THE RESURGENCE OF "SECONDARY CONSIDERATIONS"

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I. INTRODUCTION

Modern patent systems are based on the notion that exclusive rights to inventors may be granted only if their invention meets certain high standards. Even in the earliest patent systems, exclusive rights were granted to those inventions that were, for example, "ingenious." Patent systems require that inventions be both new and useful in order to qualify for patent protection. While there are some interesting complications, it is comparatively easy to establish that an invention is new and useful. The problem has been to develop a final criterion, a criterion that provides a means for identifying those inventions that would not be created or disclosed but for the inducement of the patent right to exclude. The invention must have something beyond being

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1 See Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI. L. REV. 1017, 1021-22 (1989).
“new”; it needs some level of “innovation” or “creativity,” however defined. Patent systems around the world have struggled with and have articulated this final criterion in many different ways. In Japan, for example, an invention is not entitled to patent protection if it could have been easily made. In Europe, the European Convention requires that the invention exhibit an inventive step. In Taiwan, a patent is not available if the invention “can be easily accomplished by persons skilled in the art.”

II. THE U.S. PATENT SYSTEM EARLY CRITERION

For many decades, the U.S. patent system struggled with a criterion that would not be so high so as to still provide adequate incentive to create new inventions, but not so low a standard so as to discourage innovation. At one point, the Supreme Court articulated a standard that required the invention show a “flash of creative genius.” This, of course, was a difficult standard not only to meet but was clearly difficult to prove.

In 1952, the U.S. Patent Act was significantly overhauled. In order to address the problem of trying to define the standard that inventions would be judged beyond novelty and usefulness, § 103 was added to the Patent Act specifically to articulate such a standard, and §

5 See Cuno Eng’g Corp. v. Automatic Devices Corp., 314 U.S. 84, 90-91 (1941).
7 MINPO, supra note 6.
8 Convention on the Grant of European Patents, supra note 6.
9 MIN FA, CH’IN SHU PIEN, supra note 6.
10 See infra notes 11-23.
11 Cuno Eng’g Corp. v. Automatic Devices Corp., 314 U.S. 84, 91 (1941).
12 See Falkenberg v. Bernard Edward Co., 175 F.2d 427, 428 (7th Cir. 1949); Brown & Sharpe Mfg. Co. v. Kar Eng’g Co., 154 F.2d 48, 51 (1st Cir. 1946); Chi. Steel Foundry Co. v. Burnside Steel Foundry Co., 132 F.2d 812, 817 (7th Cir. 1943).
14 Id. at 703-04.
103 is stated in the negative. You cannot obtain a patent, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The last sentence of § 103 was widely regarded as overturning the "flash of genius" test of the Cuno Engineering Corp. v. Automatic Devices Corp. decision. Twelve years after the enactment of § 103 of the Patent Act, the Supreme Court decided the case of Graham v. John Deere Co. of Kansas City. The Court first concluded that the 1952 Patent Act was intended to codify judicial precedent and was not intended to change anything from previous Supreme Court decisions. It specifically stated that "the general level of innovation necessary to sustain patentability remains the same."

The Supreme Court in Graham v. John Deere Co. articulated the process by which the inquiry into the obviousness requirement was to be conducted: "Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved."

The Court went on to say the following:

Against this background, the obviousness or nonobviousness of the subject matter is determined.

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15 See 35 U.S.C. § 103 (1952). There have been changes to the Patent Act over the years not pertinent to this discussion.
16 Id.
19 Id. at 3-4.
20 Id. at 4.
21 Id.
Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.22

There continues to be a debate regarding the role of these so-called "secondary considerations" or "objective indicia."23 Are they indeed "secondary"? What does "secondary" really mean? What is meant when it is said that they "might be utilized" and "may" have relevancy?24

In almost every obviousness case, in order to establish that an invention is obvious, two or more references need to be combined.25 A line of cases in the Court of Appeals for the Federal Circuit ("CAFC") established a process to determine when it might be appropriate to combine references.26 The CAFC established that there must be a teaching, suggestion, or motivation in the references themselves before they can be combined, the so-called "TSM" test.27

The TSM test was indeed a fairly powerful tool for the party seeking to establish that their invention was not obvious.28 It is typically very difficult to find an explicit teaching, suggestion, or motivation in a reference to combine it with another reference.29

In 2007, the Supreme Court decided the KSR International Co. v. Teleflex Inc. case.30 In that case, the Court rejected what it

22 Id. at 17-18.
27 KSR Int’l Co., 550 U.S. at 407.
28 See id. 415-16.
29 See id. at 417-18.
30 Id. at 398.
considered to be a rigid TSM test and instead articulated a much broader test for determining whether something was obvious or not.\textsuperscript{31} As a result, it became much more difficult for patentees in litigation or applicants in the U.S. Patent Office to establish that their intention was not obvious.\textsuperscript{32} Such things as “common sense” and “routine” became buzzwords in patent decisions.\textsuperscript{33} The test articulated by the Court is thought by many to be a very high standard: “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”\textsuperscript{34}

Prior to 2007, and even for several years after 2007, many considered the concept that one could prove his or her invention was not obvious by showing some evidence of the various secondary considerations to be desperation and a low probability argument.\textsuperscript{35} However, the Court in \textit{KSR} did leave the door open.\textsuperscript{36} From the quote above, an invention is only “likely” to be obvious if the test is met.\textsuperscript{37} Perhaps secondary considerations or objective indicia can turn “likely” around.\textsuperscript{38} Perhaps because of the perceived more difficult standard in \textit{KSR}, patentees began to argue objective indicia more often.\textsuperscript{39}

The case of \textit{Pfizer, Inc. v. Apotex, Inc.} is a typical decision from this era.\textsuperscript{40} The panel consisted of Judge Michel, Judge Mayer, and Judge Linn with the decision by Judge Michel.\textsuperscript{41} In that case, a district

\textsuperscript{31} \textit{Id.} at 415.
\textsuperscript{33} \textit{KSR Int'l Co.}, 550 U.S. at 421.
\textsuperscript{34} \textit{Id.} at 416.
\textsuperscript{36} \textit{See KSR Int'l Co.}, 550 U.S. at 415.
\textsuperscript{37} \textit{See id.} at 416.
\textsuperscript{39} \textit{See, e.g.}, \textit{KSR Int'l Co.}, 550 U.S. at 415.
\textsuperscript{40} Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348 (Fed. Cir. 2007).
\textsuperscript{41} \textit{Id.} at 1352.
court finding of nonobviousness was reversed by the CAFC. While the CAFC did say that secondary considerations must be taken into account, it ultimately found that “[h]ere, the record establishes such a strong case of obviousness that Pfizer’s alleged unexpectedly superior results are ultimately insufficient.”

The CAFC did take a hard look at the proffered unexpected results but, nevertheless, the sense of this case is that if there is a strong case of obviousness it will require a very substantial showing of secondary considerations to overcome. There seems to be a sense that you first determine whether or not something is obvious; if you conclude that it is obvious, only then do you consider these secondary considerations. There is a strong sense of balancing a prima facie case against secondary considerations or objective indicia.

Statements from KSR reinforce this type of analysis. “Like the District Court, finally, we conclude Teleflex has shown no secondary factors to dislodge the determination that claim 4 is obvious.” The Supreme Court provided no discussion of the secondary factors. The sense seems to be that a prima facie case is “king of the hill” requiring something to “dislodge” it.

For many years, arguing secondary considerations or objective indicia continued to be a high-risk “Hail Mary” kind of argument. For example, in 2009, Boston Scientific Scimed, Inc. v. Cordis, Corp. was decided by the CAFC. The panel consisted of Judge Lourie, Judge Rader, and Judge Prost with the opinion by Judge Lourie. In the

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42 Id. at 1372.
43 Id.
44 Id.
45 See id. at 1369-70.
46 See id. at 1370.
48 Id.
49 See id. at 425-28.
50 Id. at 426.
52 Id.
53 Id. at 983.
district court, the jury had found that the invention was not obvious.\(^{54}\) The district court judge had found that there was a failure to combine references for decades and that there was praise for the commercial embodiment.\(^{55}\) Further, the district court found that commercial success was due to the claimed features of the invention and not for other reasons.\(^{56}\) In spite of these findings, the CAFC reversed.\(^{57}\)

In some unfortunate language harking back to days before the 1952 § 103 of the Patent Act, the CAFC found that it "does not require a leap of inventiveness" to produce the claimed invention.\(^{58}\) Moreover, "given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion that [the claim] would have been obvious."\(^{59}\)

While the CAFC did discuss the long-felt need, it nevertheless found weak secondary considerations.\(^{60}\) This was contrary to the jury finding and contrary to the district court judge.\(^{61}\) Interestingly, there was no discussion of the praise for the invention or the commercial success that it enjoyed.\(^{62}\)

### III. THE RESURGENCE OF SECONDARY CONSIDERATIONS

In 2010, the CAFC decided the *Rolls-Royce, PLC v. United Technologies Corp.* case.\(^{63}\) The panel consisted of Judge Michel, Judge Rader, and Judge Schall, with the opinion by Judge Rader.\(^{64}\) In the *Rolls-Royce* case, the CAFC affirmed the nonobviousness finding of the district court.\(^{65}\) The case involved "swept fan blades used on turbofan

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54 *Id.* at 990.
55 *Id.* at 985.
56 *Id.*
57 *Id.* at 992.
58 *Id.* at 991.
59 *Id.* at 991-92 (quoting Leapfrog Enters., Inc. v. Fisher-Price, Inc., 485 F.3d 1157, 1162 (Fed. Cir. 2007)).
60 *Id.* at 989-91.
61 *Id.* at 991-92.
62 *Id.*
63 *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325 (Fed. Cir. 2010).
64 *Id.* at 1327.
65 *Id.*
jet engines.\textsuperscript{66} There had been an interference between Rolls Royce and United Technologies.\textsuperscript{67} Rolls Royce lost in the United States Patent and Trademark Office but won in the district court.\textsuperscript{68}

The district court considered a number of secondary considerations in coming to the conclusion that the invention was not obvious.\textsuperscript{69} As far as unexpected results were concerned, the district court found that a 1.8\% efficiency improvement in turbofan engines was unexpected.\textsuperscript{70} Further, the invention had received a prestigious Flight International Award, in other words, praise by peers.\textsuperscript{71} Still further, the district court found that the invention became an industry standard for large commercial aircraft engines.\textsuperscript{72} The industry had largely copied the invention.\textsuperscript{73}

In affirming the district court the CAFC found: "In the obviousness analysis, secondary considerations are often some of the best 'independent evidence of nonobviousness.' The secondary considerations in this case reinforce and substantiate the district court's correct conclusion of non-obviousness."\textsuperscript{74} The CAFC thus found that the secondary considerations cemented nonobviousness.\textsuperscript{75}

Even in 2010, the analysis seemed to be to decide whether or not you believe the invention to be obvious or not, and only then look to the secondary considerations.\textsuperscript{76} In this case, the secondary considerations were used to reinforce a decision that the invention was not obvious, and that decision seems to have been already made by the CAFC.\textsuperscript{77}

\begin{itemize}
  \item \textsuperscript{66} Id.
  \item \textsuperscript{67} Id. at 1328.
  \item \textsuperscript{68} Id. at 1329.
  \item \textsuperscript{69} Id. at 1339-40.
  \item \textsuperscript{70} Id.
  \item \textsuperscript{71} Id. at 1340.
  \item \textsuperscript{72} Id.
  \item \textsuperscript{73} Id.
  \item \textsuperscript{74} Id. at 1339 (quoting Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc., 520 F.3d 1358, 1365 (Fed. Cir. 2008)).
  \item \textsuperscript{75} Id. at 1340.
  \item \textsuperscript{76} See id. at 1338.
  \item \textsuperscript{77} Id. at 1339.
\end{itemize}
Again in 2010, the CAFC decided the *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.* ("Transocean 1") case. The patent at issue related to “improved apparatus for conducting offshore drilling.”

Prior apparatus had used two separate derricks. The patents describe an apparatus that includes two stations in one apparatus. One of the stations is a main advancing station. A second station is an auxiliary advancing station. As a result of this configuration, drilling became much more efficient.

The district court had granted summary judgment to the defendant. The district court held that the asserted claims of the patents were invalid and not infringed. Further, the district court found that the defendant did not act willfully.

The CAFC discussed the validity issue and more particularly the issue of the role of secondary considerations in determining whether the inventions were obvious. The CAFC found that two references indeed established that the claims would have been obvious. However, it went on to discuss the secondary considerations. In this case, the secondary considerations included industry skepticism that the apparatus would work as proposed, long-felt industry need for more efficient drilling, commercial success of the patented drilling apparatus, and copying by others in the industry.

The CAFC held that the district court must always consider

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78 *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296 (Fed. Cir. 2010) [hereinafter *Transocean 1*].
79 *Id.* at 1300-01.
80 *Id.* at 1301.
81 *Id.*
82 *Id.*
83 *Id.*
84 *Id.* at 1301-02.
85 *Id.* at 1300.
86 *Id.*
87 *Id.*
88 *Id.* at 1302-03.
89 *Id.* at 1303.
90 *Id.* at 1304.
91 *Id.* at 1303-04.
secondary considerations. More particularly, the CAFC found that their case law was "clear that this type of evidence must be considered in evaluating the obviousness of a claimed invention." "While it is true that we have held in individual cases that objective evidence of nonobviousness did not overcome the strong prima facie case—this is a case-by-case determination."

The prima facie case of obviousness in this situation was fairly strong. The CAFC found that the combination of two references teach all of the limitations of the asserted claims. In addition, the CAFC found that one of the references disclosed a reason for combining the references to achieve the claimed invention. But, the CAFC held that this was not the end of the inquiry and that the district court opinion ignored the objective evidence of nonobviousness. This, the CAFC found, was reversible error. Further, this was at a summary judgment stage and the CAFC held that all of the evidence of secondary considerations should be resolved in favor of the patentee Transocean.

On remand, a jury made findings of fact supporting seven types of objective evidence. The district court concluded that the record failed to support these jury findings. The case was again appealed. In Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc., ("Transocean II") the CAFC again found the invention not to be obvious, now after a full consideration of the objective indicia. Of

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92 Id. at 1305.
93 Id. (quoting Richardson-Vicks, Inc. v. Upjohn Co., 122 F.3d 1476, 1483 (Fed. Cir. 1997)).
94 Id.
95 Id. at 1303-04.
96 Id. at 1303.
97 Id.
98 Id. at 1304.
99 Id. at 1305.
100 Id.
102 Id.
103 Id. at 1345.
104 Id. at 1355.
particular note: “The district court’s analysis seems to have been clouded by its view that the asserted claims would have been obvious over the prior art. This is precisely the sort of hindsight bias that evaluation of objective evidence is intended to avoid.” The panel in Transocean I included Judge Gajarsa, Judge Mayer, and Judge Moore, with the opinion by Judge Moore; the panel for Transocean II included Judge Prost, Judge Moore, and Judge Wallach, again with the opinion by Judge Moore. In 2012, the CAFC decided WM. Wrigley Jr. Co. v. Cadbury Adams USA LLC. The panel consisted of Judge Newman, Judge Bryson, and Judge Fogel. In an opinion written by Judge Bryson, the court found that a claim was obvious, even in light of secondary considerations. Judge Newman dissented.

The Wrigley case involved chewing gum compositions that “provides a cooling sensation when chewed.” Both parties filed similar patent applications, which involved the use of menthol with a second compound from a particular class of compounds. The Cadbury composition used a compound referred to as WS-3, while the Wrigley composition used a compound referred to as WS-23. The district court had found that the evidence of secondary considerations that Wrigley offered was insufficient to overcome a strong case of obviousness. The CAFC acknowledged that unexpected results could

105 Id. at 1350.
106 Id. at 1345; Transocean I, 617 F.3d 1296, 1300 (Fed. Cir. 2010). A significant part of this case involves the issue of whether infringement can be found based on the negotiation and signing of a contract outside of the United States. Transocean I, 617 F.3d at 1307-09. The district court found that this did not support infringement liability. Id. at 1307-08. The CAFC disagreed and vacated that portion of the decision. Id. at 1310. That issue was the subject of continuing litigation but the parties settled, and the Supreme Court dismissed. Ryan Davis, Maersk, Transocean Settle High Court Drilling Patent Case, LAW360.COM (May 21, 2014).
108 Id. at 1358. Judge Fogel is from the Northern District of California and was sitting by designation. Id.
109 Id. at 1365.
110 Id. at 1366-72.
111 Id. at 1358.
112 Id.
113 Id.
114 Id. at 1360.
establish nonobviousness, but found that it did not do so in this case.\textsuperscript{115}

In order to show unexpected results, “Wrigley needed to demonstrate that the results were unexpected to a significant degree beyond what was already known about the effect of combining WS-3 and menthol.”\textsuperscript{116} As evidence of unexpected results, Wrigley pointed to an internal Cadbury study that compared the Wrigley product with the Cadbury product.\textsuperscript{117} The internal report concluded that the Wrigley product was superior.\textsuperscript{118} However, the CAFC pointed out that there were significant differences, other than merely the substitution of WS-23 for WS-3, that made it impossible to determine whether the unexpected results were due to that substitution.\textsuperscript{119} Similarly, when Wrigley argued commercial success, the CAFC found that there was an insufficient nexus linking the success to the claimed invention because the compositions differed by more than just the feature of the claimed invention.\textsuperscript{120} For example, in addition to the difference between WS-23 and WS-3, the compositions used different materials, such as sweeteners and different levels of materials.\textsuperscript{121} Thus, there was not a direct comparison to establish the required nexus.\textsuperscript{122} Wrigley needed to show that the commercial success “was directly attributable to combining WS-23, rather than WS-3, with menthol,” and that “the district court properly discounted the evidence of commercial success as a secondary consideration.”\textsuperscript{123}

In July of 2013, the CAFC decided the \textit{Plantronics, Inc. v. Aliph, Inc.} case.\textsuperscript{124} The case was decided by a panel consisting of Judge Rader, Judge O’Malley, and Judge Wallach, with the opinion written by Judge Wallach.\textsuperscript{125} The case was on appeal from a grant of summary judgment in favor of the defendant, where the district court found that

\begin{itemize}
\item \textsuperscript{115} \textit{Id.} at 1362.
\item \textsuperscript{116} \textit{Id.} at 1363.
\item \textsuperscript{117} \textit{Id.}
\item \textsuperscript{118} \textit{Id.}
\item \textsuperscript{119} \textit{Id.} at 1363-64.
\item \textsuperscript{120} \textit{Id.} at 1363.
\item \textsuperscript{121} \textit{Id.}
\item \textsuperscript{122} \textit{Id.} at 1363-64.
\item \textsuperscript{123} \textit{Id.} at 1364.
\item \textsuperscript{124} \textit{Plantronics, Inc. v. Aliph, Inc.}, 724 F.3d 1343 (Fed. Cir. 2013).
\item \textsuperscript{125} \textit{Id.} at 1345.
\end{itemize}
the claims of the Plantronics patent were invalid, among other issues. The Plantronics patent was directed to a "concha-style headset" for use with cell phones. Plantronics argued that it had enjoyed commercial success and that its headset was copied by the defendant.

The CAFC found that the district court did not give adequate consideration to the secondary considerations proffered by Plantronics. The case contains some strong statements regarding the process and the role of these secondary considerations.

As a safeguard against "slipping into use of hindsight and to resist the temptation to read into the prior art the teachings of the invention in issue," we have required courts to consider evidence of the objective indicia of nonobviousness prior to making the ultimate determination of whether an invention is obvious. Graham, 383 U.S. at 36, 86 S. Ct. 684; Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538 (Fed. Cir. 1983) (objective considerations "may often be the most probative and cogent evidence [of nonobviousness] in the record"). Failure to give proper consideration to such evidence, as in this case, can be fatal because "common sense" may not be so apparent in view of objective evidence of nonobviousness (e.g., commercial success and copying), particularly when all reasonable inferences are drawn in favor of the patentee.

Here, the district court concluded that the '453 patent was invalid as obvious before considering objective indicia of nonobviousness. The district court addressed Plantronics' objective evidence of nonobviousness—including copying and commercial success—only after reaching this conclusion. To the extent the district court conducted a post hoc analysis of

126 Id. at 1346.
127 Id.
128 Id. at 1356.
129 Id. at 1356-57.
130 E.g., id. at 1354-55.
objective considerations, it was improper.

This court has consistently pronounced that all evidence pertaining to the objective indicia of nonobviousness must be considered before reaching an obviousness conclusion. The significance of this fourth Graham factor cannot be overlooked or be relegated to "secondary status."131

At least this panel of the CAFC gave some strong guidelines.132 Where a patentee raises the possibility that there are secondary considerations in the § 103 analysis, the district court must consider these factors.133 These factors must be considered before reaching any conclusions.134 They must be given proper consideration and they are not to be "relegated to 'secondary status.'"135

Shortly after the Plantronics decision in 2013, the CAFC decided the Apple Inc. v. International Trade Commission case.136 The panel consisted of Judge Moore, Judge Linn, and Judge Reyna, with the opinion by Judge Moore.137 Apple appealed from a final decision of the International Trade Commission ("ITC") that its asserted claims were invalid and not infringed.138

The patents involved smartphone touchscreens having "a touch panel with a transparent capacitive sensing medium."139 One patent relates to a method of making such a touch screen and another patent relates to a method of determining which node the finger touches.140 Apple asserted that the secondary considerations of industry praise, copying by competitors and commercial success reinforced that the

131 Id. (citation omitted).
132 See id.
133 Id.
134 Id. at 1355.
135 Id. (quoting In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1078 (Fed. Cir. 2012)).
137 Id. at 1359.
138 Id.
139 Id.
140 Id. at 1359-60.
invention was not obvious.\textsuperscript{141}

Again, the case contains some strong language regarding the role of secondary considerations.\textsuperscript{142} The CAFC pointed out that its cases “have repeatedly held that evidence relating to all four Graham factors—including objective evidence of secondary considerations—\textit{must be considered before} determining whether the claimed invention would have been obvious to one of skill in the art at the time of invention.”\textsuperscript{143} The CAFC was troubled that before mentioning the secondary considerations the administrative law judge had made his conclusion that the invention was “clearly and convincingly” obvious.\textsuperscript{144} The ITC, in its final decision, “never even mentioned, much less weighed” the secondary considerations.\textsuperscript{145} The CAFC found that “Apple presented compelling secondary considerations evidence that may have rebutted even a strong showing under the first three Graham factors, and the ITC failed to grapple with it.”\textsuperscript{146} They also found that Apple had presented a sufficient case of nexus between the secondary factors and the claimed inventions.\textsuperscript{147}

In another decision in the summer of 2013, the CAFC decided the \textit{Leo Pharmaceutical Products v. Rea} case.\textsuperscript{148} The panel consisted of Judge Rader, Judge O’Malley, and Judge Reyna, with the opinion written by Judge Rader.\textsuperscript{149} The case arose out of an inter partes reexamination of a Leo Pharmaceutical Products (“Leo”) patent relating to the topical treatment of skin conditions.\textsuperscript{150} The CAFC disagreed with the Patent Office Board of Appeals and Interferences (“Board”) on the issue of claim construction.\textsuperscript{151} In addition, the CAFC disagreed with the Board that the invention would have been obvious because the
Board “incorrectly weighed the objective indicia of nonobviousness.”

The patent at issue teaches that the combination of vitamin D and corticosteroids heals psoriasis. Unfortunately, while both compounds had been known singly for the treatment of skin conditions, they have divergent requirements for optimum stability. Several formulations suggested by the prior art did not solve the stability problem and there was still a need for a single formulation containing both ingredients. Leo found a new set of solvents that solved the problem.

The CAFC found that the Leo inventors solved a problem with the stability of the combination of the two components, “a problem that the prior art did not recognize” and had not “solved for over a decade.” Reasoning that “an invention can often be the recognition of a problem itself,” the court found that several articles presented by Leo in the reexamination taught away from mixing vitamin D with other drugs. Leo’s proffered experimental results showed that none of the formulations taught by the prior art solved the stability problem.

One of the arguments that was convincing to the CAFC related to the timing of the prior art relative to the making of the invention. “If these discoveries and advances were routine and relatively easy, the record would undoubtedly have shown that some ordinary artisan would have achieved this invention within months of Dikstein or Serup. Instead, this invention does not appear for more than a decade.”

In fact, the CAFC mentioned the timing of the invention multiple times: “The record also shows evidence of long felt but

152 Id.
153 Id. at 1349.
154 Id.
155 Id.
156 Id.
157 Id. at 1353.
158 Id.
159 Id. at 1354.
160 Id. at 1359.
161 Id. at 1354.
unsolved need, i.e., the need for a single formulation to treat psoriasis. The length of the intervening time between the publication dates of the prior art and the claimed invention can also qualify as an objective indicator of nonobviousness.”

The CAFC found that the combination would not have been obvious to try since there were numerous combinations that might have been possible. This was not a situation like KSR where there were a finite number of identified and predictable solutions. The timing was again pertinent: “The elapsed time between the prior art and the ‘013 patent’s filing date evinces that the ‘013 patent’s claimed invention was not obvious to try.”

The CAFC disagreed with the Board’s approach. “Thus, the Board should give the objective indicia its proper weight and place in the obviousness analysis, and not treat objective indicia of nonobviousness as an afterthought.”

In close succession, the CAFC admonished district courts to properly consider objective indicia in Plantronics, the ITC in Apple, and the Board in Leo. Participating in these decisions were Judge Linn, Judge Moore, Judge O’Malley, Judge Rader, Judge Reyna, and Judge Wallach. If you include Judge Newman for her dissent in Wrigley (and in the next case, Galderma Laboratories v. Tolmar, Inc.), it appears that there are at least seven CAFC judges who are taking a consistent approach to secondary considerations or objective indicia. To these judges, objective indicia appears very important, and it should

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162 Id. at 1359.
163 Id. at 1356.
165 Leo Pharm. Prods., 726 F.3d at 1356.
166 Id. at 1357.
167 Id. at 1358.
168 See, e.g., id. at 1358; Apple, Inc. v. Int’l Trade Comm’n, 725 F.3d 1356, 1365 (Fed. Cir. 2013); Plantronics, Inc. v. Aliph, Inc., 724 F.3d 1343, 1355 (Fed. Cir. 2013).
169 See, e.g., Leo Pharm. Prods., 726 F.3d at 1348; Apple, Inc., 725 F.3d at 1359; Plantronics, Inc., 724 F.3d at 1345.
always be considered, and should not be relegated to an afterthought.  

The CAFC decided Galderma in December of 2013. The panel consisted of Judge Newman, Judge Bryson, and Judge Prost, with the opinion written by Judge Prost. Judge Newman filed a dissent to the opinion. As noted above, Judge Bryson wrote the opinion in Wrigley, holding that the objective indicia were not sufficient. In Galderma, on appeal from a district court finding that the claims were not obvious because of secondary considerations, the CAFC reversed. The invention relates to a topical medication containing 0.3% by weight of adapalene for the treatment of acne. The prior art showed the use of adapalene, “preferably between 0.01 and 1 weight percent.” The prior art also showed the use of adapalene at 0.3% for other conditions, for example, the treatment of photodamage of the skin.

The CAFC found that “Tolmar presents an obviousness case that is both straightforward and potent.” The claimed composition fell within the range cited in the prior art. Thus, one reference showed all the limitations of the claims except the precise 0.3% limitation. As noted, the 0.3% concentration was known for other conditions.

The basis for the district court finding of nonobviousness was a heavy reliance “on evidence showing that increasing the dose of adapalene was likely to increase the incidence of certain side effects and evidence showing that 0.1% was considered the optimal adapalene concentration for the treatment of acne.” Presumably, this was

171 See Leo Pharm. Prods., 726 F.3d at 1358.
172 Galderma Labs., L.P., 737 F.3d at 731.
173 Id. at 734.
174 Id. at 741.
175 Wm. Wrigley Jr. Co., 683 F.3d at 1366.
176 Galderma Labs., L.P., 737 F.3d at 741.
177 Id. at 734.
178 Id. at 735 (quoting U.S. Patent No. 4,717,720 col. 5 ll. 61-64 (filed Jan. 5, 1988)).
179 Id.
180 Id. at 736.
181 Id.
182 Id.
183 Id. at 735.
184 Id. at 737 (citing Galderma Labs., L.P. v. Tolmar, Inc., 891 F. Supp. 2d 588, 641-
considered to be "teaching away." The district court also relied on commercial success and unexpected results.

The CAFC found the following:

In these circumstances, where there is a range disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence that (1) the prior art taught away from the claimed invention; (2) there were new and unexpected results relative to the prior art; or (3) there are other pertinent secondary considerations.

The standard for "teaching away" comes from an earlier case: "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." Furthermore, "[a] reference does not teach away, however, if it merely expresses a general preference for an alternative invention but does not 'criticize, discredit, or otherwise discourage' investigation into the invention claimed."

The CAFC found that even though the references showed increased side effects with the increased dosage, they failed to discourage others from continuing research. The CAFC found that there was nothing in the references to suggest that the side effects were serious enough.

With regard to unexpected results, the CAFC found that the

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42 (D. Del. 2012)).
185 Id. at 738.
186 Id. at 737 (citing Galderma Labs., L.P., 891 F. Supp. 2d at 642-44).
187 Id. at 738.
189 Id. (quoting In re Fulton, 391 F.3d 1195, 1201 (Fed. Cir. 2004)).
190 Galderma Labs., L.P., 737 F.3d at 738-39.
191 Id. at 739.
differences must be "difference[s] in kind, not in degree.""¹⁹² "Thus, where an unexpected increase in efficacy is measured by a small percentage, as here, and the evidence indicates that skilled artisans were capable of adjusting the percentage, the result constitutes a difference in degree, not kind."¹⁹³

With regard to commercial success, the district court found that the patentee’s product quickly gained market share, and that the defendant needed to use 0.3% to compete, precisely because it was commercially successful.¹⁹⁴ However, the CAFC found that just because the defendant thinks it can make a profit does not speak to the merits of the invention relative to what is already in the prior art.¹⁹⁵ The CAFC did not disturb the finding that the patentee’s product quickly gained market share.¹⁹⁶ However, the CAFC found that the reason was that an earlier, now-expired patent blocked the market entry.¹⁹⁷

Judge Newman dissented, believing that the obviousness question was a close call.¹⁹⁸ Judge Newman was critical of the others on the panel.¹⁹⁹ She pointed to the fact that the district court had "held an eight-day bench trial" and "heard thirteen live witnesses."²⁰⁰ The district court’s issued opinion was fifty pages with "thoughtful explanation and reasoning."²⁰¹

In refusing to credit any of the demonstrated "secondary considerations" my colleagues foreclose patentability to a vast body of improvement patents. In the field of medicaments, the denial of patentability for improvements is a disincentive to the development of

¹⁹² *Id.* at 748.
¹⁹³ *Id.* at 739. Recall the Rolls-Royce case, where a 1.8% improvement in that technology was considered quite significant. Rolls-Royce, PLC v. United Techs. Corp., 603 F.3d 1325, 1340 (Fed. Cir. 2010).
¹⁹⁴ *Galderma Labs., L.P.*, 737 F.3d at 740.
¹⁹⁵ *Id.*
¹⁹⁶ *Id.*
¹⁹⁷ *Id.*
¹⁹⁸ *Id.* at 741.
¹⁹⁹ *Id.*
²⁰⁰ *Id.*
²⁰¹ *Id.*
such improvements. The losers are those afflicted with disease. I respectfully dissent.\textsuperscript{202}

The CAFC decided \textit{Bristol-Myers Squibb Co. v. Teva Pharmaceuticals USA, Inc.} in June of 2014.\textsuperscript{203} The panel consisted of Judge Prost, Judge Plager, and Judge Chen, with the opinion by Judge Chen.\textsuperscript{204} The case was on appeal from a decision by the district court that claim 8 of a Bristol-Myers Squibb ("BMS") patent was invalid.\textsuperscript{205} The CAFC affirmed.\textsuperscript{206}

The claim is directed to an antiviral compound, referred to as "entecavir," which is useful for the treatment of hepatitis B.\textsuperscript{207} The compound is a derivative of a naturally occurring nucleoside, differing from the natural material in only one respect.\textsuperscript{208} Entecavir has a carbon-carbon double bond in the five position of the carbocyclic ring rather than an oxygen atom.\textsuperscript{209}

The prior art disclosed an antiviral compound, also a derivative of the naturally occurring compound, referred to as 2’-CDG.\textsuperscript{210}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{entecavir_deoxyguanosine.png}
\caption{Entecavir and deoxyguanosine}
\end{figure}

\textsuperscript{202} \textit{Id.} at 742.
\textsuperscript{203} \textit{Id.} at 969.
\textsuperscript{204} \textit{Id.}
\textsuperscript{205} \textit{Id.}
\textsuperscript{206} \textit{Id.}
\textsuperscript{207} \textit{Id.} at 969-70.
\textsuperscript{208} \textit{Id.} at 969.
\textsuperscript{209} \textit{Id.}
\textsuperscript{210} \textit{Id.} at 970.
Finally, the prior art disclosed "Madhavan [compound] 30," which was a derivative of a different naturally occurring compound.  

The main issue in the obviousness inquiry was what should be considered to be the lead compound or the starting point. The CAFC found that 2'-CDG should be the lead compound and that a skilled artisan would have made what the court referred to as a minor modification. While BMS pointed out that 2'-CDG was later discovered to be toxic, the court found that at the time of the invention, other researchers had already been using it as a lead compound. The CAFC found that "one of ordinary skill in the art would have had a motivation to modify 2'-CDG’s carbocyclic ring by substituting an exocyclic methylene group" thus arriving at the claimed compound. The CAFC found that the modification was a "minor one."

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211 Id. at 971-72.
212 Id. at 973.
213 Id.
214 Id. at 974.
215 Id. at 974-75.
216 Id. at 975.
BMS argued that the claimed compound was not obvious because of objective indicia—most notably unexpected results.\textsuperscript{217} The CAFC found that unexpected results do not per se defeat a finding that a modification will produce some expected property.\textsuperscript{218} "Unexpected properties, however, do not necessarily guarantee that a new compound is nonobvious."\textsuperscript{219} "[A] 'mere difference in degree' is insufficient."\textsuperscript{220} Differences in degree are not as persuasive as differences in kind in "rebutting obviousness."\textsuperscript{221} The district court had found that the degree of effectiveness was unexpected and that the claimed compound had the unexpected property of a high genetic barrier to resistance.\textsuperscript{222} Neither the fact of a difference in degree of effectiveness nor an unexpected property, a difference in kind, were sufficient to rebut the finding of obviousness.\textsuperscript{223} BMS also argued commercial success but because their own internal documents referred to the market performance as "sub optimal," the CAFC was unimpressed by the proffered commercial success evidence.\textsuperscript{224} Further, it held the top spot for only one year and competitive drugs were able to gain market share more rapidly than the claimed compound.\textsuperscript{225} As for long-felt need, several factors led the CAFC to conclude that it was "of limited value to BMS."\textsuperscript{226}

\textbf{IV. CONCLUSIONS}

It appears that the law, with respect to the importance of secondary considerations or objective indicia, is going through a transformation.\textsuperscript{227} For some members of the CAFC, it might be said that such indicia of nonobviousness are almost as important as the explicit teachings of individual prior art references.\textsuperscript{228} Compared to

\textsuperscript{217} \textit{Id.} at 976. "BMS also argues that a new chemical entity, as a matter of law, cannot be obvious when the claimed invention possess unexpected properties." \textit{Id.}
\textsuperscript{218} \textit{Id.}
\textsuperscript{219} \textit{Id.} at 977.
\textsuperscript{220} \textit{Id.} (citing \textit{In re Papesch}, 315 F.2d 381, 392 (C.C.P.A. 1963)).
\textsuperscript{221} \textit{Id.}
\textsuperscript{222} \textit{Id.} at 978.
\textsuperscript{223} \textit{Id.} at 977-79.
\textsuperscript{224} \textit{Id.} at 978-79.
\textsuperscript{225} \textit{Id.}
\textsuperscript{226} \textit{Id.} at 979.
\textsuperscript{227} \textit{See supra} Part III.
\textsuperscript{228} \textit{See supra} Part III.
cases as recent as 2007, it is now clear that for many CAFC judges objective indicia must be considered and properly weighed before a final determination can be made on obviousness, and that such considerations cannot be relegated to less important or secondary status.229 It is also clear that the nexus between the objective indicia and the claimed invention is crucial.230 Proving nexus can be difficult and expensive.231

However, as the Galderma case and the BMS case illustrate, the CAFC is not consistent amongst its panels.232 A 1.8% improvement in fuel consumption for a jet engine was considered a sufficient degree of improvement in the Rolls-Royce case, while an improvement in efficacy against hepatitis B was not in the BMS case.233 Also in BMS is the suggestion that objective indicia can only be used to rebut an already-made determination that the invention was obvious.234 Other panels have strongly stated that all evidence must be weighed before the final obviousness determination is made.235 Consider again the statement in Transocean II: “The district court’s analysis seems to have been clouded by its view that the asserted claims would have been obvious over the prior art. This is precisely the sort of hindsight bias that evaluation of objective evidence is intended to avoid.”236

What does all of this mean for the day-to-day practitioner? Some of the indicia, for example, commercial success or praise by competitors, might not be apparent at the time of filing. The fact that these indicia may appear later argues in favor of filing a little more aggressively on inventions where the prior art is close. For all inventions, the inventor interview should at least ask the questions that

229 See supra Part III.
230 See supra Part III.
232 See Bristol-Myers Squibb Co., v. Teva Pharm. USA, Inc., 752 F.3d 967, 977 (Fed. Cir. 2014); Galderma Labs., L.P. v. Tolmar, Inc., 737 F.3d 731, 738 (Fed. Cir. 2013).
233 Compare Rolls-Royce, PLC v. United Techs. Corp., 603 F.3d 1325, 1339-40 (Fed. Cir. 2010), with Bristol-Myers Squibb Co., 752 F.3d at 978.
234 Bristol-Myers Squibb Co., 752 F.3d at 976-77.
235 See, e.g., Transocean II, 699 F.3d 1340, 1350 (Fed. Cir. 2012).
236 Id.
could lead to evidence of “unexpected results,” “teaching away,” or the “long-felt need” as part of the patentability story. Particular attention should be made to the age of the references that are the closest prior art, potentially an objective indicia that might be growing in importance. For the potential patentee-plaintiff, prelitigation due diligence should include a focus on any possible objective indicia. Clearly such indicia are no longer the “Hail Mary” of the past.

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238 Id.