

MOTIVATING THE PERSON OF ORDINARY SKILL IN THE ART: *ELI LILLY AND CO. ET AL. V. TEVA PARENTERAL MED., INC.* AND THE FEDERAL CIRCUIT’S INTERPRETATION OF THE “TEACHING, SUGGESTION, OR MOTIVATION” TEST IN OBVIOUSNESS-TYPE DOUBLE PATENTING

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*Intellectual property law dictates that there can only be one patent per invention, and this patent can only remain in effect for a limited time. However, patent holders sometimes try to avoid this restriction by patenting a similar invention to the previously claimed art under the guise of being a new invention. In the pharmaceutical industry, the courts avoid this problem through the general requirement of nonobviousness, which is the prohibition against patenting an item that is obvious in light of existing knowledge on the subject. The Federal Circuit and the United States Supreme Court differ in their applications of nonobviousness, resulting in a complicated standard. Nonobviousness is a central concept in obviousness-type double patenting, which is a prohibition of patenting something that is too similar to a previously patented item. *Eli Lilly and Co. v. Teva Parenteral Medicines, Inc.*, illustrates that, in the motivational aspect of nonobviousness, the Federal Circuit has moved beyond mere motivation.*

I. INTRODUCTION

Functionally, a patent is a limited legal monopoly over an invention, providing the inventor with an exclusive right to the “fruits of [his or her] labors”¹ for a limited time.² During the period of the patent, society is allowed to benefit from the work by

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¹ ROGER E. SCHECHTER & JOHN R. THOMAS, INTELLECTUAL PROPERTY: THE LAW OF COPYRIGHTS, PATENTS & TRADEMARKS 289 (2003).

² U.S. CONST. art. I, § 8, cl. 8.

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“invent[ing] around” the technology.³ This relationship can be viewed as a “grand bargain” between inventors and invention users, in which the patent holder receives financial benefit from innovation in exchange for eventually sharing the innovation with the public.⁴ However, patent holders sometimes try to stretch the time limit of their exclusive monopoly through a process called evergreening or life-cycle management.⁵ Patenting improved versions of previously patented products is a typical evergreening method.⁶

The pharmaceutical industry is plagued with evergreening.⁷ According to a congressional report, the pharmaceutical industry’s patents on compounds, medical treatment methods, and manufacturing processes are the most common subjects of evergreening in *any* industry.⁸ On the one hand, supporters of evergreening defend the practice as an instrumentality by which drug companies rightfully receive extended limited monopolies for improving prior work.⁹ On the other hand, opponents of the practice state that drug companies manipulate products to prevent generic versions of the compounds from coming to the market, thereby harming consumers and the healthcare industry in general.¹⁰ When the critics refer to “evergreening” in this context, they are describing double patenting.¹¹

Double patenting is “*claim[ing] the same or related subject matter twice,*”¹² thereby patenting something already functionally

³ SCHECHTER & THOMAS, *supra* note 1, at 289.

⁴ See David Kappos, Under Sec’y of Commerce for IP & Dir. of the USPTO, *The America Invents Act: A Patent Law Game-Changer* (Sept 30, 2011), available at http://www.uspto.gov/news/speeches/2011/kappos_brookings.jsp.

⁵ See JOHN R. THOMAS, CONG. RESEARCH SERV., R40917, PATENT “EVERGREENING”: ISSUES IN INNOVATION AND COMPETITION 1 (2009).

⁶ *Id.* at 1.

⁷ See *id.* at 4.

⁸ *Id.* at 1.

⁹ See *id.* at 7.

¹⁰ *Id.*; Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63 FOOD & DRUG L.J. 275, 298–99 (2008) (discussing arguments for and against evergreening practices).

¹¹ Furrow, *supra* note 10, at 298–99.

¹² 3A DONALD S. CHISUM, CHISUM ON PATENTS § 9.03[1][a], at 9-14 (Matthew Bender 2013).

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patented.¹³ According to the Federal Circuit, “[t]he purpose of the rule against double patenting is to prevent an inventor from effectively extending the term of exclusivity by the subsequent patenting of variations that are not patentably distinct from the first-patented invention.”¹⁴

There are two types of double patenting.¹⁵ The first is defined by statute,¹⁶ and plainly prohibits patenting the same invention twice, which the courts have taken to mean that inventions cannot be patented if they are “identical in scope.”¹⁷ A second form of double patenting is called obviousness-type double patenting, which is the subject of this Recent Development. Obviousness-type double patenting exists when “one claim defines merely an obvious variation of the other patent claim” and provides no “patentable distinction.”¹⁸ Unlike the prohibition on patenting the same invention twice, sometimes called “identity-type double patenting,”¹⁹ obviousness-type double patenting is a judge-made doctrine.²⁰

To determine whether a product is merely an “obvious modification of [another patented] invention,”²¹ the courts ask whether a person of “ordinary skill in the art” would be *motivated* to “combine the prior art teachings.”²² The Supreme Court interprets

¹³ See *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1568 (Fed. Cir. 1996).

¹⁴ *Id.*

¹⁵ See 3A CHISUM, *supra* note 12, § 9.03[3], at 9-72.

¹⁶ See 35 U.S.C. § 101 (2006).

¹⁷ *In re Goodman*, 11 F.3d 1046, 1052 (Fed. Cir. 1993).

¹⁸ *Id.*

¹⁹ 3A CHISUM, *supra* note 12, § 9.03[3], at 9-72.

²⁰ See *id.* at 9-73 (citing *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.* 916 F.2d 683, 686 (Fed. Cir. 1990)).

²¹ GARY MYERS, *PRINCIPLES OF INTELLECTUAL PROPERTY LAW* 297 (2008) (citation omitted).

²² *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007) (citing *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1323–24 (Fed. Cir. 1999)). A “person of ordinary skill in the art” is an objective hypothetical person who embodies the state of the industry when analyzing obviousness. See 2 CHISUM, *supra* note 12, § 5.02[5][d], at 5-49 to -51. Prior art teachings include “prior knowledge or use, prior patents, and prior publications.” *Id.* § 5.03[3], at 5-148.

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the motivation standard broadly, thinking of it as a guiding principle that is viewed in light of the rest of the patented art.²³ However, the U.S. Court of Appeals for the Federal Circuit interprets motivation narrowly, requiring something more than mere motivation to combine prior art.²⁴

In *Eli Lilly and Co. v. Teva Parenteral Medicines, Inc.*,²⁵ the Federal Circuit denied an obviousness-type double patenting claim brought by a generic pharmaceutical manufacturer.²⁶ In doing so, the court illustrated its narrow conception of motivation. The manufacturer attempted to invalidate a drug patent, arguing that the compound was an obvious modification of a previous invention.²⁷ The Federal Circuit determined that there was no reason that “would have led a chemist to modify the earlier compound to make the later compound with a reasonable expectation of success.”²⁸ The *Eli Lilly* case demonstrates that the court has moved beyond requiring mere motivation and now requires that the change leading to the new patent is the *most desirable* change from the perspective of a “person of ordinary skill in the art.”²⁹ Alternatively, rather than purposefully narrowing the standard, the Federal Circuit may be utilizing “teaching away” doctrine in obviousness-type double patenting issues.

Part II of this Recent Development traces the evolution of obviousness-type double patenting and provides details on the theoretical basis behind the different motivation standards. Part III analyzes the theoretical and historical bases of nonobviousness in patent law, specifically as the Supreme Court has explained them. Part IV sets forth the facts and the Federal Circuit’s reasoning in the recent *Eli Lilly* case. Part V of this Recent Development sets

²³ See *KSR Int’l Co.*, 550 U.S. at 421.

²⁴ See *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1378 (Fed. Cir. 2012).

²⁵ 689 F.3d 1368 (Fed. Cir. 2012).

²⁶ *Id.* at 1381.

²⁷ *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, No. 08-335-GMS, 2011 WL 3236037, at *1 (D. Del. July 28, 2011).

²⁸ *Eli Lilly & Co.*, 689 F.3d at 1378 (quoting *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012)).

²⁹ See *infra* Part V.

forth the argument that the Federal Circuit has narrowed motivation beyond the Supreme Court's intent. Part VI provides the possible alternative explanation that the Federal Circuit is applying teaching away doctrine.

II. NONOBVIOUSNESS VS. OBVIOUSNESS-TYPE DOUBLE PATENTING

Nonobviousness is a general statutory prohibition against patenting subject matter that “would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the said subject matter pertains.”³⁰ The analysis for nonobviousness is centered on “the differences between the subject matter sought to be patented and the prior art.”³¹ The law has hovered around a factual analysis over “(1) the scope and content of prior art, (2) difference between claims and prior art, (3) the level of ordinary skill in pertinent art, and (4) secondary considerations such as commercial success and satisfaction of a long-felt need.”³² This analysis is fundamentally objective.³³

The two doctrines are similar in that nonobviousness is part of the analysis for obviousness-type double patenting.³⁴ However, the scope of the analysis for obviousness-type double patenting is narrowed from being nonobvious in light of prior art to nonobvious

³⁰ SCHECHTER & THOMAS, *supra* note 1, at 369 (citing 35 U.S.C. § 103(a) (2006)).

³¹ *Id.* at 371.

³² *Procter & Gamble Co. v. Teva Pharm. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (citing *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966)). These concepts come from *Graham v. John Deere Co.*, a fundamental establishing case of nonobviousness analysis. See *John Deere Co.*, 383 U.S. at 17. The *Graham* factors have been developed by the courts over the last half-century, and have become incredibly complex. See, e.g., *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). As such, these factors are stated in this part of the Recent Development purely to illustrate the form of nonobviousness analysis, and the current view of the courts will be explained in Part III.

³³ See 2 CHISUM, *supra* note 12, § 5.04[1][e][4], at 5-395 (“The factual inquiry whether to combine references must be thorough and searching’ . . . It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.”).

³⁴ See 3A CHISUM, *supra* note 12, § 9.03[3][c], at 9-82.

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in light of a prior patent.³⁵ Ten years ago, the Federal Circuit stated three differences between these ideas.³⁶ In addition to comparing a prior patent rather than prior art, the Federal Circuit stated that “[o]bviousness requires inquiry into a motivation to modify the prior art; nonstatutory double patenting does not; [and] [o]bviousness requires inquiry into objective criteria suggesting nonobviousness; nonstatutory double patenting does not.”³⁷ These two statements are not cited to case law in the decision, but the Federal Circuit and district courts have applied these statements in decisions.³⁸

III. THE EVOLUTION OF THE LEGAL STANDARD FOR OBVIOUSNESS

The evolution of nonobviousness demonstrates a conflict between the Supreme Court and the Federal Circuit over the breadth of the standard. The Federal Circuit has focused on a strict interpretation of obviousness, eventually requiring a “teaching, suggestion, or motivation” to modify a prior art in a way that results in the contested patent.³⁹ While the Court allowed the inclusion of the Federal Circuit’s test,⁴⁰ it required that the analysis be based on the historical factors of obviousness.⁴¹ The “teaching, suggestion, or motivation” test can inform the standard, but it cannot control.⁴²

A. *Historical Underpinnings*

Nonobviousness analysis begins at statutory analysis, which has been applied by the courts to obviousness-type double

³⁵ See *id.*; *In re Bartfeld*, 925 F.2d 1450, 1453 (Fed. Cir. 1991).

³⁶ 3A CHISUM, *supra* note 12, § 9.03[3][c], at 9-82.

³⁷ *Id.* (citing *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1378 n.1 (Fed. Cir. 2003)).

³⁸ *SEE id.*

³⁹ See *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 407 (2007). See generally 2 CHISUM, *supra* note 12, § 5.04 (explaining the historical development of the TSM test in greater detail).

⁴⁰ See *KSR Int’l Co.*, 550 U.S. at 419.

⁴¹ *Infra* Part III.B.2.

⁴² See *KSR Int’l Co.*, 550 U.S. at 419.

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patenting.⁴³ Stated plainly, the law invalidates a patent that is an obvious extension of a prior art.⁴⁴ This standard involves a qualitative judgment about the new invention's originality, which must "involve a significant creative or inventive step beyond what was already known."⁴⁵ The law, set out in 35 U.S.C. § 103, has been interpreted by the Supreme Court to mean that "patentability is to depend, in addition to novelty and utility, upon the 'nonobvious' nature of the 'subject matter sought to be patented' to a person having ordinary skill in the pertinent art [sic]."⁴⁶ When the court refers to a "person of ordinary skill in the art," it implicates an objective test, in which the party's personal expectations are not explored.⁴⁷

In *Graham v. John Deere Co. of Kansas City*,⁴⁸ the Supreme Court set a framework for nonobviousness.⁴⁹ The *Graham* Court determined that courts should conduct a three part factual inquiry in the obviousness determination.⁵⁰ The courts must analyze "[1]

⁴³ See *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F. 3d 1368, 1377 (Fed. Cir. 2012). The Federal Circuit relies on their previous ruling in *Amgen Inc. v. Hoffman-La Roche Ltd.*, to state that "obviousness-type double patenting analyses is analogous to an obviousness analysis under 35 U.S.C. § 103(a)." *Id.*

⁴⁴ See MYERS, *supra* note 21, at 291. Prior art is a broad term compared to obviousness-type double patenting's focus on the previously patented material:

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.

Id. at 290 (quoting 35 U.S.C. § 103(a) (2006)).

⁴⁵ See *id.* at 290.

⁴⁶ *General Mills, Inc. v. Pillsbury Co.*, 378 F.2d 666, 667 (8th Cir. 1967) (quoting *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 14 (1966)).

⁴⁷ *Amgen Inc. v. F. Hoffmann-La Roche Ltd.*, 580 F.3d 1340, 1363 (Fed. Cir. 2009) ("[O]ne should not go about determining obviousness under § 103 by inquiring into what *patentees* (i.e., inventors) would have known or would likely have done, faced with the revelations of references." (quoting *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985))).

⁴⁸ 383 U.S. 1 (1966).

⁴⁹ See *id.* at 17.

⁵⁰ See *id.*

the scope and content of the prior art . . . [2] [the] differences between the prior art and the claims at issue . . . and [3] the level of ordinary skill in the pertinent art resolved.”⁵¹ Furthermore, the *Graham* Court allowed “[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc.” to illuminate the subject matter.⁵² In that decision, the Court stated that the constitutional history and basis of nonobviousness require a “functional approach.”⁵³ Courts should compare “subject matter of the patent, or patent application, [to] the background skill of the calling.”⁵⁴

The *Graham* Court’s language on this issue has become the basis for Federal Circuit and Supreme Court reasoning in obviousness analysis.⁵⁵ In relation to obviousness-type double patent cases, the most important aspect of *Graham* is the Supreme Court’s decision that it “provides an expansive and flexible approach,” which tends to be at odds with Federal Circuit decisions.⁵⁶ The Court was clear in stating that secondary considerations may be relevant as indicia of obviousness,⁵⁷ thus allowing courts more discretion than provided by the three *Graham* factors.⁵⁸ The Supreme Court has interpreted this fourth consideration as a way for courts to “take account of the inferences and creative steps that a person of ordinary skill in the art would employ”⁵⁹ by examining

⁵¹ *Id.*

⁵² *Id.*

⁵³ *See id.* at 12.

⁵⁴ *Id.* The Supreme Court derived this analysis from examining *Hotchkiss v. Greenwood*, which laid the groundwork for determining which innovations are worthy of patent, which the *Graham* court traced to Jeffersonian principles. *See id.* at 11.

⁵⁵ *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007).

⁵⁶ *See id.* at 415. *KSR*, like most of the cases discussed in this article, deals with nonobviousness, rather than obviousness-type double patenting specifically. *See id.* at 406. However, the Federal Circuit has not treated obviousness-type double patenting differently than nonobviousness, citing 35 U.S.C. § 103 as applying to both nonobviousness in patent formation and obviousness-type double patenting in infringement defense. *See Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1377 (Fed. Cir. 2012).

⁵⁷ *Graham*, 383 U.S. at 17–18

⁵⁸ *See KSR Int’l Co.*, 550 U.S. at 415.

⁵⁹ *Id.* at 418.

the “interrelated teachings of multiple patents . . . and the background knowledge possessed by a person having ordinary skill in the art.”⁶⁰

B. *Modern Obviousness Considerations and KSR International Co. v. Teleflex Inc.*

As an extension of the earlier nonobviousness considerations, the Federal Circuit places controlling emphasis on a motivational aspect of the analysis. Under the circuit’s analysis, a patent is obvious only if “‘some motivation or suggestion to combine the prior art teachings’ can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art.”⁶¹ This standard, called the “teaching, suggestion, or motivation” (“TSM”) test, was developed by the Federal Circuit to create a consistent standard within the nonobviousness doctrine.⁶² The court recognized that obviousness requires more than just a demonstration that the elements of the patent were known in the prior art.⁶³ Instead, the court wanted to establish a method by which other courts could consistently analyze whether the combination of those known elements is obvious.⁶⁴ In providing this consistent method, the Federal Circuit began to rigidly apply the test as if it were a formula, with a “formalistic conception of the words teaching, suggestion, and motivation.”⁶⁵ However, the Supreme Court found that the Federal Circuit’s application of the TSM test was contrary to the factors laid out in *Graham*. The Court stated that the TSM test should only be a part of the obviousness analysis, and not a “rigid rule that limits the obviousness inquiry.”⁶⁶

⁶⁰ *Id.*

⁶¹ *Id.* at 407 (quoting *Al-Site Corp. v. VSI Int’l, Inc.*, 174 F.3d 1308, 1323–24 (Fed. Cir. 1999)).

⁶² *See id.* at 407.

⁶³ *See id.*

⁶⁴ *See id.*

⁶⁵ *Id.* at 419.

⁶⁶ *Id.*

1. KSR's TSM Test

The Supreme Court recently analyzed the TSM test in *KSR International Co. v. Teleflex Inc.*⁶⁷ This case involved a patent for digital throttle control in automobiles, which is “a position-adjustable pedal assembly with an electronic pedal position sensor attached to the support member of the pedal assembly . . . [that] allows the sensor to remain in a fixed position while the driver adjusts the pedal.”⁶⁸ Computer controlled throttles are not a new idea in the automotive industry, and such technology has been patented for years.⁶⁹ However, the instant patent allowed for comfortable adjustment of a car's accelerator pedal, without sacrificing advantageous positioning of the electronic acceleration sensor.⁷⁰ This type of technology also previously existed, but the Teleflex patent improved the mechanism by “simplify[ing] [the] vehicle control pedal assembly [to be] less expensive . . . use[] fewer parts and [facilitate] easier packag[ing] within the vehicle.”⁷¹ KSR similarly developed throttle sensors on adjustable pedals, and was sued by Teleflex for infringement.⁷² Teleflex argued that “any supplier of a product that combines an adjustable pedal with an electronic throttle control necessarily employs” patented

⁶⁷ 550 U.S. 398.

⁶⁸ *Id.* at 411. (quoting *Teleflex Inc. v. KSR Int'l Co.*, 298 F. Supp. 2d 581, 586–87 (E.D. Mich. 2003)). This statement was the District Court's summary of the patent. The patent itself claimed:

a vehicle control pedal apparatus comprising: a support adapted to be mounted to a vehicle structure; an adjustable pedal assembly having a pedal arm moveable in for[e] and aft directions with respect to said support; a pivot for pivotally supporting said adjustable pedal assembly with respect to said support and defining a pivot axis; and an electronic control attached to said support for controlling a vehicle system; said apparatus characterized by said electronic control being responsive to said pivot for providing a signal that corresponds to pedal arm position as said pedal arm pivots about said pivot axis between rest and applied positions wherein the position of said pivot remains constant while said pedal arm moves in fore and aft directions with respect to said pivot.

Id. at 410–11.

⁶⁹ *See id.* at 409.

⁷⁰ *See id.* at 408–10.

⁷¹ *See id.* at 410.

⁷² *See id.* at 410, 412.

technology.⁷³ KSR asserted that the patent was obvious in light of prior art.⁷⁴ The District Court ruled that the patent was indeed obvious, as the “state of the industry would lead inevitably to combinations of electronic sensors and adjustable pedals” at issue in this case.⁷⁵

The Federal Circuit reversed this decision.⁷⁶ The court found the motivation aspect of the TSM test lacking in the district court’s decision.⁷⁷ The district court analyzed an older adjustable pedal that could be combined with a well-known solution to a problem in placing a throttle sensor on an adjustable pedal.⁷⁸ It is important to note that the court stated that this prior art *could* be combined to result in Teleflex’s patent. The district court provided a basis for a suggestion to combine in the prior art, and certainly a possibility to combine, but it did not provide a specific motivation to combine.⁷⁹

The Federal Circuit used a narrow approach, stating that the District Court must have found “the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the] invention” to make the patented changes to the technology.⁸⁰ Under the Federal Circuit’s analysis, the lower court was not strict enough in finding motivation under the TSM test, implying that the mere fact that “the state of the industry would lead inevitably to combinations of

⁷³ *Id.* at 412. (quoting *Teleflex Inc. v. KSR Int’l Co.*, 298 F. Supp. 2d 581, 585 (E.D. Mich. 2003)). This statement is a quote of the district court’s argument summary. Teleflex did not actually plead this.

⁷⁴ *See id.*

⁷⁵ *Id.* at 413.

⁷⁶ *Id.*

⁷⁷ *See id.*

⁷⁸ The prior adjustable pedal is called the “Asano Pedal.” *Id.* at 400, 413. It was designed as an improvement to adjustable pedals, so that the “the force necessary to push the pedal down is the same regardless of adjustments to its location.” *Id.* at 408. A common problem with these pedals was that their movement would often chafe the wires used to transmit the throttle data. *Id.* at 409. Another patent demonstrated that placing the throttle sensor on a “fixed part of the pedal assembly” prevented wire chafing. *Id.* at 408–09.

⁷⁹ *See id.* at 413.

⁸⁰ *Id.* at 414 (quoting *KSR Int’l Co. v. Teleflex Inc.*, 119 Fed. App’x. 282, 288 (Fed. Cir. 2005)).

electronic sensors and adjustable pedals” was not enough to motivate a person of skill in the art.⁸¹ The court stated that, while combining the sensor and the pedal may have been “obvious to try,” “‘obvious to try’ has long been held not to constitute obviousness.”⁸² However, the Supreme Court rejected this narrow construction of what would motivate one of ordinary skill in the art.⁸³

2. *KSR’s TSM Test Reanalyzed by the Supreme Court*

The Supreme Court affirmed that the legal history of nonobviousness supports a broad standard, stating that the motivation of the patentee cannot be the controlling issue.⁸⁴ Rather, as demonstrated by the historical underpinnings of nonobviousness from *Hotchkiss* and *Graham*, a patent is obvious when there is a “known problem for which there was an obvious solution encompassed by the patent’s claims.”⁸⁵

The Supreme Court felt that the TSM test alone is not flexible enough to support the “diversity of inventive pursuits” and that the “obvious techniques or combinations, and . . . market demand, rather than scientific literature . . . will drive design trends.”⁸⁶ The Supreme Court stated 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.”⁸⁷ The Court presented the idea that obviousness is based on preventing patents from being granted to advances made in the “ordinary course without real innovation.”⁸⁸ The TSM test should be a method to achieve this goal but should not be the defining test itself.⁸⁹

⁸¹ *See id.* at 413.

⁸² *Id.* at 414 (quoting *KSR Int’l Co.*, 119 Fed. App’x. at 289).

⁸³ *See id.* at 415–16.

⁸⁴ *See id.* at 419.

⁸⁵ *See id.*

⁸⁶ *Id.* at 419.

⁸⁷ *Id.* at 420.

⁸⁸ *See id.* at 419.

⁸⁹ *See id.* (“Granting patent protection to advances that would occur in the ordinary course without real innovation retards progress and may, in the case of patents combining previously known elements, deprive prior inventions of their

The Court emphasized the common sense aspect of nonobviousness, stating “[c]ommon sense teaches . . . that familiar items may have obvious uses beyond their primary purposes, and in many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”⁹⁰ Most importantly, the Court broadened the motivation standard by stating 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 person of ordinary skill has good reason to pursue the known options within his or her technical grasp.”⁹¹ These statements stand in direct opposition to the narrow stance of the Federal Circuit, which the Circuit applies again in *Eli Lilly*.

IV. ELI LILLY AND CO. V. TEVA PARENTERAL MEDICINES INC.

In a 2012 pharmaceutical patenting case, the Federal Circuit rejected an obviousness-type double patenting claim because there was no motivation to derive the contested compound from an earlier patented drug.⁹² The court held that there is no obviousness-type double patenting without “identifying some reason that would have led a chemist to modify the earlier compound to make the later compound with a reasonable expectation of success.”⁹³ The court reasoned that a “person of ordinary skill in the art” would have modified the earlier compound in a manner that would not have resulted in the contested drug.⁹⁴ This language is the basis of the

value or utility. In the years since the Court of Customs and Patent Appeals set forth the essence of the TSM test, the Court of Appeals no doubt has applied the test in accord with these principles in many cases. There is no necessary inconsistency between the test and the *Graham* analysis. But when a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.”)

⁹⁰ *Id.* at 420.

⁹¹ *See id.* at 421.

⁹² *See Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1378 (Fed. Cir. 2012).

⁹³ *Id.* (quoting *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012).

⁹⁴ *See id.*

Federal Circuit's increasingly narrow obviousness standard and indicative of the court's divide with the Supreme Court.

A. *Background*

Eli Lilly and Co. is a large pharmaceutical company that holds several patents over drugs similar to methotrexate, an antifolate used in cancer treatments for the drug's DNA synthesis inhibiting effects.⁹⁵ Pemetrexed, like methotrexate, is structurally similar to folic acid and was developed in response to the older methotrexate's propensity to destroy healthy cells along with the cancer cells.⁹⁶ Developed by Eli Lilly and Co., the drug was successful in its cancer inhibiting effects with reduced drug toxicity, so the company began developing pemetrexed-related pharmaceuticals.⁹⁷ The '608 patent⁹⁸ was claimed in 1991 for a pemetrexed type drug.⁹⁹ This patent expired long before Eli Lilly brought this case to court.¹⁰⁰ Eli Lilly also has a more general patent, the '932 patent,¹⁰¹ which encompasses Pemetrexed and other related antifolates.¹⁰²

⁹⁵ *See id.* at 1371; Press Release, Eli Lilly & Co., ALIMTA® Extends Survival in Continuation Maintenance Setting for Specific Lung Cancer Patients (Oct. 17, 2012), available at <http://newsroom.lilly.com/releasedetail.cfm?releaseid=714361> ("Alimta® (pemetrexed for injection) [is approved for use] as a maintenance therapy following first-line ALIMTA plus cisplatin for locally advanced or metastatic nonsquamous non-small cell lung cancer (NS NSCLC).").

⁹⁶ *Eli Lilly & Co.*, 689 F.3d at 1372. The key structural difference between pemetrexed and methotrexate is pemetrexed's pyrrolopyrimidine bicyclic core, rather than methotrexate's, and folic acid's, pteridine core. *Id.* at 1373. Pemetrexed is "characterized by a five-member ring fused with a six-member ring," while methotrexate is characterized by dual six-member rings. *Id.* Testing revealed that Pemetrexed works very similarly to methotrexate, on top of being structurally similar. *Id.* While Eli Lilly explored other derivatives of Pemetrexed, as described in the Recent Development, no other derivatives were as effective at treating mesothelioma and non-small cell lung cancer. *Id.* The drug is now FDA approved to treat both of these cancers. *Id.*

⁹⁷ *Id.*

⁹⁸ U.S. Patent No. 5,028,608 (filed May 24, 1990).

⁹⁹ *See id.*

¹⁰⁰ *Eli Lilly & Co.*, 689 F.3d at 1375.

¹⁰¹ U.S. Patent No. 5,344,932 (filed Mar. 22, 1991).

¹⁰² *Eli Lilly & Co.*, 689 F.3d at 1373.

The '932 patent is in effect until July 24, 2016.¹⁰³ The differences between these two drugs is highly technical and outside the scope of this analysis. In the context of the court's reasoning, the change can be summarized as a difference in a common chemical structure, with both chemicals still retaining extreme similarity to folic acid.¹⁰⁴

Another pharmaceutical company, Teva Parenteral Medicines, Inc., filed an abbreviated new drug application to sell a generic version of the '932 patent drug, Pemetrexed.¹⁰⁵ While this sale would be clear patent infringement, Teva asserted that the '932 patent is invalid for obviousness-type double patenting.¹⁰⁶ Teva claimed that the change in the aryl region of pemetrexed, which resulted in the '932 compound, was obvious.¹⁰⁷ The district court rejected this argument, stating that, while the difference in the compounds was primarily in the aryl region, there is persuasive evidence that "one of skill in the art" would have made different changes to Pemetrexed than adding a phenyl group.¹⁰⁸

¹⁰³ *Id.* at 1375.

¹⁰⁴ The '608 patent "differs from Pemetrexed only in its aryl region . . . contain[ing] a five-member thiophene ring in place of pemetrexed's six-member benzene ring." *See id.* at 1373–74. Stated plainly, the difference between the two compounds is the aryl region, with Pemetrexed having phynl as the aryl type, while the earlier compound has thienyl. *Id.* at 1374.

¹⁰⁵ *Id.* at 1375. An Abbreviated New Drug Application is an application to market a generic version of an FDA approved pharmaceutical. *See* 5 CHISUM, *supra* note 12, §§ 16.03[1][d], at 16-278. If the patent for the drug has not yet expired, as is true in the instant case, the application must assert that the patent is invalid. *Id.* at 16-281. Successfully filing this application provides the manufacturer, Teva, with a 180-day exclusive marketing right. *See id.* Naturally, that exclusive period is worth a significant amount of money in the drug-manufacturing world. Thus, Teva's claim that Eli Lilly's patent is invalid for obviousness-type double patenting is central to Teva's ability to manufacture and market its generic drug.

¹⁰⁶ *Eli Lilly & Co.*, 689 F.3d at 1376.

¹⁰⁷ *Id.* at 1375.

¹⁰⁸ *Id.* at 1376.

B. *Federal Circuit's Decision to Uphold*

The Federal Circuit upheld the district court's ruling.¹⁰⁹ The court stated that the relevant standard is not limited only to looking at the obvious differences between the two patents.¹¹⁰ The court can also determine how "one of skill in the art" would change the compound as a whole to achieve desired results by looking at the compound as a whole.¹¹¹ The Federal Circuit emphasized that the '608 compound could be modified in many different ways, and the court did not decide that "substituting a phenyl group into the aryl position" would be the move "one of skill in the art" would pursue.¹¹² Teva's argued that the structural change in methotrexate that results in Pemetrexed is the "inescapable conventional wisdom in the field" and presented evidence that a person of skill in the art would not consider the structural difference undesirable.¹¹³ Although the language is structurally awkward, it is purposefully stated this way. The Federal Circuit rejected motivation for the change because a person of ordinary skill in the art would modify the chemicals in a different way than alleged obvious.¹¹⁴

V. *ELI LILLY & CO. AS APPLIED TO KSR*

Despite the Supreme Court's instruction to the Federal Circuit to broaden the application of the TSM standard,¹¹⁵ *Eli Lilly* indicates that the judges of the Federal Circuit have not complied with the mandate.¹¹⁶ Not only does the Federal Circuit put decisive weight on the specific motivation of the "one of skill in the art" but also requires that the "one of skill" be more motivated to make the obvious change than any other changes.¹¹⁷ The *KSR* Court indicates the motivation aspect was never supposed to be as stringent as the

¹⁰⁹ *Id.* at 1377.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.* at 1378.

¹¹³ *Id.* at 1377.

¹¹⁴ *Id.*

¹¹⁵ See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007).

¹¹⁶ See *Eli Lilly & Co.*, 689 F.3d at 1377.

¹¹⁷ See *id.*

Federal Circuit portrayed it.¹¹⁸ While the Supreme Court prefers a broader analysis of indicia of obviousness than the TSM test allows,¹¹⁹ the Federal Circuit narrows the motivation component beyond what would motivate a person of skill in the art to make the change.¹²⁰ Rather, the court wants the change to be the most desirable change a person of skill in the art would make when viewed in light of the previous patent.¹²¹

A. The Federal Circuit's Narrow TSM Standard

Unlike the cases previously discussed, the *Eli Lilly* Court specifically analyzed obviousness-type double patenting, rather than simply nonobviousness.¹²² Thus, the *KSR* Court compared obviousness to the state of prior art in general, while the *Eli Lilly* court compared obviousness to the prior patent. The court states “obviousness-type double patenting ‘requires identifying some reason that would have led a chemist to modify the earlier compound to make the later compound with a reasonable expectation of success.’”¹²³ The Federal Circuit applies this idea extremely narrowly, in conflict with the Supreme Court’s instruction.

The *Eli Lilly* court functionally ignores the Supreme Court’s express aversion to the motivation aspect being the only deciding factor in nonobviousness.¹²⁴ Motivation is essentially the only point of discussion for the Federal Circuit.¹²⁵ Although the court provides a detailed analysis of the obviousness of a compound in general,¹²⁶ the discussion itself is focused entirely on the motivation aspect of

¹¹⁸ See *KSR Int’l Co.*, 550 U.S. at 419.

¹¹⁹ See *id.*

¹²⁰ See *Eli Lilly & Co.*, 689 F.3d at 1377.

¹²¹ See *id.*

¹²² See *id.* at 1378. Although this difference is not particularly important from a doctrinal position, it should be noted for clarity.

¹²³ *Id.* at 1378 (quoting *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012)).

¹²⁴ See *id.*

¹²⁵ See *id.*

¹²⁶ See *id.* at 1381.

obviousness.¹²⁷ The court dubiously cites the requirement of examining objective indicia of nonobviousness, without actually giving that standard any weight.¹²⁸ In that sense, the Federal Circuit deftly cites the reasoning of the Supreme Court, without actually applying it.

B. *Beyond Simple Motivation*

Beyond simply putting weight on the TSM test in obviousness-type double patent claims, the Federal Circuit seems to require a standard above mere motivation. In *Eli Lilly*, the court frames its analysis in a peculiar fashion. Rather than focus on whether a “person of ordinary skill in the art” would be motivated to change the ’608 compound to create Pemetrexed, the court instead focuses on the fact that “the ways in which a person of ordinary skill would modify [the ’608 compound] would not result in Pemetrexed.”¹²⁹ The Federal Circuit states that it requires “some reason that would have led” a chemist to change the ’608 patent into Pemetrexed.¹³⁰ Yet the court bases its decision on the fact that a chemist would make many different changes instead of the one resulting in Pemetrexed.¹³¹

The difference in language is apparent when comparing *Eli Lilly* to another important obviousness-type double patenting case. In *Otsuka Pharmaceutical Co. v. Sandoz, Inc.*,¹³² the Federal Circuit denied an obviousness-type double patenting claim involving an antipsychotic drug.¹³³ In relating earlier nonobviousness analysis to the issue, the court decided that the “prior art would not have provided a skilled artisan with a reason to make the necessary structural changes”¹³⁴ The court further stated that it could find “no teaching that suggests” the change between the patents

¹²⁷ *See id.*

¹²⁸ *Id.* at 1381. Analyzing objective indicia is more in line with how the Supreme Court reviews nonobviousness than the TSM test. *See supra* Part II.B.

¹²⁹ *Eli Lilly & Co.*, 689 F.3d at 1378.

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² 678 F.3d 1280 (Fed. Cir. 2012).

¹³³ *Id.* at 1299.

¹³⁴ *Id.*

would have led to a safe drug.¹³⁵ The language in this case is centered on the fact that the prior art—and prior patent—showed no reason that would have led a chemist to make the contested change.¹³⁶ This question is fundamentally different from *Eli Lilly*'s focus on all the other ways in which a person of skill in the art would change the '608 compound that would not result in Pemetrexed. The *Otsuka* court examines simply whether a person would make the disputed change, while the *Eli Lilly* court interprets motivation in light of all the other ways a person of ordinary skill in the art would change a patented compound. As a result, the *Otsuka* court's analysis is far broader in regard to obviousness-type double patenting than the *Eli Lilly* court's analysis.

This reasoning is not plainly visible from *Eli Lilly*, as the Federal Circuit simply accepts the lower court's findings.¹³⁷ However, the district court ruling clarifies this way of examining nonobviousness. For example, the district court states that a "person of ordinary skill in the art would have no reason to make Pemetrexed from among the many [suggested] final antifolates," as the generally preferred change is different than the one the patent holder made.¹³⁸ The district court further specifies the way a "person of ordinary skill in the art" would change the compound, and it is not in such a manner that would result in Pemetrexed.¹³⁹

While not rejecting the TSM test in its entirety, the *KSR* court specifically rejected the type of narrow reasoning used by the *Eli Lilly* court. The Supreme Court stated that "the analysis need not seek out precise teachings directed to the specific subject matter of

¹³⁵ *Id.*

¹³⁶ *See id.*

¹³⁷ *See id.*

¹³⁸ *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, No. 08-335-GMS, 2011 WL 3236037, at *3 (D. Del. July 28, 2011).

¹³⁹ *Id.* The court stated that, rather than make changes in the aryl region of the thierinyl compound, a "person of ordinary skill in the art" would change the amino acid of the thierinyl compound to methyl. *Id.* The reasoning is scientifically complicated, but the result is the same as discussed above. *See supra* Part V.B. The change is not obvious because there is a different way in which a "person of skill in the art" would change the compound.

the challenged claim.”¹⁴⁰ Instead of questioning whether this person would be motivated to make the change, the *Eli Lilly* court is doing exactly what the Supreme Court wanted it to avoid. In *KSR*, the Supreme Court stated that there is motivation to try when there is a design need to solve a problem and a finite number of solutions.¹⁴¹ This statement implicates the idea that the Supreme Court would not want motivation to be determined by what other changes a “person of ordinary skill in the art” would make but rather only focus on whether the person would make the change in the patent.

It is possible, however, that examining nonobviousness in this manner is closer to the broad standard set forth by the Supreme Court than the alternative narrow motivation standard. In examining the different ways a person of “ordinary skill in the art” would change the compound before the person would make the patented change, the Federal Circuit may very well be analyzing more objective indicia of nonobviousness than the court would if it only focused simply on the motivation behind changing the drug to the patented compound.¹⁴² Furthermore, it is possible that the Federal Circuit did indeed mean that there is no evidence to support that a chemist would change the ’608 compound to Pemetrexed. The court cited evidence from *Eli Lilly* that “earlier reports of associated inefficacy and toxicity would have actively dissuaded one [from making the change].”¹⁴³ However, that consideration does not explain the language used by the court in its ruling. Also, this language is evidence of a teaching away standard, discussed in Part VI.

C. The Impact of the Narrower Standard

The prime impact of this case is that generic drug companies claiming obviousness-type double patenting, such as Teva, need to demonstrate more than just a reason why a person of “ordinary skill in the art” would be motivated to make a change. The

¹⁴⁰ *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

¹⁴¹ *Id.* at 421.

¹⁴² *See infra* Part VI.

¹⁴³ *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1378 (Fed. Cir. 2012).

company needs to show why this change would be the most desirable activity to the hypothetical person and present evidence as to why other changes are not as attractive.

One important result from the *Eli Lilly* decision is that it relies heavily on an objective measure, yet treats it in a subjective manner. The person of ordinary skill in the art is empowered by the court beyond just believing something is obvious and being motivated to combine prior art. This person now has the power to prefer different combinations of prior art—prior patents in an obviousness-type double patenting context—and to determine obviousness based on this preference.

The person of ordinary skill in the art is an objective standard.¹⁴⁴ In *KSR*, the Court stated that particular motivation or purpose does not determine obviousness.¹⁴⁵ Rather, it is the “objective reach of the claim” that controls.¹⁴⁶ In an older decision, the Seventh Circuit stated, “modern standards for judging the obviousness of a claimed invention are designed to focus on objective rather than subjective factors.”¹⁴⁷ In other decisions where this person of ordinary skill is analyzed, even when the “skill of the artisan” is central to the analysis, the court still emphasizes objective considerations.¹⁴⁸ However, examining the most desirable change that a person of ordinary skill would make to a compound in light of prior patents goes a step beyond the standard objectivity of the courts. In its decision, the *Eli Lilly* court accepts Eli Lilly’s argument that a chemist motivated to develop a drug that has the pharmacological impact of Pemetrexed would have examined specific data from the “emerging sub-discipline” of Pemetrexed mechanism.¹⁴⁹ Eli Lilly also successfully argues that the person of ordinary skill in the art would not follow conventional practice in

¹⁴⁴ See *supra* note 22 and accompanying text.

¹⁴⁵ *KSR Int’l Co.*, 550 U.S. at 419.

¹⁴⁶ *Id.*

¹⁴⁷ *Brunswick Corp. v. Champion Spark Plug Co.*, 689 F.2d 740, 750 n.11 (7th Cir. 1982).

¹⁴⁸ See *In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998).

¹⁴⁹ *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 1377–78 (Fed. Cir. 2012).

this regard, implied as “emulat[ing] conventional antifolates.”¹⁵⁰ There is a point reached in analyzing the motivation of a person of ordinary skill where the court changes from analyzing the objective factors of obviousness to analyzing with such specificity that it is basically subjective. The Federal Circuit in *Eli Lilly* allows so much specific information to control in its decision that objective indicia of nonobviousness no longer has any real meaning in the decision.

VI. TEACHING AWAY DISGUISED AS PURE MOTIVATION

One explanation for the *Eli Lilly* court’s narrow view of motivation is that the Federal Circuit is applying teaching away doctrine to obviousness-type double patenting. Teaching away is the term used by the courts to describe the impact of prior art that would push a person of ordinary skill in the art away from making the change in the art deemed obvious.¹⁵¹ This concept applies uniquely within the nonobviousness standard and has historically not been applied in nonstatutory double patenting.¹⁵² However, the Federal Circuit’s focus on secondary considerations in *Eli Lilly* can be considered an extension of the standard.

A. Teaching Away Legal Standard

Teaching away is related to motivation in obviousness-type double patenting as articulated in *Eli Lilly*.¹⁵³ Specifically, teaching away is related to the requirement that the claimant provide “some reason that would have led a chemist to modify the earlier compound to make the later compound with a reasonable expectation of success.”¹⁵⁴ The reasonable expectation of success

¹⁵⁰ *Id.* at 1378.

¹⁵¹ See 2 CHISUM, *supra* note 12, § 5.03[3][a][i][G], at 5-160.

¹⁵² See *infra* note 167.

¹⁵³ See 2 CHISUM, *supra* note 12, § 5.03[3][a][i][G], at 5-164. According to Donald Chisum, teaching away is related to the “reasonable expectation of success” standard in obviousness-type double patenting. See *id.* The *Eli Lilly* decision is based largely on motivation as it relates to the reasonable expectation of success. See *Eli Lilly & Co.*, 689 F.3d at 1377–78.

¹⁵⁴ *Eli Lilly & Co.*, 689 F.3d at 1378 (quoting *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012)).

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concept also means that factors decreasing the expectation of success will lead a person of ordinary skill away from combining prior art.¹⁵⁵

Just as courts applying obviousness doctrine begin with the *Graham* factors,¹⁵⁶ courts applying the teaching away doctrine begin with *Graham*'s companion case, *United States v. Adams*.¹⁵⁷ *Adams* involved a disputed patent for an improved battery design.¹⁵⁸ The government disputed the patent on the ground that the improvement had been "previously well known in the art."¹⁵⁹ The government argued that the technology used in the innovative battery was "old in the art" and, thus, combining the technology in the battery was not a real change in the technology.¹⁶⁰ The Supreme Court denied the claim but agreed that the technology used was well known.¹⁶¹ However, the Court ruled based on the fact that combining the well-known prior art was undesirable to a person of ordinary skill in the art.¹⁶² Decades later, the Supreme Court cited this case as an example of the "[t]he Court rel[ying] upon the corollary principle that when the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious."¹⁶³

¹⁵⁵ See 2 CHISUM, *supra* note 12, § 5.03[3][a][i][G], at 5-164 to -165.

¹⁵⁶ See MYERS, *supra* note 21, at 290.

¹⁵⁷ 383 U.S. 39 (1965).

¹⁵⁸ *Id.* at 42. The battery was unusual in that it involved a magnesium electrode and a cupreous chloride electrode in an electrolyte and water solution. *Id.* at 43. Once water was added to the electrodes, a chemical reaction would generate constant electricity with a wide range of currents. *Id.* The battery could be stored indefinitely and delivered a large current in comparison to its weight and size. *Id.* Based on its innovative design, it could operate at a wide variety of temperatures. *Id.* This design was the first practical application of these valuable characteristics in a battery. *Id.*

¹⁵⁹ *Id.* at 39.

¹⁶⁰ *Id.* at 48.

¹⁶¹ *Id.*

¹⁶² *Id.* at 40. ("Though each of the battery's elements was well known in the prior art, to combine them as Adams did required that a person reasonably skilled in that art ignore that open-circuit batteries which heated in normal use were not practical and that water-activated batteries were successful only when combined with electrolytes harmful to the use of magnesium.")

¹⁶³ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007).

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*In re Gurley*¹⁶⁴ further clarified the teaching away language, stating that “[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.”¹⁶⁵ The *Gurley* language has become the baseline for teaching away analysis.¹⁶⁶ In that case, the Federal Circuit determined teaching away on highly fact-specific grounds, applying a wide range of factors that would discourage a person of ordinary skill in the art from inventing the patented product.¹⁶⁷ Discouraging factors included known disadvantages in the prior art,¹⁶⁸ auxiliary principles taught by the art,¹⁶⁹ and evidence that combining the prior art would not lead to the desired result.¹⁷⁰ This language is similar to the Federal Circuit language in *Eli Lilly*.¹⁷¹ However, courts do not usually apply this concept to obviousness-type double patenting cases.¹⁷² Teaching away fundamentally concerns analyzing

¹⁶⁴ 27 F.3d 551 (Fed. Cir. 1994).

¹⁶⁵ *Id.* at 553.

¹⁶⁶ See 2 CHISUM, *supra* note 12, § 5.03[3][a][i][G], at 5-165. The language used in the *Gurley* case can be seen used repeatedly in subsequent teaching away cases. For an in-depth glance at the *Gurley* language in the courts see *id.* at 5-165 n.98.

¹⁶⁷ See *In re Gurley*, 27 F.3d at 553.

¹⁶⁸ *Id.* (citing *United States v. Adams*, 383 U.S. 39, 52 (1966)).

¹⁶⁹ *Id.* (citing *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550–51 (Fed. Cir. 1983)).

¹⁷⁰ *Id.* (citing *In re Caldwell*, 319 F.2d 254, 256 (C.C.P.A. 1963)).

¹⁷¹ See *supra* Part IV.B. The court stated that it would examine the compound as a whole, determining how “one of skill in the art” would change the compound as a whole to achieve desired results. *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368, 1377 (Fed. Cir. 2012). The court accepted *Eli Lilly*’s argument that a chemist seeking to develop the compound would have examined the sub-discipline of that specific field, rather than the properties of antifolates in general. *Id.* at 1378.

¹⁷² See generally 2 CHISUM, *supra* note 12, § 5.03[3][a][i][G], at 5-160 to -177 (describing the teaching away standard in relation to nonobviousness). Despite the importance of teaching away in obviousness discussions, there are no cases applying this concept to obviousness-type double patenting. See generally 3A CHISUM, *supra* note 12, § 9.03, at 9-14 to -100 (discussing obviousness-type double patenting at length, but not mentioning teaching away).

prior art,¹⁷³ while obviousness-type double patenting concerns analyzing prior patents.¹⁷⁴ Thus, determining whether prior art teaches away is illogical when there is no prior art to analyze, only a prior patent.

B. *Teaching Away Applied in Eli Lilly*

The *Eli Lilly* decision is indicative of the Federal Circuit's willingness to apply outside factors in obviousness-type double patenting. The way in which outside considerations were analyzed is more in line with teaching away than with obviousness-type double patenting. The first example of this issue appears when the Federal Circuit discusses analyzing the patent as a whole. Teva argued that the court should only analyze the differences between the patented compounds.¹⁷⁵ The court rejected this argument, stating that the analysis is centered on "the differences in subject matter between the claims."¹⁷⁶ In making this decision, the court stated that the comparison of the subject matter requires examining the claims "as a whole,"¹⁷⁷ which is "analogous to an obviousness analysis."¹⁷⁸ Examining a claim as a whole by examining the subject matter is the same language cited in *In re Gurley* when describing the considerations in teaching away analysis.¹⁷⁹ The common language in the cases implies that the Federal Circuit considers teaching away in obviousness-type double patenting.

The second example of the *Eli Lilly* court blurring the line between obviousness-type double patenting and teaching away in obviousness comes from *Eli Lilly's* successful argument that earlier reports dissuade an ordinary chemist from attempting the

¹⁷³ See 2 CHISUM, *supra* note 12, § 5.03[3][a][i][G], at 5-160.

¹⁷⁴ See *supra* Part II.

¹⁷⁵ *Eli Lilly & Co.*, 689 F.3d at 1377.

¹⁷⁶ *Id.* (citing *Amgen Inc. v. Hoffman-La Roche Ltd.*, 580 F.3d 1340, 1361 (Fed. Cir. 2009)).

¹⁷⁷ *Id.* at 1377.

¹⁷⁸ *Id.* (citing *Amgen Inc.*, 580 F.3d at 1361).

¹⁷⁹ *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). The *Gurley* court cites a previous case, stating that "the totality of the reference's teachings must be considered." *Id.* (citing *W.L. Gore & Assoc. v. Garlock, Inc.*, 721 F.2d 1540, 1550-51 (Fed. Cir. 1983)).

change.¹⁸⁰ Teva argued that a person of ordinary skill in the art would follow the “conventional wisdom” in antifolate structures.¹⁸¹ Eli Lilly, on the other hand, argued that specific data from the art suggests that the change resulting in the disputed compound would reduce efficacy and increase toxicity.¹⁸² This likely result would dissuade a person of ordinary skill in the art from producing Pemetrexed.¹⁸³ This language is identical to teaching away analysis language.¹⁸⁴ According to the Federal Circuit, there was enough evidence to find that a person of ordinary skill in the art would believe that the changes necessary to derive Pemetrexed from the earlier patent would lead to an undesirable result.¹⁸⁵ This statement mirrors the *In re Gurley* language that likely undesirable results teach away from combining prior art.¹⁸⁶

However, the conclusion that the Federal Circuit now examines secondary considerations in the same way as it examines prior art in teaching away doctrine has two major flaws. First, the court stated that it was not applying secondary considerations analysis.¹⁸⁷ The lower court stated that secondary considerations are not relevant in the analysis, which the Federal Circuit rejected.¹⁸⁸ The *Eli Lilly* court determined that secondary considerations can be considered in the analysis but also stated that this issue is not determinative in this case.¹⁸⁹ Because the lower court made its determination without dealing with secondary consideration, the *Eli Lilly* court ignored the secondary consideration analysis.¹⁹⁰ The fact that the Federal Circuit made a determination while also plainly stating that secondary considerations were not part of the analysis supports the idea that *Eli Lilly* does not involve extending

¹⁸⁰ *Eli Lilly & Co.*, 689 F.3d at 1378.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *See supra* Part IV.A.

¹⁸⁵ *Eli Lilly & Co.*, 689 F.3d at 1377–78.

¹⁸⁶ *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994) (citing *In re Caldwell*, 319 F.2d 254, 256 (C.C.P.A. 1963)).

¹⁸⁷ *Eli Lilly & Co.*, 689 F.3d at 1381.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

teaching away analysis to obviousness-type double patenting. A second flaw in applying teaching away in this case is that the language could be the natural result of analyzing “the reasonable expectation of success” component of motivation.¹⁹¹ If the court is allowed to analyze secondary considerations,¹⁹² and the court must determine whether there is a reasonable expectation of success,¹⁹³ then the teaching away may simply be the application of the analysis. Thus, the teaching away issue may be explained by the words of the *Eli Lilly* court and the practicalities of applying the obviousness-type double patenting test.

C. *Support and Impact*

This method of analysis has already been demonstrated in *Eli Lilly*’s application in other cases. In *Wyeth Holdings Corp. v. Sandoz, Inc.*,¹⁹⁴ a Delaware district court used the lower court’s *Eli Lilly* decision to deny summary judgment for an obviousness-type double patenting claim.¹⁹⁵ Like *Eli Lilly*, the *Wyeth* case was based on an Abbreviated New Drug Application for a pharmaceutical.¹⁹⁶ In *Wyeth*, the court stated that, while obviousness-type double patenting analysis is largely analogous to non-obviousness analysis, the analysis differs in that the contested patent is not considered in light of prior art.¹⁹⁷ However, the court also cited *Eli Lilly* as allowing consideration of secondary factors.¹⁹⁸ The court decided that, while obviousness-type double patenting is focused on what is claimed in the patent, the patent is a “starting point” for further analysis.¹⁹⁹ Presuming that this “starting point” does not *only* lead to obviousness findings, this language can be used to find that information from prior art discourages the contested change in

¹⁹¹ *Id.* at 1378 (citing *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012)).

¹⁹² *Id.* at 1381.

¹⁹³ *Id.* at 1378.

¹⁹⁴ Civ. Action No. 09-955-RGA-CJB, 2012 WL 1748008 (D. Del. Apr. 5, 2012).

¹⁹⁵ *Id.* at *16.

¹⁹⁶ *Id.* at *1.

¹⁹⁷ *Id.* at *5.

¹⁹⁸ *Id.* at *9.

¹⁹⁹ *Id.*

the patent. Thus, this language would support teaching away in obviousness-type double patenting.

Similarly, in *Janssen Pharmaceuticals, Inc. v. Watson Laboratories, Inc.*,²⁰⁰ the court analyzed an issue based on nonobviousness and then cited *Eli Lilly* as support for extending its analysis to obviousness-type double patenting.²⁰¹ Also, the court cited *Eli Lilly* in support of allowing the court to examine secondary considerations.²⁰² The court cites teaching away in its analysis of nonobviousness.²⁰³ After the court found that the patent was nonobvious, it determined that there was “[no] difference in the law of obviousness-type double patenting [that would] lead to a different conclusion.”²⁰⁴ The court did not state that it was utilizing teaching away while analyzing secondary considerations. However, the language of the court implies that it did not change its analysis when it moved from nonobviousness to obviousness-type double patenting. Thus, it seems as though the court was indirectly utilizing teaching away when it made its decision.

If the *Eli Lilly* decision means that secondary considerations and teaching away are now synonymous, then the standard analysis will change. First, the main difference between nonobviousness and obviousness-type double patenting analysis will be lessened. While obviousness-type double patenting requires examination of the patent rather than prior art, teaching away functionally makes prior art a serious consideration. As such, the differences between the two doctrines described in Part II of this Recent Development may no longer be meaningful.

Second, the standard could be narrowed as proposed in Part V of this Recent Development. If teaching away is implemented in obviousness-type double patenting, then the barrier to a successful claim will be higher than before. However, this barrier is not as high as that which would be set by a court requiring the *most*

²⁰⁰ Civ. Action No. 08-5103(SRC), 2012 WL 3990221 (D.N.J. Sept. 11, 2012).

²⁰¹ *Id.* at *27.

²⁰² *Id.*

²⁰³ *Id.* at *26.

²⁰⁴ *Id.*

desirable change to a person of ordinary skill in the art for a successful claim. Prior art influencing a court's decision could support an obviousness-type double patenting claim, while requiring the *most desirable change* would only block claims. Thus, the impact of the court's implementation of teaching away to obviousness-type double patenting is less extreme than the impact of the policy described in Part V of this Recent Development.

VII. CONCLUSION

With the increasing cost of pharmaceuticals and the debate over the healthcare system, drug availability has become a serious topic. Through evergreening, some companies are able to manipulate the legal system to extend their exclusive right over the drugs they own. If the patent holders select obviousness-type double patenting as their evergreening method, then they are at the mercy of the Federal Circuit's interpretation of the mythical person of ordinary skill in the art.

After *Eli Lilly*, patent holders have another defense against challenges to their exclusive right. Whether through an overall narrowing of the obviousness-type double patenting standard, or through an extension of teaching away to this type of claim, the factors influencing a person of ordinary skill in the art are viewed more strictly after *Eli Lilly*. The *Eli Lilly* court provides an example of how the motivation standard has resulted in a far narrower view of the requirements to prove obviousness than the Supreme Court set forth in *KSR*. At least in a pharmaceutical context, the Federal Circuit's analysis of obviousness-type double patenting is a significant deviation from the Supreme Court's interpretation of nonobviousness, an analogous standard.

Considering the fact that *KSR* is not a drug patent case, it is possible that the highly technical nature of pharmaceutical patents justifies the difference between the Supreme Court's standard and the Federal Circuit's application of that standard. As *KSR* demonstrates, the Supreme Court has reined in the Federal Circuit before on this issue. Preferably, the nation's highest court will clarify the necessary interpretation of the TSM test, as well as nonobviousness in general. Until that clarification occurs, those

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aiming to prove obviousness-type double patenting will have difficulty getting past the Federal Circuit, either through a newly narrowed standard, or through teaching away of the change in the patent.