanic, that is, be "sufficiently great to warrant a patent," was adopted and applied by other courts for more than a century before it was finally codified by Congress in 1952.<sup>34</sup>

The 1952 Patent Act, which is still in force today, reads in part:

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.<sup>35</sup> The similarity between the statutory language and the language of Hotchkiss a century earlier was admittedly intentional, as Congress explicitly recognized in the legislative history of the Act that it was paraphrasing the common law nonobviousness requirement.<sup>36</sup> Congress went on to note that, in doing so, it was attempting to bring order and definiteness to this area of patent law, as the expression of the requirement had been made in a "large variety of ways in decisions of the courts and in writings" during its common law evolution.<sup>37</sup> However, it remained to be seen whether Congress had accurately codified the common law.

In 1966, the Supreme Court in *Graham* addressed Congress's distillation of the nonobviousness requirement.<sup>38</sup> The two companion cases presented in *Graham* questioned "what effect the 1952 [Patent] Act had upon traditional statutory and judicial tests of patentability and what definitive tests [were] now required."<sup>39</sup> One patent at issue was for a device designed to absorb shock from plow shanks as they moved through rocky soil, and the second patent was for a hold-down cap to be used on spray bottles, such as for insecticide, during shipping.<sup>40</sup> Both patents had undergone various types of nonobviousness analyses, which had been developed in \*87 response to the 1952 Patent Act, in the lower courts.<sup>41</sup> The Supreme Court ultimately granted certiorari to provide the lower courts with some direction for performing a proper nonobviousness analysis under the new federal statute.<sup>42</sup>

The Court initially noted that Congress had succeeded in codifying the additional requirement for patentability first posited in *Hotchkiss*.<sup>43</sup> It then went on to outline the appropriate method for determining if an invention was obvious.<sup>44</sup>

The Supreme Court explained that, to determine if an invention is obvious, a court must first conduct three factual inquiries.<sup>45</sup> Specifically, a court needs to: (1) determine the scope and content of the prior art, (2) ascertain the differences between the prior art and the claims at issue, and (3) resolve the level of ordinary skill in the art.<sup>46</sup> Then, in light of the factual background created by these three inquiries, a court must determine the obviousness or nonobviousness of the subject matter.<sup>47</sup> Finally, the Court noted that some "secondary considerations," such as "commercial success, long-felt but unsolved needs, [and the] failure of others" to solve the problem at hand, might be relevant as "indicia of obviousness or nonobviousness."<sup>48</sup>

In explaining this test, the Supreme Court recognized that the nonobviousness decision would not be an easy one, but that the difficulties that would arise would be no more daunting than those faced by courts in other areas of the law.<sup>49</sup> Ultimately, the Court was confident that Congress's stated goals of creating uniformity and definiteness in patent law would be readily

accomplished if the lower courts would follow the specified method for making the nonobviousness decision.<sup>50</sup>

Following Graham, the Supreme Court was content to leave the nonobviousness analysis in the hands of the lower courts for the next forty years. Then, in 2007, the Court in *KSR International Co. v. Teleflex Inc.* revisited the subject.<sup>51</sup>

**\*88** The patent at issue in KSR was for an automobile pedal assembly combined with an electronic sensor that sensed the pedal's position and transmitted that information to the throttle control computer.<sup>52</sup> In determining if the patent was invalid as obvious, the Court of Appeals for the Federal Circuit applied its "teaching, suggestion, or motivation" test (TSM test).<sup>53</sup> The TSM test was originally posited by the Court of Customs and Patent Appeals in 1961,<sup>54</sup> and was subsequently adopted by the Federal Circuit<sup>55</sup> shortly after the court's creation in 1982.<sup>56</sup> Under the TSM test, an invention was only obvious if some teaching, suggestion, or motivation to create the invention was found in the prior art, the nature of the problem to be solved, or the knowledge of a person having ordinary skill in the art.<sup>57</sup> This test, according to the Supreme Court in KSR, was not problematic.<sup>58</sup> What was problematic, however, was how the test had been applied by the Federal Circuit in KSR.<sup>59</sup>

The Supreme Court held that the Federal Circuit erred in applying the TSM test by only considering the problem the inventor wished to solve and by assuming that the person of ordinary skill in the art would only look to prior art elements designed to solve that same problem.<sup>60</sup> Instead, the Court reaffirmed the "broad" and "flexible" approach of Graham, in contrast to the Federal Circuit's rigid application of its "teaching, suggestion, or motivation" test.<sup>61</sup> The Supreme Court went on to note that, under the TSM test, the requisite motivation could also come from the knowledge and creativity of a person having ordinary skill in the art.<sup>62</sup> Thus, the Supreme Court in KSR made it easier for a court to find an invention obvious using the TSM test, as the motivation to create it could come from more than just explicit statements in the prior art.

**\*89** In response to the Supreme Court's admonishment in KSR, the Federal Circuit issued a string of nonobviousness decisions where it applied the TSM test more broadly than it had before KSR.<sup>63</sup> In doing so, the court often found that inventions were obvious based on a teaching, suggestion, or motivation to create the invention that arose solely from the knowledge and creativity of a person having ordinary skill in the art.<sup>64</sup> For example, in *In re Translogic Technology, Inc.*, the Federal Circuit held that a person having ordinary skill in the art would have been motivated by his own knowledge and creativity to combine a known electronic device with a known method of arranging different electronic devices to create the invention, an arrangement of those specific electronic devices.<sup>65</sup> In doing so, the court noted that the obviousness analysis did not require "precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ."<sup>66</sup>

With this increased emphasis on the "inferences and creative steps" of a person having ordinary skill in the art in the Federal Circuit's post-KSR jurisprudence, the way in which the level of ordinary skill is determined becomes much more critical. If the level of ordinary skill in the art is high, then a person having that ordinary level of skill will necessarily be more creative. Thus, more inventions will be obvious to a person having ordinary skill in the art where the level of ordinary skill in the art is high.<sup>67</sup> Likewise, where the level of ordinary skill in the art is low, few inventions will be obvious to the less creative person having that ordinary skill level. This increased focus on the level of ordinary skill in the art, however, is problematic because the Federal Circuit's test for determining the level of ordinary skill has been in a state of flux since its adoption in 1983.<sup>68</sup>

### **\*90 III. Inconsistent from Start to Finish: The Evolution of the Federal Circuit's Test for Resolving the Level of Ordinary Skill in the Art**

The Federal Circuit's test for determining the level of ordinary skill in the art was first adopted in early 1983 and quickly became the subject of a confusing and inconsistent line of cases.<sup>69</sup> In several decisions, the court argued that the inventor's skill level might be helpful in determining the ordinary level of skill in the art, but that it was certainly not conclusive.<sup>70</sup> Yet in other cases, the court held that the inventor's skill level had no bearing on the "ordinary" level of skill in the art and thus had no place in the determination.<sup>71</sup> The Federal Circuit had its most recent opportunity to clear up this confusion in 2007 but instead succeeded in only muddying the waters further. By determining the ordinary level of skill in the art based solely on the inventor's skill level,<sup>72</sup> the Federal Circuit applied the test in a way that diverged from the already inconsistent case law.

The Federal Circuit's test for determining the level of ordinary skill in the art initially developed over the course of four months in 1983. In March of that year, the Federal Circuit in *Orthopedic Equipment Co. v. United States (Orthopedic Equipment)* adopted a five-factor test that was initially developed by the U.S. Court of Claims.<sup>73</sup> The invention at issue in Orthopedic Equipment was a system for use by businesses, such as retail stores and restaurants, where employees input

customer orders into pre-programmed electronic order-taking machines.<sup>74</sup> On appeal, the court considered whether certain claims in the patent were obvious and thus invalid.<sup>75</sup> The court noted that, in order to address that question, it first had to determine the level of ordinary skill in the art.<sup>76</sup> The court explained that a number of factors can demonstrate the level of ordinary skill, including: (1) the “various prior art approaches employed,” (2) the “types of problems encountered in \*91 the art,” (3) the “rapidity with which innovations are made,” (4) the “sophistication of the technology involved,” and (5) the “educational background of those actively working in the field.”<sup>77</sup> In light of appellee’s evidence, including prior art patents and the testimony and educational qualifications of workers in the art, the Federal Circuit affirmed the district court’s finding regarding the level of ordinary skill in the art, as well as its holding that the claims were invalid for obviousness.<sup>78</sup>

Two months later, in *Orthopedic Equipment Co., Inc. v. All Orthopedic Appliances, Inc. (All Orthopedic Appliances)*, the Federal Circuit cited its previous recitation of the factors for determining the level of ordinary skill in the art from Orthopedic Equipment and appeared to add an additional factor-- the education level of the inventor.<sup>79</sup> The patent at issue was for a knee immobilizer with adjustable Velcro straps.<sup>80</sup> In analyzing the validity of the patent, the district court identified the ordinary level of skill in the art as that of “an engineer having at least a few years of design experience working in the field of developing orthopedic soft goods” and ultimately found the patent invalid as obvious.<sup>81</sup> On appeal, the patent holder argued that the district court had set the level of skill at an unnecessarily high level with no evidentiary support.<sup>82</sup> However, the Federal Circuit noted that the patent holder pointed “to no evidence in the record establishing that the district court’s finding [was] clearly erroneous, although the inventor himself was not an engineer.”<sup>83</sup> The court then restated the test for determining the level of ordinary skill in the art from Orthopedic Equipment, with the additional caveat that “[a]lthough the educational level of the inventor may be a factor to consider in determining the level of ordinary skill in the art, it is by no means conclusive.”<sup>84</sup> Ultimately, the court sustained the district court’s determination of the level of ordinary skill in the art based solely on expert testimony regarding the education level of those in the field.<sup>85</sup> No weight was given to the inventor’s actual level of education.<sup>86</sup>

Although the court in *All Orthopedic Appliances* had not actually considered the inventor’s skill level to determine the level of ordinary skill in the art, the \*92 decision did appear to have created a six-factor version of the original test.<sup>87</sup> This divergence was confirmed on July 25, 1983, when the court issued two opinions that articulated different versions of the test to determine the level of ordinary skill in the art.

In *Environmental Designs Ltd. v. Union Oil Co. of California*, while considering the invalidity due to obviousness of a patent for a process to remove sulfur from effluent gas, the Federal Circuit cited to *All Orthopedic Appliances* for the test to determine the level of ordinary skill in the art.<sup>88</sup> In doing so, the court included the inventor’s skill level directly in the list of factors.<sup>89</sup> Ultimately, since both parties agreed that their respective expert witnesses were persons of ordinary skill in the art, the Federal Circuit did not actually apply the test, but the Orthopedic Equipment five-factor test had nonetheless gained a sixth factor.<sup>90</sup>

This was not the case, however, in another Federal Circuit opinion issued that same day. In *Stratoflex, Inc. v. Aeroquip Corp.*, while considering the invalidity of another patent due to obviousness, the Federal Circuit panel cited not to *All Orthopedic Appliances*, but to Orthopedic Equipment, for the test to determine the level of ordinary skill in the art.<sup>91</sup> Although it did not explicitly list the factors in its opinion, the Federal Circuit only cited to cases that had used the five-factor test and did not expressly consider the inventor’s skill level in determining the ordinary level of skill in the art.<sup>92</sup>

For the next several years, the Federal Circuit vacillated between the five-factor and six-factor tests.<sup>93</sup> Then, in 2007, the court was presented with its most \*93 recent opportunity to resolve this inconsistency in *Daiichi Sankyo Co. v. Apotex, Inc.*<sup>94</sup> Unfortunately, the Federal Circuit not only added to the existing tangle of inconsistent case law, but also violated § 103(a) of the Patent Act by basing its determination of the level of ordinary skill in the art exclusively on the education and skill level of the inventors.

#### **IV. A Lost Opportunity and a Statutory Violation: *Daiichi Sankyo Co. v. Apotex, Inc.***

The Federal Circuit’s decision in *Daiichi* was counter to all of the court’s previous case law, because it not only considered the inventor’s level of skill, but it also made that factor determinative of the level of ordinary skill in the art. Even more problematic than that, however, is that the decision in *Daiichi* is contrary to § 103(a) of the Patent Act.

The patent at issue in *Daiichi* was for a method of treating bacterial ear infections using a topical administration of antibiotic

ofloxacin.<sup>95</sup> Following a bench trial, the district court held that the patent was not invalid and was infringed.<sup>96</sup>

The district court's analysis was based on a finding that the level of ordinary skill in the art at the time of the invention was that of a pediatrician or general practitioner of medicine with "basic pharmacological knowledge."<sup>97</sup> In light of that level of ordinary skill, the district court dismissed a key piece of prior art because it was not within the knowledge of a person having that level of skill in the art.<sup>98</sup> Then, the court held that the invention would not have been obvious to a person having ordinary skill in the art in light of the remaining prior art.<sup>99</sup>

On appeal, the Federal Circuit held that the district court's method for determining the level of ordinary skill in the art had been improper and had in turn tainted the rest of the nonobviousness analysis.<sup>100</sup> The Federal Circuit noted that the district court should have considered the factors from Environmental Designs to determine the level of ordinary skill in the art.<sup>101</sup> In doing so, the Federal Circuit \*94 appeared to be moving away from its previous group of cases decrying the use of the inventor's level of skill at all<sup>102</sup> and toward those cases where the inventor's level of skill was a part of the analysis.<sup>103</sup> However, the Federal Circuit then diverged from that group of cases as well, which had explicitly held that the inventor's skill level was not conclusive, when the court focused exclusively on the education level of the inventors in its determination of the level of ordinary skill in the art.<sup>104</sup>

The Federal Circuit noted that the inventors were not general practitioners or pediatricians but were specialists in drug and ear treatments.<sup>105</sup> One inventor was a university professor in otorhinolaryngology, another was a clinical development department manager involved with new drug development and clinical trials, and the third was a research scientist engaged in the development of antibiotics.<sup>106</sup> Further, the court observed, the patent described animal testing and the development of a compound, both of which would have been outside the knowledge and ability of a general practitioner.<sup>107</sup> Then, after making these observations and with no consideration of the remaining Environmental Designs factors,<sup>108</sup> the court held that the level of ordinary skill in the art was "that of a \*95 person engaged in developing pharmaceutical formulations and treatment methods for the ear or a specialist in ear treatments such as an otologist, otolaryngologist, or otorhinolaryngologist who also has training in pharmaceutical formulations"<sup>109</sup>--an amalgamation of the actual skill levels of all three inventors.

This increased level of ordinary skill in the art was important because the Federal Circuit next considered the prior art reference that the district court had dismissed as being outside of the knowledge of the person having ordinary skill in the art.<sup>110</sup> The Federal Circuit determined that this prior art could now be considered because it would have been within the knowledge of a person having this increased skill level.<sup>111</sup> In light of this prior art, the court then determined that the patent at issue would have been obvious to a person having ordinary skill in the art at the time of the invention and was thus invalid.<sup>112</sup>

By focusing solely on the inventor's skill level in determining the level of ordinary skill in the art, the Federal Circuit in Daiichi diverged from its already inconsistent case law and, in doing so, squandered an important opportunity to explicitly define a controlling test. Contrary to the Orthopedic Equipment line of cases, Daiichi considered the inventor's level of skill in making the determination of the level of ordinary skill in the art, and contrary to the All Orthopedic Appliances line of cases, Daiichi made this consideration determinative. Even more problematic than its inconsistency with previous case law, however, is the fact that the decision in Daiichi violates § 103(a) of the Patent Act.

The Federal Circuit's test for determining the level of ordinary skill in the art, as applied in Daiichi, violates both sentences of 35 U.S.C. § 103(a).<sup>113</sup> The decision violates the first sentence because the test gauges only the inventor's level of skill, and it violates the second sentence because the test makes the patentability of the invention at issue dependant on how it was made. This Part will examine these two issues in turn.

**\*96** The Federal Circuit's test for determining the level of ordinary skill in the art, as applied in Daiichi, violates the first sentence of 35 U.S.C. § 103(a), which reads:

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.<sup>114</sup> By considering only the inventor's level of skill in determining the level of ordinary skill in the art, the Federal Circuit's test in Daiichi effectively rewrote this sentence to read:

A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having the inventor's skill in the art to which said subject matter pertains.

The problem is that the inventor's skill level will rarely, if ever, be that of the ordinary worker in the field. An inventor is commonly defined as someone who creates something for the first time by imaginative or ingenious thinking and experimentation.<sup>115</sup> The word "ordinary," on the other hand, implies something routine or usual.<sup>116</sup> Thus, the level of ordinary skill would be the routine or usual level of skill, or the level of skill reflected in the normal order of events. Therefore, it is nonsensical to base the determination of the level of ordinary skill on the inventor's generally extraordinary skill level. The Federal Circuit itself made this argument multiple times in the group of cases that opposed the inclusion of the inventor's skill level as a factor in the level of ordinary skill in the art test.<sup>117</sup> As the court in *Standard Oil Co. v. Am. Cyanimid Co.* put it:

The actual inventor's skill is irrelevant to the inquiry, and this is for a very important reason. The statutory emphasis is on a person of ordinary skill. Inventors, as a class, according to the concepts underlying the Constitution and the statutes that have created the patent system, possess something-call it what you will-which sets them apart from the workers of ordinary skill . . . . A person of ordinary skill in the art is . . . one who thinks along the line of conventional wisdom in the art and is not one who undertakes to innovate, whether by patient, and often expensive, systematic research or by extraordinary insights, it makes no difference which.<sup>118</sup>

Further, even in those previous Federal Circuit cases that did consider the inventor's skill level, including the first one to do so, *All Orthopedic Appliances*, \*97 the court consistently advised that the factor not be viewed as conclusive.<sup>119</sup> Even the court in *Environmental Designs*, while citing *All Orthopedic Appliances* and including the inventor's level of skill in its consideration, explicitly observed:

The important consideration lies in the need to adhere to the statute, i.e., to hold that an invention would or would not have been obvious, as a whole, when it was made, to a person of "ordinary skill in the art" -not to the judge, or to a layman, or to those skilled in remote arts, or to geniuses in the art at hand.<sup>120</sup>

The test applied by the Federal Circuit in *Daiichi* considered only the inventor's skill level in determining the level of ordinary skill in the art. Since, by definition, an inventor would tend to have an extraordinary level of skill, considering only this factor would not actually yield the level of ordinary skill in the art. Thus, the Federal Circuit's test for determining the level of ordinary skill in the art, as applied in *Daiichi*, violates the first sentence of 35 U.S.C. § 103(a).

The Federal Circuit's test, as applied in *Daiichi*, also violates the second sentence of 35 U.S.C. § 103(a), which reads: "Patentability shall not be negated by the manner in which the invention was made."<sup>121</sup> This sentence was added by Congress in 1952 as an explicit statement that whether an invention "resulted from long toil and experimentation or from a flash of genius" was immaterial to its ultimate patentability, despite what federal courts, including the Supreme Court, had previously held.<sup>122</sup> However, the Federal Circuit in *Daiichi* violated this prohibition by creating a test that made patentability entirely dependent on the identity of the inventor.

If the inventors in *Daiichi* had not been researchers but instead had been general practitioners who had merely stumbled upon the invention, the Federal Circuit would have determined that the level of ordinary skill in the art was that of a general practitioner based solely on consideration of the inventors' skill level. Then, from that point on, the nonobviousness analysis at the Federal Circuit would have been identical to that done at the district court. The key piece of prior art would not have been within the knowledge of the person having ordinary skill in the art, and the invention would have been nonobvious and patentable.

\*98 However, because the inventors were highly skilled and educated researchers, the Federal Circuit instead found that the level of ordinary skill was that of a highly skilled and educated researcher. In light of that level of ordinary skill, the key piece of prior art was brought back into consideration and the invention was unpatentable as obvious.

Thus, the same invention that was found to be unpatentable by the Federal Circuit in *Daiichi* would have been patentable if it had been made by less skilled inventors. Its patentability was limited by the manner in which it was made, a clear violation of the second sentence of 35 U.S.C. § 103(a).<sup>123</sup>

## V. Back to the Future: Recommending a Return to the Federal Circuit's Original Five-Factor Test in Order to Satisfy

### **35 U.S.C. § 103(a) in the Future**

As described in Part I, the Federal Circuit's post-KSR jurisprudence has made the level of ordinary skill in the art central to the ultimate question of nonobviousness, and the court must now provide some meaningful guidance in this area. The Federal Circuit should return to its original five-factor test, as first adopted in *Orthopedic Equipment*, and explicitly remove the inventor's skill level from the consideration in the next case that it hears involving the level of ordinary skill in the art. To do so would not only resolve the current inconsistency within the Federal Circuit's case law, but would also ensure that the test conforms to 35 U.S.C. § 103(a).

By removing the inventor's level of skill from the analysis, the five-factor test would result in a more objective and realistic determination of the level of ordinary skill in the art, as required by the first sentence of 35 U.S.C. § 103(a). Additionally, it would not condition an invention's patentability on the method in which the invention was made, as required by the second sentence of 35 U.S.C. § 103(a).

The five-factor test would better conform with the first sentence of 35 U.S.C. § 103(a) because the factors that make up that test, which include (1) the various prior art approaches employed, (2) the types of problems encountered in the art, (3) the rapidity with which innovations are made, (4) the sophistication of the technology involved, and (5) the educational background of those actively working in the field<sup>124</sup> are much more objective than the inventor's skill level alone. Thus, they would lead to a more realistic analysis of the actual ordinary level of skill \*99 across the field of art, which might vary significantly from the individual inventor's skill level.<sup>125</sup>

The five-factor test would also satisfy the second sentence of 35 U.S.C. § 103(a). It would remove any possibility that the ordinary skill level might be determined by reference to the inventor's level of skill, which would make the nonobviousness (and therefore patentability) of an invention dependant upon the method by which the invention was made. The objective nature of the factors would help to define a background level of skill in the art that would not fluctuate with the individual inventor's skill level.

The efficacy of this test has already been demonstrated in the previously-discussed group of cases in which the Federal Circuit refused to consider the inventor's level of skill. In all of those cases, the court was able to ascertain the level of ordinary skill in the art with enough clarity to make the ultimate nonobviousness determination. There was no need to consider the inventor's level of skill, and those decisions remain completely within the bounds of § 103(a) of the Patent Act.

#### **Footnotes**

<sup>a1</sup> Juris Doctor, May 2008, Chicago-Kent College of Law. Thank you to Dean Krent as well as my fellow Honors Scholars for your comments, questions, and encouraging words. Thank you to my wife, the most beautiful editor the world has ever known.

<sup>1</sup> *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1254 (Fed. Cir. 2007).

<sup>2</sup> 1952 Patent Act, Pub. L. No. 82-593, §103, 66 Stat. 792, 798 (codified at 35 U.S.C. §103(a) (2006)).

<sup>3</sup> S. Rep. No. 82-1979 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399.

<sup>4</sup> 1952 Patent Act §103.

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

<sup>6</sup> See *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007) (writing favorably about the principles laid down by Graham).

7 Id. at 1735.

8 Id. at 1734.

9 See *id.* at 1741-42.

10 See, e.g., *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1262 (Fed. Cir. 2007); *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1382 (Fed. Cir. 2007); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1370 (Fed. Cir. 2006); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1295 (Fed. Cir. 2006).

11 See, e.g., *Translogic Tech.*, 504 F.3d at 1262; *ICON Health & Fitness*, 496 F.3d at 1382; *Fisher-Price*, 485 F.3d at 1161; *DyStar*, 464 F.3d at 1370; *Alza Corp.*, 464 F.3d at 1295.

12 See, e.g., *Dystar*, 464 F.3d at 1370 (noting that a broader array of inferences will be available to the average worker in the field where the level of ordinary skill in the art is high).

13 The five factors used to evaluate level of ordinary skill in the art are (1) “[t]he various prior art approaches employed,” (2) “the types of problems encountered in the art,” (3) “the rapidity with which innovations are made,” (4) “the sophistication of the technology involved,” and (5) “the educational background of those actively working in the field.” *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (quoting *Jacobson Bros. v. United States*, 512 F.2d 1065, 1071 (Ct. Cl. 1975)).

14 Compare, e.g., *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983) (considering inventor’s skill level as a possible factor in determining the level of ordinary skill in the art, but noting that it is not conclusive), with *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (noting that the inventor’s level of skill is irrelevant to the determination of the level of ordinary skill in the art).

15 All *Orthopedic Appliances*, 707 F.2d at 1382.

16 Cf. *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254 (Fed. Cir. 2007), cert. denied, 128 S. Ct. 1259 (2008).

17 The first sentence of §103(a) states that “[a] patent may not be obtained ... if the differences between the subject matter ... and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.” 35 U.S.C. §103(a) (2006).

18 The second sentence of §103(a) states that “[p]atentability shall not be negated by the manner in which the invention was made.” *Id.*

19 Compare, e.g., *Daiichi*, 501 F.3d at 1257 (considering only the inventor’s skill level in determining the level of ordinary skill in the art), with *Standard Oil*, 774 F.2d at 454 (noting that the inventor’s level of skill is irrelevant to the determination of the level of ordinary skill in the art), and *All Orthopedic Appliances*, 707 F.2d at 1382 (considering the inventor’s skill level as a possible factor in determining the level of ordinary skill in the art, but noting that it is not conclusive).

20 *Hotchkiss v. Greenwood*, 52 U.S. 248, 268-70 (1850).

21 1952 Patent Act, Pub. L. No. 82-593 §103, 66 Stat. 792, 798 (codified as 35 U.S.C. §103 (2006)).

<sup>22</sup> Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 3, 10-19 (1966).

<sup>23</sup> KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739-42 (2007).

<sup>24</sup> See, e.g., *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1262 (Fed. Cir. 2007); *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1382 (Fed. Cir. 2007); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1370 (Fed. Cir. 2006); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1295 (Fed. Cir. 2006).

<sup>25</sup> Orthopedic Equip. Co. v. United States, 702 F.2d 1005, 1011-12 (Fed. Cir. 1983).

<sup>26</sup> See, e.g., *All Orthopedic Appliances*, 707 F.2d at 1382 (introducing the inventor's level of skill as a possible factor); *Envrl. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696 (Fed. Cir. 1983) (including the inventor's level of skill in the list of factors).

<sup>27</sup> Compare, e.g., *All Orthopedic Appliances*, 707 F.2d at 1382 (considering the inventor's level of skill as a possible factor in the determination of the level of ordinary skill in the art), and *Envrl. Designs*, 713 F.2d at 696 (including the inventor's level of skill in the list of factors), with *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (noting that the inventor's level of skill is irrelevant to the determination of the level of ordinary skill in the art).

<sup>28</sup> See, e.g., *Standard Oil*, 774 F.2d at 454 (noting that the inventor's level of skill is irrelevant to the determination of the level of ordinary skill in the art); *All Orthopedic Appliances*, 707 F.2d at 1382 (considering the inventor's skill level as a possible factor in determining the level of ordinary skill in the art, but noting that it is not conclusive).

<sup>29</sup> See *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850).

<sup>30</sup> *Id.* at 264.

<sup>31</sup> *Id.* at 252.

<sup>32</sup> *Id.* at 265.

<sup>33</sup> *Id.* at 267.

<sup>34</sup> See S. Rep. No. 82-1979 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399 (observing that “[s]ection 103, for the first time in our statute, provides a condition which exists in the law and has existed for more than 100 years, but only by reason of decisions of the courts.”)

<sup>35</sup> 1952 Patent Act, Pub. L. No. 82-593, 66 Stat. 792 (codified at 35 U.S.C. §103(a) (2006)).

<sup>36</sup> S. Rep. No. 82-1979 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2399-2400.

<sup>37</sup> *Id.*, as reprinted in 1952 U.S.C.C.A.N. at 2399.

<sup>38</sup> *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1 (1966).

<sup>39</sup> Id. at 3.

<sup>40</sup> Id. at 4.

<sup>41</sup> Id. at 4, 29.

<sup>42</sup> Id. at 12-15.

<sup>43</sup> Id. at 15.

<sup>44</sup> *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17-18 (1966).

<sup>45</sup> Id. at 17.

<sup>46</sup> Id.

<sup>47</sup> Id.

<sup>48</sup> Id. at 17-18.

<sup>49</sup> Id. at 18.

<sup>50</sup> *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 18 (1966).

<sup>51</sup> *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727 (2007).

<sup>52</sup> Id. at 1734.

<sup>53</sup> Id. at 1738-39.

<sup>54</sup> Id. at 1741.

<sup>55</sup> See *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1551 (Fed. Cir. 1983).

<sup>56</sup> For discussions of the creation and history of the Federal Circuit, see Frank P. Cihlar & Jack C. Goldstein, *A Dialogue About the Potential Issues in the Patent Jurisdiction of the Court of Appeals for the Federal Circuit*, 10 Am. Pat. L. Ass'n Q.J. 284 (1982); Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. Rev. 1 (1989); Paul M. Janicke, *To Be or Not to Be: The Long Gestation of the United States Court of Appeals for the Federal Circuit*, 69 Antitrust L.J. 645 (2001); Howard T. Markey, C.J., *The Phoenix Court*, 10 Am. Pat. L. Ass'n Q.J. 227 (1982); Daniel J. Meador, *Origin of the Federal Circuit: A Personal Account*, 41 Am. U. L. Rev. 581 (1992).

<sup>57</sup> KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1734 (2007).

<sup>58</sup> Id. at 1741.

<sup>59</sup> Id. at 1741-42.

<sup>60</sup> Id. at 1742.

<sup>61</sup> Id. at 1739.

<sup>62</sup> Id. at 1740-41.

<sup>63</sup> See, e.g., *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1262 (Fed. Cir. 2007); *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1382 (Fed. Cir. 2007); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1161 (Fed. Cir. 2007); *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1370 (Fed. Cir. 2006); *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1295 (Fed. Cir. 2006).

<sup>64</sup> See, e.g., *Translogic Tech.*, 504 F.3d at 1262; *ICON Health & Fitness*, 496 F.3d at 1382; *Fisher-Price*, 485 F.3d at 1161; *DyStar*, 464 F.3d at 1370; *Alza Corp.*, 464 F.3d at 1295.

<sup>65</sup> *Translogic Tech.*, 504 F.3d at 1262.

<sup>66</sup> Id. (quoting *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007)).

<sup>67</sup> See, e.g., *DyStar*, 464 F.3d at 1370 (noting that a broader array of inferences will be available to the average worker in the field where the level of ordinary skill in the art is high).

<sup>68</sup> Compare, e.g., *Daiichi Sankyo Co. v. Apotex, Inc.*, 501 F.3d 1254, 1258-59 (Fed. Cir. 2007) (considering only the inventor's skill level in determining the level of ordinary skill in the art), with *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (noting that the inventor's level of skill is irrelevant to the determination of the level of ordinary skill in the art), and *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983) (considering the inventor's skill level as a possible factor in determining the level of ordinary skill in the art, but noting that it is not conclusive).

<sup>69</sup> Compare, e.g., *All Orthopedic Appliances*, 707 F.2d at 1382 (considering the inventor's level of skill as a possible factor in the determination of the level of ordinary skill in the art) and *Env'tl. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696 (Fed. Cir. 1983) (including the inventor's level of skill in the list of factors), with *Standard Oil*, 774 F.2d 448, 454 (Fed. Cir. 1985) (noting that the inventor's level of skill is irrelevant to the determination of the level of ordinary skill in the art).

<sup>70</sup> See, e.g., *All Orthopedic Appliances*, 707 F.2d at 1382; *Env'tl. Designs*, 713 F.2d at 696.

<sup>71</sup> See, e.g., *Standard Oil*, 774 F.2d at 454.

<sup>72</sup> *Daiichi*, 501 F.3d 1254.

<sup>73</sup> *Orthopedic Equip. Co., Inc. v. United States*, 702 F.2d 1005, 1011 (Fed. Cir. 1983) (citing *Jacobson Bros., Inc. v. United States*,

512 F.2d 1065 (Ct. Cl. 1975)).

74       Id. at 1007-08.

75       Id. at 1006.

76       Id. at 1008.

77       Id. at 1011 (quoting *Jacobson Bros., Inc. v. United States*, 512 F.2d 1065, 1065 (Ct. Cl. 1975)).

78       Id. at 1011, 1013.

79       *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983).

80       Id. at 1379.

81       Id. at 1378, 1382.

82       Id. at 1382.

83       Id.

84       Id.

85       *Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc.*, 707 F.2d 1376, 1382 (Fed. Cir. 1983).

86       See *id.*

87       Id.

88       *Envil. Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 696 (Fed. Cir. 1983).

89       Id.

90       Id. at 697.

91       *Stratoflex, Inc. v. Aeroquip Corp.* 713 F.2d 1530, 1538 (Fed. Cir. 1983).

92       Id.

<sup>93</sup> See, e.g., Ruiz v. A.B. Chance Co., 234 F.3d 654, 666-67 (Fed. Cir. 2000) (omitting inventor's skill level from the list of factors for determining the level of ordinary skill in the art); U.S. Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554, 1564 (Fed. Cir. 1997) (stating no particular test but affirming district court's jury instructions for determining the level of ordinary skill in the art that did not include the inventor's level of skill); In re GPAC Inc., 57 F.3d 1573, 1579 (Fed. Cir. 1995) (omitting inventor's skill level from the list of factors for determining the level of ordinary skill in the art); Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 718 (Fed. Cir. 1991) (including inventor's skill level in the list of factors for determining the level of ordinary skill in the art); Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962 (Fed. Cir. 1986) (omitting the inventor's level of skill from the list of factors for determining the level of ordinary skill in the art); Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 449 (Fed. Cir. 1986) (including the inventor's level of skill in the list of factors for determining the level of ordinary skill in the art); Standard Oil Co. v. Am. Cyanamid Co. 774 F.2d 448, 454 (Fed. Cir. 1985) (stating no particular test but noting that the actual inventor's level of skill was irrelevant to the nonobviousness inquiry); Stewart-Warner Corp. v. City of Pontiac, Mich., 767 F.2d 1563, 1570 (Fed. Cir. 1985) (stating no particular test, but noting that the nonobviousness determination is not concerned with the inventor's level of skill but with the level of ordinary skill in the art).

<sup>94</sup> Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254 (Fed. Cir. 2007), cert. denied, 128 S. Ct. 1259 (2008).

<sup>95</sup> *Id.* at 1257.

<sup>96</sup> *Id.* at 1255.

<sup>97</sup> *Id.* at 1256 (citing Daiichi Pharm. Co. v. Apotex, Inc., 380 F. Supp. 2d 478, 485 (D.N.J. 2005)).

<sup>98</sup> *Id.* at 1258.

<sup>99</sup> *Id.* at 1256.

<sup>100</sup> Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 1257 (Fed. Cir. 2007), cert. denied, 128 S. Ct. 1259 (2008).

<sup>101</sup> *Id.* at 1256. In making its determination of the level of ordinary skill in the art, the district court had begun its analysis using the Environmental Designs factors, but the parties had not submitted anything more than "conclusory arguments" on the subject. *Id.* at 1256-57. Therefore, the court ultimately abandoned the factors and instead looked to a prior decision by the Federal Circuit which had held that, for a patent on a method of medical treatment, the person skilled in the art was a general practitioner. *Id.* at 1256-57. The Federal Circuit found that this was improper because the level of skill in the art had not been in dispute in that case and, thus, those findings had been merely dicta and were not binding. *Id.* at 1257.

<sup>102</sup> See, e.g., Ruiz v. A.B. Chance Co., 234 F.3d 654 (Fed. Cir. 2000) (omitting inventor's skill level from the list of factors for determining the level of ordinary skill in the art); United States Surgical Corp. v. Ethicon, Inc., 103 F.3d 1554 (Fed. Cir. 1997) (stating no particular test but affirming district court's jury instructions for determining the level of ordinary skill in the art that did not include the inventor's level of skill); Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955 (Fed. Cir. 1986) (omitting the inventor's level of skill from the list of factors for determining the level of ordinary skill in the art); Stewart-Warner Corp. v. City of Pontiac, Mich., 767 F.2d 1563 (Fed. Cir. 1985) (stating no particular test, but noting that the nonobviousness determination is not concerned with the inventor's level of skill but with the level of ordinary skill in the art); Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448 (Fed. Cir. 1985) (stating no particular test but noting that the actual inventor's level of skill was irrelevant to the nonobviousness inquiry).

<sup>103</sup> See, e.g., Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 718 (Fed. Cir. 1991) (including inventor's skill level in the list of factors for determining the level of ordinary skill in the art); Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc., 796 F.2d 443, 449 (Fed. Cir. 1986) (including the inventor's level of skill in the list of factors for determining the level of ordinary skill in the art).

<sup>104</sup> See Daiichi, 501 F.3d at 1257.

105 Id.

106 Id.

107 Id.

108 The court did mention one other factor--the educational background of others working in the field--but did not cite any evidence that actually addressed that factor. Id. The only evidence that the court did provide regarding this factor was a single quote from materials that were prepared by the patent holder for a conference stating that "there are many voices among medical persons concerned with otorhinolaryngology for demanding development of an otic solution making use of [ofloxacin]." Id. (quoting Daiichi Material for [C]onference on Development at 1 (Nov. 11, 1987), Daiichi, 501 F.3d 1254 (No. 2006-1564)). However, this quote only demonstrates that those people who wanted someone to develop an otic solution making use of ofloxacin were medical persons concerned with otorhinolaryngology. It does not actually provide any evidence regarding the educational background of the people who might actually be working to create an otic solution making use of ofloxacin.

109 Id. It should be noted that the author does not disagree with the court's ultimate conclusion with respect to the level of ordinary skill in the art, but with how the court reached that conclusion (i.e., focusing on the skill level of the inventors).

110 Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 1258 (Fed. Cir. 2007).

111 Id.

112 Id. at 1259.

113 Compare Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254 (Fed. Cir. 2007), with 35 U.S.C. §103(a) (2006).

114 35 U.S.C. §103(a) (2006) (emphasis added).

115 Merriam-Webster, Inc., Merriam-Webster's Collegiate Dictionary 658 (11th ed. 2004).

116 Id. at 873.

117 See *supra* note 93 and accompanying text.

118 Standard Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985).

119 See, e.g., Ryko Mfg. Co. v. Nu-Star, Inc., 950 F.2d 714, 718 (Fed. Cir. 1991) (noting that the education level of both the inventor and those who work in the industry are relevant factors and observing that, in making the nonobviousness determination, the court must determine what is objectively obvious to a person having the ordinary level of skill in the art at the time of the invention, not what would have been subjectively obvious to the inventor at the time of the invention); Orthopedic Equip. Co. v. All Orthopedic Appliances, Inc., 707 F.2d 1376, 1382 (Fed. Cir. 1983) (noting that the inventor's level of skill is a factor but is by no means conclusive).

<sup>120</sup> Envtl. Designs, Ltd. v. Union Oil Co. of Cal., 713 F.2d 693, 697 (Fed. Cir. 1983).

<sup>121</sup> 35 U.S.C. §103(a) (2006).

<sup>122</sup> S. Rep. No. 82-1979 (1952), as reprinted in 1952 U.S.C.C.A.N. 2394, 2411 (stating the desire that §103 have a “stabilizing effect” in court and Patent Office decisions with respect to the requirements of patentability).

<sup>123</sup> This would become even more apparent if the Federal Circuit were to make the leap to determining nonobviousness from the perspective not of the person having the inventor’s level of skill, as it did in *Daichi*, but from the perspective of the inventor. In that case, nearly every invention would be obvious, even those discovered in a flash of genius--the only exception would be those inventions that were discovered by complete accident!

<sup>124</sup> Orthopedic Equip. Co. v. United States, 702 F.2d 1005, 1011 (Fed. Cir. 1983).

<sup>125</sup> Furthermore, even in those rare cases where the inventor did possess the ordinary level of skill in the field, these five factors alone could still be used to determine the level of ordinary skill in the art with no risk of violating 35 U.S.C. §103(a).