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# LEAD PRIOR ART METHODOLOGY: APPLYING LEAD COMPOUND CASE LAW TO OTHER DISCIPLINES FOR ENHANCED OBJECTIVITY\*

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## *Abstract*

*The present paper aims to complement the traditional Graham-KSR obviousness framework by extrapolating the well-established "lead compound" approach used in the obviousness analysis of new chemical compounds across all fields of innovative endeavor. This extrapolation is designed to provide proponents and opponents of prima facie obviousness for a particular claimed invention, judges, and patent examiners with tools to analyze obviousness to an improved degree of objectivity. To that end, the authors present a methodology for identifying those pieces of prior art ("Lead Prior Art") that the mythical person of ordinary skill in the art ("POSITA"), without employing hindsight, would have selected for subsequent modification at the time that the invention was made. That method is based on identification of starting point(s) for further*

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*innovation that one of ordinary skill in the art would have selected based on the relevant available information at the time the invention was made, as statutorily required. "Relevant available information" includes teachings or suggestions in the prior art as well as inferences that would have been apparent to a POSITA based on ordinary creativity and common sense. In general, any information properly available to a POSITA that is capable of elevating the desirability of one or more potential starting points over others is relevant to the identification of the Lead Prior Art. In some situations, the Lead Prior Art's potential for modification to achieve the claimed invention may have been very apparent or even certain to a POSITA, given the relevant information that would have been available to the POSITA. In other situations, however, a POSITA's ability to have achieved the claimed invention given the Lead Prior Art may implicate questions of lack of straightforwardness and "reasonable expectations of success." Once Lead Prior Art is selected, modifications to that Lead Prior Art may be identified and evaluated to determine whether a POSITA could have achieved the claimed invention from the Lead Prior Art. That evaluation is then used in a determination of nonobviousness or of prima facie obviousness. Thus, rather than making a single, and quite possibly relatively difficult, determination of whether the differences between the prior art and the claimed invention as a whole would have been prima facie obvious, our methodology allows that difficult determination, given appropriate facts, to be partitioned into several simpler, objective determinations that lead to a deduction that the claimed invention is either nonobvious or prima facie obvious. A major goal, of course, is to reduce problems caused by hindsight bias, "pigeonholing," and/or lack of harmonized analytical methodology. Accordingly, we present our proposal, essentially a synthesis and extension of existing principles, as a step forward in obviousness analysis that can be utilized by patent prosecutors, patent litigators, and decision makers at both the United States Patent and Trademark Office ("USPTO") and in the relevant U.S. courts.*

## I. INTRODUCTION

There comes a point when the question [of patentable novelty] must be resolved by a subjective opinion as to what seems like an easy step and what does not. We must try to correct our standard by such objective references as we can, but in the end the judgment will appear, and no doubt be, to a large extent personal, and in that sense arbitrary. —Judge Learned Hand<sup>1</sup>

We can easily forgive a child who is afraid of the dark; the real tragedy of life is when men are afraid of the light. —Plato<sup>2</sup>

The Patent Act of 1952 is widely recognized as the greatest contribution to American patent law of the twentieth century.<sup>3</sup> One of its key components was 35 U.S.C. § 103, which established an objective test for patentability: whether a person of ordinary skill in the art would have found the claimed invention to be “obvious.”<sup>4</sup> Development of this objective test came in direct response<sup>5</sup> to

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1. *Kirsch Mfg. Co. v. Gould Mersereau Co.*, 6 F.2d 793, 794 (2d Cir. 1925) (Hand, L., J.). Although a careful reader may notice that Learned Hand’s quotation from 1925 predates the 1952 creation of 35 U.S.C. § 103, Learned Hand’s quotation nonetheless pertains to the same patentable novelty question whose current standard, from § 103, we now refer to as “obviousness.” Case law dating from at least the Supreme Court’s *Hotchkiss* decision in 1850 held that a minor variation from the prior art was not patentable even if the claimed invention was technically “novel” (i.e., “new.” See *Hotchkiss v. Greenwood*, 52 U.S. (1 How.) 248 (1850)). Courts and patent examiners since at least *Hotchkiss* have struggled mightily to determine whether variations from the prior art were “minor” and thus unpatentable, as discussed *infra*.

2. BOB KELLY, WORTH REPEATING: MORE THAN 5000 CLASSIC AND CONTEMPORARY QUOTES 120 (Kregel Academic & Professional 2003).

3. See George Sirilla, *35 U.S.C. § 103: From Hotchkiss to Hand to Rich, The Obvious Patent Law Hall-of-famers*, 32 J. MARSHALL L. REV. 437, 557 (1999) (“As we near the end of the 20th Century, we see that our country’s patent system is not only alive and well, but flourishing. That condition is due in no small part to the 1952 enactment of the 103 standard, and the vision and unremitting efforts of Learned Hand and Giles Rich in developing and propagating that standard.”).

4. See 35 U.S.C.A. § 103(a).

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

*Id.*

5. See S.R. Rep. No. 82-1979, at 6 (1952) (“[Future § 103] paraphrases language which has often been used in decisions of the courts, and the section is added to the statute for uniformity and definiteness. This section should have a stabilizing effect and minimize great

uncertain<sup>6</sup> and purely subjective tests<sup>7</sup> for patentability that courts applied prior to § 103. Although the evils of subjectivity may be impossible to completely remove from patentability determinations,<sup>8</sup> considerable reduction in the *amount* of subjectivity employed during patentability determinations seemed necessary. Enactment of § 103 represented a leap forward in that regard.

Judge Rich described the benefits of § 103 as follows:

The question will, of course, be asked, "What difference does [the addition of § 103] make, it must still be a subjective decision?" True, but now the statute provides a standard according to which the subjective decision must be made. There is a vast difference between basing a decision on exercise of the inventive or creative faculty, or genius, ingenuity, patentable novelty, flashes, surprises and excitement, on the one hand, and basing it on unobviousness to one of ordinary skill on the other. It is possible to determine what art is involved, what type of skill is possessed by ordinary workers in it, and come to some conclusion as to what "ordinary skill" would be at a given time. This may present knotty problems but it is a definite pattern of thinking and does not leave the Patent Office or the courts free to conclude that a thing is not patentable for any old reason and then stand on the proposition that something indefinable and impalpable called "invention" was not involved. At least they have to talk in terms of obviousness to a man of ordinary skill in the art. While the ultimate decision as to what his skill would be and what would be obvious to him is subjective, it is one definite proposition on which evidence can be adduced. The best the courts could do in the past was to assume, under certain sets of circumstances such as the existence of a long-felt want and

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departures which have appeared in some cases.").

6. See Giles S. Rich, *Why and How Section 103 Came to Be*, in *NONOBVIOUSNESS – THE ULTIMATE CONDITION OF PATENTABILITY 1:201-07* (John F. Witherspoon ed., 1980) (Speaking about the "invention" legal standard for determining whether a claimed invention was worthy of patent protection, author of § 103 and former Federal Circuit Judge Giles Sutherland Rich (Judge Rich) stated: "[i]nvention" was that 'beautiful uncertainty in the law' from which the Patent Bar made its living—practicing what was essentially a mystery.").

7. See Sirilla, *supra* note 3, at 472 ("The attitude of the Supreme Court toward patents from the turn of the century to before 1930 was mixed. At times, the Court used the *Hotchkiss* test, or variations of it, and at other times it used the so-called subjective tests, such as the 'inventive genius' test, the 'creative faculties' test, and the like.").

8. *Consolidated Rubber Tire Co. v. Diamond Rubber Co.*, 226 F. 455, 464 (2d Cir. 1915) (L. Hand, J.) ("At just what step of novelty the ingenuity of the skilled artisan becomes transmuted into the genius of an inventor, men will always differ, and their differences will be very largely dependent upon personal beliefs too remote for successful statement."); see also Sirilla, *supra* note 3, at 451 ("The problem of what is obvious and hence not patentable is still of necessity one of judgment.") (quoting P.J. Federico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1, 23 (1954)).

an immediate market acceptance of an invention, that there must have been “invention.”<sup>9</sup>

Nonetheless, “obviousness” has been and remains a frequently litigated issue in patent law,<sup>10</sup> as well as “the most common rejection made by patent examiners.”<sup>11</sup> The underlying determination—whether a claimed invention is sufficiently novel to justify patent protection<sup>12</sup>—has been characterized as one of the most difficult determinations in the field of law.<sup>13</sup> That situation does not diminish the contributions that § 103 has brought to patent law, but it reflects that further evolution is needed. Although § 103 brought a large measure of objectivity to questions of patentability,<sup>14</sup> hindsight remains an inherent and significant influence on an obviousness analysis.<sup>15</sup> As any judge, patent examiner, or patent practitioner realizes, anything can appear obvious when viewed with hindsight.<sup>16</sup>

Case law applying § 103 involves several objective factual determinations, collectively known as the *Graham*<sup>17</sup> factors, which include ascertaining “the differences between the claimed invention

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9. Giles S. Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393, 406 (1960).

10. See DONALD S. CHISUM, 2 CHISUM ON PATENTS § 5.06 (2003) (“The nonobviousness requirement of Section 103 is the most important and most litigated of the conditions of patentability.”); Samson Vermont, *A New Way to Determine Obviousness: Applying the Pioneer Doctrine to 35 U.S.C. § 103(a)*, 29 AIPLA Q.J. 375, 379-80 n.5 (2001) (“In the litigation context, validity challenges based on obviousness are more common than those based on novelty. Litigated patents are almost twice as likely to be found invalid for section 103 reasons than for section 102 ‘prior art reasons’ . . . .”) (citing John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 208 (1998) and George Edwards, *That Chumsy Word Nonobviousness*, 60 J. PAT. & TRADEMARK OFF. SOC’Y 3, 5-6 (1978)).

11. Sirilla, *supra* note 3, at 444 (Statement by Judge Giles Rich of the Court of Appeals for the Federal Circuit).

12. See *Bonito Boats Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989) (“[F]ederal patent law has been about the difficult business ‘of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.’”) (quoting 13 WRITINGS OF THOMAS JEFFERSON 335 (Memorial ed. 1904)).

13. See *Harries v. Air King Products Co.*, 183 F.2d 158, 162 (2d Cir. 1950) (Judge Learned Hand expressed this sentiment well, prior to § 103, more than sixty years ago: “[T]he question [of] whether there is a patentable invention . . . is as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts.”).

14. See discussion *infra* Section II.A.

15. Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1391 (2006) (“[T]he hindsight problem pervades patent law to an extent not previously recognized”).

16. See *Diamond Rubber Co. v. Consolidated Rubber Tire Co.*, 220 U.S. 428, 435 (1911) (“Knowledge after the event is always easy, and problems once solved present no difficulties[.]”).

17. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

and the prior art”<sup>18</sup> in view of the scope and content of the prior art and the level of skill in the art. Yet, problematically, the current structural barriers to applying hindsight during obviousness analysis sometimes lie only in economic secondary consideration evidence of sometimes limited persuasive power,<sup>19</sup> a statutory requirement to evaluate obviousness at the time of the invention,<sup>20</sup> and a requirement to establish a reason to combine or modify prior art references.<sup>21</sup> In practice, none of those current barriers, however, successfully vaccinates against hindsight.<sup>22</sup>

Hindsight during an obviousness analysis is particularly seductive when a factfinder has knowledge of an inventor’s solution.<sup>23</sup> Such hindsight often presents itself in the form of a primary prior art reference and several supporting prior art references that would not necessarily exist together outside the artificial environment of the obviousness analysis made in plain view of inventor’s solution. A party advocating obviousness can thus easily work backwards from the inventor’s solution to identify the references needed to support a prima facie case of obviousness.

For example, the primary reference may teach certain elements of the claimed invention but may not be a realistic starting point for creating the invention. Additionally, the secondary references may teach or suggest any claim elements not taught by the primary reference, but, except for hindsight, those references may not fit

18. See discussion *infra* Section II.A.

19. See discussion *infra* Section III.

20. See 35 U.S.C.A. § 103(a).

21. See *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1303 (Fed. Cir. 2010) (“But it is not enough to simply show that the references disclose the claim limitations; in addition, ‘it can be important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.’”) (quoting *KSR v. Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 401 (2007)); *Ex parte Ravi Subramanyam*, No. 2010-002463, 2010 WL 1253713, at \*3 (B.P.A.I. March 29, 2010) (“While the analysis under 35 U.S.C. § 103 allows flexibility in determining whether a claimed invention would have been obvious, *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007), it still requires showing that ‘there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.’ *Id.* ‘We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention.’ *Innogenetics, N.V. v. Abbott Labs.*, 512 F.3d 1363, 1374 n.3 (Fed. Cir. 2008).”).

22. See *Mandel*, *supra* note 15, at 1421-25 (discussing the ineffectiveness of secondary consideration evidence).

23. See *id.* at 1403 n.41 (“once an outcome is known, ‘it becomes difficult to accurately reconstruct a previous state of mind’”) (citing David A. Schkade & Lynda M. Kilbourne, *Expectation-Outcome Consistency and Hindsight Bias*, 49 *ORGANIZATIONAL BEHAV. & HUM. DECISION PROCESSES* 105, 108 (1991)); see also discussion *infra* Section II.C.

together with the primary reference in the context of the problem that the inventor faced or that the hypothetical person of ordinary skill in the art (“POSITA”) would face in trying to innovate further.<sup>24</sup> Thus, such references are not an accurate indication of whether an invention at the time it was made would have been *prima facie* obvious. Accordingly, the *Graham* factors, if not accurately applied, can unfairly prejudice a patentability determination in favor of a finding of obviousness and thus unpatentability.<sup>25</sup>

After discussing the current obviousness framework, this article analyzes the “lead compound” approach the Federal Circuit has applied when assessing obviousness of new chemical compounds. In those cases, in an attempt to avoid hindsight, the Federal Circuit analyzed the context in which a patent challenger (1) selected the starting compounds (“lead compounds”) and then (2) suggested subsequent modifications to these lead compounds to allege that the claimed chemical compounds would have been *prima facie* obvious.<sup>26</sup> In particular, the Federal Circuit expressly engaged in a determination of whether the prior art compounds proposed by the patent challenger would have been the compounds that a POSITA would have chosen as starting points for further innovation, based on an analysis of all relevant information available at the time the invention was made.<sup>27</sup>

Based on the legal framework from the “lead compound” cases, and as a first step of this methodology, we propose a process for selecting the proper prior art (“Lead Prior Art”) that should be used in a *prima facie* obviousness analysis. This methodology aims to avoid hindsight and is consistent with the application of the *Graham* factors requiring consideration of the scope and content of the prior art in view of the POSITA’s level of skill. Our methodology proposes a selection of prior art that discloses promising options to solve *any* problem for which the claimed invention could potentially be a solution. In general, any information that would have properly been

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24. In considering “the problem that the inventor faced” the authors of course take into the account the possibility that the inventor and POSITA do not necessarily have to face the same problem. See discussion *infra* Section IV.D.

25. See Mandel, *supra* note 15 (although the *Graham* factors provide a very helpful and legally binding framework for assessing obviousness, the results achieved through conscientious application of the *Graham* factors empirically indicate a clear bias in favor of finding obviousness).

26. See, e.g., *Takeda Chemical Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007); *Daiichi Sankyo Co., Ltd. v. Matrix Labs., Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010), *cert. denied*, 2011 WL 940897 (Mar 21, 2011).

27. See *Takeda Chemical Indus.*, 492 F.3d at 1356-57; *Daiichi Sankyo Co.*, 619 F.3d at 1346.



available to the POSITA that would have been useful in determining the desirability of one or more potential starting points is relevant to identification of the Lead Prior Art. Relevant available information includes teachings or suggestions in the prior art as well as inferences that would have been apparent to a POSITA based on ordinary creativity and common sense.

Once the factfinder selects one or more pieces or teachings of Lead Prior Art, the second step of this methodology provides for identifying and evaluating modifications of that Lead Prior Art to determine whether a POSITA would have had a reason to pursue one or more modifications to achieve the claimed invention. The process for identifying modifications to the Lead Prior Art parallels identification of the Lead Prior Art in important ways; all "relevant available information" would be considered. For example, this relevant available information includes teachings or suggestions in the prior art as well as inferences that would have been apparent to a POSITA based on ordinary creativity and common sense and are useful in determining the desirability of one or more potential modifications to the Lead Prior Art over others to achieve the claimed invention.

Once one or more modifications have been identified, the decision maker can draw informed conclusions of nonobviousness or of prima facie obviousness. For example, identification of the Lead Prior Art and identification of one or more modifications that would have allowed a POSITA to achieve the claimed invention in a straightforward manner justifies a conclusion of prima facie obviousness if reasonable expectations of success would have existed for the POSITA. By contrast, an inability to identify the Lead Prior Art that would have allowed a POSITA to achieve the claimed invention in a straightforward way or with a reasonable expectation of success, justifies a conclusion of nonobviousness.

In factual circumstances where *all* starting points and *all* available modifications could be *exhaustively* considered (i.e., where *all* prior art and suggestions therein, as well as *all* inferences therefrom are known and considered), a conclusion of nonobviousness per se would be logically appropriate if a Lead Prior Art could not be identified that could have led to the claimed invention. Conclusions of nonobviousness per se, however, would only be appropriate where the prior art is *exhaustively* identified. Thus, no "undiscovered" art or inferences therefrom would be possible. Factual practical circumstances that judges, practitioners, and patent examiners face may rarely lead to a conclusion of

nonobviousness per se, based on practical considerations of existing-but-undiscovered art in crowded fields.

By reducing a relatively difficult determination into a series of relatively easy determinations that allow for a deduction of nonobviousness or of prima facie obviousness, objectivity, reliability, and transparency of the determination can be significantly improved. When properly applied, Lead Prior Art provides a methodology for obviousness analysis that at least asymptotically approaches an objective analysis. Thus, proper application of Lead Prior Art may allow proponents of obviousness to make more persuasive arguments of prima facie obviousness. Additionally, opponents of obviousness and factfinders may analyze the veracity of such arguments more critically than would be possible under the existing obviousness rubric.

In addition to facilitating a logical and transparent obviousness determination, Lead Prior Art is designed to harmonize various principles and “negative rules for invention”<sup>28</sup> into a related set of affirmative considerations. Through that harmonization, a frequently-lamented aspect of patent law can be reduced or eliminated: a tendency for parties debating obviousness to characterize the claims at issue as fitting neatly within one of a series of discrete factual scenarios (i.e., to “pigeonhole” the claims).<sup>29</sup> Under the existing obviousness rubric, if a litigant or patent examiner is successful in fitting a claim into a “negative rule for invention” (e.g., “obvious to try,”<sup>30</sup> “known elements achieving predictable results”<sup>31</sup>, etc.), a finding of prima facie obviousness is difficult to avoid notwithstanding other legitimate patentability considerations.<sup>32</sup> By turning the “negative rules for invention” into affirmatives that are part of an overall framework, Lead Prior Art diminishes or removes incentives for any participant<sup>33</sup> in the obviousness analysis to

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28. See CHISUM, *supra* note 10, at § 5.04[5][a] (“Negative Rules for Invention”); see also Sirilla, *supra* note 3, at 442 (referring to “negative tests for invention”).

29. See *In re Dillon*, 892 F.2d 1554, 1567 (Fed. Cir. 1989) (“We join the [United States Court of Customs and Patent Appeals] in deploring the ‘formal exercise of squeezing new factual situations into preestablished pigeonholes.’”) (quoting *In re Yates*, 663 F.2d 1054, 1056 n.4 (C.C.P.A. 1981)), *withdrawn and superseded on reh’g*, 919 F.2d 688 (Fed. Cir. 1990).

30. See discussion *infra* Section II.A.2.

31. See discussion *infra* Section II.A.2.

32. See discussion *infra* Section V.D.

33. Although the examples of factual scenarios noted above involve arguments of prima facie obviousness, any participant in an obviousness analysis could fall victim to pigeonholing: a proponent of obviousness, an opponent of obviousness inappropriately arguing “unexpected results,” and even a judge or patent examiner.

pigeonhole claims or place undue reliance on argument rather than objective analysis.

The harmonizing effect of Lead Prior Art should preclude disrupting any settled expectations relative to the existing obviousness framework,<sup>34</sup> except in cases where hindsight was an influential yet inappropriate factor in outcomes. Accordingly, Lead Prior Art should provide consistency with existing case law in many settings and enhanced clarity, transparency, and intellectual defensibility in difficult cases. For these reasons, we believe that the Lead Prior Art methodology is a worthy extension of the objective test introduced in § 103 and represents a meaningful contribution to the practice of patent law.

## II. THE EXISTING OBVIOUSNESS RUBRIC

The existing legal framework for analyzing obviousness represents a decades-long effort to apply an objective test for patentability under 35 U.S.C. § 103, using the tools articulated by the Supreme Court in *Graham v. John Deere Co. of Kansas City*.<sup>35</sup> This effort has attempted to avoid hindsight and continues to attempt to avoid hindsight while determining which inventions are patentable.<sup>36</sup> This section of the article describes the Supreme Court's *Graham* tools (the "*Graham* Factors"<sup>37</sup>) and their place in the existing obviousness rubric. Issues associated with "negative rules for invention"<sup>38</sup> in the context of the *Graham* Factors are discussed. Then, the authors address requirements for a prima facie case of obviousness. This section will facilitate the reader's understanding of the why Lead Prior Art is consistent with the existing obviousness rubric.

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34. See discussion *infra* Section V.D.

35. *Graham v. John Deere Co.* 383 U.S. 1 (1966).

36. See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007) ("A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning."); see *Graham*, 383 U.S. at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "guard against slipping into use of hindsight") (quoting *Monroe Auto Equip. Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 (6th Cir. 1964)).

37. See *Siemens Medical Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, Nos. 2010-1145, 2010-1177, 2011 WL 651790, at \*8 (Fed. Cir. 2011) ("Obviousness . . . requires analysis under the four *Graham* factors.").

38. See discussion *supra* Section I and *infra* Section V.D.

### A. Graham/KSR

As noted in Section I, *infra*, when § 103 was added to the Patent Law in 1952, it was a major development: an objective standard by which to judge obviousness during a patentability determination. Prior to 1952, case law described standards of patentability in terms of “ingenuity” and “genius.” For example, in *Sinclair & Carroll Co. v. Interchemical Corp.*,<sup>39</sup> the Supreme Court noted:

A long line of cases has held it to be an essential requirement for the validity of a patent that the subject-matter display ‘*invention*’, ‘*more ingenuity* \* \* \* than the work of a mechanic skilled in the art.’ . . . This test is often difficult to apply; but its purpose is clear. Under this test, some substantial innovation is necessary, an innovation for which society is truly indebted to the efforts of the patentee.<sup>40</sup>

And in *Cuno Engineering Corp. v. Automatic Devices Corp.*:<sup>41</sup>

[T]he new device, however useful it may be, must reveal the *flash of creative genius* not merely the skill of the calling. If it fails, it has not established its right to a private grant on the public domain.<sup>42</sup>

Similarly, in *In re Holt*:<sup>43</sup>

It seems to us that appellant, by building his structure in the manner defined by the appealed claims has made such a useful improvement in the art, under the circumstances and facts heretofore stated, that it should not be held that he had done that only which would be obvious to the skilled mechanic without the exercise of *inventive genius* and that he is entitled to a patent as a regard for his labors . . . .<sup>44</sup>

The Supreme Court first interpreted § 103 in 1966 and set forth a framework for analyzing obviousness in *Graham v. John Deere Co. of Kansas City*.<sup>45</sup> The *Graham* framework is consistent with an objective standard for determining patentability<sup>46</sup> and is fundamental to the existing obviousness rubric. The *Graham* Court recognized that

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39. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327 (1945).

40. *Id.* at 330 (emphasis added).

41. *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U.S. 84 (1941).

42. *Id.* at 91 (emphasis added).

43. *In re Holt*, 162 F.2d 472 (C.C.P.A. 1947)(emphasis added).

44. *Id.* at 477.

45. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

46. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007) (“In *Graham* . . . , the Court set out a framework for applying the statutory language of § 103 . . . . The analysis is objective . . .”).

§ 103 was intended to move the standard for patentability from a subjective “inventive genius” test to an objective test:

It also seems apparent that Congress intended by the last sentence of § 103 to abolish the test it believed this Court announced in the controversial phrase “flash of creative genius,” used in *Cuno*.[<sup>47</sup>

The Court went on to explain that the obviousness inquiry was a legal question supported by factual findings:

While the ultimate question of patent validity is one of law, the § 103 condition, . . . lends itself to several basic factual inquiries.<sup>48</sup>

Four underlying factual issues were identified, consistent with an objective standard for determining patentable inventiveness:

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. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such [objective indicia] 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.<sup>49</sup>

For the purposes of this article, the *Graham* Factors will be identified by number as:

- Factor 1: scope and content of the prior art;
- Factor 2: differences between the prior art and the claims at issue;
- Factor 3: level of ordinary skill in the pertinent art; and
- Factor 4: objective indicia.

In April 2007, the Supreme Court confirmed the *Graham* Factors as the proper framework for determining obviousness in *KSR*:<sup>50</sup>

In *Graham v. John Deere Co. of Kansas City*,<sup>51</sup> the Court set out a framework for applying the statutory language of § 103, language itself based on the logic of the earlier decision in *Hotchkiss v. Greenwood*<sup>52</sup> and its progeny.<sup>53</sup> The analysis is objective:

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47. *Graham*, 383 U.S. at 15.

48. *Id.* at 17 (citation omitted).

49. *Id.* at 17-18.

50. *See KSR*, 550 U.S. at 406-07.

51. *Graham*, 383 U.S. at 17-18.

52. *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1850).

53. *See Graham*, 383 U.S. at 15-17.

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. Against this background, the obviousness or nonobviousness of the subject matter is determined. 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.<sup>54</sup>

While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid or unpatentable under § 103.<sup>55</sup>

#### 1. Application of the *Graham* Factors

##### a) *Graham Factor 1: Scope and Content of the Prior Art*

In ascertaining *Graham* Factor 1, the scope and content of the prior art, one must first determine what constitutes legally-cognizable prior art.<sup>56</sup> In making this initial determination, one considers the earliest effective date of the publication or patent or the exact date of any alleged prior knowledge, use or sale to see if it “fits” into one or more subparagraphs of 35 U.S.C. § 102. Section 102 establishes what qualifies as prior art for both anticipation and obviousness purposes, but prior art for § 103 purposes can also be created by the admissions of the parties.<sup>57</sup>

The scope and content of the prior art is important to the Lead Prior Art methodology because that methodology identifies one or more starting points and one or more modifications to such starting points from the prior art. As will be discussed further *infra*,<sup>58</sup>

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54. *Id.* at 17-18.

55. *KSR*, 550 U.S. at 407.

56. *See Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987) (“Before answering *Graham*’s ‘content’ inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102.”).

57. *Riverwood Int’l Corp. v. R.A. Jones & Co., Inc.*, 324 F.3d 1346, 1354 (Fed. Cir. 2003) (citing *In re Fout*, 675 F.2d 297, 301 (C.C.P.A. 1982)); *Tyler Refrigeration v. Kysor Indus. Corp.*, 777 F.2d 687, 690 (Fed. Cir. 1985); *see In re Nomiya*, 509 F.2d 566, 570-71 (C.C.P.A. 1975).

58. *See* discussion *infra* Section V.C.

evaluation of starting points and modifications may allow for a deduction of nonobviousness or of prima facie obviousness. Therefore, a determination of the scope and content of the prior art is fundamental to obviousness analysis, in general, and Lead Prior Art, specifically.

A POSITA will not likely know about prior art in a different and unrelated field of technology. Such art, therefore, would not have rendered an invention obvious.<sup>59</sup> But, as explained in *In re Clay*, a reference relating to a field of endeavor differing from the inventor's may still be relevant prior art if "it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."<sup>60</sup>

If there is relevant prior art, the analysis of its scope and content (*Graham* Factor 1) must consider the prior art *as a whole*; it is not proper to "pick and choose" or isolate portions of references from the whole.<sup>61</sup> As explained by the Federal Circuit in *Panduit*:

Among legal standards for determining scope and content of the prior art, for example, are: a prior patent must be considered in its entirety, i.e., as a whole, including portions that would lead away from the invention in suit, *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550, 220 USPQ 303, 311 (Fed.Cir. 1983), *cert. denied*, 469 U.S. 851, 105 S.Ct. 172, 83 L.Ed.2d 107 (1984); elements of separate prior patents cannot be combined when there is no suggestion of such combination anywhere in those patents, *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984); and a court should avoid hindsight, *W.L. Gore & Assocs., Inc.*, 721 F.2d at 1553, 220 USPQ at 313.<sup>62</sup>

The "prior art as a whole" principle corresponds to the statutory requirement that the claimed invention subject matter is considered

59. *In re Clay*, 966 F.2d 656, 658-59 (Fed. Cir. 1992). *See also In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992); *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986); MANUAL OF PATENT EXAMINING PROCEDURE, PAT. & TRADEMARK OFFICE, U.S. DEP'T OF COMMERCE § 2141.01(a) (8th ed. Rev. 8, July 2010) [hereinafter M.P.E.P.].

60. *Clay*, 966 F.2d at 659 ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem."); *In re ICON Health and Fitness, Inc.*, 496 F.3d 1374, 1379-80 (Fed. Cir. 2007).

61. *See In re Kuderna*, 426 F.2d 385, 389 (C.C.P.A. 1970); *In re Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965); *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1348 (Fed. Cir. 2010) (quoting *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 810 (1986)).

62. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568 (Fed. Cir. 1987).

“as a whole.”<sup>63</sup>

An obviousness analysis is, of course, vulnerable to impermissible hindsight when a factfinder has knowledge of an inventor’s solution.<sup>64</sup> Hindsight in the context of *Graham* Factor 1 means using the inventor’s disclosure to determine the scope and content of the prior art, rather than objectively determining what a POSITA, at the time of the invention, would consider the specific scope and content of the prior art for further innovation. Using Lead Prior Art when assessing the scope and content of the prior art (*Graham* Factor 1) helps the factfinder avoid hindsight because it ensures that the factfinder is objectively determining the correct scope and content of the prior art: that which a POSITA would have considered the most “sensible starting point(s)” in the context of whatever problem the POSITA faced at the time of the invention.

*b) Graham Factor 2: Differences Between the Prior Art and the Claimed Invention*

The requirement to consider the prior art “as a whole” leads logically to *Graham* Factor 2: differences between the prior art and the claims at issue.<sup>65</sup> Once the scope and content of the prior art is known, a comparison between that prior art and the claimed invention is appropriate to determine any differences. Analysis of *Graham* Factor 2 involves construing the claims at issue and comparing them to the prior art.<sup>66</sup> As noted above, comparison of the construed claims is performed relative to the prior art *as a whole*, because “[i]t is

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63. See 35 U.S.C.A. § 103(a); *Jones v. Hardy*, 727 F.2d 1524, 1530, (Fed. Cir. 1984) (treating an unclaimed advantage as the gist of the patented invention “disregards the statutory requirement that the invention be viewed ‘as a whole’, ignores the problem-recognition element, and injects an improper ‘obvious to try’ consideration”); *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004) (“The ‘as a whole’ instruction in title 35 prevents evaluation of the invention part by part. . . . This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result—often the very definition of invention.”).

64. See discussion *infra* Section II.C; see also *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988) (“One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983) (“To imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. . . . [T]he decisionmaker [must] cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art.”).

65. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966).

66. See *Panduit*, 810 F.2d at 1566-68.



impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.”<sup>67</sup>

*Graham* Factor 2 is another component of obviousness analysis where hindsight may arise due to a temptation to use the claimed invention as the roadmap through the prior art, seeing signposts and similarities that are only visible because of the disclosure.<sup>68</sup> The Federal Circuit explained in *Princeton Biochemicals, Inc. v. Coulter, Inc.*:

As this court outlined in *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004), in making the assessment of differences between the prior art and the claimed subject matter, section 103 specifically requires consideration of the claimed invention “as a whole.” . . . The “as a whole” instruction in title 35 prevents evaluation of the invention part by part. . . . Without this important requirement, an obviousness assessment might successfully break an invention into its component parts, then find a prior art reference corresponding to each component. . . . This line of reasoning would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result—often the essence of invention.<sup>69</sup>

An objective assessment of the differences between the prior art and the claimed invention (*Graham* Factor 2), including all properties and

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67. *In re Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965); *see also* *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448-49 (Fed. Cir. 1986) (holding that the district court, by failing to consider a prior art reference in its entirety, ignored portions of the reference that led away from obviousness); *In re Boe*, 355 F.2d 961, 965 (C.C.P.A. 1966) (all of the disclosures in a reference, including non-preferred embodiments, “must be evaluated for what they fairly teach one of ordinary skill in the art”); *Merck & Co. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) (“the fact that a specific [embodiment] is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered”) (quoting *In re Lamberti*, 545 F.2d 747, 750 (C.C.P.A. 1976)).

68. *See Fine*, 837 F.2d at 1075 (“One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”); *see also* discussion *infra* Section II.C.

69. *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 411 F.3d 1332, 1337 (Fed. Cir. 2005) (internal citations omitted). *See also* *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004) (“The ‘as a whole’ instruction in title 35 prevents evaluation of the invention part by part. . . . This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result—often the very definition of invention.”).

in the context of whatever problem the POSITA faced at the time of the invention, will shed light on what a POSITA would have considered the most sensible starting point(s) in the prior art.

Lead Prior Art relies on an awareness of the differences between the prior art and the claimed invention as a whole to direct objective analysis toward those elements of the claimed invention that are not present in a particular Lead Prior Art starting point, as discussed *infra*.<sup>70</sup> By recognizing the differences between the Lead Prior Art starting point and the claimed invention, this analysis can determine whether teachings or suggestions in the prior art, or application of common sense and ordinary creativity would allow for modifying the starting point prior art to achieve the claimed invention. If so, a starting point prior art can be modified in pursuit of achieving the claimed invention.<sup>71</sup> Accordingly, the differences between the prior art and the claimed invention as a whole are very influential to the obviousness analysis in general and Lead Prior Art specifically.

c) *Graham Factor 3: Level of Ordinary Skill in the Art*

Determining “[t]he level of ordinary skill in the art” is required by *Graham* Factor 3.<sup>72</sup> The actual inventor’s skill is irrelevant because the inventor does not necessarily represent a worker of ordinary skill.<sup>73</sup> By focusing on the level of skill of the POSITA rather than the actual inventor in the determination of *Graham* Factor 3, a factfinder maintains an objective perspective and avoids hindsight.<sup>74</sup>

A POSITA represents a hypothetical person presumed to be aware of all pertinent prior art in the area of the invention.<sup>75</sup> A

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70. See discussion *infra* Section IV.

71. See discussion *infra* Section V.

72. See *In re* GPAC Inc., 57 F.3d 1573, 1579 (Fed. Cir. 1995).

73. See *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 448 (Fed. Cir. 1986) (citing *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985)); *Stewart-Warner Corp. v. City of Pontiac*, 767 F.2d 1563, 1570 (Fed. Cir. 1985); *Environmental Designs, Ltd. v. Union Oil Co. of Cal.*, 713 F.2d 693, 697 (Fed. Cir. 1983) (evaluating obviousness requires ascertaining what would have been obvious to the ordinary skilled person, not to the inventor, judge, layman, those skilled in remote arts, or geniuses in the art at hand).

74. See discussion *infra* Section II.C.

75. *In re* Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998) (“Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. See 35 U.S.C. § 103(a). . . . The legal construct also presumes that all prior art references in the field of the invention are available to this hypothetical skilled artisan. See *In re* Carlson, 983 F.2d 1032, 1038, 25 U.S.P.Q.2d 1207, 1211 (Fed. Cir. 1993).”).

POSITA also possesses ordinary creativity and exercises common sense when analyzing the available knowledge in the art.<sup>76</sup>

A dispute over *Graham* Factor 3 may arise in the context of a dispute over the relevant scope and content of the prior art (*Graham* Factor 1). The Federal Circuit faced an example of this in *Dystar*:<sup>77</sup> “[T]he parties disagree over the relevance of the cited prior art, which, fundamentally, is a disagreement over the level of ordinary skill in the art . . . .”<sup>78</sup> Finding a higher “level of ordinary skill in the art,” may mean a broader “scope and content of prior art.”<sup>79</sup> The “level of skill in the art” may also assist the factfinder in an obviousness analysis if the issue is whether the claimed invention was “obvious to try,”<sup>80</sup> particularly in the context of optimizing parameters.<sup>81</sup>

One of the most important contributions of *Graham* Factor 3 to the obviousness analysis is to remind the factfinder of the requirement to evaluate obviousness from the objective perspective of a POSITA who would have been working in the art at the time the invention was made.<sup>82</sup> As explained by the Federal Circuit in *Al-Site Corp. v. VSI Intern., Inc.*:<sup>83</sup>

In the first place, the level of skill in the art is a prism or lens through which a judge or jury views the prior art and the claimed invention. This reference point prevents these deciders from using

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76. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007); *W. Union Co. v. MoneyGram Payment Sys, Inc.*, 626 F.3d 1361, 1371 (Fed. Cir. 2010).

77. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006).

78. *Id.* at 1361-62; *see also* *Litton Indus. Prods., Inc. v. Solid State Sys. Corp.*, 755 F.2d 158, 163-64 (Fed. Cir. 1985).

79. *See* *Innovation Toys, LLC v. MGA Entertainment, Inc.*, No. 2010-1290, 2011 WL 941563, at \*8 (Fed. Cir. 2011). (“A less sophisticated level of skill generally favors a determination of nonobviousness, and thus the patentee, while a higher level of skill favors the reverse.”).

80. *See* discussion *infra* Section II.A.2.

81. *See, e.g., Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1350 (Fed Cir. 2009) (“Ecolab’s expert admitted that one skilled in the art would know how to adjust application parameters to determine the optimum parameters for a particular solution. The question then is whether it would have been obvious to combine the high pressure parameter disclosed in the Bender patent with the PAA methods disclosed in FMC’s ‘676 patent. The answer is yes.”); *see also* Examination Guidelines Update: Developments in the Obviousness Inquiry After *KSR v. Teleflex*, 75 Fed. Reg. 53,643, 53,648 (Sept. 1, 2010) [hereinafter 2010 KSR Guidelines Update] (“If optimization of the application parameters had not been within the level of ordinary skill in the art, the outcome of the *Ecolab* case may well have been different.”).

82. *See* *Ryko Mfg. Co. v. Nu-Star Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991) (“The importance of resolving the level of ordinary skill in the art lies in the necessity of maintaining objectivity in the obviousness inquiry.”).

83. *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308 (Fed. Cir. 1999).

their own insight or, worse yet, hindsight, to gauge obviousness. . . . Skill in the art does not act as a bridge over gaps in substantive presentation of an obviousness case, but instead supplies the primary guarantee of objectivity in the process.<sup>84</sup>

With the objective information provided by *Graham* Factor 3 (“level of skill” of POSITA), the factfinder can proceed with the determination of whether the claimed subject matter would have been obvious to a POSITA at the time of the invention.

d) *Graham Factor 4: Objective Indicia*

In *Graham v. John Deere Co. of Kansas City*,<sup>85</sup> the Supreme Court instructed that “secondary considerations,” such as “commercial success, long felt but unsolved needs, failure of others, etc., . . . may have relevancy.”<sup>86</sup> i.e., objective factors that may show that an invention was not obvious from the prior art. Post-*Graham* case law filled in “etc.” with other “objective indicia”: copying, licensing activity, teaching away, and unexpected results.<sup>87</sup> The Courts often refer to *Graham* Factor 4 “secondary considerations” as “objective indicia of nonobviousness.”<sup>88</sup> Similarly, this article will use the term “objective indicia of nonobviousness.” Analysis of objective indicia applies in both *ex parte* patent examination<sup>89</sup> and *inter partes* patent litigation.<sup>90</sup>

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84. *Id.* at 1324.

85. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

86. *Id.* at 17-18; *see also* *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

87. *See* *Arkie Lures, Inc. v. Gene Larew Tackle, Inc.*, 119 F.3d 953, 957 (Fed. Cir. 1997) (“In this case the considerations of commercial success, licensing activity, and copying were markedly prevalent, and were not disputed. Such aspects may be highly probative of the issue of nonobviousness.”); *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1245 (Fed. Cir. 2010) (“Wyers presented evidence of secondary indicia of nonobviousness, including commercial success, copying, and unexpected results.”).

88. *See* *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1338-39 (Fed. Cir. 2008) (“These underlying factual findings . . . include the familiar *Graham* factors: the scope and content of the prior art, the differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and secondary considerations, otherwise known as objective indicia of nonobviousness.”) (citing *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966).); *Ecolab Inc. v. FMC Corp.*, 569 F.3d 1335, 1349 (Fed. Cir. 2009).

89. *See* *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997) (“Rather than permit a court to ignore evidence of unexpected results, *In re* Soni makes clear that such evidence must be considered in evaluating the obviousness of a claimed invention. In arriving at its judgment regarding whether the claimed invention would have been obvious, the trial court should have given appropriate weight to the evidence of unexpected results. . . . This proposition holds not only in *ex parte* proceedings before the PTO but also in *inter partes* proceedings in the district courts.” (internal citation omitted)).

90. *See* *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (“It is jurisprudentially inappropriate to disregard any relevant evidence on any issue in any case,

Objective indicia evidence may be submitted to rebut a prima facie case of obviousness,<sup>91</sup> and it may also have relevance in the determination of whether a prima facie case of obviousness has been established.<sup>92</sup> The prima facie case of obviousness is discussed in detail in *Section II.B*, *infra*. Objective indicia of nonobviousness provide an objective indication of economic and motivational issues and enlighten whether the POSITA would have started with the allegedly invalidating prior art and modified it in such a way as to have arrived at the claimed invention.<sup>93</sup>

Federal Circuit case law has recognized the importance of objective indicia as a check on impermissible hindsight.<sup>94</sup>

In determining the question of obviousness, inquiry should always be made into whatever objective evidence of nonobviousness there may be. *Connell v. Sears Roebuck & Co.*, 722 F.2d 1542, 1549, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983). *The so-called "secondary considerations" can often prevent a court from slipping into an impermissible hindsight analysis.* They should be considered as a *fourth* factual inquiry under *Graham* before coming to a conclusion concerning obviousness.<sup>95</sup>

Claimed inventions that may have been obvious through hindsight bias might not truly be obvious under an unbiased evaluation. Objective indicia reduces impermissible hindsight and provides indirect evidence of the nonobviousness of the claimed invention. Hindsight will be explored in detail in *Section II.C*, *infra*.

According to the Federal Circuit in *Geo M. Martin Co. v. Alliance Machine Systems Intern. LLC*,<sup>96</sup> *Graham* Factor 4 must be addressed if the evidence is of record:

Secondary considerations of non-obviousness must be considered when present. *Sud-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1008 (Fed. Cir. 2009). As the Supreme Court recently

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patent cases included. Thus evidence rising out of the so-called "secondary considerations" must always when present be considered en route to a determination of obviousness. (citations omitted)".

91. See *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1293 (Fed. Cir. 2006) ("After making these factual determinations, it concluded that Mylan had established a strong prima facie case of obviousness, which Alza had failed to rebut through secondary considerations.").

92. See discussion *infra* Section II.B.

93. See discussion *infra* Section III.

94. See discussion *infra* Section II.C.

95. *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984) (first emphasis added) (citation omitted) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549 (Fed. Cir. 1983); *Stratoflex*, 713 F.2d at 1538).

96. *Geo M. Martin Co. v. Alliance Mach. Sys. Int'l LLC*, 618 F.3d 1294 (Fed. Cir. 2010).

reaffirmed, “[s]uch 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.” *KSR*, 550 U.S. at 406, 127 S.Ct. 1727 (quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966)).<sup>97</sup>

Objective indicia may show that the allegedly invalidating prior art was *not* suggested by the prior art and the general level of knowledge in the field. If that is the case, then that prior art would not have been a “sensible starting point” for a POSITA and would not have been part of the Lead Prior Art.<sup>98</sup>

With any type of objective indicia evidence, an applicant/patentee bears the burden of establishing a nexus between the merits of the claimed invention and the evidence.<sup>99</sup> Specifically, that means the applicant/patentee must show that the objective indicia evidence is the result of the inventive aspect of the claimed subject matter.<sup>100</sup> For example, commercial success resulting from an advertising campaign or packaging does not have a sufficient nexus to the invention to rebut a *prima facie* case of obviousness.<sup>101</sup> In *Hearing Components, Inc. v. Shure Inc.*,<sup>102</sup> the Federal Circuit found a sufficient nexus between the evidence of commercial success and the inventive aspect of the invention. The evidence showed that “the licensing fee for a covered product was more than cut in half

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97. *Id.* at 1304; *see also* *TriMed, Inc. v. Stryker Corp.*, 608 F.3d 1333, 1343 (Fed. Cir. 2010) (“We have repeatedly held that evidence of secondary considerations must be considered if present. . . . ‘Our precedents clearly hold that secondary considerations, when present, must be considered in determining obviousness.’”) (quoting *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 667 (Fed. Cir. 2000)).

98. *See* discussion *infra* Section IV.

99. *See In re Huang*, 100 F.3d 135, 140 (Fed. Cir. 1996); *In re GPAC, Inc.*, 57 F.3d 1573, 1580 (Fed. Cir. 1995) (“For objective evidence to be accorded substantial weight, its proponent must establish a nexus between the evidence and the merits of the claimed invention.”); *Wyers v. Master Lock Co.*, 616 F.3d 1231, 1246 (Fed. Cir. 2010) (“Our case law clearly establishes that the patentee must establish a nexus between the evidence of commercial success and the patented invention.”).

100. *See W. Union Co. v. MoneyGram Payment Sys., Inc.*, 626 F.3d 1361, 1373 (Fed. Cir. 2010) (“Here, Western Union failed to present any relevant evidence proving a nexus between its commercial success and its claimed invention. . . . It cannot therefore claim any commercial success that arose from features of the system found in the prior art as a consideration for nonobviousness of its claimed invention.”).

101. *See McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1370 (Fed. Cir. 2003) (“The court found that McNeil had launched a massive marketing and advertising campaign in connection with the launch of the Imodium<sup>®</sup> Advanced product, obscuring any nexus that might have existed between the merits of the product and its commercial success.”).

102. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357 (Fed. Cir. 2010).

immediately upon the expiration of the . . . patent, supporting its contention that the success of the device was related to the patent.”<sup>103</sup>

“Unexpected results” are often characterized in the case law as an “objective indicia” for rebutting the prima facie cases of obviousness, even though it is not listed in *Graham*.<sup>104</sup> Unexpected results are evidence that a POSITA would not have expected success from the modification to the prior art, and was therefore unlikely to make that modification.<sup>105</sup>

Unexpected results may be disclosed in the specification, or may involve testing to show that the claimed invention possesses “unexpectedly improved properties or properties that the prior art does not have,”<sup>106</sup> or that “a person of ordinary skill in the relevant art would have found surprising or unexpected.”<sup>107</sup>

“Teaching away” is considered objective indicia evidence that will rebut a prima facie case of obviousness.<sup>108</sup> A reference “teaches away” from the claimed invention when a POSITA, upon reading the reference, may have been led in a direction divergent from the path that was taken by the applicant.<sup>109</sup> In *DePuy Spine, Inc. v. Medtronic Sofamor Danek*,<sup>110</sup> the Federal Circuit explained that a reference teaches away if it shows that a proposed modification would not work

103. *Id.* at 1374-75.

104. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966) (“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.”); *In re Glatt*, 630 F.3d 1026, 1028 (Fed. Cir. 2011) (“In addition to traversing the examiner’s obviousness rejection, Glatt offered various types of secondary considerations evidence, including evidence of unexpected results, long-felt need, and commercial success due to the improvement, to rebut the examiner’s prima facie case.”); *Daiichi Sankyo Co. v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1351-52 (Fed. Cir. 2010) (“Finally, the district court concluded that even if Mylan had established a *prima facie* case of obviousness, secondary considerations counseled against a finding of obviousness. Specifically, the court found evidence of unexpected results in olmesartan medoxomil’s enhanced potency and other favorable biological properties.”) (citations omitted).

105. *See Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009).

106. *Id.* at 997 (quoting *In re Dillon*, 919 F.2d 688, 692-93 (Fed. Cir. 1990)).

107. *Id.* at 994 (quoting *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995)).

108. *See In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003) (“[A]n applicant may rebut a *prima facie* case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect.”).

109. *Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1328 (Fed. Cir. 1998) (“[I]n general, a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.”) (quoting *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130, 1131 (Fed. Cir. 1994)).

110. *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009).

for the intended purpose:

[t]he opposite conclusion would follow, however, if the prior art indicated that the invention would not have worked for its intended purpose or otherwise taught away from the invention. See *United States v. Adams*, 383 U.S. 39, 52, 86 S.Ct. 708, 15 L.Ed.2d 572 (1966) (upholding nonobviousness where references teaching away from the claimed combination would “deter any investigation into such a combination”); *In re ICON Health & Fitness, Inc.*, 496 F.3d 1374, 1382 (Fed.Cir.2007) (“[A] reference teaches away from a combination when using it in that combination would produce an inoperative result.”). An inference of nonobviousness is especially strong where the prior art’s teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.<sup>111</sup>

Another form of “teaching away” is when some teachings of the prior art conflict with other parts of the same reference or another reference.<sup>112</sup> Since the prior art must be evaluated “as a whole,”<sup>113</sup> everything in the prior art must be considered. “Teaching away” evidence reflects the assumption that a POSITA, at the time of the invention, evaluates all the pros and cons of the prior art teachings. In terms of Lead Prior Art, this evaluation would determine a “sensible starting point.” Sufficient conflict in the prior art may be considered a teaching away because a POSITA would have no reason to expect success from combining or modifying the references. As noted by the Federal Circuit in *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*,<sup>114</sup> “[a]n inference [that a claimed combination would not have been obvious] is especially strong where the prior art’s teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements.”<sup>115</sup>

A POSITA at the time of the invention would not have considered a prior art reference that taught away to be a “sensible starting point” for developing the claimed subject matter. Instead, the POSITA would have been led in a different direction by the teachings

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111. *Id.* at 1326.

112. See *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) (“Where the prior art contains ‘apparently conflicting’ teachings (i.e., where some references teach the combination and others teach away from it) each reference must be considered ‘for its power to suggest solutions to an artisan of ordinary skill. . . . consider[ing] the degree to which one reference might accurately discredit another.’”) (quoting *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991)).

113. See 35 U.S.C.A. § 103(a).

114. *DePuy Spine, Inc.*, 567 F.3d 1314.

115. *Id.* at 1326.



of the prior art.

## 2. “Negative Rules to Invention”

Various “negative rules to invention” related to the obviousness inquiry have developed in the case law.<sup>116</sup> Some, such as “obvious to try,” and “known elements achieving predictable results” are discussed in detail, *infra*.<sup>117</sup> The danger presented by “negative rules to invention” is that the factfinder pigeonholes the specific circumstances as one of the “negatives to invention” rather than conducting a full, fact-specific inquiry, as mandated by the Supreme Court in *Graham v. John Deere Co. of Kansas City*<sup>118</sup> and Federal Circuit precedent.<sup>119</sup> Such labeling is also contrary to the explicit instructions from the USPTO to the examiners:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q. 2d 1329, 1336 (Fed. Cir. 2006), stated that “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”<sup>120</sup>

The Supreme Court described “obvious to try” in *KSR* as:

When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.<sup>121</sup>

The USPTO *2010 Guidelines*<sup>122</sup> discuss the appropriate use of “obvious to try” in detail:

116. See CHISUM, *supra* note 10, at § 5.04[5][a].

117. See *infra* notes 118 and 121.

118. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966).

119. See *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1089 (Fed. Cir. 2008) (“The determination of obviousness is dependent on the facts of each case.”).

120. M.P.E.P., *supra* note 59, at § 2141.

121. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

122. 2010 *KSR Guidelines Update*, *supra* note 81, at 53,643.

[T]his rationale is only appropriate when there is a recognized problem or need in the art; there are a finite number of identified, predictable solutions to the recognized need or problem; and one of ordinary skill in the art could have pursued these known potential solutions with a reasonable expectation of success.<sup>123</sup>

“Known elements achieving predictable results” represents another example of a “negative rule to invention.”<sup>124</sup> Such subject matter would normally be considered obvious.<sup>125</sup> In *Agrizap, Inc. v. Woodstream Corp.*,<sup>126</sup> for example, the court concluded that the only difference between the claimed device and the prior art device was an electrical switch rather than a mechanical switch.<sup>127</sup> In addition, using an “animal body as a resistive switch to complete a circuit for the generation of an electric charge was already well known in the prior art.”<sup>128</sup> The Federal Circuit concluded that the facts in *Agrizap* presented a strong case of obviousness, and, in fact, “a textbook case of when the asserted claims involve a combination of familiar elements according to known methods that does no more than yield predictable results.”<sup>129</sup>

*Ecolab, Inc. v. FMC Corp.*<sup>130</sup> provides another case law example of the “negative to invention,” “known elements achieving predictable results.” In *Ecolab*, the Federal Circuit found the claimed subject matter obvious in light of known prior art elements, a reason to combine these known prior art elements, and the technical ability to do so.<sup>131</sup>

Rather than justifying a superficial pronouncement, this article advocates for a fact-specific inquiry into obviousness, in the context of the subject matter in question, “including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest.”<sup>132</sup> By relying on labels rather than articulated analysis, the obviousness inquiry gets short-

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123. *Id.* at 53,653.

124. See CHISUM, *supra* note 10, at § 5.04[5][c].

125. See 35 U.S.C.A. § 103(a).

126. *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008).

127. See *id.* at 1344.

128. *Id.*

129. *Id.*; see also 2010 KSR Guidelines Update, *supra* note 81, at 53,650 (*Agrizap* is included in the 2010 Guidelines as an example of Rationale B: “Substituting One Known Element for Another.”).

130. *Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335 (Fed. Cir. 2009).

131. *Id.* at 1350.

132. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1352 (Fed. Cir. 2008).

circuited. A fact-specific inquiry is required to correctly conclude the obviousness or nonobviousness of the invention at issue.<sup>133</sup>

Lead Prior Art neutralizes “negative rules to invention” within the existing obviousness rubric by objectively determining the *Graham* factors and consequently objectively determining whether a POSITA, at the time of the invention, would have considered the invention obvious.<sup>134</sup>

## B. *The Prima Facie Case of Obviousness*

### 1. The Dance Steps and the Burdens

The *summum bonum* of our Lead Prior Art methodology is to reduce subjectivity in determining whether a prima facie case of obviousness exists or not. We will now thoroughly explore the concept of prima facie case:

“A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.” . . . If the examiner fails to establish a *prima facie* case, the rejection is improper and will be overturned.<sup>135</sup>

The legal issue of whether a given subject matter would have been obvious, and thus unpatentable, is first determined during patent prosecution. In that context, the prima facie case of obviousness has been explained by the Federal Circuit:

“[as] a procedural tool of patent examination, allocating the burdens of going forward as between examiner and applicant. . . . As discussed in *In re Piasecki* [. . .], the examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability. If that burden is met, *the burden of coming forward with evidence or arguments shifts to the applicant.*”<sup>136</sup>

133. See 35 U.S.C.A. § 103(a); see also *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1089 (Fed. Cir. 2008) (“The determination of obviousness is dependent on the facts of each case.”).

134. See discussion *infra* Section V.D.

135. *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (quoting *In re Bell*, 991 F.2d 781, 782 (Fed. Cir. 1993)).

136. *In re Soni*, 54 F.3d 746, 752-53 (Fed. Cir. 1995) (Michel, J., dissenting) (emphasis added) (quoting *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992)). As will be discussed further *infra*, an equivalent two step process of burden allocation from challenger (first) to patentee (second) takes place once the patent issues, although the standard of proof for ultimately proving obviousness changes from “preponderance of the evidence” during prosecution to “clear and convincing evidence” during litigation.

Thus, establishment of a *prima facie* case of obviousness shifts the *burden of production* of evidence from the examiner to the applicant. In contrast, although no specific statute provides for burden allocation during patent prosecution, courts have held that the *burden of persuasion* on the issue of obviousness remains with the Office. As explained in *In re Oetiker*:

Specifically, when obviousness is at issue, the examiner has the burden of persuasion and therefore the initial burden of production. Satisfying the burden of production, and thus initially the burden of persuasion, constitutes the so-called *prima facie* showing. Once that burden is met, the applicant has the burden of production to demonstrate that the examiner's preliminary determination is not correct. The examiner, and if later involved, the Board, *retain the ultimate burden of persuasion on the issue.*<sup>137</sup>

After a given patent application matures into an issued patent claim, 35 U.S.C. § 282 mandates that “[the] patent shall be presumed valid. . . . [And] [t]he burden of establishing invalidity of [the] patent or any claim thereof shall rest on the party asserting such invalidity.”<sup>138</sup> Consequently, the Federal Circuit has applied the same procedural “*prima facie* case” mechanism to patent validity/invalidity rulings. The standard of proof is elevated from “preponderance of the evidence” during prosecution, to “clear and convincing evidence” during litigation.<sup>139</sup> The Federal Circuit has applied that elevated standard regardless of what prior art was specifically considered during patent prosecution.<sup>140</sup> But, the Supreme Court is currently scheduled to rule on whether the court should differentiate and afford less deference to the validity of a patent when “the prior art on which the invalidity defense rests was not considered by the Patent and Trademark Office prior to the issuance of the asserted patent.”<sup>141</sup>

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137. *In re Oetiker*, 977 F.2d 1443, 1449 (Fed. Cir. 1992) (emphasis added).

138. 35 U.S.C. § 282 (2002).

139. *See Schumer v. Lab. Computer Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002).

140. *See Gillette Co. v. S.C. Johnson & Son, Inc.*, 919 F.2d 720, 722-23 (Fed. Cir. 1990) (“The claims of Monson are entitled to a presumption of validity and Gillette faces the burden of showing, by clear and convincing evidence, their invalidity. . . . This burden is not lessened by Gillette’s introduction at trial of prior art not before the PTO during prosecution.”) (internal citation omitted).

141. *See i4i Ltd. Partnership v. Microsoft Corp.*, 598 F.3d 831 (Fed. Cir. 2010), *cert. granted*, 131 S.Ct. 647 (2010); Petition for Writ of Certiorari, *Microsoft Corp.*, 131 S.Ct. 647 (No. 10-290).

QUESTION PRESENTED: The Patent Act provides that “[a] patent shall be presumed valid” and that “[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. § 282. The Federal Circuit held below that Microsoft was required to prove its

Nevertheless, aside from the question on the appropriate level of deference afforded by the Court, the law remains that the burden of persuasion “is constant and remains throughout the suit on the challenger” and “does not shift at any time to the patent owner.”<sup>142</sup>

The significance of a *prima facie* case of obviousness is central to the Lead Prior Art methodology. That methodology seeks to force a conscientious, forward-looking analysis of the prior art and suggestions therein to determine whether appropriate starting point(s) and one or more modifications would allow for arriving at the claimed invention. If so, the claimed invention may be *prima facie* obvious subject to other considerations discussed *infra*.<sup>143</sup> Thus, understanding the strategic and technical issues surrounding *prima facie* obviousness is important to understanding Lead Prior Art.

## 2. Challenging the *Prima Facie* Case

The examiner’s burden is to establish obviousness under the law, as the law is set forth in 35 USC § 103, and by applying “the controlling inquiry” outlined in *Graham v. John Deere Co. of Kansas City*.<sup>144</sup> Consequently, once the Office asserts its alleged *prima facie* case of obviousness, applicants can consider replying with a two-part argument: an attack and, if the attack fails, a rebuttal. Indeed, “[o]nce Office personnel have established the *Graham* factual findings and

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defense of invalidity under 35 U.S.C. § 102(b) by “clear and convincing evidence,” even though the prior art on which the invalidity defense rests was not considered by the Patent and Trademark Office prior to the issuance of the asserted patent. The question presented is: Whether the court of appeals erred in holding that Microsoft’s invalidity defense must be proved by clear and convincing evidence.

*Id.*

142. See *TP Labs., Inc. v. Prof'l Positioners, Inc.*, 724 F.2d 965, 971 (Fed. Cir. 1984).

143. See discussion *infra* Section V.C.

144. See discussion *supra* Section II.A; *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.”) (citations omitted); *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406-07 (2007) (“*Graham v. John Deere Co. of Kansas City* . . . set out a framework for applying the statutory language of § 103. . . . While the sequence of these questions might be reordered in any particular case, the factors continue to define the inquiry that controls.”) (emphasis added). In general, 37 C.F.R. §1.56(b) states:

A *prima facie* case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

concluded that the claimed invention would have been obvious, the burden then shifts to the applicant to:

- (A) show that the Office erred in these findings, or
- (B) provide other evidence to show that the claimed subject matter would have been nonobvious.”<sup>145</sup>

To be sure, Option (A) provides an opportunity for “attacking” the existence of a prima facie case of obviousness and option (B) provides an opportunity and need for coming forward with “rebutting” evidence overcoming an established prima facie case (i.e., evidence that, even if the examiner raised a prima facie case, the invention might have been, nevertheless, non-obvious in face of the additional evidence).<sup>146</sup>

Thus, applicants have the opportunity to challenge every *Graham* factual finding, including the initial prima facie determination by the Patent and Trademark Office (“PTO”). That is, applicants can challenge the PTO’s determination of the scope and content of the prior art and its *selection* of a subset of that prior art for its prima facie case (*Graham* Factors 1 and 2). Failure to challenge that choice could undermine the applicants’ case, at least because applicants are required to “distinctly and specifically point out the supposed errors in the Office’s action and reply to every ground of objection and rejection in the Office action.”<sup>147</sup>

As discussed above, examiners are required to consider all evidence, including “secondary considerations,” at all stages of the obviousness determination.<sup>148</sup> To be sure, “any initial obviousness determination”<sup>149</sup> and “all rejections of record and proposed rejections should be reviewed to confirm their continued viability.”<sup>150</sup>

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145. M.P.E.P., *supra* note 59, at § 2141.

146. See *In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992) (“The patent applicant may then attack the Examiner’s prima facie determination as improperly made out, or the applicant may present objective evidence tending to support a conclusion of nonobviousness.”).

147. M.P.E.P., *supra* note 59, at § 2141 (citing 37 C.F.R. § 1.111(b)).

148. See 2010 KSR Guidelines Update, *supra* note 81, at 53,643, 54,657 (“Once the applicant has presented rebuttal evidence, Office personnel should reconsider any initial obviousness determination in view of the entire record. See, e.g., *In re Piasecki*, 745 F.2d 1468, 1472, 223 U.S.P.Q. 785, 788 (Fed. Cir. 1984); *In re Eli Lilly & Co.*, 90 F.2d 943, 945 (Fed. Cir. 1990). All the rejections of record and proposed rejections and their bases should be reviewed to confirm their continued viability.”) (citing M.P.E.P., *supra* note 59, at § 2141); *id.* (“Example 5.2; *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). *Teaching point*: All evidence, including evidence rebutting a *prima facie* case of obviousness, must be considered when properly presented”).

149. M.P.E.P., *supra* note 59, at § 2141 V.

150. *Id.*

Indeed, the USPTO's 2010 *Guidelines* on obviousness explicitly remind examiners that "[a]s reflected in the MPEP, such evidence should not be considered simply for its 'knockdown' value; rather, all evidence must be reweighed to determine whether the claims are nonobvious."<sup>151</sup> The Director's statement that the "evidence must be reweighed" must refer to weighing evidence against evidence, not to weighing evidence against a previous conclusion or a presumption (such as the *prima facie* case).<sup>152</sup> Nonetheless, the Office still has the burden to show that, under a preponderance of the evidence standard, the evidence supporting the existence of a *prima facie* case of obviousness outweighs the evidence against it.<sup>153</sup> Otherwise, there cannot be a *prima facie* case of obviousness.<sup>154</sup> Consequently, as the Federal Circuit stated in *In re Piasecki*:

After a *prima facie* case of obviousness has been established, the burden of going forward shifts to the applicant. Rebuttal is merely "a showing of facts supporting the opposite conclusion", [sic] . . . and may relate to any of the *Graham* factors including the so-called secondary considerations. . . . If rebuttal evidence of adequate weight is produced, the holding of *prima facie* obviousness, being but a legal inference from previously uncontradicted evidence, is dissipated. *Regardless of whether the prima facie case could have been characterized as strong or weak, the examiner must consider all of the evidence anew.*<sup>155</sup>

Once the Office has established a *prima facie* case of obviousness, the "burden shifts to the applicant to come forward with

151. 2010 KSR Guidelines Update, *supra* note 81, at 54,657 (quoting M.P.E.P., *supra* note 59, at § 2145).

152. *In re Eli Lilly & Co.*, 902 F.2d 943 945 (Fed. Cir. 1990) ("After a *prima facie* case of obviousness has been made and rebuttal evidence submitted, all the evidence must be considered anew. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984) states:

When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over. . . . An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence then be evaluated only on its knockdown ability. . . . Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself.)

(quoting *In re Piasecki*, 745 F.2d at 1472).

153. *See Eli Lilly*, 902 F.2d at 948; *In re Oetiker*, 977 F.2d 1443, 1445, 1446 (Fed. Cir. 1992) ("After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.") ("the term '*prima facie* obvious' relates to the burden on the examiner at the initial stage of the examination, while the conclusion of obviousness *vel non* is based on the preponderance of evidence and argument in the record.").

154. *See Oetiker*, 977 F.2d at 1447.

155. *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (emphasis added).

arguments and/or evidence to rebut the prima facie case.”<sup>156</sup> The case law shows that successfully overcoming an established prima facie case of obviousness requires certain types of evidence, or at least evidence that meets certain thresholds or limitations.<sup>157</sup> More specifically, for example, the rebuttal evidence takes the form of objective indicia of nonobviousness, which includes the type of evidence discussed in *Graham* Factor 4.<sup>158</sup> The evidence can,<sup>159</sup> but need not be in the application “as filed,” because affidavits and declarations by an inventor or an expert opinion as to what a POSITA would have done under the circumstance can be introduced during prosecution.<sup>160</sup> To be sure, one challenging the validity of an issued patent has the burden of proof with respect to all of the *Graham* Factors, including objective evidence of nonobviousness.<sup>161</sup> Accordingly, the Court has held that:

[i]n the instant case, the patent has been granted. [The patentee] does not have any burden of proving superior results. The burden is on [the patent challenger] to prove by clear and convincing evidence that the invention does not produce superior results; [the patent challenger] has failed to meet that burden.<sup>162</sup>

Cases have held that rebuttal evidence must also be “commensurate in scope” with the claims.<sup>163</sup> But an applicant or

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156. M.P.E.P., *supra* note 59, at § 2145 (2001).

157. *See id.* at § 716.

158. *See* discussion *infra* Section II.A.1.d.

159. *See In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (“[c]onsistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results”).

160. 37 CFR § 1.132. However, where practical, the latter may be avoided because they possibly, depending on all facts and circumstances, expose applicants and practitioners to the vulnerabilities of attack under Rule 56 (Duty of Candor and Good Faith) and allegations of inequitable conduct. 37 CFR § 1.56 (“§ 1.56 Duty to disclose information material to patentability. (a) . . . Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.”).

161. *Gillette Co. v. S.C. Johnson & Son, Inc.* 12 U.S.P.Q.2d 929 (D. Mass. 1989), *aff’d*, 919 F.2d 720 (Fed. Cir. 1990); *see also* *Am. Hosp. Supply Corp. v. Travenol Labs., Inc.*, 745 F.2d 1, 8 (Fed. Cir. 1984) (holding that the burden is not on patentee to prove new and surprising results, but is on the patent challenger to establish the lack of new and surprising results).

162. *Gillette*, 12 U.S.P.Q.2d at 960.

163. *See In re Tiffin*, 448 F.2d 791, 792 (C.C.P.A. 1971) (objective evidence of nonobviousness including commercial success must be commensurate in scope with the claims). M.P.E.P., *supra* note 59, at § 716.03(a).



patentee “need not sell every conceivable embodiment of the claims in order to rely upon evidence of commercial success” and “[c]ommercial success evidence should be considered [by the examiner] ‘so long as what was sold was within the scope of the claims.’”<sup>164</sup> And in this context, the court has held that “commensurate in scope” means that “the commercial success must be due to claimed features, and not due to unclaimed features.”<sup>165</sup> Alternatively, if the applicant seeks to rely on evidence of “unexpected results,” the court has held that the testing and results must at least provide one of skill in the art with an “adequate basis for reasonably concluding that [all of the] compositions included by the claims would behave in the same [unexpectedly superior] manner as the . . . test composition[s].”<sup>166</sup> Thus, courts have held that although not all species within a claim must be tested, those tested must be sufficiently “representative” to support a conclusion of unexpected results.<sup>167</sup>

### C. Hindsight Is Impermissible in an Obviousness Analysis

As previously stated *supra*,<sup>168</sup> neither the subjective motivations<sup>169</sup> of the inventors,<sup>170</sup> nor their level of skill is relevant during an obviousness determination.<sup>171</sup> Rather, by statute, the proper

164. *In re Glatt Air Techniques, Inc.*, 630 F.3d 1026, 1030 (Fed. Cir. 2011) (citations omitted).

165. M.P.E.P., *supra* note 59, at § 716.03(a).

166. *In re Greenfield*, 571 F.2d 1185, 1189 (C.C.P.A. 1978).

167. *See In re Payne*, 606 F.2d 303, 316 (C.C.P.A. 1979) (“[W]here an applicant tests less than all the cited compounds, the test must be sufficient to permit a conclusion respecting the relative effectiveness of applicant’s claimed compounds and the compounds of the closest prior art.”) (citations omitted); *see also In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987) (“In *Payne*, the Court of Customs and Patent Appeals said the mere submission of some evidence that a new compound possesses some unpredictable properties does not require an automatic conclusion of nonobviousness in every case. The *Payne* court held that the evidence submitted in that case was insufficient to rebut a *prima facie* case of obviousness, because the claimed compound was compared with too few prior art compounds. . . . That is not the situation in this case.”) (citations omitted).

168. *See* discussion *infra* Section II.A.1.c.

169. Subjective motivations are, for example, what the applicant(s) “would have known or would likely have done, faced with the revelations of references.” *See, e.g., Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985) (“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, and one should not go about determining obviousness under § 103 by inquiring into what patentees . . . would have known or would likely have done, faced with the revelations of references.”).

170. *See Life Techs., Inc. v. Clontech Labs., Inc.*, 224 F.3d 1320, 1325 (Fed. Cir. 2000).

171. *See Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 963 (Fed.

perspective is that of a POSITA.<sup>172</sup> A POSITA represents a hypothetical person presumed to be aware of all pertinent prior art in the area of the invention.<sup>173</sup> A POSITA also possesses ordinary creativity and exercises common sense when analyzing the available knowledge in the art.<sup>174</sup>

Thus, in theory, the obviousness determination should be carried out considering the state of the art at the time the invention was made without taking into account any knowledge derived from the claimed invention.<sup>175</sup> Accordingly, the proper analysis should be done through the eyes of a POSITA who is mindful of all relevant information but without using the invention as a blueprint in order to piece together the teachings of the prior art. As explained by the Federal Circuit:

It is difficult but necessary that the decision maker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made . . . *to occupy the mind of one skilled in the art who is presented only with the references*, and who is normally guided by the then-accepted wisdom in the art.<sup>176</sup>

The Supreme Court has equally cautioned against the risk of retracing the inventor's path with hindsight: "[a] factfinder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning."<sup>177</sup> Thus, in general, practitioners, USPTO officials, and judges agree that hindsight is impermissible in an obviousness analysis. In practice, however, it is often difficult for the factfinder to set aside any knowledge of the claimed invention to avoid "picking and choosing" isolated disclosures to improperly render the claimed invention obvious.<sup>178</sup>

Despite admonitions against employing hindsight during obviousness analysis, proponents of obviousness often fall into the

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Cir. 1986).

172. See 35 U.S.C.A. § 103(a).

173. *In re Rouffet*, 149 F.3d 1350, 1357 (Fed. Cir. 1998) ("Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. See 35 U.S.C. § 103(a). . . . The legal construct also presumes that all prior art references in the field of the invention are available to this hypothetical skilled artisan. See *In re Carlson*, 983 F.2d 1032, 1038, 25 U.S.P.Q.2d 1207, 1211 (Fed. Cir. 1993).").

174. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007); see also *W. Union Co. v. MoneyGram Payment Sys, Inc.*, 626 F.3d 1361, 1371 (Fed. Cir. 2010).

175. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

176. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983) (emphasis added).

177. *KSR*, 550 U.S. at 421.

178. See *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992).

trap of doing so, presumably unknowingly. Unfortunately, judges can find such arguments to have facial appeal, based on the appearance of an easy solution to an acknowledged need, even though the appearance starts from the solution and works backwards to the problem. Lead Prior Art directly addresses the problems of hindsight bias during obviousness analysis. Understanding the sources and nature of such biases, however, is important for understanding why Lead Prior Art is a justifiable improvement to the existing obviousness rubric.

1. Hindsight Could Be Improperly Employed to Retrace the Inventor's Path and Piece Together Prior Art Elements That Would Not Have Been Combined Otherwise

The law requires that an invention be considered "as a whole" for purposes of assessing its obviousness.<sup>179</sup> As the late Chief Judge Markey remarked, "[o]nly God works from nothing. Men must work with old elements."<sup>180</sup> Thus, at first impression, many inventions may seem to differ from the prior art only in that they are "new combinations of existing principles or features."<sup>181</sup> Nonetheless, the value of these inventions should not be immediately discounted. Moreover, because "[h]umans do not create from nothing; they must employ the principles of engineering and physics and their experience. It cannot be the law that the only inventions patentable are those that cannot be explained by any known principles of engineering or physics."<sup>182</sup> Consequently:

The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of *hindsight* reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining

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179. See 35 U.S.C.A. § 103(a).

180. *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 n.3 (Fed. Cir. 1985) ("Only God works from nothing. Men must work with old elements.") (quoting Markey, *Why Not the Statute?*, 65 J. PAT. OFF. SOC'Y 331, 345 (1983)).

181. See *Environmental Designs, Ltd. v. Union Oil Co. of C.A.*, 713 F.2d 693, 698 (Fed. Cir. 1983) ("virtually all inventions are combinations of old elements.").

182. *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1097-98 (Fed. Cir. 1985) (citations omitted).

various existing features or principles in a new way to achieve a new result—often the very definition of invention.<sup>183</sup>

The courts have recognized that, sometimes,

a patentable invention may lie in the discovery of a source of a problem even though the remedy may be obvious once the source of the problem is identified. This is *part* of analyzing the “subject matter as a whole,” which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103.<sup>184</sup>

For example, before the Federal Circuit came into existence, the United States Court of Customs and Patent Appeals (“CCPA”) considered a case where a problem of “undesirable stressing of fuel rods” in nuclear reactors was known in the prior art, but where the inventor was the only person who recognized that the source of the stressing was “sticking” between certain elements.<sup>185</sup> In that case, the inventor prevailed over the Board of Patent Appeals and Interferences (“BPAI”)<sup>186</sup> because,

“[where] there is no evidence of record that a person of ordinary skill in the art at the time of [an applicant’s] invention would have expected [a problem],” *e.g.*, sticking, “to exist at all, it is not proper to conclude that [an invention],” *e.g.*, roughening one of the contact surfaces, “which solves this problem, . . . would have been obvious to that hypothetical person of ordinary skill in the art.”<sup>187</sup>

Similarly, an unclaimed advantage of an invention cannot be isolated and treated with hindsight as being *the invention* itself, because “treating the advantage as the invention disregards the

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183. Ruiz v. A. B. Chance Co., 357 F.3d 1270, 1275 (Fed. Cir. 2004) (emphasis added); see also Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383 (Fed. Cir. 1986) (“The large number of references, as a whole, relied upon by the district court to show obviousness, about twenty in number, skirt all around but do not as a whole suggest the claimed invention, which they must, to overcome the presumed validity, . . . . Focusing on the obviousness of substitutions and differences instead of on the invention as a whole . . . was a legally improper way to simplify the difficult determination of obviousness.”) (citations omitted).

184. *In re Spinnoble*, 405 F.2d 578, 585 (C.C.P.A. 1969).

185. See *In re Peehs*, 612 F.2d 1287, 1290 (C.C.P.A. 1980).

186. The Board of Patent Interferences and Appeals is the body within the U.S. Patent and Trademark Office in which a patent applicant may appeal an examiner’s final rejection, including *ex parte* and *inter partes* reexamination rejections, as well as the forum for deciding priority disputes in interferences. See 35 U.S.C. § 6(b) (“The Board of Patent Appeals and Interferences shall, on written appeal of an applicant, review adverse decisions of examiners upon applications for patents and shall determine priority and patentability of invention in interferences . . . .”)

187. *Chapman v. Casner* 315 F. App’x. 294, 299 (Fed. Cir. 2009) (citations omitted).

statutory requirement that the invention be viewed ‘as a whole,’ ignores the problem-recognition element, and injects an improper ‘obvious to try’ consideration.”<sup>188</sup> To be sure, in analyzing “obvious to try,” the Federal Circuit has articulated two specific situations where “obvious to try” was “erroneously equated” with obviousness. In one such improper situation

what would have been “obvious to try” would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful.<sup>189</sup>

In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness. . . . The second class of O’Farrell’s impermissible “obvious to try” situations occurs where “what was ‘obvious to try’ was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.”<sup>190</sup>

In cases where an inventive contribution lies in a discovery of a cause of a problem, obviousness analysis does not turn on whether *the solution to the problem* would have been obvious. Specifically, in a recent dissenting opinion, Judge Rader recognized that, in such cases, as in *Eibel*, *Conover*, and *Sponnable*, “the crux of the matter is the discovery by appellant [of the cause of a problem]”, and the determinative question is whether that cause would have been recognized by a POSITA at the time the invention was made.<sup>191</sup>

He noted how “[t]his case, as are *Eibel*, *Conover*, *Sponnable*, and *Peehs*, is distinguished from *KSR* because there were no ‘finite number of identified, predictable solutions’ that were used to discover the source of and solution to the problems.”<sup>192</sup> This distinction is particularly relevant because

[w]hen there is a design need or market pressure to solve a

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188. *Jones v. Hardy*, 727 F.2d 1524, 1530 (Fed. Cir. 1984) (citing *In re Antonie*, 559 F.2d 618 (C.C.P.A. 1977)).

189. *In re Kubin*, 561 F.3d 1351, 1359 (Fed. Cir. 2009) (citing *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

190. *Id.* (citing *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988)).

191. *Chapman*, 315 F. App’x. at 299 (Rader, J., dissenting).

192. *Id.*

problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.<sup>193</sup>

Yet, frequently, the cause of the problem to be solved is well known and the claimed solution, once disclosed, appears simple.<sup>194</sup> However, “[a]n inventor will not be denied a patent simply because his invention embodies a solution which seems simple and obvious with the benefit of hindsight.”<sup>195</sup> Fortunately, courts have also noted that “[t]he invention here in dispute is simple and there is an inclination to find such simple things to be obvious. *However, if the invention were so obvious, why hadn’t anyone come up with it . . . ?*”<sup>196</sup>

Under the theory of § 103, particularly as construed in *Graham*, if after a proper search and review of the prior art, an invention is found to be novel, the invention is also not obvious until proven otherwise.<sup>197</sup> That is the essence of placing the burden of establishing a prima facie case of obviousness, and ultimately obviousness, on both the PTO and the patent challenger.

As the *2010 Guidelines* note, several “lines of reasoning” could be used to support an obviousness determination.<sup>198</sup> For example, even if the PTO asserts a prima facie case of obviousness against an invention alleging it to be an obvious modification or combination of select prior art references, the law requires that the PTO provide more than the identity of the selected applied references to establish a

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193. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

194. *See Goodyear Tire & Rubber Co. v. Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944) (“Viewed after the event, the means Anthony adopted seem simple and such as should have been obvious to those who worked in the field, but this is not enough to negative invention.”)

195. *Globe Linings, Inc. v. City of Corvallis*, 555 F.2d 727, 731 (9th Cir. 1977), *cert. denied*, 434 U.S. 985 (1977).

196. *State Industries, Inc. v. Mor-Flo Industries, Inc.*, 639 F. Supp. 937, 945 (E.D. Tenn. 1986) (emphasis added); *see also DePuy Spine v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1328-29 (Fed. Cir. 2009) (the Federal Circuit considered objective evidence of “failure of others” to show that the alleged infringer was unsuccessfully working on a solution different to the claimed invention until the alleged infringer found out about the claimed invention and changed its research accordingly).

197. *See In re Fritch*, 972 F.2d 1260, 1265 (Fed. Cir. 1992) (“In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a prima facie case of obviousness based upon the prior art.”); *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984) (“As adapted to *ex parte* procedure, *Graham* is interpreted as continuing to place the ‘burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103.’”) (quoting *In re Warner*, 379 F.2d 1011, 1016, 154 U.S.P.Q. 173, 177 (C.C.P.A. 1967)); *see also M.P.E.P.*, *supra* note 59, at §§ 701, 706.

198. *See 2010 KSR Guidelines Update*, *supra* note 81, at 53,643, 53,644.

legitimate prima facie case.<sup>199</sup> Rather, the PTO needs to provide a *rationale* explaining why a POSITA would have had reason to (i) “select,”<sup>200</sup> “combine,” and “modify” all prior art teachings that the PTO seeks to apply against the invention, and (ii) to do so for the purpose of obtaining the claimed invention with a reasonable expectation of success.<sup>201</sup>

Courts have held that the PTO’s rationale can differ from that relied on by the inventor during the inventor’s development efforts.<sup>202</sup> If the Office cannot assemble any such rationale, however, the proponent of obviousness has not carried its burden of pleading the elements of a prima facie case of obviousness. The same requirement applies to a litigant seeking to invalidate an issued patent.<sup>203</sup> Accordingly, the patented invention is presumptively nonobvious over the asserted references, absent subsequent evidence to the

199. See *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1290-91 (Fed. Cir. 2006) (“legal determinations of obviousness . . . should be based on evidence rather than on mere speculation or conjecture. . . . [R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be *some* articulated reasoning with *some* rational underpinning to support the legal conclusion of obviousness.”) (quoting *In re Kahn*, 441 F.3d 977, 987-88 (Fed. Cir. 2006)); see also *M.P.E.P.*, *supra* note 59, at § 706.02(j).

200. See *Daiichi Sankyo Co., Ltd. v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1352 (Fed. Cir. 2010); see, e.g., *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007).

201. See Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, 72 Fed. Reg. 57,526, 57,529 (Oct. 10, 2007) (“To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.”).

202. See *In re Lintner*, 458 F.2d 1013, 1016 (C.C.P.A. 1972) (“The fact that appellant uses [an invention] for a different purpose does not alter the conclusion that its use in a prior art composition would be prima facie obvious from the purpose disclosed in the references.”); *In re Fulton*, 391 F.3d 1195, 1202 (Fed. Cir. 2004) (“the Board need not have found the combination of Bowerman and Pope to be desirable for the reason stated in the . . . application.”); *In re Dillon*, 919 F.2d 688, 703 (Fed. Cir. 1990) (“It is immaterial that the prior art homologue may not be recognized or *known* to be useful for the same purposes or to possess the same properties as the claimed compound.”) (citation omitted).

203. See *Stratoflex, Inc., v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983) (“[T]he party asserting invalidity not only has the procedural burden of proceeding first and establishing a prima-facie case, but the burden of persuasion on the merits remains with that party until final decision. The party supporting validity has no initial burden to prove validity, having been given a procedural advantage requiring that he come forward only after a prima-facie case of invalidity has been made. With all the evidence in, the trial court must determine whether the party on which the statute imposes the burden of persuasion has carried that burden.”).

contrary. While no such legal presumption can be said to exist until a patent issues, the Board of Patent Appeals and Interferences<sup>204</sup> has reiterated that:

[w]hile the analysis under 35 U.S.C. § 103 allows flexibility in determining whether a claimed invention would have been obvious [citing *KSR*], it still requires showing that ‘there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.’ . . . ‘We must still be careful not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention.’<sup>205</sup>

Ultimately, the *Graham* factors provide the “background” against which “the obviousness or nonobviousness of the subject matter is determined.”<sup>206</sup> As such, ascertaining the proper “background” is the sine qua non to a proper obviousness analysis. Lead Prior Art provides the means to ascertain the proper “background” objectively and in a manner that avoids hindsight.

## 2. Lead Prior Art Paradigm Provides the Proper “Background” Against Which the Obviousness or Nonobviousness of the Subject Matter Is Determined

Having plumbed the depths of the prima facie case and focused on the evils of hindsight, we now turn to instructive judicial examples to see how the Lead Prior Art paradigm can be used to understand judicial results. Indeed, one of the contexts providing instructive examples on how the courts have applied such principles to avoid hindsight in a way that is consistent with our Lead Prior Art methodology is the use of the Lead Compound approach in determining the patentability of chemical compounds. As such, applicants seeking to undermine a prima facie case of obviousness raised over a particular structurally-similar compound in the prior art can remind the Office that it has the initial burden to come forth with a “reasoned identification of [that structurally similar compound] as a lead compound” in the prior art.<sup>207</sup>

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204. See *supra* note 186.

205. See, e.g., *Ex parte* Subramanyam, No. 2010-002463, 2010 WL 1253713, at \*3 (B.P.A.I. Mar. 29, 2010); *Ex parte* Han, No. 2010-008633, 2011 WL 798184, at \*3 (B.P.A.I. Mar. 3, 2011).

206. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966).

207. See *Procter & Gamble Co. v. Teva Pharm. USA Inc.*, 566 F.3d 985, 994 (Fed. Cir. 2009) (“An obviousness argument based on structural similarity between claimed and prior art compounds ‘clearly depends on a preliminary finding that one of ordinary skill in the art would



To be sure, as the *2010 Guidelines* summarized, “[a]ny known compound may serve a lead compound when there is some reason for starting with that lead compound and modifying it to obtain the claimed compound.”<sup>208</sup> That is consistent with our Lead Prior Art methodology, wherein it is made clear that the Office has the initial burden of establishing a reason for selecting a prior art compound(s) as well as some reason<sup>209</sup> for modifying the applied art. Logically, because the Office needs to find a reason for each of those steps, the easiest argument to build is for the Office to select the closest structural homolog as the lead compound and allege as the requisite rationale for both its selection and modification that “the claimed and prior art compounds possess a ‘sufficiently close relationship . . . to create an expectation,’ [the reason to modify] in light of the totality of the prior art, that the new compound will have ‘similar properties’ to the old.”<sup>210</sup>

Nevertheless, the Office will need to provide a rationale for narrowing the possibilities to the so-called closest prior art the Office seeks to apply. Perhaps, an exception occurs when the Office can prove that the invention would have been “obvious to try.” However, that line of reasoning will only work if the Office shows:

there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions [that] a person of ordinary skill has good reason to pursue . . . . In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.<sup>211</sup>

Patents to pharmaceutical blockbusters are frequently challenged,<sup>212</sup> due to the potentially lucrative outcome of generic entry if generic manufacturers can overcome the innovator’s exclusivity.<sup>213</sup> In such cases, non-obviousness of the claimed

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have selected [the prior art compound] as a lead compound.’ *Takeda*, 492 F.3d. at 1359; see also *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008) (stating that ‘post-KSR, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a lead compound’ in the prior art).”)

208. 2010 KSR Guidelines Update, *supra* note 81, at 53,651.

209. See *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007).

210. *Eisai Co. Ltd. v. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1357 (Fed. Cir. 2008) (quoting *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007)).

211. *KSR Int’l. Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

212. See *Generics’ Patent Challenges Reached Record Level in 2010*, FDANEWS, Mar. 21, 2011, <http://www.fdanews.com/newsletter/article?articleId=135219&issueId=14567>.

213. See Krishan Maggon, *Top Ten/Twenty Best Selling Drugs 2009*, KNOL,

compounds or compositions is almost always at issue.<sup>214</sup> At least one generic manufacturer unsuccessfully tried recently to catch the Supreme Court's attention by urging that the patentee wins in a disproportionate number of cases.<sup>215</sup>

Over the last decade, the presumption of validity for various new chemical compounds has been upheld on the lack of a rationale for selecting suitable starting points in the prior art to arrive at the claimed invention.<sup>216</sup> Typically, the challenger successfully located a closely related compound in the prior art but failed to make one of two related showings; either that a POSITA would have selected that compound for modification from many alternatives (in our view, the prior art compound selected was not within the relevant scope and content of the prior art and was thus not a piece(s) of Lead Prior Art), or that the POSITA would possess a requisite motivation for engaging in the modifications of the selected compound to achieve the claimed compound. In other words, the prior art compound may well have been within the piece(s) of the Lead Prior Art, but there was no straightforward pathway for bridging the differences between the claimed compound and the prior art.<sup>217</sup>

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<http://knol.google.com/k/top-ten-twenty-best-selling-drugs-2009#> (last visited Feb. 26, 2011) (showing that annual sales of the top 5 best-selling brand-name drugs in 2009 were between \$6.91M-\$12.45M).

214. The Hatch-Waxman Act, Act (21 U.S.C. § 355) is the statutory scheme whereby generic drug manufacturers can file an Abbreviated New Drug Application ("ANDA") seeking FDA approval for a generic version of a patented drug. The ANDA applicant either requests approval upon the expiration of the patent or requests approval based on an assertion that the patent is invalid (a paragraph IV certification). If an ANDA is filed with a paragraph IV certification, the patentee has a certain amount of time in which to sue the ANDA applicant for infringement and defend the validity of its patent. The result is that the vast majority of pharmaceutical patent litigation is ANDA litigation, with an assertion of invalidity.

215. See *Mylan Inc. v. Daiichi Sankyo Co., Ltd.*, No. 10-770, 2010 WL 5069543, at \*12 (Appellate Petition, Motion and Filing) (U.S. Dec. 8, 2010) (arguing that 6 of 8 post-KSR Federal Circuit compound and pharmaceutical method of treatment cases found nonobviousness: "As the following table demonstrates, the Federal Circuit is effectively applying a much higher standard to chemical compounds than it does to other inventions, even within the chemical arts.").

216. See, e.g., *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008); *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989 (Fed. Cir. 2009); *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007); *Eisai Co. Ltd. V. Dr. Reddy's Labs., Ltd.*, 533 F.3d 1353 (Fed. Cir. 2008); *Daiichi Sankyo Co., Ltd. v. Matrix Labs., Ltd.*, 619 F.3d 1346 (Fed. Cir. 2010); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008).

217. See discussion of *Eisai* *infra* Section IV.B.

### 3. Hindsight Could Also Wrongly Be Employed to Identify “Similar” Subject Matter or to Say That Existing Elements in the Prior Art Could Be Predictably Modified to Solve Other Problems

Similarity between the prior art and the claimed invention are questions of quality, i.e., is it a sensible prior art starting point, and of degree, i.e., is there a straightforward path from that starting point to the claimed invention. As the court said in *In re Papesch*,<sup>218</sup> in the context of chemical compounds, “the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter.”<sup>219</sup> Proper questions to ask are: “how similar and dissimilar are the two molecules; and what are the implications of these similarities and dissimilarities to a person of ordinary skill in the art in light of prior art at the time of the invention.”<sup>220</sup> In other words, obviousness-type “similarity” should exist only if a person of ordinary skill in the art would have had a reasonable expectation of success in the modification or combination.<sup>221</sup> Thus, nonobviousness exists in performing a modification or combination in the absence of a reasonable expectation of success, because without a *reasonable* expectation of success, there is no prima facie case of obviousness. And, of course, the modification/combination must be straightforward. In Lead Prior Art terminology, a straightforward path from a sensible starting point to the claimed invention is lacking and/or a reasonable expectation of success is lacking.

In addition, modifications to starting points grounded in proposed lead prior art may not provide a reasonable expectation of success because the modification would destroy what would be otherwise known as advantageous properties of the prior art compound. In other words, assuming that the challenger happens upon a sensible prior art starting point, there can be no straightforward path to the claimed invention if that path would destroy touted advantages and/or properties of the sensible starting point prior art.

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218. *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963).

219. *Id.* at 391.

220. *Abbott Laboratories v. Andrx Pharm., Inc.* 452 F.3d 1331, 1352 (Fed. Cir. 2006).

221. *See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc.*, 471 F.3d 1369, 1377-78 (Fed. Cir. 2006) (discussing how a POSITA cannot simply take various components and combine them without a commonality of purpose or characteristics that gives the artisan some reasonable expectation of success).

For example, in *Eisai*, the court explained that “[t]he record, however, shows no discernible reason for a skilled artisan to begin with lansoprazole only to drop the very feature, the fluorinated substituent, that gave this advantageous property.”<sup>222</sup> Consequently, although lansoprazole was “the closest prior art,” it was not the proper starting point in the prior art for a prima facie case of obviousness.<sup>223</sup>

In such contexts, pharmaceutical activity of a prior art compound is not always required. The *2010 Guidelines* caution examiners to recognize that:

[A] proper obviousness rejection of a claimed compound that is useful as a drug might be made beginning with an inactive compound, if, for example, the reasons for modifying a prior art compound to arrive at the claimed compound have nothing to do with pharmaceutical activity. The inactive compound would not be considered to be a lead compound by pharmaceutical chemists, but could potentially be used as such when considering obviousness. Office personnel might also base an obviousness rejection on a known compound that pharmaceutical chemists would not select as a lead compound due to expense, handling issues, or other business considerations.<sup>224</sup>

In that situation, the use of hindsight is possibly avoided because, in an allegation of the existence of a prima facie case, “there must be some reason for starting with that lead compound other than the mere fact that the ‘lead compound’ merely exists.”<sup>225</sup> In that sense, the PTO guidelines are consistent with *Dillon*, discussed *infra*,<sup>226</sup> in looking for and establishing a reason on the record, other than its mere existence, for why that inactive prior art compound is a sensible starting point.

In *Sanofi-Synthelabo*,<sup>227</sup> a decision consistent with the Lead Prior Art paradigm, the issue was whether the claimed dextrorotatory isomer was obvious in view of its presence in the known racemate.<sup>228</sup> The patent challenger, Apotex, argued that the prior art PCR 4099 was the “lead candidate” for prior research and the fact that PCR 4099 was an enantiomer of the claimed compound “outweighs the effect of any unexpected or unpredictable properties of the separated

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222. *Eisai Co. Ltd. V. Dr. Reddy’s Labs., Ltd.*, 533 F.3d 1353, 1358 (Fed. Cir. 2008).

223. *Id.* at 1359.

224. 2010 KSR Guidelines Update, *supra* note 81, at 53,643, 53,651-52.

225. *Id.* at 53,652.

226. See discussion *infra* Section IV.C.

227. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008).

228. *Id.* at 1078, 1082.

dextrorotatory enantiomer.”<sup>229</sup> Sanofi submitted contrary evidence, for example, that although “a person of ordinary skill in this field in the mid-1980s would have known that enantiomers can exhibit different biological activities . . . that it was not predictable whether such differences, if any, would be weak, moderate, or strong, or how they would be manifested.”<sup>230</sup>

The district court in *Sanofi* was convinced that a POSITA would not have considered the allegedly invalidating prior art as the appropriate starting point for modification; it was not the “lead candidate” at the time of the invention. Nor was there a reasonable expectation of success for the claimed invention in view of PCR 4099. In particular, a POSITA would “not reasonably have predicted that the dextrorotatory enantiomer would provide all of the antiplatelet activity and none of the adverse neurotoxicity.”<sup>231</sup> The district court recognized that “the wide range of possible outcomes and the relative unlikelihood that the resulting compound would exhibit the maximal increase in anti-platelet aggregation activity and the absence of neurotoxicity makes clopidogrel bisulfate non-obvious.”<sup>232</sup> In other words, PCR 4099 provided no expectation of the success ultimately discovered in clopidogrel bisulfate.

In *Sanofi*, the Federal Circuit affirmed the holding of nonobviousness, noting that only hindsight supported the argument that the enantiomer was the appropriate starting point:

*Only with hindsight* knowledge that the dextrorotatory enantiomer has highly desirable properties, can Apotex argue that it would have been obvious to select this particular racemate and undertake its arduous separation. The application of hindsight is inappropriate where the prior art does not suggest that this enantiomer could reasonably be expected to manifest the properties and advantages that were found for this particular dextrorotatory isomer. *See Graham*, 383 U.S. at 36, 86 S.Ct. 684 (cautioning against hindsight whereby the teachings of the invention are read into the prior art); *see also KSR v. Teleflex*, 127 S.Ct. at 1742 (recognizing “hindsight bias” and “ex post reasoning” as inappropriate in determination of obviousness).<sup>233</sup>

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229. *Id.* at 1086.

230. *Id.* at 1087.

231. *Id.*

232. *Id.* at 1089.

233. *Id.* at 1088 (emphasis added).

### III. PROBATIVE VALUE OF OBJECTIVE INDICIA EVIDENCE MAY SOMETIMES BE LIMITED

Objective indicia of nonobviousness may be used to rebut a prima facie case of obviousness, as discussed *supra*,<sup>234</sup> and can be helpful or even important to an obviousness determination. But, as discussed below, empirical evidence from Federal Circuit opinions post-*KSR* suggests that the persuasive value of *economic* objective indicia of nonobviousness, discussed below, can be in-practice secondary<sup>235</sup> to the persuasive value of evidence supporting prima facie obviousness. In some cases, the court stated that strong evidence supporting a prima facie case of obviousness could not be rebutted by any amount of economic objective indicia of nonobviousness.<sup>236</sup> Thus, the issue of obviousness can be “won or lost” at the determination of prima facie obviousness.

The authors use the term “economic objective indicia of nonobviousness” to refer to objective indicia of nonobviousness that are unrelated to particular elements of the claimed invention, such as “long-felt but unresolved needs,” “commercial success,” “licensing,” “copying,” “praise of others,” “failure of others,” and other similar concepts.<sup>237</sup> Non-economic objective indicia of nonobviousness, which relate to particular elements of the claimed invention, include “unexpected results” and “teaching away.”<sup>238</sup>

This conclusion regarding the importance of the determination of prima facie obviousness naturally arises from the requirement to consider all evidence<sup>239</sup> and render a conclusion of obviousness or nonobviousness with respect to the appropriate burden of proof.<sup>240</sup> Naturally, weak evidence supporting nonobviousness should not overcome strong evidence supporting obviousness. This conclusion, however, also arises from a pattern of attributing differing *weights* to differing types of evidence, as discussed below.

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234. See discussion *supra* Section II.A.1.d.

235. The authors acknowledge that some cases expressly state that secondary considerations evidence can be the most probative evidence to the determination of obviousness or nonobviousness. See *supra* note 87.

236. See cases cited *infra* note 242.

237. Recall that the objective indicia of nonobviousness identified in *Graham* were not intended to be an exhaustive list. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (“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.”) (emphasis added).

238. See discussion *supra* Section II.A.1.d.

239. See discussion *supra* Section II.A.1.d.

240. See discussion *supra* Section II.B.

Case law evaluating the probative value of objective indicia of nonobviousness, however, suggests that this type of evidence can be attributed less probative weight than evidence of prima facie obviousness, as discussed in the paragraphs that follow. As the empirical results below show, establishing a prima facie case of obviousness can nearly or literally preclude the practical possibility of rebutting strong evidence supporting a prima facie case of obviousness through economic objective indicia of nonobviousness. Accordingly, the importance of correctly determining in the first place whether a *proper* prima facie case of obviousness has been established is extremely important because a rebuttal of that prima facie case may be practically impossible under certain circumstances.

This conclusion was reached after reviewing twenty-five Federal Circuit opinions involving economic objective indicia of nonobviousness published post-*KSR*. For each case, the court's characterization of the overall strength of the evidence supporting a prima facie case of obviousness and the overall strength of economic objective indicia of nonobviousness was discerned from the court's opinion. Then, cases involving similar strengths of evidence supporting the prima facie obviousness determination were organized into distinct groups.

What emerged from this analysis was that the factual patterns of the cases fell into four distinct categories. A first category involved what might be termed "very strong evidence of prima facie obviousness." In cases within the first category, every element of the claimed invention was undisputedly taught in the cited references or at most a small number of elements of the claimed invention were merely minor variations from what was disclosed in the references and a strong "motivation to combine" or "reasonable expectation of success" existed under the facts of these cases.<sup>241</sup>

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241. See *Geo M. Martin Co. v. Alliance Machine Sys. Int'l. LLC.*, 618 F.3d 1294 (Fed. Cir. 2010) (differences between cited references and claims were only minimal and those differences were limited to only a few options); *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 616 F.3d 1267 (Fed. Cir. 2010) (all elements disclosed by the references); *Wyers v. Master Lock Co.*, 616 F.3d 1231 (Fed. Cir. 2010) (all claim elements taught by combination of three references, involving known elements achieving predictable results); *Dow Jones & Co. v. Ablaise Ltd.*, 606 F.3d 1338 (Fed. Cir. 2010) (all elements disclosed in references save one, which was readily apparent to the Court); *Media Techs. Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334 (Fed. Cir. 2010) (one element not disclosed by references but differences between references and claims were minor); *Perfect Web Techs., Inc. v. InfoUSA, Inc.*, 587 F.3d 1324 (Fed. Cir. 2009) (all elements disclosed but one—repeat steps on failure, which was readily apparent because "one could do little else"); *Ritchie v. Vast Resources, Inc.*, 563 F.3d 1334 (Fed. Cir. 2009) (all elements disclosed; new use of known material achieved predictable results); *Rothman v. Target Corp.*, 556 F.3d 1310 (Fed. Cir. 2009) (all elements clearly

Seventeen cases fell into this first category and all seventeen holdings ultimately found the claimed invention to be obvious; attempts to rebut the prima facie case of obviousness with economic objective indicia of nonobviousness were uniformly unsuccessful. Some opinions expressly acknowledged the analytical importance of objective indicia of nonobviousness but effectively stated that no secondary considerations evidence could rebut such a strong showing of prima facie obviousness.<sup>242</sup>

This characterization of cases in the first category is not intended to suggest that the court was unwilling to consider objective indicia of nonobviousness because the court has (post-*KSR*) stated that objective indicia of nonobviousness *must* be considered and can be very important to a proper evaluation of obviousness.<sup>243</sup>

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disclosed and motivation to combine existed); *Ball Aerosol & Speciality Container, Inc. v. Limited Brands, Inc.*, 555 F.3d 984 (Fed. Cir. 2009) (all elements undisputedly disclosed in references; “motivation to combine” disputed by parties but Court felt that it was clear; combination involved familiar elements achieving predictable results); *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982 (Fed. Cir. 2009) (all elements disclosed and motivation to combine was apparent to Court); *Sundance, Inc. v. Demonte Fabricating Ltd.*, 550 F.3d 1356 (Fed. Cir. 2008) (two references combined to teach all elements; mere mechanic’s skill required to combine the references, rather than inventive skill); *In re DBC*, 545 F.3d 1373 (Fed. Cir. 2008) (only one element was missing from references but that element was readily apparent); *Asyst Techs., Inc. v. Emtrak Inc.*, 544 F.3d 1310 (Fed. Cir. 2008) (all elements disclosed); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318 (Fed. Cir. 2008) (all elements disclosed but one—use of web browser, which was readily apparent); *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365 (Fed. Cir. 2008) (minor variation of the claims was taught in a single reference but differences between reference and claims were well within the ordinary skill of a POSITA); *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008) (very strong prima facie obviousness evidence [all elements disclosed except for a resistive switch rather than a mechanical switch]); *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007) (all elements disclosed in references; reasonable expectation of success established through inventor admission); *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157 (Fed. Cir. 2007) (all elements disclosed but one—the use of electronics, which was readily apparent).

242. See *Wyers*, 616 F.3d at 1246 (“Moreover, secondary considerations of nonobviousness—considered here by the district court—simply cannot overcome a strong prima facie case of obviousness.”); *Sundance*, 550 F.3d at 1368 (“Secondary considerations of nonobviousness—considered here by the district court—simply cannot overcome this strong prima facie case of obviousness.”); see also *Agrizap*, 520 F.3d 1337.

243. In the context of a post-*KSR* motion for summary judgment of invalidity, the Federal Circuit has held that refusal to consider objective evidence of nonobviousness, where a genuine issue of material fact exists, is reversible error. *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1304-05 (Fed. Cir. 2010) (Moore, J.) (“In its opinion, the district court ignored [the “substantial” proffered] objective evidence of nonobviousness. Though the court cited *Graham*, it indicates that the court is required to consider only the first three factors. . . . We hold that the district court erred by failing to consider . . . objective evidence of nonobviousness. Our case law is clear that this type of evidence ‘must be considered in evaluating the obviousness of a claimed invention.’ . . . To be clear, a district court must *always* consider any objective evidence of nonobviousness presented



That characterization does reflect, however, that the court finds certain evidence more probative of obviousness or nonobviousness, as a general matter, than other types of evidence. Accordingly, cases in this first category, involving strong evidence supporting a prima facie case of obviousness, may be difficult to rebut.

It is statistically rather remarkable that seventeen of seventeen such cases found obviousness. For such cases, therefore, it appears that the winning argument for the patentee is to kill the prima facie case both at the USPTO and the district courts. And if not kill, at least maim, so that the inter partes judges will not be tempted to fall in line with the other 100% of the decisions. And we are most hopeful that the Lead Prior Art methodology unveiled in this article will prove to be an effective killer of *improper* prima facie cases.

A second category of cases involved what might be termed “moderately strong evidence of prima facie obviousness.” Cases within the second category involved all elements of a claimed invention being present in the cited references but a “motivation to combine” or “reasonable expectation of success” being in serious dispute, or a “teaching away” existing in the prior art. Only three cases in this empirical study fell into this category, but all three holdings relied heavily on objective indicia of nonobviousness to find that the claims were nonobvious.<sup>244</sup> Thus, although the sample size

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in a case. . . . Because of the failure to consider the objective evidence of nonobviousness and because there are genuine issues of material fact remaining, we reverse the grant of summary judgment of invalidity based on obviousness.”) (citing *Iron Grip Barbell Co. v. USA Sports, Inc.*, 392 F.3d 1317, 1323 (Fed. Cir. 2004); *Ruiz v. A.B. Chance Co.*, 234 F.3d 1270, 667 (Fed. Cir. 2004); and *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir. 1997)). See also *Geo. M. Martin*, 618 F.3d at 1304 (stating in conjunction with an appeal of an obviousness determination as a matter of law: “[s]econdary considerations of non-obviousness must be considered when present”; claims nonetheless later held to be obvious).

In the context of a pre-*KSR* appeal from summary judgment of invalidity, the Court has shown a willingness to make its evaluation of objective indicia of nonobviousness in a first instance on appeal. See *Iron Grip*, 392 F.3d at 1323-24 (“Our precedents . . . establish that failure to cite secondary considerations, alone, is not reversible error.”) (quoting *Ruiz*, 234 F.3d at 668). In *Iron Grip*, Plaintiff asserted objective evidence of nonobviousness, including “commercial success,” “copying,” and “licensing.” The Court rejected each of these assertions, based on a lack of nexus between the claims and the success, as well as other factors, and concluded that “[the record] does not show the existence of relevant secondary factors to support patentability.” On that basis, the district court’s finding of obviousness was properly affirmed. *Iron Grip*, 392 F.3d at 1323-25.

244. See *Power-one, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1351-52 (Fed. Cir. 2010) (all elements disclosed in cited references but “reasonable expectation of success” was lacking because combination of references may not have worked if combined; objective indicia of nonobviousness was important to ultimate determination that claims were not obvious); *Proctor & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 995-98 (Fed. Cir. 2009) (although all elements were disclosed in cited references, reasonable expectation of success was lacking and

for this category is small (at three opinions), the results stand in stark contrast to the results from the first category of cases, which uniformly reached the opposite conclusion in seventeen cases.

A third category of cases involved what might be termed “moderately weak evidence of prima facie obviousness.” Cases within this third category involved most but not all elements of the claimed invention being disclosed in the cited references and other weaknesses in the prima facie case of obviousness.<sup>245</sup> In these cases, the role of economic objective indicia of nonobviousness seemed important to the determination of nonobviousness, but one wonders whether such evidence merely reinforced a conclusion of nonobviousness mandated by the inability of the party asserting obviousness to persuasively establish a prima facie case of obviousness.

A fourth category of cases involved what might be termed “very weak evidence of prima facie obviousness.” Cases within this category involved an absence of a significant number of elements of the claimed invention from the prior art or other serious evidentiary shortcomings for the allegation of prima facie obviousness.<sup>246</sup> Thus, a prima facie case of obviousness could not be persuasively established, and the court, not surprisingly, found that the claimed invention was not obvious. In one case, the court even said that evaluation of objective indicia of nonobviousness was unnecessary in light of the weak evidence supporting prima facie obviousness.<sup>247</sup> And one can

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unexpected results were seen; objective indicia of nonobviousness in the form of long-felt need was influential to finding of non-obviousness); *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326-29 (Fed. Cir. 2009) (strong prima facie case of obviousness but strong teach-away also present; objective indicia of nonobviousness of Defendant pursuing other path until discovering patented technique was influential to finding of non-obviousness).

245. See *Crocs, Inc. v. Int’l. Trade Comm’n.*, 598 F.3d 1294 (Fed. Cir. 2010) (one element not taught by cited references; teach-away existed and unexpected results were achieved; commercial success evidence was not rebutted so claims were non-obvious); *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1372-75 (Fed. Cir. 2010) (one disputed element was not disclosed in cited references; motivation to combine was weak; objective indicia of nonobviousness was useful to finding of non-obviousness); *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1339-40 (Fed. Cir. 2010) (one element undisputedly not disclosed in cited references; Defendant argued “obvious to try”; objective indicia of nonobviousness led to conclusion of non-obviousness).

246. See *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350 (Fed. Cir. 2007) (although structurally similar compounds were disclosed in cited references, nothing guided selection of the claimed compound from large number of potential candidate compounds; teaching-away from claimed compound existed in one reference); *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008) (significant unexpected results, strong evidence of copying, and surprise of experts led to finding of non-obviousness).

247. See *Takeda*, 492 F.3d at 1363 (“In light of our conclusion that Alphapharm failed to

certainly envision that the Lead Prior Art methodology could well lead to the same result under those circumstances.

The pattern that emerges from the twenty-five cases discussed above has vital importance to how the obviousness determination is performed. An inescapable conclusion is that once strong evidence supporting a prima facie case of obviousness is established, a party asserting nonobviousness has a reduced chance of prevailing, although of course every case depends on its own facts.

Thus, the importance of identifying the correct evidence, and particularly the sensible prior art starting place when making the initial determination of prima facie obviousness, is exceptionally high. In essence, if the USPTO or party opponent in litigation relies on strong but improper prior art evidence that incorrectly establishes a prima facie case of obviousness, the shooting match may well be over.

Therefore, parties and factfinders should realize that the obviousness determination may be won or lost at the stage of evaluating prima facie obviousness. For these reasons, the contribution of Lead Prior Art methodology towards identify whether a prima facie case of obviousness has been established—particularly by focusing on the sensible starting point(s) in the prior art, and whether there is a straightforward path from that art to the claimed invention, with a reasonable expectation of success—cannot be overstated.

#### IV. IDENTIFICATION OF THE PROPER LEAD PRIOR ART IN A MANNER THAT AVOIDS HINDSIGHT

The article now turns to a fundamental issue: how does one pick one or more sensible starting point(s) for further development in the prior art? As has been seen, we view that question as a linchpin holding together the prima facie analysis.

In general, we found it surprising that methods for determining the relevant scope and content of the prior art under *Graham* Factor 1, or for selecting the proper prior art to be compared for differences to the claimed invention in *Graham* Factor 2, have not been an object of central focus by the courts.<sup>248</sup> In many cases, with exceptions noted below, the prior art is selected by the examiner during prosecution or

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prove that the claimed compounds would have been prima facie obvious, we need not consider any objective indicia of nonobviousness.”)

248. See, for example, the cases discussed *infra* Section IV.A.

by a patent challenger during litigation.<sup>249</sup>

Our observation is that, often, the propriety of the selection of that prior art is not questioned.<sup>250</sup> So rather than witnessing a battle as to whether the selected prior art was the appropriate prior art starting point for that particular factual situation (“starting prior art”), we have seen the battle shift to: (1) *Graham* Factor 2, i.e., the differences between the prior art (whose selection is presumed to be correct) and the claimed invention; and (2) whether those differences rendered the claimed invention as a whole obvious, with various sub-battles involving motivation, reasonable expectation of success, teaching away, etc. As will be discussed below, however, identification of the proper prior art used to begin an obviousness determination under the *Graham* Factors is of the *utmost* importance because improper selection of the starting prior art could erroneously lead to the wrong conclusion, be it obviousness or non-obviousness.

Various options exist for determining an appropriate and sensible starting prior art during an obviousness analysis. We call this starting prior art the “Lead Prior Art,” to be distinguished from the “Lead Prior Art” methodology or paradigm discussed throughout this article. The case law makes clear that the Lead Prior Art may contain one or more than one piece of prior art; i.e., more than one starting point for further development.

Of course, as mentioned before,<sup>251</sup> the burden is on the USPTO to establish obviousness by a preponderance of the evidence<sup>252</sup> and on the alleged infringer to establish obviousness by clear and convincing evidence.<sup>253</sup> So, practically, the patent applicant/patentee may NEVER have to establish what is the Lead Prior Art. It may suffice instead for the patent applicant/patentee to simply establish that the USPTO and/or the alleged infringer has NOT picked the sensible prior art starting point.

To initiate the analysis, let us provide a brief historical perspective discussing how the courts have approached the determination of obviousness of new chemical compounds before *KSR* was decided. We also discuss recent post-*KSR* Federal Circuit chemical/pharmaceutical cases that focused their obviousness analysis

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249. See, for example, the cases discussed *infra* Section IV.A.; see also discussion *infra* Section IV.B for a brief review of the exceptions mentioned in the text.

250. See discussion *infra* Section IV.B for a brief review of the exceptions.

251. See discussion *supra* Section II.B.

252. See, e.g., *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304, 1315 (Fed. Cir. 2002).

253. See *id.*

on the identification of compounds that a POSITA would have selected for further modification (“lead compounds”). We then show how the lead compound approach can be extrapolated to other technologies to assert, or defend against, a *prima facie* case of obviousness.

*A. Determination of Obviousness of New Chemical Compounds Pre-KSR*

Before *KSR*, courts held in chemical cases that sufficient “structural similarity” between previously-disclosed compounds and new compounds may, under certain circumstances, form the basis of a *prima facie* case of obviousness.<sup>254</sup> Those cases required a factually-intensive analysis of the determination of what constitutes a “sufficiently similar” compound and the circumstances where such structural similarity, without more, would have been sufficient to establish a *prima facie* case.<sup>255</sup> Examples of “particular types or categories of structural similarity” that apparently, “without more,” were at least sometimes deemed to result in a *prima facie* case of obviousness included stereoisomers, adjacent homologs, structural isomers, and acids and their ethyl esters.<sup>256</sup>

As the Federal Circuit’s *en banc* decision in *Dillon* explained, however, this scenario is more likely to exist where “the claimed and prior art compounds possess a ‘sufficiently close relationship . . . to create an expectation,’ in light of the totality of the prior art, that the new compound will have ‘similar properties’ to the old.”<sup>257</sup> Indeed, *Dillon* recognized that something else, i.e., a reason or motivation, beyond structural similarity was required to find obviousness:

This court, in reconsidering this case *in banc* [sic], reaffirms that structural similarity between claimed and prior art subject matter, proved by combining references or otherwise, *where the prior art gives reason or motivation to make the claimed compositions, creates a prima facie case of obviousness.*<sup>258</sup>

In that case, the “sufficiently close relationship” itself provided the requisite reason or suggestion to prepare those structurally-related

254. See, e.g., *In re Payne*, 606 F.2d 303, 314-16 (C.C.P.A. 1979).

255. See, e.g., *id.*; *In re Jones*, 958 F.2d 347 (Fed. Cir. 1992); *In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990).

256. See *In re Jones*, 958 F.2d 347, 349-50 (Fed. Cir. 1992) (reviewing the existing case law in this regard up to that date).

257. *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007) (citing *In re Dillon*, 919 F.2d at 692).

258. *Dillon*, 919 F.2d at 692 (emphasis added).

compounds because the prior art compounds had a sufficiently desirable utility for a POSITA to prepare close compounds.<sup>259</sup>

In responding to the dissent, the *Dillon* majority also presented a series of scenarios where the closest prior art would not have created a prima facie case of obviousness. For example, the court explained that “a presumption is not created when the reference compound is so lacking in any utility that there is no motivation to make close relatives.”<sup>260</sup> Nor would there be a prima facie case where the negative properties of the prior art meant the compound could not be regarded as useful and therefore could not have been a basis to make related compounds.<sup>261</sup>

*Dillon* is also important because it explained that the reason to modify the prior art compound to arrive at the claimed compounds need not arise from seeking the same properties displayed by the claimed compounds:

Properties, therefore, *are* relevant to the creation of a *prima facie* case in the sense of affecting the motivation of a researcher to make compounds closely related to or suggested by a prior art compound, but it is not required, as stated in the dissent, that the prior art disclose or suggest the properties newly-discovered by an applicant in order for there to be a *prima facie* case of obviousness.<sup>262</sup>

Thus, although “properties . . . are relevant, failure of the prior art to disclose or suggest applicant’s “newly-discovered” properties does not preclude the possibility of finding a prima facie case of obviousness. As long as a sufficiently similar compound has been previously disclosed as useful for some purpose and, thus, would have suggested creating the claimed compound, “even if . . . for a reason entirely separate from the problem faced by the inventor at hand,” a prima facie case of obviousness likely exists against the claimed compound.<sup>263</sup>

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259. See *id.* at 692, 696 (explaining that “[i]n brief, the cases establish that if an examiner considers that he has found prior art close enough to the claimed invention to give one skilled in the relevant chemical art the motivation to make close relatives (homologs, analogs, isomers, etc.) of the prior art compound(s), then there arises what has been called a presumption of obviousness or a *prima facie* case of obviousness.”) (citations omitted).

260. *Id.* at 697 (citing to *In re Steminski*, 444 F.2d 581, 586 (C.C.P.A. 1971)).

261. See *Dillon*, 919 F.2d at 697 (citing to *In re Albrecht*, 514 F.2d 1389, 1392 (C.C.P.A. 1975)).

262. *Dillon*, 919 F.2d at 697

263. Brief for the Respondent in Opposition at 4, *Dillon v. Manbeck*, No. 90-1264, 1991 WL 11177794, at \*6 (U.S. April 10, 1991) (“[T]he principal question considered in the detailed opinions of the en banc court below: whether the patent examiner establishes a *prima facie* case

In more recent times, the first articulation of an obviousness determination in terms of a “lead compound” analysis occurred pre-KSR in *Yamanouchi v. Danbury*.<sup>264</sup> That approach took place, however, because the Federal Circuit decided not to analyze the case in terms of “lead compounds.” Instead, the defendant, Danbury, rested its obviousness attack on the selection of two “lead compounds” from the prior art from which it created an alleged obvious path to the patented compound.<sup>265</sup> The commercial product in *Yamanouchi* was famotidine, an inhibitor of gastric acid secretion useful in the treatment of heartburn.<sup>266</sup>

Danbury argued that a POSITA would have selected two known compounds as lead compounds because they were three and eleven times more active, respectively, than cimetidine, the benchmark compound for heartburn treatment at that time.<sup>267</sup> Danbury then proposed that a POSITA would have combined certain moieties of those two compounds to create a third, intermediate, compound that required further modification to arrive at famotidine.<sup>268</sup> The Federal Circuit disagreed with this argument because other compounds were more active than at least one of the two lead compounds proposed by Danbury.<sup>269</sup> The court also found that a POSITA would not have followed the path suggested by Danbury to synthesize famotidine.<sup>270</sup> Accordingly, the court ruled in favor of the patentee.<sup>271</sup>

Without considering *Yamanouchi* for the moment, we can conclude that, in general, in the pre-KSR cases of new chemical compounds, the courts focused more on (1) whether the differences between the claimed compounds and the prior art were relatively small, such that the claimed compound would have been obvious, and/or (2) whether there would have been a reason to modify the prior art to arrive at the claimed compounds, even if that was a different reason than the one the inventor(s) had.<sup>272</sup> Those cases, however, did

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that a composition is obvious by showing motivation to create the composition in the prior art, even if the prior art would have suggested creating the composition for a reason entirely separate from the problem faced by the inventor at hand.”).

264. *Yamanouchi Pharm. Co., v. Danbury Pharm., Inc.*, 231 F.3d 1339 (Fed. Cir. 2000).

265. *See id.* at 1343-44.

266. *See id.* at 1341.

267. *See id.* at 1344.

268. *See id.*

269. *See id.*, at 1344-45.

270. *See id.* at 1345.

271. *See id.* at 1346.

272. Consider, for example, the rationales supporting the decisions in *Jones* and *Dillon*, which represent typical pre-KSR chemical compound cases. In *Jones*, the Court held that the

not focus on whether the selected prior art was the proper art for the obviousness analysis.

Even in *Yamanouchi*, the Federal Circuit's analysis was centered on the then-accepted "motivation to combine" requirement<sup>273</sup> and only referred to "lead compounds" in the opinion because that is how the defendant articulated its patentability attack.<sup>274</sup> That position is confirmed by the fact that in a later pre-*KSR* new-compound case involving parties articulating their attacks and defenses in terms of a "lead compound," the Federal Circuit refused to decide the case on those terms.<sup>275</sup> Rather, the Federal Circuit held that an analysis of the applied prior art evidenced a preference for preparation of compounds different from those claimed;<sup>276</sup> and, therefore, the prior art taught away from the claimed invention.<sup>277</sup>

*B. Identification of a "Lead Compound" as Part of the  
Obviousness Determination of New Chemical Compounds  
Post-KSR*

Based on the pre-*KSR* case law discussed in the previous section, a typical approach litigants and USPTO examiners followed during an obviousness analysis of new chemical compounds involved the identification of a structurally-close compound in the prior art, and then a proposal of suitable modifications to arrive at the claimed compounds.<sup>278</sup> The prior art disclosing the structurally-close compound could be easily identified through hindsight structure-based searches of publicly available databases using the claimed compound itself as the search template.<sup>279</sup> That approach, clearly

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claimed compounds were not obvious because they were not sufficiently close to the applied prior art. *In re Jones*, 958 F.2d 347, 350 (Fed. Cir. 1992). In *Dillon*, the Federal Circuit concluded that the claimed compounds were obvious because one of ordinary skill in the art would have had a reason to modify the applied art to arrive at the invention. *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990).

273. See *Yamanouchi*, 231 F.3d at 1345.

274. See *id.* at 1343-44.

275. See *Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 471 F.3d 1369, 1377-80 (Fed. Cir. 2006).

276. See *id.* at 1380.

277. See *id.*

278. See, e.g., *In re Jones*, 958 F.2d 347,349 (Fed. Cir. 1992); *Yamanouchi*, 231 F.3d at 1344-45.

279. See *The Digital Age – STN, SciFinder, and more*, AMERICAN CHEMICAL SOCIETY, [http://portal.acs.org/portal/acs/corg/content?\\_nfpb=true&\\_pageLabel=PP\\_ARTICLEMAIN&no\\_de\\_id=930&content\\_id=CTP\\_004593&use\\_sec=true&sec\\_url\\_var=region1&\\_\\_uuid=34bc1e59-6954-470a-8b75-72a87a5174a7#P55\\_18082](http://portal.acs.org/portal/acs/corg/content?_nfpb=true&_pageLabel=PP_ARTICLEMAIN&no_de_id=930&content_id=CTP_004593&use_sec=true&sec_url_var=region1&__uuid=34bc1e59-6954-470a-8b75-72a87a5174a7#P55_18082) (last visited March 25, 2011) (indicating that STN International, part of Chemical Abstract Service, has been providing structure-based searches



loaded with hindsight, did not supply a reason why a POSITA would have selected a closest compound as a reasonable starting point, particularly when the POSITA, statutorily,<sup>280</sup> would not have had the benefit of knowing ahead of time the structure of the claimed compound.

In an attempt to avoid hindsight in the obviousness analysis of new compound cases post-*KSR*, the Federal Circuit has, in relatively recent times, expressly engaged in a determination of whether the applied prior art was indeed the proper prior art starting point for the obviousness analysis.<sup>281</sup> In those cases, the court has analyzed whether prior art compounds selected by a party as a POSITA's starting point, for challenging a patent can be properly considered "lead compounds," or in Lead Prior Art terminology, "sensible prior art starting points." A lead compound represents a compound that a POSITA would have selected as a sensible starting point for further modification given the knowledge available in the prior art and the specific circumstances of each case,<sup>282</sup> and remembering from *en banc Dillon*, that the POSITA might select prior art for a different reason than that of the inventor(s).<sup>283</sup>

### 1. *Takeda*

To illustrate the concept of the lead compound analysis, consider the facts of *Takeda v. Alphapharm*,<sup>284</sup> which was apparently the first lead compound case decided after *KSR*.<sup>285</sup> In *Takeda*, the patented compounds were useful in the treatment of diabetes and had the following general structure (claim 1):

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since the 1990s).

280. See *supra* note 4.

281. See, e.g., *Takeda Chemical Industries, Ltd. v. Alpharm Pty., Ltd.*, 492 F.3d 1350, 1356 (Fed. Cir. 2007); *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, 533 F.3d 1353, 1356-57 (Fed. Cir. 2008); *Daiichi Sankyo Co., Ltd. v. Matrix Laboratories, Ltd.*, 619 F.3d 1346, 1352 (Fed. Cir. 2010).

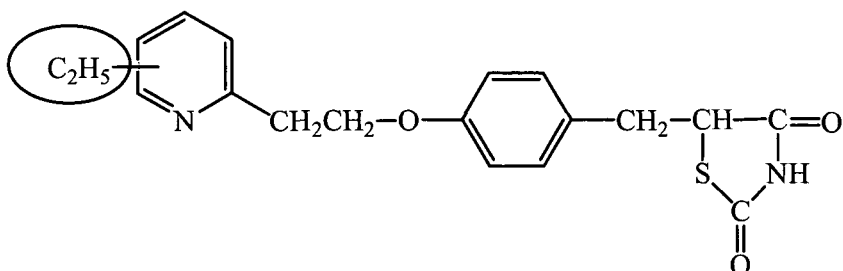
282. See, e.g., *Takeda*, 492 F.3d at 1357; *Daiichi*, 619 F.3d at 1353-54.

283. See discussion *supra* Section IV.A.

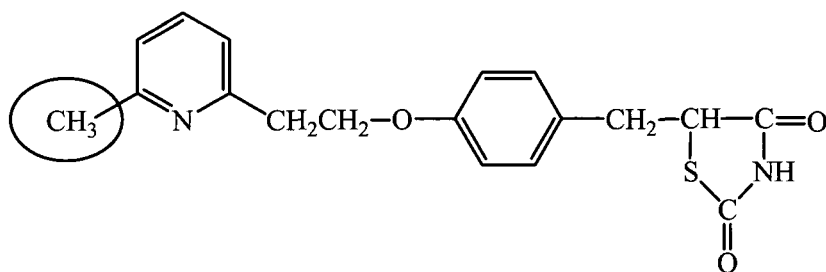
284. See, e.g., *Takeda*, 492 F.3d at 1357; *Eisai*, 533 F.3d at 1357.

285. The authors could not identify any other case decided after *KSR* but before *Takeda* in which the Federal Circuit employed the lead compound approach.

General formula of patented compounds in *Takeda*<sup>286</sup>



Alphapharm, the accused infringer, argued that the claimed compounds were obvious in light of a compound known in the prior art, "Compound *b*," which has the formula shown below:<sup>287</sup>



Compound *b*, known in the prior art

Because the structure of the patented compounds allowed the substitution by the ethyl group ( $C_2H_5-$ ) (circled in the drawing above) on any available carbon atom in the corresponding ring, the only difference between the prior art compound, Compound *b*, and the genus of claimed compounds was the presence of a methylene group ( $-CH_2-$ ) in the circled substituent (the difference between  $C_2H_5-$  and  $CH_3-$ ).<sup>288</sup> The actual commercial embodiment (pioglitazone) marketed by the patentee was claimed in a dependent claim.<sup>289</sup>

286. See *Takeda*, 492 F.3d at 1354.

287. See *id.*

288. See *id.*

289. See *id.* The structure of pioglitazone is shown below.

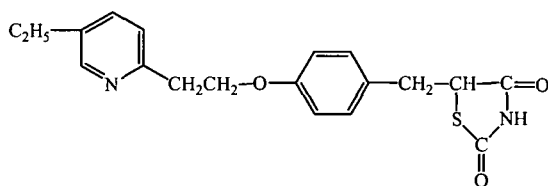
Pioglitazone had an additional difference with respect to Compound *b* regarding the location of the ethyl group within the pyridyl ring.<sup>290</sup>

Alphapharm argued that a POSITA would have selected Compound *b* as a starting compound for further modification (lead compound), and that once selected, the POSITA would have made two obvious changes.<sup>291</sup> These changes were (1) replacing the methyl group with an ethyl group, and then (2) selecting the position of the ethyl group within the ring to match the position in the commercial compound pioglitazone.<sup>292</sup>

Indeed, a comparison of the above structures clearly shows that the degree of structural similarity between the prior art Compound *b* and the patented compound is high. The Federal Circuit, however, after analyzing the relevant prior art, found the claims non-obvious.<sup>293</sup>

Instrumental to the Federal Circuit's decision was a determination that Compound *b*, contrary to Alphapharm's assertion, and despite being undisputedly the most structurally similar compound to the claimed compounds, *would not have been the compound that a POSITA would have chosen for further modification when faced with the problem of finding new compounds for the treatment of diabetes.*<sup>294</sup> The court determined, instead, when analyzing the differences between the claimed compounds and the prior art, that Compound *b* was *not the proper prior art against which to compare the claimed invention.*<sup>295</sup> It may well have been that Compound *b* was within the relevant scope and content of the prior art, but so were myriad other compounds. And there was no evidence that Compound *b* represented a sensible starting point, using our terminology, for the § 103 calculus.

In order to understand this decision, it is important to recount some of the relevant prior art that the Federal Circuit considered in its analysis. Compound *b* was one of fifty-four explicitly-disclosed compounds in a prior art patent (U.S. Patent No. 4,287,200, "the '200



*Id.*

- 290. *Id.*
- 291. *See id.* at 1357.
- 292. *See id.*
- 293. *See id.* at 1360.
- 294. *See id.* at 1358.
- 295. *See id.* at 1360.

patent”).<sup>296</sup> During prosecution of the ‘200 patent, the applicant submitted results for nine compounds, one of which was Compound *b*.<sup>297</sup> In fact, Compound *b* was specifically claimed in one of the dependent claims of the ‘200 patent.<sup>298</sup>

Also during the prosecution of the ‘200 patent, the applicant explicitly singled out Compound *b* as especially important by stating that “the compounds in which these heterocyclic rings are substituted have become important, especially [Compound *b*].”<sup>299</sup> However, a prior art journal article (“the *Sodha II* reference”) disclosed undesirable physiological effects of Compound *b*.<sup>300</sup> Those undesirable side effects included “considerable increases in body weight and brown fat weight.”<sup>301</sup> The *Sodha II* reference also identified three specific compounds among 101 disclosed compounds that were deemed to be the most favorable in terms of toxicity and biological activity.<sup>302</sup> Compound *b* was not among them.<sup>303</sup>

After weighing the available evidence, the Federal Circuit found that a POSITA would not have selected Compound *b* as a lead compound because of the undesirable side effects.<sup>304</sup> The Federal Circuit explained:

Rather than identify predictable solutions for antidiabetic treatment, the prior art disclosed a *broad selection of compounds any one of which could have been selected as a lead compound for further investigation*. Significantly, the closest prior art compound (compound *b*, the 6-methyl) exhibited *negative properties that would have directed one of ordinary skill in the art away from that compound*.<sup>305</sup>

In the context of the appeal, the Federal Circuit indicated that a lead compound was “a compound in the prior art that would be most promising to modify in order to improve upon its antidiabetic activity and obtain a compound with better activity.”<sup>306</sup>

Even if Alphapharm had shown that a POSITA would have selected Compound *b* as a lead compound, the Federal Circuit also held that Alphapharm had failed to show that a POSITA would have

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296. *Id.* at 1357.

297. *Id.*

298. *Id.* at 1358.

299. *Id.*

300. *See id.*

301. *Id.*

302. *Id.*

303. *Takeda*, 492 F.3d at 1358.

304. *See id.*

305. *Id.* at 1359 (emphasis added).

306. *Id.* at 1357.

modified Compound *b* in the manner necessary to arrive at the claimed compound.<sup>307</sup> Referring to this additional requirement, the Federal Circuit explained that post-*KSR*:

[I]n cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new compound.<sup>308</sup>

As can be seen, the Federal Circuit's analysis in *Takeda* laid the foundation for the lead compound approach, and also for our Lead Prior Art methodology, establishing that mere structural similarity was not sufficient to establish a prima facie case of obviousness if: (1) a POSITA would not have selected the close-structural compound (which was not a sensible prior art starting point in our parlance) or if (2) a POSITA would not have made the modifications necessary to arrive at the claimed compound (which would indicate that no straightforward path could have bridged the differences between the sensible starting point and the claimed invention with a reasonable expectation of success).<sup>309</sup>

As will be seen in Section 5, *infra*, Lead Prior Art methodology, therefore, is consistent with *Takeda* in requiring the party alleging invalidity to explain why the allegedly invalidating prior art (in *Takeda*, not surprisingly, a related structural homolog picked with the benefit of hindsight) would have been identified as the starting point for modification. The challenger must establish what desirable properties the allegedly invalidating prior art has that would have motivated a POSITA to choose it as a sensible starting point for further modification. If a POSITA would not have selected the allegedly invalidating prior art as the sensible starting point for further investigation, whether or not it is established what other prior art would in fact have been the sensible starting point, no prima facie case of obviousness has been established.

Ultimately, nonobviousness may be attributable to a combination of factors, particularly where there was a failure to establish a linear, straightforward path for a POSITA from a demonstrably sensible starting point to the invention. Such inability to factually establish a sensible starting point, from which a straightforward path existed, may well explain the difficulty challengers in "lead compound" cases face in proving obviousness arguments, however logical their arguments may seem with *20:20* hindsight vision.

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307. See *id.* at 1362-63.

308. *Id.* at 1357.

309. See *id.* at 1356-63.

## 2. *Eisai*

In the second lead compound case decided post-*KSR*, *Eisai Co. v. Dr. Reddy's Labs*,<sup>310</sup> the Federal Circuit confirmed the approach employed in *Takeda* for the obviousness analysis of a new chemical compound. The Federal Circuit explicitly articulated the first step of the analysis: “post-*KSR*, a prima facie case of obviousness for a chemical compound still, in general, begins with the reasoned identification of a *lead compound*.”<sup>311</sup>

*Eisai* is also important because the decision shed light on the type of prior art that could be considered when searching for a lead compound. The Federal Circuit explained that although the claimed compounds were useful in the treatment of ulcers, the obviousness analysis could also consider compounds inhibiting gastric acid, which the record showed in that case to be physiologically different from anti-ulcer compounds.<sup>312</sup>

Thus, to the extent that a POSITA could have selected those gastric acid inhibitors as starting compounds for preparation of the claimed compounds, such prior art inhibitor compounds represented sensible starting points for obviousness analysis.<sup>313</sup> In particular, when considering the evidence in the light most favorable to the patent challenger,<sup>314</sup> the *Eisai* court assumed that the proposed lead compounds *possessed either superior biological activity to other known compounds or other characteristics* that made them desirable to a POSITA.<sup>315</sup> In essence, the Federal Circuit assumed that the prior art selected by the patent challenger was indeed within the relevant scope and content of the prior art in that specific obviousness determination.

Nonetheless, the court found that a POSITA would not have modified the selected prior art compounds in the manner proposed by the patent challenger because such modification would have removed the very same property that conferred the compounds their advantages over the other prior art compounds.<sup>316</sup> Accordingly, the Federal Circuit held that the claimed compounds would not have been

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310. *Eisai Co. Ltd. v. Dr. Reddy's Laboratories, Ltd.*, 533 F.3d 1353, 1357 (Fed. Cir. 2008).

311. *Id.* at 1359 (emphasis added).

312. *See id.* at 1358 (citing *KSR* as support for the decision to include compounds inhibiting gastric acid in the obviousness analysis).

313. *See id.*

314. *See id.* at 1355 (*Eisai* dealt with a review of a district court decision granting the patentee's summary judgment motion of validity and enforceability in favor of the patentee.); *id.* at 1356, 1358 (When deciding a summary judgment motion, the court takes the evidence in the light most favorable to the non-movant party.).

315. *See id.* at 1358.

316. *See id.* at 1358-59.

obvious to a POSITA in light of the prior art.<sup>317</sup> In other words, there was no straightforward path from those selected prior art compounds to the claimed invention and, hence, no obviousness.

The approach followed in *Eisai*, considering prior art useful in solving a problem different from that of the inventors', is also consistent with the Federal Circuit *en banc Dillon*<sup>318</sup> decision and with *KSR*.<sup>319</sup> As explained *infra*,<sup>320</sup> the *Dillon* court refused to institute the requirement that a *prima facie* case of obviousness required an expectation that the proposed combination of prior art references would have the same utility as the claimed compounds.<sup>321</sup> Although the court's statements in *Dillon* were directed to the reasons a POSITA could have had when combining the references,<sup>322</sup> the statements nonetheless demonstrate a willingness to consider prior art that evidences a utility different from that of the claimed invention.

### 3. *Daichi*

The next lead compound case from the Federal Circuit is *Daiichi Sankyo Co., Ltd. v. Matrix Labs*.<sup>323</sup> In *Daiichi*, the Federal Circuit reiterated and confirmed the requirements of the lead compound approach by explaining that:

Proof of obviousness based on structural similarity requires clear and convincing evidence that a medicinal chemist of ordinary skill would have been motivated [1] to select and then [2] to modify a prior art compound (e.g., a lead compound) to arrive at a claimed compound with a reasonable expectation that the new compound would have similar or improved properties compared with the old. In keeping with the flexible nature of the inquiry after [*KSR*], the motivation to select and modify a lead compound need not be explicit in the art.<sup>324</sup>

More importantly, the Federal Circuit also provided further guidance on how to implement the lead compound approach. For example, the court named factors helpful in identifying potential lead

317. *See id.* at 1359.

318. *In re Dillon*, 919 F.2d 688, 697 (Fed. Cir. 1990).

319. *KSR International Co. v. Teleflex, Inc.*, 550 U.S. 398, 420 (explaining that “[t]he question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art” and that “[u]nder the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed.”).

320. *See supra* text accompanying notes 254-277.

321. *See Dillon*, 919 F.2d at 693.

322. *See supra* text accompanying notes 254-277.

323. *Daiichi Sankyo Co., Ltd. v. Matrix Labs*, 619 F.3d 1346 (Fed. Cir. 2010).

324. *Id.* at 1352 (citations omitted).

compounds: “it is the possession of promising useful properties in a lead compound that motivates a chemist to make structurally similar compounds.”<sup>325</sup> The court also blamed hindsight for the improper selection of structurally-close lead compounds and provided a foundation for a forward-looking approach to select a lead compound:

Yet the attribution of a compound as a lead compound after the fact must avoid hindsight bias; it must look at the state of the art *at the time the invention was made* to find a motivation to select and then modify a lead compound to arrive at the claimed invention. *Accordingly, proving a reason to select a compound as a lead compound depends on more than just structural similarity, but also knowledge in the art of the functional properties and limitations of the prior art compounds.* Potent and promising activity in the prior art trumps mere structural relationships.<sup>326</sup>

Thus, *Daiichi* not only confirmed the applicability of the lead compound approach to the analysis of new chemical compounds, but also provided further guidance on how to implement the approach. Further details of the facts involved in *Daiichi* are presented below in Section D, where the details illustrate how the scope of the search for prior art under *Graham* Factor 1 could influence the *prima facie* obviousness analysis.

#### 4. *Ortho-McNeil*

*Ortho-McNeil v Mylan*,<sup>327</sup> a case involving the epilepsy drug TOPO-MAX<sup>®</sup>, is also instructive because, as the court noted, “[i]n retrospect, [the inventor’s] pathway to the invention, of course, seems to follow the logical steps to produce these properties, but at the time of invention, the inventor’s insights, willingness to confront and overcome obstacles, and yes, even serendipity, cannot be discounted.”<sup>328</sup> In other words, Mylan, the challenger, was not able to provide a clear and convincing reason why a POSITA would have had a reason to follow a straightforward path from Mylan’s proposed starting point in the prior art, an intermediate, to the claimed invention.

The failure was even broader, as Mylan also failed to establish why a POSITA would have started with the prior art compound they selected.<sup>329</sup> And, “[e]ven beyond that, the ordinary artisan in this field

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325. *Id.* at 1354.

326. *Id.* (citations omitted, second emphasis added).

327. *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358 (Fed. Cir. 2008).

328. *Id.* at 1364.

329. *See id.*



would have had to (at the time of invention without any clue of potential utility of topiramate) stop at that intermediate and test it for properties far afield from the purpose for the development in the first place (epilepsy rather than diabetes).”<sup>330</sup>

Because no such rationale was offered, the court concluded that Mylan “simply retraced the path of the inventor with hindsight, discounted the number and complexity of the alternatives, and concluded that the invention of topiramate was obvious.”<sup>331</sup> In Lead Prior Art terms, Mylan failed to establish that its proposed prior art starting point was sensible. That failure was also dispositive, because if one starts at a wrong prior art starting point, it is hard to envision a straightforward path between that ill-considered prior art choice and the claimed invention. Of course, wholly apart from the Lead Prior Art paradigm, such flawed reasoning should rarely, if ever, be successful, for establishing obviousness, particularly in view of the language of Title 35 that requires the analysis to examine “the subject matter as a whole” to ascertain if it “would have been obvious at the time the invention was made.”<sup>332</sup>

*C. Extrapolation of the “Lead Compound” Approach to All Technologies to Identify the Proper Lead Prior Art Used in a Prima Facie Obviousness Determination*

As mentioned previously,<sup>333</sup> to avoid the use of impermissible hindsight, a prima facie obviousness analysis should proceed without considering the claimed invention and should only take into account the knowledge available in the art before the invention was made. Below, we propose our Lead Prior Art methodology, introduced earlier in the article, to identify suitable prior art to be used as part of *Graham* Factor 2 when determining whether a prima facie case of obviousness exists. This proposed methodology attempts to minimize the use of hindsight when making an obviousness determination by focusing on a forward-looking view of only information that would have been properly available to a POSITA.

The initial step in an obviousness assessment, according to *Graham* Factor 1, consists of reviewing the available art,<sup>334</sup> which should consist of that information that was available at the time of the invention, to avoid use of hindsight.<sup>335</sup> The purpose of that review is

330. *Id.*

331. *Id.*

332. *See supra* note 4.

333. *See discussion supra* Section II.C.

334. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1965).

335. *See supra* note 4.

to identify sensible starting points in the prior art. Our proposed methodology, however, allows for one notable exception because it also permits the inclusion of other objective indicia of nonobviousness that might have been developed after the invention was made (commercial success, long felt but unsolved needs, failure of others, unexpected results, etc.)<sup>336</sup> This approach, however, is entirely consistent with existing Federal Circuit precedent<sup>337</sup> and with the USPTO's own guidelines for examination,<sup>338</sup> which indicate that such objective indicia of nonobviousness could aid in a determination of whether a *prima facie* case of obviousness exists.<sup>339</sup>

That initial review of the art seeks to identify any prior art that would have been available that a POSITA would have considered relevant to solve a problem for which the claimed invention is also the solution, whether or not that problem was the same problem the applicant or patentee was trying to solve.<sup>340</sup>

Although knowledge of the claimed invention may seem to suggest an element of hindsight in application of our methodology, any use of hindsight is merely an analytical expedient that should not affect the accuracy of the results reached by our methodology. The logical justification for this statement relies, however, on some advanced concepts whose foundation has not yet been properly laid. Therefore, the authors ask that the reader take this statement as true until a subsequent discussion, *infra*.<sup>341</sup>

The Lead Prior Art methodology then demands that the most sensible starting point(s) be chosen, which will not necessarily be the most similar structurally. The Lead Prior Art paradigm seems superior to a hindsight search—selecting the most structurally similar compound and then applying it as the closest prior art with no investigation if other less structurally similar compounds are in fact more sensible starting points.

As mentioned previously, the POSITA represents a hypothetical person who: (1) is presumed to be aware of all the pertinent prior art in the area of the invention, (2) possesses ordinary creativity, and

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336. See discussion *supra* Section II.A.1.d. That evidence is not part of the scope and content of the prior art. But it goes to the level of skill in the art and the import of differences between the prior art and the claimed invention, i.e. *Graham* Factors 1 and 2. See discussion *supra* Section II.A.

337. See, e.g., *Siemens Med. Solutions USA, Inc. v. Saint-Gobain Ceramics & Plastics, Inc.*, Nos. 2010-1145, 2010-1177, 2011 WL 651790 (Fed. Cir. 2011).

338. 2010 KSR Guidelines Update, *supra* note 81 at 53,657 § 5.

339. See discussion *supra* Sections II.A.1.d and II.B.

340. See discussion *supra* Section IV.A.

341. See discussion *infra* Section V.E.

(3) exercises common sense when analyzing the available knowledge in the art.<sup>342</sup>

Although selection of a starting point based on solutions to a similar problem may facially appear similar to traditional principles of analogous art,<sup>343</sup> important differences exist. Principally, precedent concerning what prior art constitutes analogous art for existing obviousness rubric determines how broad the scope and content of prior art under consideration should be, for purposes of including as much prior art as possible within the obviousness consideration. By contrast, however, selection of a sensible starting point in the prior art concerns narrowing the prior art to that of a solution to the most similar problem, to assist in identifying a starting point that would presumably require fewer minimum modifications to reach the claimed invention. Thus, the inquiries for analogous art and identifying a sensible starting point are related but not identical. In fact, under the Lead Prior Art methodology, sensible starting point will always be analogous prior art but analogous prior art will not always be a sensible starting point.

The prior art analyzed in the initial step mentioned above for the Lead Prior Art methodology represents the pool of knowledge from which one or more starting prior art documents will be selected during the analysis involving *Graham* Factor 2 (differences between the prior art and the claimed invention). It is this sensible piece(s) of starting point prior art that makes up the “Lead Prior Art,” to then be analyzed in the Lead Prior Art methodology.

### 1. Identification of the Proper Lead Prior Art

Identification of that Lead Prior Art will be the focus of this section of the article. The legal framework for this analysis is founded on the rationale behind the Federal Circuit decisions in the lead compound cases discussed above.<sup>344</sup>

If a review of the available prior art according to *Graham* Factor 1 yields the existence of a problem that requires a solution, the analysis proceeds to determine whether the art also provides one or more of those needed solutions. Indeed, as part of the analysis of the “obvious to try” approach,<sup>345</sup> the Supreme Court indicated that “[w]hen there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a

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342. See discussion *supra* Section II.A.

343. See discussion *supra* Section II.A.1.a.

344. See discussion *supra* Section IV.B.

345. See discussion *supra* Section II.A.2.

person of ordinary skill has good reason to pursue the known options within his or her technical grasp.”<sup>346</sup>

The above passage is most commonly understood as providing a rationale to reach a conclusion that a given invention was obvious when a limited number of solutions were available to a known problem and the inventor merely pursued one of those solutions with a reasonable expectation of success. However, the passage also provides guidance for selecting a proper starting point for an obviousness analysis from among the available prior art. If the claimed invention is among a few, easily traversed, identified, and predictable solutions flowing from the prior art starting point, it is more likely that a *prima facie* case of obviousness exists.<sup>347</sup>

Hence, identified proposals in the art to solve a specified need can also be the source of suitable starting prior art for an obviousness analysis. Of course, among those identified proposals may be one or more that is more promising than the next. As in the Lead Compound cases, those one or more then may be the sensible prior art starting point(s).

If, alternatively, the prior art provides no solution to the aforementioned need, the next step in our proposed methodology identifies information that a POSITA would have considered relevant to find a solution to that need. As the line of chemical cases discussed previously dealing with the patentability of new chemical compounds suggests,<sup>348</sup> relevant information could be obtained by analyzing the available options that a POSITA could have followed for further innovation to solve the problem. In the new-chemical compound field, for example, prior art compounds that possess “promising useful properties . . . that motivate[] a chemist to make structurally similar compounds”<sup>349</sup> are considered suitable lead compounds.<sup>350</sup> And similarly, those like Compound *b* in the *Takeda* case, discussed *supra*, that possess undesirable properties may end up not being sensible prior art starting points. As further seen in *Takeda*, that consideration can be a deciding factor in determining obviousness.

Thus, in analogy with the lead compound cases, our Lead Prior Art methodology for identifying the Lead Prior Art proposes the selection of prior art that discloses promising options to solve any problem for which the claimed invention could potentially be a

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346. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007).

347. *See id.*

348. *See discussion supra* Section IV.B.

349. *Daiichi Sankyo Co., Ltd., v. Matrix Labs., Ltd.*, 619 F.3d 1346, 1354 (Fed. Cir. 2010).

350. *See id.*

solution. If only one possible starting solution is available to a POSITA, then such starting point could be considered the Lead Prior Art, unless, of course, that very solution is fraught with at least one factor precluding its selection as starting point.

However, if more than one possible prior art starting point exists, and if they all fail to possess some significant negative, then it would be necessary, in determining the sensible prior art starting point(s), to review all available prior art and consider whether there is information that either (1) identifies one or more potential starting points as more promising than others or (2) teaches away from particular approaches.

Examples of information that could point towards potential sensible starting points include information that evidences that a starting point: (1) displays some kind of superior performance over other starting points,<sup>351</sup> (2) possesses desirable characteristics not present in other starting points,<sup>352</sup> (3) highlights the availability of more information about a particular starting point that would make the development of an improved solution easier than from other starting points,<sup>353</sup> and (4) lacks undesirable features or characteristics present in other starting points.<sup>354</sup> Needless to say, this is a non-exhaustive list of potential circumstances that could tilt the balance towards particular starting points while disfavoring others. In general, any information properly available to a POSITA that is capable of elevating the desirability of one or more potential starting points over others is relevant to the identification of the Lead Prior Art.

Under those considerations, it becomes apparent why the “structurally closest” prior art<sup>355</sup> might not necessarily be the proper Lead Prior Art. For instance, there could be information in the art that could have dissuaded a POSITA from having selected that closest prior art, in favor of other more desirable references. For example, as mentioned above in *Takeda*, the Federal Circuit determined that a

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351. See, e.g., *Daiichi*, 619 F.3d at 1351 (explaining that higher potency is an acceptable reason to select lead compounds).

352. See, e.g., *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1363 (Fed. Cir. 2007) (explaining that solubility and bioavailability are acceptable reasons to select suitable anions for salt formation).

353. See, e.g., *Daiichi*, 619 F.3d at 1353-54 (explaining that a POSITA would have selected the proper lead compounds, *inter alia*, because they were “better-studied” than the compounds proposed by the patent challenger).

354. See, e.g., *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1358 (Fed. Cir. 2007) (finding that undesirable side effect would have dissuaded a POSITA from selecting a particular compound as a lead compound); *Sanofi-Synthelabo v. Apotex Inc.*, 550 F.3d 1075, 1090 (Fed. Cir. 2008) (suggesting that the absence of toxicity in a compound is desirable).

355. The structurally closest prior art is generally understood to be that which possesses the least number of differences with the claimed invention. See, e.g., *Daiichi*, 619 F.3d at 1354.

POSITA would not have selected the Compound *b* that was structurally closest to the claimed compound for further modification because of its undesirable physiological side effects.<sup>356</sup>

We posit that even the level of unpredictability in the art and the degree of expectation of success associated with some of the starting points available to a POSITA should be considered in the determination of the Lead Prior Art. Although unpredictability and expectation of success are normally considered in an obviousness analysis at stages subsequent to the selection of the proper prior art,<sup>357</sup> they could be nonetheless relevant to a POSITA in the selection of a suitable starting point against a backdrop of particularized facts. For example, if a POSITA considers that the results from the steps required to modify a given starting point are unpredictable or lack an expectation of success, then the POSITA would be more likely to disfavor that non-straightforward option and instead pursue other more predictable or promising starting points.<sup>358</sup>

Also, as mentioned previously,<sup>359</sup> while objective indicia of nonobviousness (commercial success, long felt but unsolved needs, failure of others, unexpected results, etc.)<sup>360</sup> are commonly viewed as evidence used to rebut a prima facie case of obviousness, they nonetheless could provide an indication of whether a prima facie case of obviousness has even been established.<sup>361</sup> To the extent that evidence from those objective indicia of nonobviousness suggests that a certain potential starting point would not have been selected by a POSITA, that evidence is relevant to the determination of the Lead Prior Art.

For instance, evidence that a particular starting point has been tried unsuccessfully in the past would tend to indicate that such a starting point would not have been chosen again by a POSITA. Similarly, if evidence shows that the results obtained from following a particular starting point are unexpectedly as good as, or even superior to, results obtained from other starting points, then the

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356. See *Takeda*, 492 F.3d at 1359-60.

357. See discussion *supra* Section II.A.

358. See discussion *supra* Section II.A.

359. See discussion *supra* Section II.A.

360. See discussion *supra* Section II.A.

361. See *Geo M. Martin Co. v. Alliance Machine Systems Int'l. LLC*, 618 F.3d 1294, 1304 (“Secondary considerations of nonobviousness must be considered when present.”); *Vandenberg v. Dairy Equip. Co.*, 740 F.2d 1560, 1567 (Fed. Cir. 1984) (“In determining the question of obviousness, inquiry should always be made into whatever objective evidence of nonobviousness there may be. The so-called ‘secondary considerations’ can often prevent a court from slipping into an impermissible hindsight analysis. They should be considered as a fourth factual inquiry under *Graham* before coming to a conclusion concerning obviousness.”) (citations omitted).

evidence could show that a POSITA, absent knowledge of those later-revealed unexpected results, could well have selected those other starting points that a priori suggested a better outcome. Also, if the art had identified a pressing need for which a solution had not been provided, then the development of a solution to that need could suggest that a POSITA could well *not* have selected options that had been available in the art for some time as the starting points and/or the paths followed from that starting point to the claimed invention. Simply put, those options/paths had not been used to solve the problem previously, so why rely on them now?

The discussion of the scenarios in the previous paragraphs makes it clear that any information tending to show that a given prior art starting point is better or worse than any other potential starting point can be used to identify the Lead Prior Art. Once all available information has been analyzed and one or more potential starting points have been recognized, the evidence is assessed to determine which of those potential starting points would have been chosen by a POSITA. The resulting starting points constitute the Lead Prior Art to be compared with the claimed invention according to *Graham* Factor 2.

In this regard, it is important to keep in mind that the identification of the Lead Prior Art is most relevant to the determination of whether a prima facie case of obviousness exists. Even if a prima facie case is present, the applicant or patentee can still present evidence to rebut it in the form of any of the objective indicia of nonobviousness mentioned previously.<sup>362</sup> But as also discussed previously, a more sure position is to defeat, rather than rebut, a prima facie case of obviousness.<sup>363</sup>

In summary, our proposed Lead Prior Art methodology to identify the Lead Prior Art is not constrained to any particular field of endeavor and can be applied across all technologies. Our proposed methodology requires that all relevant information available, that could have a bearing on the overall desirability of certain prior art starting points, should be considered. All of the available relevant evidence is sifted to determine whether a POSITA would have selected one or more particular pieces of prior art as a sensible starting point(s) for further innovative modification.

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362. See discussion *supra* Section II.A.

363. See discussion *supra* Section II.B.

*D. The Scope of the Problem Analyzed Could Impact the Selection of the Lead Prior Art*

The decision-maker faced with tasks of determining the “scope and content of the prior art” under *Graham* Factor 1<sup>364</sup> needs to decide how broad the scope of the inquiry needs to be to identify the sensible prior art starting points.

There are two possible outcomes of changing the scope of the search of the prior art under *Graham* Factor 1. Under a first scenario, if the scope is too broad, the number of available starting solutions in the prior art to the problem at hand can be potentially quite large. This situation may lead to a higher probability that one or more of those starting points will represent an attractive alternative that appears superior to the rest of the alternatives and that, when pursued, *would lead away from the claimed invention*. Still under the first scenario, if the scope of the inquiry is too narrow, the number of available starting solutions in the prior art might be reduced, potentially leading to a situation where the only reasonable prior art solution is one that naturally leads to the claimed invention. Thus, under the first scenario, broadening the search for prior art in the Lead Prior Art methodology could actually lead to a determination that the invention *is not* prima facie obvious, while narrowing the search in that methodology could lead to a determination that the invention *is* prima facie obvious.

But it is not quite that simple. Under a second scenario, it is also possible that narrowing the scope of the inquiry could lead to no viable starting points that a POSITA could pursue. In this case, there would not be a reasonable piece of Lead Prior Art available to a POSITA; accordingly, the invention is not prima facie obvious. Conversely, still under the second scenario, broadening the scope of the search could yield various potential starting points. If one of those starting points would naturally lead to the invention based on suggestions available in the prior art, then the invention could be found to be prima facie obvious.

The different outcomes of the two scenarios described above illustrate that varying the scope of the search of prior art during *Graham* Factor 1 could influence the type and number of references available as Lead Prior Art. It is evident that the type of scenario encountered in a real-life situation, either the first or second scenarios above, would be very fact-specific and, consequently, the outcome would vary with the facts of each case.

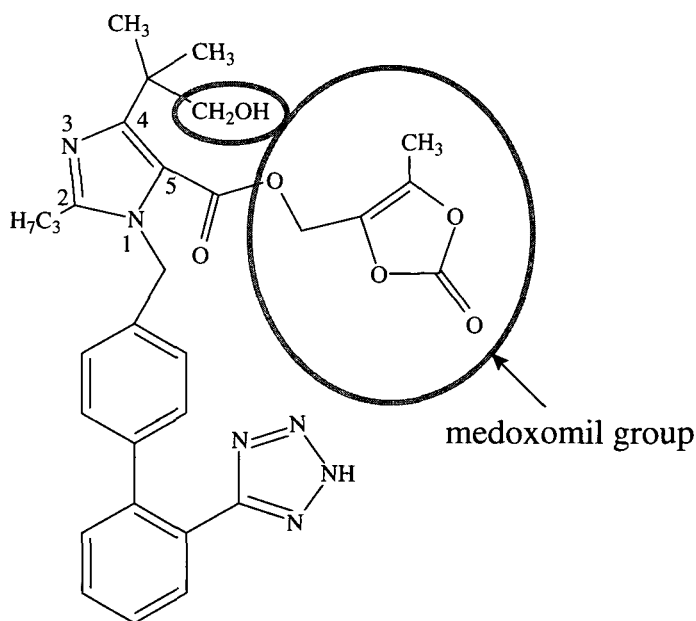
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364. See discussion *supra* Section II.A.1.a.



We will draw on the facts of the *Daiichi* case, which was previously discussed,<sup>365</sup> to illustrate the first scenario described above and demonstrate how narrowing or broadening the scope of the search for prior art under *Graham* Factor 1 could affect the obviousness analysis. In *Daiichi*, the Federal Circuit rejected the compound chosen by the patent challenger, Mylan, as the lead compound, despite it being the most structurally similar compound to the claimed compound.<sup>366</sup> That decision rested in part on the fact that there were other prior art compounds displaying higher potency, which had been better studied than the compounds proposed by Mylan.<sup>367</sup>

In *Daiichi*, the claimed compound was an angiotensin receptor blocker (“ARB”) useful in the treatment of high blood pressure.<sup>368</sup> The only issue in *Daiichi* was whether claim 13 was valid.<sup>369</sup> Claim 13 claimed Olmesartan medoxomil, which has the following chemical formula:<sup>370</sup>



Olmesartan medoxomil<sup>371</sup>

365. See discussion in Section III.B.

366. See *Daiichi Sankyo Co., Ltd. v. Matrix Laboratories, Ltd.*, 619 F.3d 1346, 1353-54 (Fed. Cir. 2010).

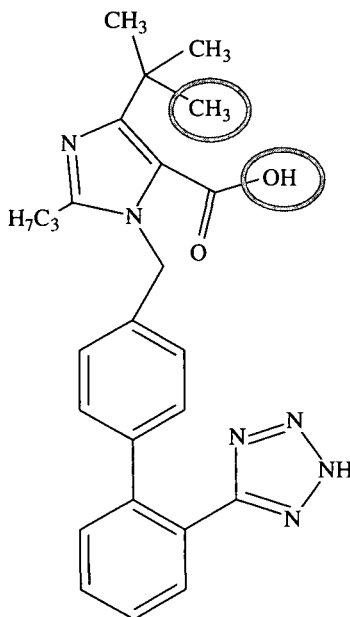
367. See *id.* at 1354.

368. See *id.* at 1347.

369. See *id.* at 1351.

370. See *id.* at 1350.

371. *Id.*



Example 6 from U.S. Patent No. 5,137,902 (prior art)<sup>372</sup>

For comparison, the structurally-closest compound from the prior art (Example 6 from U.S. Patent No. 5,137,902 (“the ‘902 patent”)) is also shown above and the differences between the two compounds are highlighted.<sup>373</sup> From the drawings, it can be seen that the only differences between the two compounds are two substituents in the imidazole ring, whose atoms are numbered from 1 to 5 in olmesartan medoxomil.

As can also be seen, the substituent on carbon atom 4 in olmesartan medoxomil has a hydroxymethyl group (-CH<sub>2</sub>OH), whereas the prior art compound has a methyl group (-CH<sub>3</sub>) in the corresponding position (circled). The other difference is the presence of the medoxomil pro-drug masking a carboxylic acid in olmesartan medoxomil, whereas the prior art compound has the unmasked carboxylic group in the corresponding position. It was known in the art, however, that the medoxomil pro-drug improved oral absorption and that it is metabolized in the body to liberate the carboxylic group, as it is present in the prior art compound.<sup>374</sup>

372. *Id.* at 1351.

373. *See id.*

374. *See id.* at 1350.

Regardless of the differences in the two substituents, both compounds have the same core structure, which is an imidazole ring containing a biphenyltetrazole substituent at position 1.<sup>375</sup> In addition to Example 6, Mylan argued that five other compounds disclosed in the '902 patent had properties that would have made them lead compounds.<sup>376</sup>

According to Mylan, the compounds from the '902 patent were already second-generation ARB compounds that improved on the potency and physiological behavior of the compounds taught in U.S. Patent No. 5,138,069 ("the '069 patent").<sup>377</sup> The '069 patent included Losartan, the first orally-active ARB compound.<sup>378</sup> Losartan later became the reference standard against which potency of later-developed ARB compounds was measured.<sup>379</sup>

The court approached the issue of finding the lead compound for the obviousness analysis by determining *the type of compounds that a POSITA would have chosen to prepare new ARB compounds*.<sup>380</sup> As mentioned previously,<sup>381</sup> the court rejected Mylan's choice of lead compounds, including Example 6 from the '902 patent. The court reasoned that there were other, more potent and better studied, prior art ARB compounds that would have been selected by a POSITA for further development over the compounds from the '902 patent.<sup>382</sup>

From the four compounds that the court indicated would have been selected for further development as lead compounds, the two most potent had 180 and 100 times the potency of the first-generation Losartan.<sup>383</sup> Those two compounds did not have the same core structure as compounds in the '902 patent or olmesartan medoxomil.<sup>384</sup> From among the four court-selected lead compounds, the only compound that had the same core structure as olmesartan medoxomil had a potency of only about seven times that of the reference Losartan.<sup>385</sup> The compounds of the '902 patent advanced by Mylan as lead compounds had an activity approximately "2 to 4 fold higher than the most active compounds [of the '069 patent, which disclosed Losartan]."<sup>386</sup>

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375. *Id.* at 1349.

376. *See id.* at 1352-53.

377. *See id.* at 1353.

378. *See Daiichi*, 619 F.3d at 1348-49.

379. *See id.* at 1353.

380. *See id.*

381. *See supra* note 326.

382. *See id.* at 1353.

383. *Id.*

384. *Id.* at 1351.

385. *Id.* at 1353.

386. *Id.* at 1353-55.

With that background, had the court chosen to frame the search for the lead compound in terms of a POSITA searching for an improved Losartan molecule (i.e. one having an imidazole ring containing a biphenyltetrazole substituent as core), all but one of the original lead compounds would have been eliminated from the pool. Under those circumstances, arguably, the court could have had a harder time justifying the selection of the one remaining prior art compound from the four as lead compound, especially because the compounds of the '902 patent were said to "exhibit[] remarkable and unexpected potency as antihypertensives."<sup>387</sup> However, by broadening the search and framing it in terms of seeking new ARB's in general, other more potent compounds were brought into the pool of leading compounds.<sup>388</sup>

Nonetheless, it is unclear whether the outcome in *Daiichi* would have been any different. In its decision, the Federal Circuit indicated that, even if the compounds from the '902 patent had been selected as lead compounds, Mylan failed to articulate a reason why a POSITA would have modified them in the manner required to arrive at olmesartan medoxomil.<sup>389</sup> In other words, Mylan, in terms of the Lead Prior Art methodology, failed to show that there was a straightforward pathway from their choice of lead compound to the claimed invention, let alone a reasonable expectation of success. Nonetheless, this scenario illustrates how the scope of the search for prior art could potentially influence the outcome of a *prima facie* obviousness analysis.

In summary, selection of a Lead Prior Art is the first of two steps for applying our methodology during an obviousness determination. Discussion of the Lead Prior Art selection step began with a legal and logical foundation for the concept of a Lead Prior Art, based on analyzing lead compound cases pre-*KSR* and post-*KSR*. From that analysis, an extrapolation of lead compound case law has been proposed, such that the concepts underlying lead compound case law could be applied to all technologies to identify a Lead Prior Art for further obviousness analysis. The preceding discussion concluded by discussing how the scope and content of the prior art could have a significant effect on Lead Prior Art selection.

Once that Lead Prior Art was selected, however, the second of two steps for our methodology would follow—identifying and evaluating one or more modifications to the Lead Prior Art to allow

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387. *Id.* at 1353.

388. *See id.*

389. *See id.* at 1356-57.

for a conclusion of nonobviousness or prima facie obviousness. A discussion of that second step follows.

## V. IDENTIFICATION AND EVALUATION OF MODIFICATIONS TO THE LEAD PRIOR ART TO DETERMINE NONOBVIOUSNESS OR PRIMA FACIE OBVIOUSNESS

### A. *Identifying a Straightforward Modification to the Starting Point*

After the POSITA had identified a piece(s) of Lead Prior Art (and we have seen in examples above that such identification can be outcome determinative), the POSITA would have attempted to ascertain whether the Lead Prior Art was a starting point that would have allowed the POSITA to reach the solution to the POSITA's problem in a straightforward way with a reasonable expectation of success. The POSITA would have faced two possible scenarios at this point. First, the claimed invention could have read directly on to the starting point. In this scenario, the Lead Prior Art was a complete solution to the POSITA's problem. That situation, however, also represents an issue of anticipation under § 102 rather than obviousness under § 103. Therefore, we set aside that possibility for purposes of our obviousness analysis.

Second, the claimed invention may not have read directly on to the starting point, so the POSITA would have faced the question of whether any apparent, straightforward "modifications" would have allowed the POSITA to reach the solution with a reasonable expectation of success. That scenario requires our discussion to consider what a "modification" is in the context of Lead Prior Art.

A "modification" represents a change that a POSITA would have considered making to a starting point, based on the POSITA having a reason to think the modification was straightforward and could have reasonably been expected to lead successfully to reaching the solution. Recall that a starting point and a solution both have properties. The starting point may possess some of the properties that the solution possesses, but may also omit at least some of the properties possessed by the solution, setting aside, as above, the § 102 scenario as discussed above.

Faced with a starting point that does not possess all the desired properties to the solution, the POSITA would have considered what straightforward modifications the POSITA could make to the starting point to potentially achieve, with a reasonable expectation of success, the solution sought by the POSITA. Functionally, a modification may add certain desirable properties to a starting point or may remove

undesirable properties from that starting point, or may even create a potential for properties to be added to or removed from the starting point through a subsequent modification. Removing undesirable properties that were not present in the claimed invention might be a necessary predicate to adding desirable properties to the sensible starting point, so this possibility is mentioned in passing. Ultimately, the POSITA would have determined which modifications were available to it by considering various modifications to the starting point that might have led to the solution, whether through direct or indirect means.

A modification in the context of Lead Prior Art corresponds to combinations of references or modifications to a primary prior art reference in an existing obviousness rubric. These modifications are selected based on teachings or suggestions in the prior art or by an exercise of ordinary creativity or common sense by a POSITA. Therefore, the nature of and the likelihood of success from potential modifications may range from “known elements achieving predictable results”<sup>390</sup> to “unexpected results,”<sup>391</sup> depending on the circumstances. Due to the range of certainties present in different factual situations, the discussion that follows refers to modifications as offering a reasonable possibility of reaching the solution, rather than certainty of reaching the solution.

Considering obviousness from the perspective of an inventor going through a multi-step inventive process is not entirely new as the following Federal Circuit quotation demonstrates:

The record . . . shows that even if an ordinarily skilled artisan sought an FBPase inhibitor, that person would not have chosen topiramate. . . . In this case, the record shows that a person of ordinary skill would not even be likely to start with 2,3:4,5 diisopropylidene fructose (DPF), as Dr. Maryanoff did. Beyond that step, however, the ordinarily skilled artisan would have to have some reason to select (among several unpredictable alternatives) the exact route that produced topiramate as an intermediate. Even beyond that, the ordinary artisan in this field would have had to (at the time of invention without any clue of potential utility of topiramate) stop at that intermediate and test it for properties far afield from the purpose for the development in the first place (epilepsy rather than diabetes).<sup>392</sup>

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390. See discussion *supra* Section II.A.2.

391. See discussion *supra* Section II.A.1.d.

392. *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Labs, Inc.*, 520 F.3d 1358, 1364 (Fed. Cir. 2008).

Although the likelihood of success from various modifications may range from expected to unexpected, as discussed above, the POSITA would not have considered all such options. Instead, the POSITA would have limited consideration to those modifications that the POSITA had reason to think possessed a reasonable likelihood of reaching a solution to the POSITA's problem, based on the POSITA's perfect knowledge of the prior art (and suggestions therein), common sense, and ordinary creativity.<sup>393</sup> Thus, only "straightforward modifications" would have been considered by the POSITA. The notion of "straightforward modifications," as a practical limit on what options the POSITA would have considered after selecting a sensible starting point, parallels the logic and process of selecting a Lead Prior Art starting point<sup>394</sup> and thus applies those principles discussed above, in the context of selecting a starting point, to the concept of identifying which straightforward modifications a POSITA would have considered.

*B. Testing Modified Starting Points and Iterating as Needed*

Once a straightforward modification had been identified by the POSITA, the POSITA would have evaluated the straightforward modification's ability and potential to solve the POSITA's problem. If the straightforward modification would have been able to solve the POSITA's problem, it could thus render the claims *prima facie* obvious, as long as the straightforward modification would have a reasonable expectation of success for solving the POSITA's problem; i.e., the claims would read directly on the modified starting point. In effect, that straightforward modification would have bridged the conceptual gap between a starting point (the Lead Prior Art) and the claimed invention. The implications of the POSITA having had the capacity to identify such a solution are discussed *infra*.<sup>395</sup>

In another example, a straightforward modification would have had the reasonable potential to solve the POSITA's problem when two conditions existed: first, the straightforward modification would have created a modified starting point that the claimed invention did not read directly on. Second, the POSITA would have nonetheless had a reason to believe that one or more additional straightforward modifications to the modified starting point might have reasonably led to a further-modified starting point that the claimed invention would have read on. In our methodology, evaluating the potential of

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393. See discussion *supra* Section II.A.

394. See discussion *supra* Section IV.

395. See discussion *infra* Section V.C.

multiple straightforward modifications to achieve the claimed invention corresponds to combining multiple prior art reference teachings or suggestions, as well as inferences from common sense and ordinary creativity. If the POSITA could have traversed from a Lead Prior Art starting point to the solution through one or more straightforward modifications with a reasonable expectation of success, the Lead Prior Art starting point would have been viable for the POSITA. The implications of the POSITA having reached a solution are discussed *infra*.<sup>396</sup>

If, however, the POSITA could not have traversed from the Lead Prior Art starting point to the solution through any available straightforward modifications, be they one or more, the Lead Prior Art starting point would not have been a viable starting point for the POSITA. The POSITA, in that situation, would have attempted to traverse from another Lead Prior Art starting point to the solution, if another Lead Prior Art starting point would have been available to the POSITA. And so on the POSITA would have continued attempting traversal from various available starting points modified through all straightforward modifications associated with each starting point until the solution had been reached or until all other starting points and associated straightforward modifications had been exhausted. Upon exhausting the available starting points and associated straightforward modifications, the POSITA would have discontinued its investigation, because no means for reaching the solution would have been available from any starting point the POSITA would have considered. The implications of the POSITA having had the ability to reach the solution or not having had that ability are discussed next.

*C. Nonobviousness or Prima Facie Obviousness Based on the POSITA Reaching or Not Reaching the Solution*

At this point in the Lead Prior Art analysis, the POSITA would have either determined that the POSITA could have straightforwardly traversed from a starting point to the solution with a reasonable expectation of success, or the POSITA would have determined that no starting point would have been available and apparent to the POSITA that would have allowed traversing to the solution with a reasonable expectation of success. Each condition tends to support an opposite conclusion of obviousness or nonobviousness, so each is discussed accordingly.

Once the POSITA had exhausted all Lead Prior Art starting points, including all straightforward modifications thereto, the

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396. See discussion *infra* Section V.C.



POSITA would have been left with no options for further investigation. This situation in the Lead Prior Art framework corresponds to shortcomings in the prior art that cannot be overcome by a proponent of obviousness; unless additional prior art is later identified, a conclusion of nonobviousness must follow because the proponent has failed to even establish a prima facie case of obviousness. This conclusion is fully warranted under the Lead Prior Art analysis above and is completely consistent with elementary principles of patent law. That conclusion is also consistent with the results in *Yamanouchi*, *Takeda*, *Esiai*, and *Ortho-McNeill*, discussed *supra*.<sup>397</sup>

Conventional determinations of nonobviousness do not preclude the possibility that other art could exist somewhere that would render the claimed invention obvious; practical experience suggests that such is often the case. In *atypical* factual circumstances, however, where *all* starting points and *all* straightforward modifications could be *exhaustively* considered (i.e., where *all* prior art and suggestions therein, as well as *all* inferences from those references, common sense, and ordinary creativity are known and considered), a conclusion of nonobviousness per se would be logically appropriate if a Lead Prior Art could not be identified that could have led to the claimed invention even under such perfect circumstances. This conclusion would correspond to a full and accurate knowledge of all prior art coupled with a clear and unmistakable but likely idealistic conclusion that “no missing art” existed somewhere but had not yet been identified. Only under those incredibly unlikely circumstances would no solution have been possible under any circumstances by the POSITA. Thus, the authors speculate that conclusions of “nonobviousness per se” may arise rarely or as a pedagogical notion that may never exist in practice.

If, however, the POSITA would have identified one or more Lead Prior Art starting points that could have been modified in a straightforward way to reach the solution with a reasonable expectation of success, Lead Prior Art allows for an inference of prima facie obviousness. That inference, however, is still subject to qualification and is thus not dispositive on the question of prima facie obviousness. And as noted, before a determination of prima facie obviousness may be made, the proponent of obviousness must establish that the straightforward way leading from the starting point

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397. See discussion *supra* Sections IV.A and IV.B.

to the solution, a solution would have been pursued with a “reasonable expectation of success.”<sup>398</sup>

In other words, under Lead Prior Art, the “straightforward way” does not necessarily equate with a reasonable expectation of success. The need to evaluate “reasonable expectation of success” arises from practical considerations in some useful arts. Courts have recognized that technology in certain fields present a large number of suggestions in the prior art; i.e., many Lead Prior Art starting points and many straightforward modifications would have been suggested to a POSITA by the prior art. In some circumstances, however, the prior art may not offer any guidance for how someone should evaluate the many options suggested by the prior art and test a practical number of the suggested approaches. For example, cases have addressed circumstances where reasons existed for considering a very large number of scenarios.<sup>399</sup> So, even though the way to test might have been straightforward, the POSITA would have abandoned the venture because there would have been simply too many choices to proceed and no reasonable way to identify a choice expected to be successful.

The Federal Circuit has specifically also recognized that, where the prior art offers numerous suggestions, without guidance on how to select from those suggestions, a patentable invention may lie in identifying a solution from among the many suggestions.

In [some] cases . . . researchers can only “vary all parameters or try each of numerous possible choices until one possibly arrive[s] at a successful result, where the prior art [gives] either no indication of which parameters [are] critical or no direction as to which of many possible choices is likely to be successful.” *In re O’Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988). In such cases, “courts should not succumb to hindsight claims of obviousness.” *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). Similarly, patents are not barred just because it was obvious “to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.” *In re O’Farrell*, 853 F.2d at 903.<sup>400</sup>

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398. See discussion *supra* Section III.

399. See *Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1341-42 (Fed. Cir. 2000) (“Of the 11,000 candidates for suitable compounds, fewer than fifty showed enough promise to warrant human clinical trials. Ultimately, the [Food and Drug Administration] approved only four for consumer use . . .”).

400. *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989, 996-97 (Fed. Cir. 2009).

Lead Prior Art credits the notion of “reasonable expectations of success” by treating a traversal from a starting point to the solution as an inference of prima facie obviousness rather than a conclusion of prima facie obvious (subject to potential rebuttal). The persuasive value of that inference must be weighed against whether a “reasonable expectation of success” would exist under the circumstances, as discussed above. Thereafter, if a “reasonable expectation of success” would not exist, the inference of prima facie obviousness is *negated* and the claimed invention is nonobvious because it is not prima facie obvious; otherwise, the inference of prima facie obviousness prevails and the claimed invention is prima facie obvious. Note that under such circumstances, the inference is negated, not rebutted, and advantages flowing therefrom have been discussed above.<sup>401</sup>

Although the preceding discussion has shown that Lead Prior Art has the capacity to indicate more objectively whether a claimed invention is nonobvious or is prima facie obvious, such capabilities merely represent the barest of provisions for evaluating obviousness. Over the last 220-plus years, patent law has identified certain patentability considerations that we discussed as “negative rules for invention”<sup>402</sup> and other affirmative considerations that support nonobviousness, such as “unexpected results” and “reasonable expectations of success.” Over the years, settled expectations have been created concerning the applicability of these principles going forward.

Fortunately, Lead Prior Art harmonizes rather than disturbs these principles by naturally providing consistent results with the above-mentioned doctrines while tending to avoid argument-based pigeonholing of factual circumstances into one of these doctrines. A comparison of results from Lead Prior Art to the results that would be expected when invoking each negative rule for invention is discussed in the following section.

#### *D. Lead Prior Art Harmonizes Existing Obviousness Rubric*

Lead Prior Art accommodates a range of situations, from a POSITA facing a small number of suggestions in the prior art, to a POSITA facing a large number of suggestions in the prior art. Additionally, Lead Prior Art considers whether the likelihood of success for those suggestions ranges from “implausible” to

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401. See discussion *supra* Section II.B.2.

402. See discussion *supra* Section II.A.2.

“plausible”<sup>403</sup> to “certain.”<sup>404</sup> Finally, in situations where a POSITA may face a large number of suggestions, Lead Prior Art considers whether the prior art included guidance for selecting a path forward among the many situations, all of which could well have been straightforward. Each situation is discussed below.

First, Lead Prior Art properly takes into account a situation where any number of teachings or suggestions are present in the sensible prior art starting point(s) and each performs exactly in combination as would be expected. The POSITA in this situation would have readily recognized and straightforwardly achieved the combination that led to the claimed invention, based on iterating through the starting points and straightforward modifications with a reasonable expectation of success in solving the problem, and the combination would have performed as expected. In that scenario, whether the number of teachings or suggestions is large or small does not affect the result in Lead Prior Art or under existing precedent because a POSITA would have recognized each teaching or suggestion necessary to reaching a solution. This correlates well with the existing obviousness rubric, which holds that the number of references or suggestions to be combined is not determinative for prima facie obviousness,<sup>405</sup> but the nature of the teachings or suggestions can be determinative. Lead Prior Art could hold that this claimed invention was prima facie obvious,<sup>406</sup> consistent with existing

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403. An example where the likelihood of success would be “plausible” is where a reference suggested but did not expressly teach a particular aspect of the claimed invention. Without express knowledge that the suggestion would have been viable, the POSITA would not have known that the POSITA could achieve the solution through that suggestion. An example where the likelihood of success would be “implausible” is where a reference “teaches away” from the claimed invention. If a reference suggests that no likelihood of success for the claimed invention, the POSITA would not have known that the POSITA could achieve the solution through modifying that reference. See discussion of “teaching away,” *supra* Section II.A.1.d; *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (“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. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference’s disclosure is unlikely to be productive of the result sought by the applicant.”).

404. An example where a likelihood of success would be “certain” would be where a prior art element was disclosed as having certain properties, and those properties were not affected in any way when the prior art element was combined with other elements.

405. See M.P.E.P., *supra* note 59, at § 2145 (“Reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention.”) (citing *In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991)) (“Gorman argues that when it is necessary to combine the teachings of a large number of references in order to support a rejection for obviousness under 35 U.S.C. § 103 (2006), this of itself weighs against a holding of obviousness. The criterion, however, is not the number of references, but what they would have meant to a person of ordinary skill in the field of the invention.”).

406. See discussion *supra* Section II.B.

precedent concerning “known elements producing expected results.”<sup>407</sup> Absent an ability to destroy that prima facie case, the patent applicant/patentee would then be forced to rebut that prima facie case through an appropriate evidentiary showing.

Second, Lead Prior Art also properly credits a situation where a small, finite number of teachings or suggestions are present in the prior art and each teaching or suggestion’s likelihood of success could range from “low” to “very high” (but would not be “certain”). Here, the number of combinations the POSITA would have had to test or verify to reach the solution would have been relatively small, and as long as there is a reasonable likelihood of success with any particular one of that small number of suggestions, there would be a tendency towards finding prima facie obviousness. This result matches what the existing obviousness rubric would mandate under the “obvious to try” doctrine.<sup>408</sup> Again, the patent applicant/patentee would then be forced to rebut that prima facie case through an appropriate evidentiary showing.

Third, Lead Prior Art also properly accommodates a situation where a solution exists in the real world but the POSITA would not have been able to achieve it regardless of the teachings and suggestions in the prior art. One potential explanation for the POSITA failing to reach the solution could be that results achieved by the real world inventor represent an “unexpected result.”<sup>409</sup> An unexpected result, i.e., no reasonable expectation of success, could exist where either a teaching or suggestion in the prior art does not produce the properties expected of it in the POSITA’s modified starting point. Since the inventor’s unexpected result is, by definition, not something that the prior art would teach or suggest, the POSITA would have been incapable of identifying that solution.

Another potential explanation for the POSITA failing to reach the solution could be that something in the prior art included a “teach away”<sup>410</sup> that discouraged the POSITA from pursuing certain suggestions therein. Since the POSITA would not have pursued a suggestion in the presence of a persuasive teach away, as discussed in *Section II.A.1.d*, supra, the POSITA would not have considered that prior art to have been a sensible starting point because the POSITA would have been incapable of identifying a solution that went against a teaching away. Accordingly, in either situation, Lead Prior Art

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407. See discussion *supra* Section II.A.2.

408. See discussion *supra* Section II.A.2.

409. See discussion *supra* Section II.A.1.d.

410. See discussion *supra* Section II.A.1.d.

properly credits the circumstances and renders a conclusion of nonobviousness.

Lastly, Lead Prior Art properly accommodates a situation where the number of teachings or suggestions in the prior art is relatively high but the prior art offers no guidance to direct the efforts of the POSITA toward finding a viable solution. One might think that if any individual combination of sensible starting point and sensible modification was at least somewhat likely to be a solution to the POSITA's problem, a reasonable expectation of success would exist for reaching the solution through only modest, straightforward experimentation. Therefore, the argument would be that the POSITA would have readily identified a sensible starting point and one or more sensible modifications that would have led to the solution. But if there is no guidance on which of the relatively high number of possibilities should even be pursued, there is a failure of sensible starting point. Courts and Lead Prior Art agree that such circumstances reflect prima facie obviousness.

From the preceding discussion, readers will recognize that Lead Prior Art shows promise for achieving consistent results with existing obviousness rubric under factual circumstances that suggest one of the "negative rules for invention" as well as affirmative considerations such as "unexpected results." Accordingly, Lead Prior Art should be consistent with settled expectations of how obviousness analysis should resolve for relatively easy determinations while providing a more objective, defensible, and transparent obviousness determination for more difficult determinations.

A question remaining to be addressed prior to summarizing this article pertains to whether our methodology is justified in attempting to reach the claimed invention and whether doing so introduces hindsight bias. We address these questions next.

#### *E. Does Our Analytical Approach Rely on Any Hindsight Bias?*

Near the beginning of the Lead Prior Art portion of this article, the authors made a remarkable claim: to show that our methodology could rely on an a priori knowledge of the claimed invention when selecting starting points and modifications to those starting points but yet not be influenced by hindsight knowledge. The time to address this issue has arrived, and the explanation is rather simple.

Indeed, an element of hindsight does exist in the sense that we are relying on a prior knowledge of the claimed invention. But that hindsight does not affect the result of our analysis; it merely helps us to avoid irrelevant combinations, thereby reducing the burden of applying Lead Prior Art analysis and allowing us to focus our interest

on starting points and modifications that are relevant to whether the claimed invention is in fact *prima facie* obvious. Accordingly, a pinch of hindsight in taking into account the claimed invention is necessary, but Lead Prior Art neutralizes that necessary pinch of hindsight in a practical, unbiased, and inherently appropriate way.

## VI. CONCLUSION

In conclusion, this article has forwarded the concept of Lead Prior Art methodology to identify, in a more objective way, the piece or pieces of Lead Prior Art that constitute sensible starting points for the POSITA in attempting to solve a problem. As has been seen, there can be no *prima facie* case of obviousness if non-sensible prior art starting points are chosen.

The authors have contemplated how the USPTO, pressed by time and resources, would be able to conduct practical examinations in a world of Lead Prior Art. It would seem that would be difficult. An easier way for the USPTO to proceed would be to utilize hindsight knowledge of the claimed invention to reject claims based on prior art that is structurally most similar to that claimed invention. Hence, in practice, application of Lead Prior Art methodology might most often be applied by the patent applicant simply to establish that in fact the USPTO has chosen an incorrect prior art starting point. By analogy to the litigated facts of *Takeda*, *Daichi*, and *Eisai*, and utilizing the 2010 *KSR* guidelines, that alone might lead to allowance.

A different scenario might ensue in litigation. In such litigations, the opponent often has great abundances of both time and skilled legal and technical resources to attempt to have patent claims adjudicated to be obvious. Hence, it is possible that the alleged infringer will come up with better prior art than did the USPTO. As in prosecution, application of the Lead Prior Art methodology might find principal use by the patentee in litigation in establishing that the prior art asserted against the patent claims is not a sensible starting point(s). Lead Prior Art provides an additional arrow in the quiver: the patentee may be able to show that the prior art asserted, even if a sensible starting point, cannot be applied straightforwardly in the hands of POSITA to achieve the claimed invention with a reasonable expectation of success.

And of course, Lead Prior Art is not a panacea for patent applicants/patentees. The facts may be such that the art asserted is a sensible starting point, leading straight forwardly to the claimed invention with a reasonable expectation of success.

But whether the patentee/patent applicant wins or loses, Lead Prior Art, when properly applied, should minimize hindsight and

provide a more objective basis for making the critical determination under § 103. In and of itself, that would be a great step forward for the U.S. Patent System.



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