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IS BEST MODE THE WORST? DUELING ARGUMENTS, EMPIRICAL ANALYSIS, AND RECOMMENDATIONS FOR REFORM

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ABSTRACT

The "best mode" requirement, which mandates that an inventor disclose in her patent application the best way to practice her invention, has become a polarizing force as Congress endeavors to comprehensively revamp U.S. patent law. This article examines the best mode requirement through a variety of lenses. In doing so, the article's ultimate goal is to recommend the ideal course of action for best mode reform-to fix best mode, if it is indeed broken, or to scuttle it if it is beyond repair. To begin, this article sets forth and evaluates the arguments advanced by both proponents and opponents of the best mode requirement, paying particular attention to the viewpoints of neutral parties such as academics, governmental actors, and quasi-governmental actors. I find that a significant majority of both interested and neutral parties favor eliminating or substantially modifying the best mode requirement. The article then shifts from the realm of the qualitative to that of the quantitative, analyzing recent decisions in patent cases from U.S. federal district courts, the Court of Appeals for the Federal Circuit, and the Board of Patent Appeals and Interferences. Unfortunately for best mode supporters, my analysis shows that, in practice, best mode only plays an important role in a small percentage of patent lawsuits and has de *minimis* impact on the patent procurement process. This article concludes by recommending a radical change to the best mode requirement: simultaneously strengthening best mode and eliminating it as a defense in patent lawsuits. This

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solution provides the optimal incentives to minimize strategic behavior by both patentees and accused infringers, reduce litigation costs, and improve meaning-ful disclosure in patent applications, thereby promoting innovation.

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INTRODUCTION

The Constitution of the United States empowers Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries."¹ In pursuit of that goal, Congress is currently working to reform the patent system in the United States "both to correct flaws in the system that have become unbearable, and to accommodate changes in the economy and the litigation practices in the patent realm."² This reform is designed to help the United States "maintain its competitive edge in the global economy."³

As part of this comprehensive patent reform effort, Congress is reevaluating the best mode requirement,⁴ which mandates that patent specifications "set forth the best mode contemplated by the inventor of carrying out his invention."⁵ At this time, it remains unclear whether Congress will keep the best mode requirement intact, eliminate it entirely, or alter the requirement in some substantial way. The goal of this article is to evaluate the merits of the best mode requirement using a variety of methods, including empirical analysis, and to recommend to Congress an ideal course of action with respect to best mode.

The policy rationale underlying the best mode requirement is straightforward. It purportedly "creates a statutory bargained-for-exchange, by which a patentee obtains the right to exclude others from practicing the claimed invention for a certain time period, and the public receives knowledge of the preferred embodiments for practicing the claimed invention."⁶ By forbidding inventors from disclosing only their second-best embodiment and keeping the best for themselves,⁷ the best mode requirement realizes basic notions of fairness.

By way of example, suppose a chemist develops a new method of making a particular drug. Based on her research, she knows that adding water to the drug production process increases both the amount and quality of the resulting

¹ U.S. CONST. art. I, § 8, cl. 8.

² S. REP. No. 111-18, at 2 (2009); *see also* 2007–2009 Patent Law Reform Archive, FISH & RICHARDSON, http://www.fr.com/patentreformarchive (last visited Sept. 22, 2010) (chronicling patent reform efforts in Congress from 2007 onward).

³ *Id.* at 1-2 (2009).

⁴ See id. at 24–25.

⁵ 35 U.S.C. § 112 (2006).

⁶ Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 963 (Fed. Cir. 2001).

⁷ See U.S. PAT. & TRADEMARK OFFICE, DEP'T OF COM., MANUAL OF PATENT EXAMINING PROCEDURE § 2165 (8th ed., 6th rev. 2007) [hereinafter M.P.E.P.] (citing *In re* Nelson, 280 F.2d 172 (C.C.P.A. 1960)).

drug. In other words, the process works fine without water, but adding water yields the best results. If the chemist applies for a patent on her drug production process, best mode requires her to disclose the "adding water" step in her patent application. The chemist has a strong incentive to keep the "adding water" step secret, namely to gain a competitive advantage in the pharmaceutical manufacturing marketplace. The best mode requirement counteracts that incentive. Additionally, disclosure of the best mode benefits the public because it provides a strong platform for future innovation. By reading the inventor's patent, other chemists will learn that adding water might boost drug production and will focus their future research accordingly. Without the best mode requirement, the original chemist might deprive these second generation inventors of valuable knowledge, thus inducing the second generation inventors to waste time and money to learn what the first chemist already knows.

With the ultimate fate of best mode hanging in the balance, industry leaders,⁸ interest groups,⁹ and academics¹⁰ have hotly debated the merits of the best mode requirement. Two diametrically opposed camps have emerged from this debate. On the one hand, a group I shall call "pro-big business" advocates eliminating the best mode requirement altogether. On the other hand, a group spearheaded by generic pharmaceutical manufacturers strongly supports retain-

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⁸ Compare Perspectives on Patents: Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary, 109th Cong. 63 (2005) [hereinafter Perspectives Hearing] (statement of Robert A. Armitage, Senior Vice President and General Patent Counsel, Eli Lilly & Co.) (arguing that best mode should be eliminated), with Perspective on Patents, Harmonization and Other Matters: Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary, 109th Cong. 9 (2005) [hereinafter Harmonization Hearing] (statement of Christine J. Siwik, Outside Counsel, Barr Laboratories, Inc.) (recommending keeping the best mode requirement).

⁹ Compare Patent Reform (111th Congress): A Comparison of H.R. 1260 (As Introduced in the House) and S. 515 (As Reported Out by the Senate Judiciary Committee) Highlighting Primary Differences 3 (2009), IPO, http://www.ipo.org/AM/Template.cfm?Section= Home&CONTENTID=22215&TEMPLATE=/CM/ContentDisplay.cfm (recommending elimination of the best mode requirement) (last visited Sept. 22, 2010), with Patent Reform: GPhA Position, GPHA, http://www.gphaonline.org/issues/patent-reform (last visited Sept. 22, 2010) (recommending keeping the best mode requirement).

¹⁰ Compare Donald S. Chisum, Best Mode Concealment and Inequitable Conduct in Patent Procurement: A Nutshell, A Review of Recent Federal Circuit Cases and a Plea for Modest Reform, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 277, 278–80 (1997) (suggesting modest modification to the best mode requirement as part of comprehensive patent reform), with Patent Reform—Injunctions and Damages: Hearing Before the Subcomm. on Intellectual Prop. Of the S. Comm. on the Judiciary, 109th Cong. 11 (2005) [hereinafter Injunctions Hearing] (statement of Prof. Mark A. Lemley, Stanford Law School) (advocating eliminating the best mode requirement).

ing best mode in its current form. I shall call this group of best mode supporters "generic- plus-others."

Led by multinational behemoths including Eli Lilly,¹¹ General Electric,¹² and 3M,¹³ the pro-big business camp complains that litigation over best mode, especially pre-trial discovery, is too costly because it focuses on the inventor's state of mind.¹⁴

To be sure, patent litigation is expensive, and the cost keeps rising.¹⁵ The median litigation cost for a patent infringement suit in 2009 was \$2.5 million if \$1 to \$25 million was at risk, and \$5.5 million if more than \$25 million was at risk, up from \$2 million and \$4.5 million, respectively, in 2005.¹⁶ Additionally, there is some evidence that litigants may be using best mode as a procedural tactic to enlarge the scope of discovery in patent lawsuits.¹⁷ In *Phillip M. Adams & Associates, L.L.C. v. Dell, Inc.*, Dell used a best mode defense to force Adams to turn over its trade secret source code.¹⁸ The court denied Adams' request for a protective order, ruling that "Adams' source code is also relevant to the issue of whether a best mode exists and was disclosed in Adams' patents."¹⁹ Similarly, in *Memry Corp. v. Kentucky Oil Technology*,²⁰ Memry claimed that KOT's trade secrets inherently overlapped with the best mode of practicing KOT's patented inventions, and therefore the trade secrets should be discoverable.²¹ The court credited this argument, granting Memry's motion to

¹¹ *Perspectives Hearing, supra* note 8, at 19 (statement of Robert A. Armitage) (arguing that best mode should be eliminated).

¹² Harmonization Hearing, supra note 8 (statement of Q. Todd Dickinson, Vice President and Chief Intellectual Property Counsel, General Electric Co.).

¹³ Patent Reform Act 2007: Hearing on H.R. 1908 Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary, 110th Cong. 121–22 (2007) [hereinafter H.R. 1908 Hearing] (statement of Gary Griswold, President and Chief IP Counsel, 3M Innovative Properties Co.).

¹⁴ See, e.g., Perspectives Hearing, supra note 8 (statement of Michael K. Kirk, Executive Director, AIPLA).

¹⁵ AIPLA, REPORT OF THE ECONOMIC SURVEY 29 (2009).

¹⁶ *Id*.

¹⁷ See Phillip M. Adams & Assocs., L.L.C. v. Dell, Inc., No. 1:05-cv-64, 2008 U.S. Dist. LEXIS 96897, at *17–26 (D. Utah Nov. 19, 2008); Memry Corp. v. Ky. Oil Tech., No. C04-03843, 2007 U.S. Dist. LEXIS 22488, at *6–7 (N.D. Cal. Mar. 19, 2007).

¹⁸ See id. at *22–26.

¹⁹ *Id.* at *23.

²⁰ No. C04-03843 RMW (HRL), 2007 U.S. Dist. LEXIS 22488 (N.D. Cal. Mar. 19, 2007).

²¹ See id. at *6-7.

compel and denying KOT's motion for a protective order.²² These recent cases lend credence to the proposition that some litigants use best mode as a tool to abuse discovery in patent lawsuits.

The pro-big business group also claims that the best mode provision is redundant because it provides minimal incentive for inventors to disclose more than is already required by the written description and enablement provisions of 35 U.S.C. § 112.²³ If patent applicants disclose the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use" it, as necessitated by the written description and enablement prongs of 35 U.S.C. § 112, should that not be a good enough starting point for the next generation of inventors?

Finally, the pro-big business camp hangs its hat on harmonization, noting that other countries do not have a best mode requirement in their patent laws.²⁴ If other countries do not require patent applicants to disclose the best way they know how to practice their inventions, why should the United States?

On the other side of the coin, the generic-plus-others group extols the virtues of best mode. Led by generic giants, such as Barr Laboratories²⁵ and the Generic Pharmaceutical Association,²⁶ this pro-best mode camp focuses on the value of best mode in promoting disclosure and innovation. According to this group, the public benefits from knowing the best mode because it does not have to "reinvent" a patented invention after the patent expires.²⁷

The generic-plus-others group also warns that eliminating best mode will lead to undesirable strategic behavior. In particular, the best mode requirement guards against any undeserved extension of the patentee's monopoly,²⁸ prevents companies from keeping the best mode a secret for commercial or strategic reasons,²⁹ and ensures that patent applicants act in good faith when filing an application.³⁰

²⁴ See, e.g., Harmonization Hearing, supra note 8, at 17 (statement of Q. Todd Dickinson).

²² See id. at *7.

²³ See, e.g., Perspectives Hearing, supra note 8, at 130–31 (statement of Michael K. Kirk).

²⁵ *Id.* at 9 (statement of Christine J. Siwik).

²⁶ *GPhA Position, supra* note 9.

²⁷ See id.

²⁸ See id.

²⁹ *Harmonization Hearing, supra* note 8, at 9 (statement of Christine J. Siwik).

³⁰ See H.R. 1908 Hearing, supra note 13, at 101 (statement of Anthony Peterman, Director, Dell, Inc.).

Finally, and not surprisingly, the generic-plus-others group candidly argues that eliminating best mode will have a detrimental effect on the generic drug industry. Specifically, generic drug companies rely on brand patent disclosures to develop generic drugs, and eliminating the best mode requirement could reduce disclosure and have a negative impact on generic drug development.³¹ Of course, it is quite possible that the motives of the generic drug industry are not so pure. For example, during a patent litigation dispute over a branded drug, generic drug companies may try to invalidate the branded drug patent by proving that the patent holder did not comply with the best mode requirement, thus clearing the way for early generic drug market entry.

So what should Congress do about the best mode requirement? Both the pro-big business and generic-plus-others camps seem to present persuasive arguments that cut in completely different directions, so how can Congress determine the optimal course of action?

This article relies on empirical analysis to help point Congress in the right direction. Recognizing that the best mode requirement has both costs and benefits, but that those costs and benefits are largely immeasurable, this article seeks to evaluate the practical significance of the best mode requirement in both patent prosecution and patent litigation.³² To that end, research shows a number of weaknesses with the best mode requirement: legitimate best mode disputes are relatively rare, best mode challenges typically fail at the district court level, the Federal Circuit is extremely unlikely to find a best mode violation, and enforcement of the best mode requirement by the USPTO during the patent examination process is essentially unheard of.³³ In other words, best mode has relatively little practical impact on the outcome of patent lawsuits and a *de minimis* impact on patent prosecution. These results strongly suggest that Congress should, at the very least, modify the best mode requirement in some fashion.

In examining various options for best mode reform, this article places particular emphasis on each option's potential to discourage strategic behavior by both a patentee and an accused infringer, minimize litigation costs, and promote meaningful disclosure by the patentee to the public, thereby spurring inno-

³¹ Harmonization Hearing, supra note 8, at 9 (statement of Christine J. Siwik).

³² See John R. Allison & Mark A. Lemley, Empirical Evidence on the Validity of Litigated Patents, 26 AIPLA Q.J. 185, 187 (1998).

³³ This research is based on a study by John Allison and Mark Lemley as well as the author's own independent research and analysis of recent U.S. district court decisions, Federal Circuit decisions, and United States Patent and Trademark Office ("USPTO") Board of Patent Appeals and Interferences ("BPAI") decisions. *Id.* at 208–210, 214.

vation. This article concludes that keeping the best mode requirement as presently formulated, i.e., the position taken by the generic-plus-others camp, is the worst course of action for a number of reasons. It encourages strategic behavior by both patentees and accused infringers, does nothing to curtail high litigation costs, and only marginally enhances effective disclosure. However, getting rid of best mode entirely, that is, the option supported by the pro-big business camp, is also undesirable because doing so would likely increase strategic behavior on the part of patentees and eliminate whatever minimal disclosure benefits best mode currently provides. If Congress' primary concern is maximizing disclosure to facilitate innovation, it should strengthen the best mode requirement in order to materially improve the quality of disclosure in patent applications. Alternatively, if Congress' primary concern is reducing litigation costs, it should keep the best mode requirement on the books to discourage strategic behavior and simultaneously remove best mode as a defense in patent litigation. Recognizing that these two admirable goals are not mutually exclusive, this article recommends simultaneously strengthening the best mode requirement and eliminating it as a defense in patent litigation.

The article proceeds as follows. Part I presents a brief overview of the best mode requirement as it currently stands in U.S. patent law. Part II elaborates on the major arguments made by proponents of best mode to keep the requirement and by opponents of best mode to eliminate it. While this article considers arguments by interested parties, that is, companies and individuals who actively participate in obtaining and/or litigating patents and the organizations and lawyers who represent them, this article pays particular attention to the views of neutral parties such as academics, governmental actors, and quasigovernmental actors.

Although the best mode requirement has a substantial number of supporters, the majority of both interested and neutral parties advocate either eliminating or significantly altering best mode.³⁴ In other words, pro-big business appears to be winning the best mode debate over generic-plus-others.³⁵ Part III posits additional arguments that might be made in favor of keeping the best mode requirement, focusing on the legitimate benefits of best mode in patent litigation. These benefits include: keeping the patentee honest, building a valid and understandable theme, and reminding the judge and the jury that the USPTO is not perfect. Part IV discusses the results of the author's empirical study on the practical effects of best mode, after which the author concludes that best mode plays only a small role in both patent prosecution and patent litiga-

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³⁴ See discussion *infra* Part II.

³⁵ See discussion *infra* Part II.

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tion. Part V includes an evaluation of potential avenues for best mode reform as well as the rationale behind my radical suggestion to simultaneously strengthen best mode and eliminate it as a defense in patent lawsuits. Part VI tracks the confused evolution of congressional views on best mode, beginning with the failed Patent Reform Act of 2005³⁶ and concluding with both the House version³⁷ and the Senate version³⁸ of the failed Patent Reform Act of 2009. As evidenced by Congress' ever-changing position on best mode, the ultimate fate of the requirement is anything but settled.

I. BEST MODE AS IT CURRENTLY STANDS

35 U.S.C. § 112, first paragraph, sets out the best mode requirement of U.S. patent law:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and *shall set forth the best mode contemplated by the inventor of carrying out his invention.*³⁹

Section 112 contains both an enablement requirement and a separate best mode requirement.⁴⁰ While the enablement requirement "ensures that a specification shall disclose an invention in such a manner as will enable one skilled in the art to make and utilize it," best mode requires an "inventor to disclose the best mode contemplated by him, as of the time he executes the application, of carrying out the invention."⁴¹

The Federal Circuit has articulated, and recently affirmed, a twopronged test to determine whether an inventor has complied with the best mode requirement.⁴² The first prong is subjective, inquiring whether the inventor in fact possessed a best mode of carrying out the invention at the time of filing the application.⁴³ The second prong is objective, asking whether "the written de-

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³⁶ Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

³⁷ Patent Reform Act of 2009, H.R. 1260, 111th Cong. (2009).

³⁸ Patent Reform Act of 2009, S. 515, 111th Cong. (2009).

³⁹ 35 U.S.C. § 112 (2006) (emphasis added).

⁴⁰ Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1314 (Fed. Cir. 2002).

⁴¹ *Id*.

⁴² TALtech Ltd. v. Esquel Apparel, Inc., 279 Fed. App'x 974, 977 (Fed. Cir. 2008).

⁴³ *Id.*

scription disclosed the best mode such that one reasonably skilled in the art could practice it."44

Unfortunately, some believe the Federal Circuit has not always been consistent when analyzing and resolving best mode disputes, leading commentators to complain that current best mode doctrine is muddy at best.⁴⁵ For example, Steven Walmsley suggests that as of 2002, the Federal Circuit had used *seven different standards* to assess what disclosure was required to comply with the best mode requirement. These include the "claims only" standard, the "essentiality" standard, the "essentiality and novelty" standard, the "necessity" standard, the "necessary and nonobvious" standard, the "material effect" standard, and the "relation" standard.⁴⁶

While neither the Supreme Court nor the Federal Circuit sitting en banc has specifically addressed the scope of disclosure necessary to comply with the best mode requirement,⁴⁷ a Federal Circuit three-judge panel attempted to clarify the doctrine in 2002.⁴⁸ In *Bayer AG v. Schein Pharmaceuticals*, the court noted that the "best mode disclosure requirement only refers to the invention defined by the claims,"⁴⁹ but a best mode violation may also be found in two limited circumstances when the inventor fails to disclose unclaimed subject matter: failure to disclose a preferred embodiment and failure to disclose a preference that materially affected making or using the invention.⁵⁰ Whether this clarification will lead to a more consistent best mode standard or, alternatively, create more confusion in the doctrine, remains to be seen.

It is important to note that under current best mode doctrine, an inventor has no obligation to identify which "mode" or embodiment he considers to be the best. He may describe in the patent specification a number of different "modes" for practicing the claimed invention without pointing out the "best" one.⁵¹ Therefore, an unscrupulous inventor may choose to bury his best mode among an avalanche of embodiments in the specification, in effect denying the public the enhanced disclosure that best mode is designed to generate. Addi-

⁴⁴ Id.

⁴⁵ See Steven B. Walmsley, Best Mode: A Plea to Repair or Sacrifice this Broken Requirement of United States Patent Law, 9 MICH. TELECOMM. TECH. L. REV. 125, 125–26 (2002).

⁴⁶ *Id.* at 153.

⁴⁷ *Id.* at 157.

⁴⁸ See generally Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306 (Fed. Cir. 2002).

⁴⁹ *Id.* at 1315.

⁵⁰ See id. at 1315–16.

⁵¹ See Randomex, Inc. v. Scopus Corp., 849 F.2d 585, 589 (Fed. Cir. 1988); Ernsthausen v. Nakayama, 1 U.S.P.Q.2d 1539, 1541 (B.P.A.I. 1985).

tionally, an inventor is not required to update his best mode either during the application process or after his patent issues.⁵²

In the litigation context, failure to comply with the best mode requirement is currently a defense in patent infringement actions, and the penalty is severe. A patentee who fails to disclose his or her best mode can have his or her patent invalidated.⁵³ Specifically, 35 U.S.C. § 282 states that invalidity of a patent or claim for lack of compliance with *any requirement of section 112* (including the best mode requirement) shall be a defense in any action involving the validity or infringement of a patent.⁵⁴ Much of the controversy surrounding the best mode requirement stems from a concern that litigants are using the best mode defense as a procedural tactic to open the door to wide-ranging discovery on an inventor's subjective beliefs, thereby increasing the cost of patent litigation.⁵⁵

II. DUELING BEST MODE ARGUMENTS: PRO-BIG BUSINESS VS. GENERIC-PLUS-OTHERS

The Senate Judiciary Committee has candidly admitted that it considered the concerns of both interested parties, for example, the Biotechnology Industry Organization, the American Intellectual Property Law Association ("AIPLA"), the Intellectual Property Owners Association ("IPO"), and the Pharmaceutical Research and Manufacturers of America, and neutral parties such as the National Academy of Sciences, when making a recommendation to Congress about how to deal with the best mode requirement.⁵⁶ Because these parties clearly influence policymaking decisions, evaluating their arguments may provide guidance on how Congress will, and perhaps should, resolve the best mode debate.

A. Pro-Big Business and Arguments Against Best Mode

As discussed in the Introduction, the pro-big business faction wants to eliminate the best mode requirement from U.S. patent law. Members of this

⁵² KIMBERLY A. MOORE ET AL., PATENT LITIGATION AND STRATEGY 570 (West 3d ed. 2008).

⁵³ 35 U.S.C. § 112 (2006).

⁵⁴ Id.

⁵⁵ See John R. Thomas & Wendy H. Schacht, Cong. Research Serv., RL33996, Patent Reform in the 110th Congress: Innovation Issues 35–36 (2007).

⁵⁶ See S. REP. No. 111-18, at 24–25 (2009).

group include: the IPO,⁵⁷ a trade association for owners of patents, trademarks, copyrights and trade secrets;⁵⁸ The Coalition for 21st Century Patent Reform, an organization comprising companies from eighteen different industry sectors;⁵⁹ AIPLA,⁶⁰ a national bar association consisting primarily of intellectual property lawyers;⁶¹ Eli Lilly;⁶² Wisconsin Alumni Research Foundation, the patent management organization for the University of Wisconsin-Madison;⁶³ General Electric Company;⁶⁴ InterDigital Communications Corporation;⁶⁵ the Biotechnology Industry Organization;⁶⁶ 3M Innovative Properties Company;⁶⁷ and the Intellectual Property Law Section of the American Bar Association.⁶⁸ Many prominent academics and patent scholars including Donald Chisum,⁶⁹ Richard Levin,⁷⁰

- ⁶² Perspectives Hearing, supra note 8, at 63 (statement of Robert A. Armitage).
- ⁶³ Injunctions Hearing, supra note 10, at 100 (statement of Carl E. Gulbrandsen, Managing Director, Wisconsin Alumni Research Foundation).
- ⁶⁴ *Harmonization Hearing, supra* note 8, at 6 (statement of Q. Todd Dickinson).

- ⁶⁷ *H.R. 1908 Hearing, supra* note 13, at 121–22 (statement of Gary Griswold).
- ⁶⁸ Patent Quality Improvement: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary, 109th Cong. 38 (2005) (statement of William L. LaFuze, Chair, Intellectual Property Law Section of the American Bar Association).
- ⁶⁹ See Chisum, *supra* note 10, at 317–19.
- ⁷⁰ A Patent System for the 21st Century: Hearing Before the S. Comm. on the Judiciary, 109th Cong. 144 (2005) [hereinafter 21st Century Hearing] (statement of Richard C. Levin, President, Yale University, & Mark B. Myers, Wharton School, University of Pennsylvania).

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⁵⁷ Patent Reform (111th Congress): A Comparison of H.R. 1260 (As Introduced in the House) and S. 515 (As Reported Out by the Senate Judiciary Committee) Highlighting Primary Differences, IPO, 3 (May 4, 2009), http://www.ipo.org/AM/Template.cfm²Section=Home&CONTENTID=22215&TEMPLATE

http://www.ipo.org/AM/Template.cfm?Section=Home&CONTENTID=22215&TEMPLATE =/CM/ContentDisplay.cfm.

⁵⁸ About IPO, IPO, http://www.ipo.org/AM/Template.cfm?Section=About_IPO (last visited Oct. 17, 2010).

⁵⁹ Coalition to Push for Patent Reform Measures, IPFRONTLINE.COM, http://www.ipfrontline.com/depts/article.asp?id=15099&deptid=8 (last visited Sept. 22, 2009).

⁶⁰ Perspectives Hearing, supra note 8, at 130–31 (statement of Michael K. Kirk).

⁶¹ The History of AIPLA, AIPLA, http://www.aipla.org/Content/NavigationMenu/About_AIPLA/History/History.htm (last visited Sept. 22, 2010).

⁶⁵ Patent Reform, The Future of American Innovation: Hearing Before the S. Comm. on the Judiciary, 110th Cong. 214–15 (2007) (statement of Bruce G. Bernstein, Chief Intellectual Property and Licensing Officer, InterDigital Communications Corp.).

⁶⁶ *Id.* at 222.

Mark Myers,⁷¹ Mark Lemley,⁷² and John R. Thomas⁷³ also support modifying or eliminating the best mode requirement.

To support their anti-best mode agenda, these parties essentially argue that best mode is expensive and useless, and eliminating it will help harmonize U.S. patent law with that of the rest of the world.

1. Cost: Litigating Best Mode is Expensive

In 1990, the Secretary of Commerce established the Advisory Commission on Patent Law Reform to advise him on "the need for any reform of the patent system of the United States."⁷⁴ In its 1992 report, the Commission recommended eliminating the best mode requirement to reduce the costs of patent litigation, asserting that the best mode requirement does not "provide a corresponding public benefit."⁷⁵ Not surprisingly, the Commission did not provide any evidence to support its contentions that best mode increases the cost of patent litigation and does not provide a corresponding benefit to the public.⁷⁶ This underscores a problem that continues to plague the best mode debate. The best mode requirement likely entails both costs (e.g., increased litigation costs) and benefits (e.g., improved disclosure to the public), but the costs and benefits are largely immeasurable. It is impossible to determine the incremental costs and benefits of the best mode requirement because it cannot be disentangled from all the other variables that also affect the very same costs and benefits. Regarding costs, innumerable factors contribute to litigation expenses, and best mode is just one of many affirmative defenses that a litigant might use as an excuse to expand the scope of discovery. Regarding benefits, the best mode requirement arguably incentivizes disclosure, but so do the written description and enablement requirements of 35 U.S.C. § 112. One cannot accurately calculate how much disclosure is attributable to best mode versus written description and enablement.

⁷¹ *Id.*

⁷² *Injunctions Hearing, supra* note 10, at 11 (statement of Prof. Mark A. Lemley).

⁷³ Amendment in the Nature of a Substitute to H.R. 2795, "The Patent Act of 2005": Hearing on H.R. 2795 Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary, 109th Cong. 40 (2005) (statement of John R. Thomas, Professor of Law, Georgetown University).

⁷⁴ ADVISORY COMM'N ON PATENT LAW REFORM, A REPORT TO THE SECRETARY OF COMMERCE ii (Aug. 1992), available at http://ipmall.info/hosted_resources/lipa/patents/patentact/ACPLR-1.pdf.

⁷⁵ *Id.* at 14.

⁷⁶ See id.

In 1997, well-known patent law scholar Donald Chisum succinctly laid out the "best mode is expensive" argument.⁷⁷ Chisum recognized that accused infringers with weak technical cases turned to best mode as a "last resort" defense.⁷⁸ He argued that best mode doctrine led to uncertainty and expense in patent procurement and litigation for several reasons. According to Chisum, the contours of best mode "(1) are not precise, (2) are subject to continuing judicial interpretation, and (3) depend on facts and states of mind at precise points of time, usually many years before the date of litigation."⁷⁹ In 2005, Levin and Myers echoed Chisum's concern and advocated significantly modifying or eliminating the best mode requirement to reduce subjective and expensive pre-trial discovery and increase the predictability of patent disputes.⁸⁰

Additionally, a 2004 report by the National Research Council ("NRC") provides a relatively thorough treatment of the "best mode is expensive" argument.⁸¹ In the report, the NRC, an organization created by the National Academy of Sciences in 1916 to "associate the broad community of science and technology with the Academy's purposes of furthering knowledge and advising the federal government," evaluated the best mode requirement in some detail and determined that it should be eliminated or significantly modified.⁸² The NRC report contended that the best mode defense depends on the inventor's state of mind, which usually can only be determined from circumstantial evidence.⁸³ Therefore, litigating best mode, especially during pre-trial discovery, can be expensive and time consuming.⁸⁴

However, there are several counterarguments to the "best mode is expensive" position taken by the NRC and many other opponents of best mode. First, neither the NRC, nor any other party, has provided evidence definitively linking a best mode defense to increased patent litigation costs. Some best mode proponents argue that routine discovery will likely encompass facts relevant to a best mode violation, so eliminating the best mode requirement will not

⁷⁷ See Chisum, *supra* note 10, at 278–80.

⁷⁸ *Id.* at 279.

⁷⁹ See id.

⁸⁰ 21st Century Hearing, supra note 70, at 144 (statement of Richard C. Levin & Mark B. Myers).

⁸¹ See generally Bd. on Science, Tech., and Econ. Policy et al., A PATENT SYSTEM FOR THE 21ST CENTURY (Stephen A. Merrill et al. eds., 2004), available at http://www.nap.edu/ catalog/10976.html.

⁸² Id.

⁸³ See id. at 121.

⁸⁴ Id.

reduce discovery costs.⁸⁵ In fact, the NRC's own study suggests that patent practitioners see willful infringement and inequitable conduct as the main litigation cost drivers, with best mode falling far behind.⁸⁶ Finally, if best mode is truly valuable to U.S. patent law, there are many options to reduce litigation costs short of eliminating best mode.⁸⁷

2. Redundancy: Adequate Disclosure Does Not Require Best Mode

Lemley states the simple proposition that the enablement and written description requirements facilitate sufficient disclosure to benefit the public.⁸⁸ The 2004 NRC report elaborated slightly, contending that best mode provides only limited motivation for inventors to disclose more than what is required by the enablement provisions of 35 U.S.C. § 112 because there is no obligation to update the best mode, and the best mode of a company cannot be imputed to the inventor.⁸⁹

This "best mode is useless" argument suffers from several flaws. First, there is no empirical evidence suggesting that best mode does, or does not, lead to disclosure above and beyond the enablement requirement. However, no one argues that eliminating best mode from U.S. patent law will actually *enhance* disclosure. Such a step will either have no effect on disclosure or will eliminate whatever disclosure benefits best mode currently provides. Second, if maximum disclosure is the chief concern, and best mode is not doing the job, a better solution may be to strengthen the best mode requirement so that it materially improves the quality of disclosure by patent applicants.

3. Harmonization: Other Patent Systems Do Not Have Best Mode

According to Chisum, best mode has no counterpart in other major patent systems and therefore poses a special hardship on foreign inventors and companies seeking U.S. patent protection.⁹⁰ Similarly, the 2004 NRC report

⁸⁵ Jerry R. Selinger, *In Defense of "Best Mode": Preserving the Benefit of the Bargain for the Public*, 43 CATH. U. L. REV. 1071, 1101 (1994).

⁸⁶ See Bd. on Science, Tech., & Econ. Policy et al., *supra* note 81, at 123.

⁸⁷ See generally AM. COLL. OF TRIAL LAWYERS, FINAL REPORT (2009).

⁸⁸ Injunctions Hearing, supra note 10, at 160 (statement of Prof. Mark A. Lemley).

⁸⁹ See Bd. on Science, Tech., & Econ. Policy et al., supra note 81, at 121.

⁹⁰ See Chisum, supra note 10, at 279.

stated that the best mode requirement has "no analog in foreign patent law" and "imposes an additional burden and element of uncertainty on foreign patentees in the United States."⁹¹ Thus, harmonizing the U.S., European, and Japanese patent systems provides an additional justification for eliminating the best mode requirement from U.S. patent law.⁹²

There are strong counterarguments one can make to rebut the "harmonization" rationale. As a preliminary matter, it appears that the NRC was incorrect in stating that the best mode requirement is unique to U.S. patent law. As of 2005, at least twenty-four countries required disclosure of the best mode.⁹³ One commentator suggested that even Japan has a form of best mode built into its patent system.⁹⁴ Taking the desirability of patent law harmonization as a given, the U.S. may be better served trying to convince other countries to adopt a best mode provision as opposed to sacrificing its own. Of course, this is only true if best mode provides some benefits to the patent system as a whole.

To summarize, pro-big business opponents of best mode stress that the subjective nature of the best mode inquiry increases discovery and litigation costs, the enablement and written description requirements ensure adequate disclosure to the public, and the U.S. best mode requirement is an outlier that should be eliminated as part of global patent law harmonization efforts.

B. Generic-Plus-Others and Arguments in Favor of Best Mode

As noted in the Introduction, the generic-plus-others camp favors retaining the best mode requirement. This group includes entities such as the Generic Pharmaceutical Organization;⁹⁵ Barr Laboratories;⁹⁶ University of California;⁹⁷ Dell;⁹⁸ and the Professional Inventors Alliance, a group of independent inventors

⁹¹ Bd. on Science, Tech., & Econ. Policy et al., *supra* note 81, at 127.

⁹² See id. at 123, 127.

⁹³ See Dale L. Carlson et al., Patent Linchpin for the 21st Century? Best Mode Revisited, 45 IDEA 267, 284–86 (2005) (finding that the U.S., Australia, Bahamas, Canada, India, Malawi, Mexico, New Zealand, Zambia, Egypt, Jordan, Madagascar, Sri Lanka, Malaysia, Argentina, Bolivia, Brazil, Guatemala, Honduras, Barbados, Costa Rica, Ghana, Pakistan, and Thailand have a best mode requirement).

⁹⁴ See id. at 284–85.

⁹⁵ *GPhA Position, supra* note 9.

⁹⁶ *Harmonization Hearing, supra* note 8, at 95 (statement of Christine J. Siwik).

⁹⁷ H.R. 1908 Hearing, supra note 13, at 9–10 (2007) (statement of William T. Tucker, Executive Director, Research Administration and Technology Transfer, University of California Office of the President).

⁹⁸ *Id.* at 12 (statement of Anthony Peterman).

that supports strong patent protection.⁹⁹ Notably, this pro-best mode faction cannot claim significant backing from neutral parties such as academics, governmental agencies, and quasi-governmental agencies.

In broad strokes, best mode proponents claim that the best mode requirement leads to enhanced disclosure and innovation, minimizes strategic behavior by patentees, and benefits the generic pharmaceutical industry.

1. Disclosure / Innovation

The Generic Pharmaceutical Organization takes the position that the public benefits from knowing the best mode because inventors do not have to "reinvent" a patented invention after the patent expires.¹⁰⁰ Similarly, The Patent Office Professional Association (POPA), an organization that represents USPTO employees, strongly defended the best mode requirement, arguing that best mode drives innovation and facilitates disclosure to the public.¹⁰¹ Mirroring POPA's concern about adequate disclosure in our patent system, Jon Dudas, then Director of the USPTO, testified in 2007 that U.S. patent law contains a best mode requirement because an "emphasis on full disclosure . . . will ensure a vibrant, modern patent system."¹⁰²

The relationship between best mode, disclosure, and innovation was discussed earlier in the Introduction and Part II.A.2. Here, it is enough to say that best mode may enhance disclosure in patent applications and it may not.

2. Preventing Strategic Behavior

According to the Generic Pharmaceutical Organization, the best mode requirement guards against any undeserved extension of the patentee's monopoly.¹⁰³ Christine Siwik, outside counsel for Barr Labs, elaborated on this theory by proposing that the best mode requirement prevents companies from keeping

⁹⁹ Patent Harmonization: Hearing Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary, 109th Cong. 12 (2006) (statement of Pat Choate, Advisor Board Member, Professional Inventors Alliance).

¹⁰⁰ See, e.g., GPhA Position, supra note 99.

¹⁰¹ PATENT OFFICE PROF'L ASS'N, THE PATENT REFORM ACT WILL HURT, NOT HELP, THE U.S. PATENT SYSTEM 2 (Sept. 2007), http://www.popa.org/pdf/misc/reform-popa-04sep2007.pdf.

¹⁰² Patent Reform, The Future of American Innovation: Hearing Before the S. Comm. on the Judiciary, 110th Cong. 265 (2007) (statement of Jon W. Dudas, Director, U.S. Patent & Trademark Office).

¹⁰³ GPhA Position, supra note 9.

the best mode a secret for commercial or strategic reasons.¹⁰⁴ In a similar vein, Anthony Peterman, a Dell Director, indicated support for the best mode requirement because it ensures that patent applicants act in good faith when filing an application.¹⁰⁵

Of course, an inventor who withholds her best mode from the public only acts "strategically" or in "bad faith" if there is, in fact, a requirement to disclose the best mode. If Congress were to eliminate the best mode requirement as urged by the pro-big business faction, the strategic behavior argument would disappear. Thus, this argument is somewhat circular.

3. Best Mode Benefits the Generic Pharmaceutical Industry

The basis for the argument that the best mode requirement helps generic drug companies is relatively straightforward. Generic drug companies rely on brand patent disclosures to develop generic drugs, and eliminating the best mode requirement could reduce disclosure and have a negative impact on generic drug development.¹⁰⁶

This argument contains one glaring flaw. Namely, it would be unwise for Congress to base a patent policy decision, which affects all industries, on whether or not the proposal benefits a particular industry, in this case the generic pharmaceutical industry. As evidenced by the wide variety of economic actors that oppose the best mode requirement, such as General Electric, 3M, and Eli Lilly, eliminating best mode might help certain industries just as much as, or more than, it would hurt the generic pharmaceutical industry. Congress must strike the appropriate balance.

In summary, best mode supporters insist that the requirement does, in fact, incentivize disclosure above and beyond the written description and enablement requirements; best mode is necessary to prevent strategic behavior by patent applicants; and eliminating best mode would harm the generic pharmaceutical industry.

¹⁰⁴ Harmonization Hearing, supra note 8, at 95 (statement of Christine J. Siwik).

¹⁰⁵ *H.R. 1908 Hearing, supra* note 13, at 12 (statement of Anthony Peterman).

¹⁰⁶ *Harmonization Hearing, supra* note 8, at 95 (statement of Christine J. Siwik).

III. OTHER ARGUMENTS IN FAVOR OF BEST MODE: LEGITIMATE BENEFITS OF BEST MODE IN PATENT LITIGATION

Many best mode critics claim that the inherently subjective best mode defense increases litigation costs. Still, some might argue that best mode plays an important, legitimate role in patent litigation. Specifically, the availability of a best mode defense keeps the patentee honest, helps the accused infringer build a valid theme, and reminds the jury that the USPTO is not perfect.

A. Keeping the Patentee Honest

During the patent examination process, the USPTO has no effective way to monitor a patent applicant's compliance with the best mode requirement because the patent examiners who review the applications are not mind readers. Simply put, the examiners cannot know what the best mode is unless the inventors disclose it. The USPTO acknowledges this limitation with respect to best mode in the Manual of Patent Examining Procedure ("MPEP"):

The examiner should assume that the best mode is disclosed in the application, unless evidence is presented that is inconsistent with that assumption. It is extremely rare that a best mode rejection properly would be made in *ex parte* prosecution. The information that is necessary to form the basis for a rejection based on the failure to set forth the best mode is rarely accessible to the examiner, but is generally uncovered during discovery procedures in interference, litigation, or other *inter parties* proceedings.¹⁰⁷

Essentially, if a dishonest inventor decides to obtain a patent while keeping the best part of the claimed invention for himself, discovery during an adversarial proceeding such as litigation provides the only check on this underhanded behavior. This kind of strategic behavior is not just a hypothetical concern. For example, in *Glaxo, Inc. v. Novopharm, Ltd.*,¹⁰⁸ an assignee deliberately failed to disclose the preferred process for converting a compound into the claimed pharmaceutical composition based on advice of counsel that such disclosure was not necessary under the U.S. best mode requirement.¹⁰⁹ Without an effective mechanism (e.g., the best mode defense in patent litigation) to police strategic behavior, self-interested patent applicants may be tempted to hide important parts of the claimed invention from the public. This tactic potentially reduces disclosure and, correspondingly, innovation.

¹⁰⁷ M.P.E.P. § 2165.03 (8th ed., 6th rev. 2007).

¹⁰⁸ 52 F.3d 1043 (Fed. Cir. 2005).

¹⁰⁹ *Id.* at 1046; *see* Chisum, *supra* note 10, at 282–83.

This line of reasoning is similar to the "preventing strategic behavior" argument addressed earlier in Part III(B)(2). To counter the argument, a best mode critic would point out that the only reason failing to disclose best mode is dishonest is because of the best mode requirement. Eliminating the best mode requirement will eliminate the dishonesty.

B. Building a Valid Theme: The Patentee Cannot Be Trusted

Patent litigation is challenging because it involves highly technical subject matter and aspects of law that are unfamiliar to jurors and many judges.¹¹⁰ Therefore, developing a compelling theme is one of the keys to winning a patent lawsuit.¹¹¹ A theme "reduces the case or the issue to its essence," and brings complex cases back to earth.¹¹² A good theme simplifies issues, unifies case presentation, and persuades the judge or jury to rule in one's favor.¹¹³

One persuasive theme anyone can understand is "the patentee cannot be trusted." If a patentee intentionally failed to describe the best mode of the invention, an accused infringer can, and should, paint the patentee as dishonest and withholding. Judges and juries are unlikely to favor those who appear to have lied or concealed information, and for good reason.

The accused infringer should stress that the patentee failed to uphold his end of the bargain—full disclosure for a limited monopoly.¹¹⁴ By failing to disclose the best mode, this theme would claim that the patentee cheated the USPTO and the public, and the judge and jury should take that fact into account. Without the best mode defense, litigants would have a harder time constructing this completely legitimate theme.

By now, it should be obvious that this argument suffers from the same circularity problem that plagues the "preventing strategic behavior" and "keeping the patentee honest" arguments discussed earlier. A patentee does not cheat the USPTO and the public by keeping his or her best mode secret unless there is a requirement to disclose the best mode.

¹¹⁰ MORGAN CHU & JOSEPH M. LIPNER, PATENT LITIGATION STRATEGIES HANDBOOK 62–65 (Barry L. Grossman & Gary M. Hoffman eds., BNA Books 2d ed. 2005).

¹¹¹ *Id.* at 62.

¹¹² *Id.* at 65–66.

¹¹³ *Id.*

¹¹⁴ *Id.* at 80.

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Is Best Mode the Worst?

C. Reminding the Jury that the USPTO is Not Perfect

Juries tend to be "impressed with the fact that the United States government issued a patent to reward the inventor's hard work."¹¹⁵ This may be one reason that juries are so pro-patentee, as evidenced by a 69% patentee victory rate in infringement suits.¹¹⁶ An accused infringer faces an uphill battle to invalidate a patent issued by the USPTO, and using a best mode defense is one good way to remind the jury of the USPTO's limitations.

The USPTO officially recognizes that it cannot effectively monitor compliance with the best mode requirement during the patent examination process.¹¹⁷ If an accused infringer brings that fact to the jury's attention, the jury may weigh the issue more evenhandedly instead of being overly deferential to the USPTO's judgment of validity and patentability. Thus, the best mode defense might be a way to level the patent litigation playing field, which is currently tilted in favor of patentees.

Put another way, exposing the USPTO's weakness in one area—that is, its inability to enforce the best mode requirement—would permit a jury to infer that the USPTO has other limitations as well, which it certainly does.¹¹⁸

IV. ANALYSIS OF EMPIRICAL DATA ON BEST MODE

Opponents of best mode routinely condemn the best mode defense as too costly, but they rarely provide empirical data on the real-life impact of best mode on patent litigation. If best mode substantially affects the outcome of a large proportion of patent cases, one might infer that best mode plays an important role in enhancing disclosure in patent applications and preventing strategic behavior by patentees. If that is the case, perhaps the benefits of best mode outweigh its litigation costs.

Unfortunately for best mode supporters such as the generic-plus-others faction, the evidence suggests that best mode only plays a decisive role in a small percentage of patent lawsuits; best mode claims usually fail at the district

¹¹⁵ MOORE ET AL., *supra* note 52, at 132.

¹¹⁶ *Id.* at 134.

¹¹⁷ See M.P.E.P. § 2165.03 (8th ed., 6th rev. 2007).

¹¹⁸ See Solveig Singleton, Improving Patent Quality: Inside Out, Outside In, or Upside Down?, PROGRESS ON POINT, PERIODIC COMMENTARIES ON THE POLICY DEBATE, 2 (Oct. 2005), http://www.pff.org/issues-pubs/pops/pop12.20patentreform.pdf (noting that problems at the USPTO "include low morale, related problems of high turnover and low salaries, inadequate databases and other technology to aid in the search for prior art, and a meager budget").

court level; and the Federal Circuit is extremely wary of finding a patent invalid for a best mode violation.

In the author's study of reported U.S. district court patent cases from 2005 through 2009,¹¹⁹ the courts discussed a best mode challenge in only fifty out of 7891 cases, or 0.6% of the cases.¹²⁰ In other words, the outcome of a patent lawsuit only depends on best mode issues in a small fraction of cases. This suggests that accused infringers either do not often raise a best mode defense, or raise a best mode defense but do not press it very hard.

Even when litigants do press a best mode defense, it is usually unsuccessful. Of the fifty reported U.S. district court patent cases from 2005 through 2009 in which the court ruled on best mode, the best mode challenge failed thirty-seven times, or 74.0% of the time, and prevailed only nine times, for a success rate of 18.0%.¹²¹ According to a prior study of all written, final validity decisions by either district courts or the Federal Circuit reported in the *United States Patent Quarterly* from 1989 through 1996, the best mode defense succeeded in sixteen out of forty-five cases, or 35.6% of the time.¹²² Both studies show that best mode is not typically a winning defense, particularly when compared to the success rates of other common defenses in patent ligation. For example, the success rates for the invalidity defenses of double patenting, anticipation under 35 U.S.C. § 102, lack of enablement, and obviousness, have been measured at 71.4%, 49.4%, 36.1%, and 36.3%, respectively.¹²³

No common thread among the successful best mode challenges at the district court level is readily apparent. In some instances, courts stressed the patentees' bad faith when holding patents invalid for failing to comply with the

¹¹⁹ Research was conducted using the "US District Court Cases" files in the LEXIS database. Raw data is on file with the author.

¹²⁰ The total number of patent cases, 7891, was generated by searching the "US District Court Cases" files in the LEXIS database for the term "patent!" in the "CORE-TERMS" field. Of course, not all of these patent cases discuss validity issues.

¹²¹ In the other four cases (eight percent of the time), the best mode challenge survived a motion for summary judgment or a motion to dismiss.

¹²² Allison & Lemley, *supra* note 32, at 209.

¹²³ *Id.*

best mode requirement.¹²⁴ In another instance, the court found a best mode violation without any evidence of bad faith at all.¹²⁵

The Federal Circuit is even more hostile to best mode challenges than the district courts are. In 2002, the Federal Circuit noted, "[i]n the history of this court and our predecessor courts, we have held claims invalid for failure to satisfy the best mode requirement on *only seven occasions*."¹²⁶ According to this author's research on more recent reported decisions, the Federal Circuit has addressed the best mode requirement thirteen times from 2002 to 2009.¹²⁷ Of those thirteen cases, the court affirmed a district court's holding that there was a best mode violation *only once*.¹²⁸ Of the remaining twelve cases, the Federal Circuit affirmed a district court's finding that there was no best mode violation five times; reversed a district court's finding that there was a best mode violation five times; and *never* reversed a district court's holding that no best mode violation had occurred.¹²⁹

Based on these statistics, even if an accused infringer puts on a substantial best mode defense, which is rare, and wins on best mode at trial, which is unlikely, the probability that the Federal Circuit will affirm a finding of invalidity based on best mode is low. Therefore, the best mode requirement does not play a significant role in the outcome of patent cases as a whole.

See, e.g., Commissariat a L'Energie Atomique v. Samsung Elecs. Co., 524 F. Supp. 2d. 511, 520 (D. Del. 2007) (finding that the inventors "concealed their best mode"); Green Edge Enters. v. Rubber Mulch Etc., No. 4:02CV566TIA, 2008 U.S. Dist. LEXIS 23378, at *17 (E.D. Mo. Mar. 25, 2008) (providing an inaccurate and non-existent product name constitutes concealment and a best mode violation).

¹²⁵ See Field Hybrids v. Toyota Motor Corp., No. 03-4121 ADM/JSM, 2005 U.S. Dist. LEXIS 1159, at *36 (D. Minn. Jan. 27, 2005) (finding plaintiff's patents invalid for a best mode violation even though defendant offered no evidence of specific intent to deceive).

¹²⁶ Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1316. (Fed. Cir. 2002) (emphasis added). The author's research uncovered one additional pre-2002 case in which the Federal Circuit found a best mode violation. *See* Consol. Aluminum Corp. v. Foseco Int'l, Ltd., 910 F.2d 804, 811 (Fed. Cir. 1990).

¹²⁷ Research was conducted using the LEXIS database. Raw data is on file with the author.

¹²⁸ See TALtech Ltd. v. Esquel Apparel, Inc., 279 Fed. App'x 974, 977 (Fed. Cir. 2008).

¹²⁹ Of the two remaining Federal Circuit cases from 2002 through 2009 discussing best mode, one involved a Federal Circuit ruling that a patent was not entitled to filing date of a parent application because the parent did not disclose the patented invention in a manner that satisfied best mode. *See* Go Med. Indus. Pty., Ltd. v. Inmed Corp., 471 F.3d 1264, 1272 (Fed. Cir. 2006). The other involved a Federal Circuit decision to vacate a district court's judgment as a matter of law that there was no best mode violation, but the Federal Circuit did not affirmatively determine that a best mode violation occurred. *See* Old Town Canoe Co. v. Confluence Holdings Corp., 448 F.3d 1309, 1321 (Fed. Cir. 2006).

Turning to the patent procurement process, the best mode requirement has absolutely no effect on whether or not the USPTO grants a patent. As mentioned earlier in this paper, a patent examiner has no way to determine whether a patent applicant disclosed the best mode because the information needed to evaluate best mode (e.g., the inventor's state of mind at the time he filed the application) is not available to the examiner.¹³⁰ Although the USPTO does not track the number of best mode rejections examiners make, the author reviewed published decisions of the USPTO Board of Patent Appeals and Interferences ("BPAI") from 1981 through 2009.¹³¹ Only six BPAI decisions involved an examiner's attempt to reject claims because of an inventor's alleged failure to disclose the best mode. The BPAI reversed the examiner's best mode rejection in five of the cases and did not reach the issue in the sixth case. In other words, in nearly thirty years, the BPAI has *never* affirmed an examiner's best mode rejection in a "precedential" or "informative" decision. This confirms that best mode has no bite during patent examination.

Even though best mode arguments rarely win in court and the USPTO cannot prevent best mode violations during the patent examination process, best mode may still play a significant role in the U.S. patent system. Specifically, one would expect best mode litigation to be infrequent if inventors routinely comply with the best mode requirement. This hypothesis is consistent with a best mode requirement that both enhances public knowledge and rarely serves as a winning defense in patent lawsuits.

V. RECOMMENDATIONS FOR REFORM

Things look bleak for best mode supporters. Most interested parties, including big business, want Congress to eliminate best mode entirely. The vast majority of neutral parties, including government agencies, quasi-governmental actors such as the NRC, and academics, also favor eliminating or substantially reworking the best mode requirement so that it cannot be used as a defense in litigation. The empirical data suggests that best mode does not make much difference in most patent lawsuits, and the USPTO has no way to ensure compliance with best mode during the patent examination process.

Despite all this, no one knows whether eliminating the best mode requirement from U.S. patent law will do more harm than good. This ambiguity results from the inherent uncertainty about the costs and benefits of best mode.

¹³⁰ See M.P.E.P. § 2165.03 (8th ed., 6th rev. 2007).

¹³¹ Research was conducted using the "USPTO Board of Patent Appeals & Interferences Decisions" file in the LEXIS database. Raw data is on file with the author.

How much meaningful disclosure does best mode produce? How many dollars does best mode add to patent litigation costs? These questions cannot be answered with any confidence.

Therefore, in deciding how to proceed, Congress should focus on each option's *potential* to achieve desirable results, since the results themselves will always be inconclusive. In particular, Congress should focus on each option's potential to discourage strategic behavior by both a patentee and an accused infringer, minimize litigation costs, and enable meaningful disclosure by the patentee to third parties in order to promote innovation.

Four alternatives Congress may choose to pursue are retaining the best mode requirement as-is (the generic-plus-others position); eliminating the best mode requirement altogether (the pro-big business position); strengthening best mode by requiring inventors to update their best mode until a patent is granted and explicitly point out which mode described in the specification is the "best;" or retaining best mode as a statutory requirement for patentability but removing it as a defense in patent litigation and post-grant opposition proceedings.

Although both polar opposite positions (keeping best mode without change and entirely eliminating best mode) enjoy popular support, these two options have the least capacity to generate desirable results. As such, Congress should not adopt either one. If enhanced disclosure is more important than litigation costs, then Congress should strengthen the best mode requirement. On the other hand, if Congress prioritizes litigation costs over full disclosure, then it should remove best mode as a defense in patent litigation.

When deciding how to best reform the best mode requirement, *it is critical that Congress recognizes these admirable goals of maximum disclosure and cost reduction are not mutually exclusive*. In order to achieve the optimal balance of reducing litigation costs, maximizing disclosure and innovation, and discouraging strategic behavior, Congress should simultaneously strengthen best mode and eliminate it as a potential defense in patent lawsuits.

A. Keeping the Best Mode Requirement Without Change

In theory, the best mode requirement aims to discourage patent applicants from behaving strategically—for example, by obtaining a broad patent while keeping the best part of the invention for themselves.¹³² In practice, the currently formulated best mode requirement actually encourages strategic behavior by *both* patent applicants and accused infringers. Since a patent applicant

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¹³² See M.P.E.P. §§ 2100–213 (8th ed., 6th rev. 2007).

does not have to point out which "mode" he believes to be the best,¹³³ he may choose to bury the best mode in a specification filled with many inferior embodiments and let the public sort it out. Accused infringers might also abuse best mode—for example, by alleging a best mode violation with minimal supporting evidence as a tactical ploy to expand the scope of discovery in a patent lawsuit.

Because a patent applicant can obscure the best mode by essentially hiding it in plain sight, the best mode requirement has limited potential to incentivize real, meaningful disclosure that actually benefits the public and spurs innovation. For example, assume a patent application discloses several hundred similar chemical compounds, one of which is significantly more effective than the rest. The inventor knows this, but does not acknowledge which compound is superior. The inventor has fulfilled his duty to disclose the best mode, but it could take months, or years, for anyone to figure out which compound to use (if the patent has expired) or design around (if the patent is still in force). Thus, any possible disclosure benefits to the public are minimal.

Finally, maintaining the status quo does nothing to reduce the litigation costs that may be attributable to the use of the best mode defense in patent law-suits.

In summary, current best mode law gives the U.S. patent system the worst of both worlds: all of the potential costs, such as uncertainty and increased litigation expenses, with none of the potential benefits, like increased public disclosure.

B. Eliminating the Best Mode Requirement Entirely

By discarding the best mode requirement, Congress would conceivably solve two problems. First, it would deter litigants from abusing the best mode defense in patent litigation because the defense would not exist. In other words, this option has the capacity to reduce strategic behavior by the accused infringer. Second, getting rid of best mode would have the related benefit of eliminating any incremental litigation costs associated with the best mode defense.

However, eliminating best mode entirely comes at a high price. First, it would incentivize, and in fact authorize, strategic behavior by patent applicants. Inventors would have free reign to knowingly and willfully withhold the best way to practice their claimed inventions and still obtain a patent. The pressure to compete in the cutthroat business world may drive even honest patent applicants to decide against including their best mode when filing a patent applica-

¹³³ See Randomex, Inc. v. Scopus Corp., 849 F.2d 585, 589 (Fed. Cir. 1988); Ernsthausen v. Nakayama, 1 U.S.P.Q.2d 1539, 1549 (B.P.A.I. 1985).

tion. After all, why give the competition a leg up by disclosing information when disclosure is not legally required? Second, it follows that eliminating the best mode requirement would also eliminate any incremental, but unquantifiable, disclosure benefits that are tied to best mode.

С. Strengthening the Best Mode Requirement

Congress could bolster the best mode requirement by, for example, mandating that inventors update the best mode throughout the patent examination process and particularly point out which mode described in the specification is the "best." Although Congress has not yet considered this option, it does have some advantages over the status quo.

Strengthening the best mode requirement would limit the ability of patent applicants to act strategically because they could no longer conceal their best mode among various other lesser-disclosed embodiments. It would also encourage real, meaningful disclosure that may have tangible benefits to the public. If the public can easily see which mode the inventor deems to be the "best," no time or money is wasted sifting through the lesser modes. The public has a clear starting point from which to innovate.

Of course, extending the best mode requirement in this manner does nothing to prevent accused infringers from abusing the best mode defense in patent litigation or to reduce whatever litigation costs are associated with best mode. In fact, it may even encourage more strategic behavior by accused infringers, who would likely claim that the patentee incorrectly identified the best mode, or did not sufficiently update the best mode when new information came to light.

D. **Retaining Best Mode as a Patentability Requirement but** Eliminating It as a Litigation Defense

As discussed in Part V.B, eliminating best mode from the realm of patent litigation would discourage accused infringers from acting strategically and reduce any litigation costs attributable to best mode. At first glance, it appears that keeping best mode as an affirmative requirement for patentability would be a nullity if best mode cannot be a defense in patent lawsuits. As acknowledged by the USPTO and suggested by the author's empirical research, there is no way to enforce the best mode requirement during patent examination. Therefore, litigants face the burden of policing best mode violations. If litigants cannot assert a best mode defense, then no one can effectively monitor a patentee's compliance with the best mode requirement.

However, upon deeper consideration of the issue, it is apparent that the *best mode requirement may promote disclosure even if best mode itself is unen-forceable*. Consider two groups of inventors: those who are honest and those who are self-interested or dishonest. If the law requires best mode disclosure, the honest inventors will comply because they do not want to break the law, even if they will not get caught. Self-interested inventors will also comply, but for entirely different reasons. First, they will continue to disclose the best mode out of concern that, should they abuse the system by obtaining and enforcing patents while concealing the best mode, Congress may amend the law to once again permit best mode invalidity defenses in patent litigation. Stated another way, "self-interested" inventors will disclose the best mode because, even if the law is unenforceable today, it may be enforceable tomorrow.

Second, if a dishonest patent applicant decides not to include the best mode in her patent application, even though the law requires it, because she believes the law cannot be enforced, a court would likely find her patent unenforceable due to inequitable conduct. The inequitable conduct doctrine, originally called "fraud on the patent office," is a defense to a patent infringement charge.¹³⁴ If a defendant can prove that the patentee "withheld material information from the PTO during prosecution of the patent with an intent to deceive," the patent will be held unenforceable.¹³⁵ An inventor willfully withholding her best mode from the USPTO because she believes she will not be caught or punished for the violation seems to be a classic case of inequitable conduct. In effect, eliminating best mode as a defense in patent litigation would fold any best mode related issues that arise into a court's general inequitable conduct analysis.

E. The Best Option for Best Mode: Strengthening Best Mode While Removing It from Litigation

Congress would be wise to consider simultaneously strengthening the best mode requirement and preventing its use in litigation. This option has more upside than any alternative previously considered by either Congress or those who have commented on best mode. First, requiring inventors to both explicitly identify and update their best mode potentially enhances the quality of disclosure in patent applications, which promotes innovation. Second, keeping the best mode requirement for patentability may discourage strategic behavior by patent applicants, even if enforcing best mode as such is practically impossible.

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¹³⁴ MOORE ET AL., *supra* note 52, at 598.

¹³⁵ Id.

Honest inventors will disclose their best mode because the law requires it, and dishonest inventors will do the same because they fear both inequitable conduct charges and future best mode challenges to their patents should Congress change its mind and permit best mode as a litigation defense. Finally, removing best mode from the realm of litigation eliminates any possible best mode related litigation costs and prevents strategic behavior by accused infringers who would otherwise assert a spurious best mode defense to improperly broaden the scope of discovery.

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VI. WHAT WILL CONGRESS DO? THE CONFUSED HISTORY OF BEST MODE IN PATENT REFORM

An examination of Congress' patent reform proposals from 2005 through 2009 reveals wide ranging views on how to deal with the best mode requirement. Part V discussed what Congress *should* do about best mode, but what *will* it do? If the past is any indication, the ultimate fate of best mode is hazy at best.

In 2005, the House of Representatives proposed comprehensive patent reform legislation that would have, in part, completely eliminated the best mode requirement from U.S. patent law.¹³⁶ Not to be outdone, the Senate put forth its own Patent Reform Act in 2006.¹³⁷ However, the Senate bill did not mention the best mode requirement at all, in essence proposing to keep the best mode requirement without change.¹³⁸ Thus, the Senate bill staked out a polar opposite position from the House bill regarding best mode.

Efforts at patent reform continued in 2007, and the tide quickly turned in both the House and Senate. The House version of the Patent Reform Act of 2007 compromised by retaining the best mode requirement for patentability but removing best mode as a defense in patent litigation and as a basis for requesting post-grant review of a patent.¹³⁹

The Judiciary Committee Report accompanying the House bill provides insight into the reasoning behind this congressional proposal.¹⁴⁰ In particular, Congress recognized three areas of growing criticism of the best mode requirement in recent years. First, because of the subjective nature of the inquiry, a best mode defense significantly increases the cost and complexity of litigation.

¹³⁶ See Patent Reform Act of 2005, H.R. 2795, 109th Cong. § 118(d) (2005).

¹³⁷ See Patent Reform Act of 2006, S. 3818, 109th Cong. (2006).

¹³⁸ See id.

¹³⁹ See Patent Reform Act of 2007, H.R. 1908, 110th Cong. §§ 13, 324 (2007).

¹⁴⁰ See H.R. REP. No. 110-314, at 43–44 (2007).

Second, since the best mode requirement only applies to what the inventor knew at the time of filing, the best mode disclosed in a patent may be obsolete by the time litigation occurs. Finally, the best mode requirement adds additional expense to international filings because foreign applicants seeking to protect their inventions in the U.S. must amend their applications to comply with a best mode requirement unnecessary anywhere else.¹⁴¹ These concerns mirror the "best mode is costly," "best mode is useless," and "harmonization" arguments espoused by the pro-big business group. In response to this criticism, the Committee recommended eliminating best mode as a defense to infringement in patent litigation in order to reduce litigation-related costs and minimize "the incentive to engage in speculative analysis."¹⁴² On the other hand, the Committee also advocated retaining the best mode requirement to promote "full disclosure of the invention, which can later be used by the public."¹⁴³ Therefore, it is clear that the House, in addressing the best mode problem, hoped to reduce litigation costs, discourage strategic behavior, and promote disclosure for the benefit of the public.

Like its 2006 predecessor, the Senate's Patent Reform Act of 2007 did not mention the best mode requirement.¹⁴⁴ However, the best mode issue sharply divided the Senate.¹⁴⁵ On July 19, 2007, Senator Specter offered an amendment that would have eliminated best mode as grounds for invalidating a patent, but the amendment was narrowly rejected, ten to nine, on a roll call vote in the Senate Judiciary Committee.¹⁴⁶ Early in 2008, several prominent Committee members suggested that the Senate would be amenable to significantly amending the best mode requirement.¹⁴⁷ Specifically, according to a March 12, 2008 press release, Senators Leahy, Specter, and Hatch outlined fifteen possible amendments to S. 1145 in an effort to "address the concerns of the wide cross-

¹⁴⁵ See S. REP. No. 110-259, at 40 (2007).

¹⁴¹ Id.

¹⁴² Id.

¹⁴³ Id

¹⁴⁴ See Patent Reform Act of 2007, S. 1145, 110th Cong. (2007).

¹⁴⁶ See id. Senators Brownback (Kan.), Feinstein (Calif.), Kyl (Ariz.), Coburn (Okla.), Graham (S.C.), Sessions, J. (Ala.), Cornyn (Texas), Hatch (Utah), and Specter (Pa.) supported the amendment. Senators Biden (Del.), Grassley (Iowa), Schumer (N.Y.), Cardin (Md.), Kennedy (Mass.), Whitehouse (R.I.), Durbin (Ill.), Kohl (Wis.), Feingold (Wis.), and Leahy (Vt.) opposed it.

¹⁴⁷ Press Release, Orrin Hatch, Senate Patent Reform Leaders Release Amendments: In Advance of Patent Reform Debate (Mar. 12, 2008), *available at* http://specter.senate.gov/public/index.cfm?FuseAction=NewsRoom.NewsReleases&ContentRecord_id=a52b16d5-feb8-3651-5ade-5c229efdcf69.

section of interested parties" with whom they have been meeting since the bill was reported out of the Senate Judiciary Committee last July.¹⁴⁸ One of the proposed amendments eliminated best mode as a defense in patent litigation, but maintained it as a requirement of patentability during the initial examination by the USPTO.¹⁴⁹ In other words, it appears that public pressure convinced at least some senators to press for best mode reform along the lines advocated by the House version of the Patent Reform Act of 2007.

By 2009, the Senate came full circle and endorsed the compromise position originally proposed by the House in 2007.¹⁵⁰ If enacted, the Senate version of the Patent Reform Act of 2009 would keep the best mode requirement for patentability but prohibit litigants from asserting best mode as a defense in patent litigation or using best mode as a basis to request post-grant review of a patent.¹⁵¹

According to the Judiciary Committee Report accompanying the bill, the Committee decided to eliminate best mode as a litigation defense "in response to [various] concerns." The Report specifically cited arguments by the National Academy of Sciences (NAS), the Biotechnology Industry Organization, the American Intellectual Property Law Association (AIPLA), the Intellectual Property Owners Association (IPO), and the Pharmaceutical Research and Manufacturers of America, that the "best mode requirement, which is unique to American patent law, is counterproductive."¹⁵² In particular, the Committee gave weight to the worry that "challenges to patents based on best mode are inherently subjective and not relevant by the time the patent is in litigation because the best mode contemplated at the time of the invention may not be the best mode for practicing the invention years later."¹⁵³ However, since the Committee "views public disclosure as an important part of the patent system," it kept best mode as a requirement for patentability and a basis for rejecting a claim during patent prosecution.¹⁵⁴ Thus, the Senate in 2009, like the House in 2007, sought to amend the best mode requirement to remove an inherently subjective inquiry from patent litigation while continuing to incentivize full disclosure by patent applicants.

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¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ See Patent Reform Act of 2009, S. 515, 111th Cong. §§ 14, 324 (2009).

¹⁵¹ See id.

¹⁵² See S. REP. No. 111-18, at 24–25 (2009).

¹⁵³ *Id.*

¹⁵⁴ *Id.*

With the Senate essentially adopting the House's 2007 compromise position on best mode, agreement appeared imminent, but it was not to be. The House version of the Patent Reform Act of 2009 would keep the best mode requirement for patentability and prohibit post-grant review based on best mode, but apparently would *not* eliminate best mode as a defense in patent lawsuits.¹⁵⁵ According to the author's research, the House has not yet officially explained its seemingly significant change in position.

All of this back-and-forth over the best mode requirement in Congress' prior patent reform efforts illuminates the future of best mode. Most importantly, both the House and Senate obviously want best mode reform that incentivizes disclosure and reduces litigation costs. This article's proposal to simultaneously strengthen best mode while removing it as a patent litigation defense would achieve these goals.

Secondarily, the pro-big business group seems to be getting the best of the generic-plus-others group in the best mode debate. A 2009 Senate Judiciary Committee Report cited concerns about best mode voiced by the Biotechnology Industry Organization, AIPLA, the IPO, and the Pharmaceutical Research and Manufacturers of America.¹⁵⁶ In contrast, the Report did not even mention any members of the generic-plus-others group that support a strong best mode requirement.

Recent actions and statements by the executive branch suggest that the Obama administration also backs pro-big business in the best mode debate. On June 18, 2009, President Obama nominated David Kappos as the Director of the USPTO.¹⁵⁷ Kappos represents the epitome of big business, having served as Assistant General Counsel at IBM and Vice President of IPO.¹⁵⁸ In an October 5, 2009 letter to the Senate Judiciary Committee, Secretary of Commerce Gary Locke stated that there should be no sanctions for failing to comply with the best mode requirement.¹⁵⁹ With both congressional and executive backing, the pro-big business camp wields significant influence and will probably play an important role in determining the fate of best mode. Since pro-big business is

¹⁵⁵ See Patent Reform Act of 2009, H.R. 1260, 111th Cong. § 324 (2009).

¹⁵⁶ See S. REP. NO. 111-18, at 24–25.

¹⁵⁷ Press Release, The White House: Office of the Press Sec'y, President Obama Announces More Key Admin. Posts, (June 18, 2009), http://www.whitehouse.gov/the_press_office/ president-obama-announces-more-key-administration-posts-6-18-09/.

¹⁵⁸ See id.

¹⁵⁹ See letter from Gary Locke, Sec'y of Commerce, to the Senate Judiciary Comm. (Oct. 5, 2009), available at http://judiciary.senate.gov/resources/documents/111thCongress/upload/ 100509LockeToLeahySessions.pdf.

anti-best mode, the odds that the best mode requirement will emerge unscathed after any significant patent reform legislation are slim.

Is Best Mode the Worst?

VII. CONCLUSION

Congress faces a daunting challenge when reforming the U.S. patent system, including the best mode requirement. Numerous interest groups push Congress in different directions, largely to advance their own personal agendas. When deciding which path to choose, Congress should give significant weight to the viewpoints expressed by neutral parties who do not have a personal interest in the outcome of patent reform, other than seeing the U.S. patent system flourish. The fact that the vast majority of neutral parties favor eliminating or amending the best mode requirement indicates that some kind of change in best mode law is objectively desirable.

The author's empirical research shows that best mode only affects the outcome in a small fraction of patent lawsuits. Substantial best mode challenges are rare and typically fail at both the district court level and the Federal Circuit. Additionally, the evidence supports what the USPTO freely admits—namely, that best mode cannot be enforced during the patent examination process. Since the practical effect of the best mode requirement on the outcome of both patent litigation and patent prosecution is small, changing the best mode requirement should not place a substantial burden on either patentees or accused infringers.

Despite all this, the consequences of changing or eliminating the best mode requirement remain unknown because the costs and benefits of best mode cannot be quantified. In light of this uncertainty, Congress should adopt a law that has the potential to do the most good. Specifically, Congress should (1) strengthen best mode by requiring inventors to specifically identify and update their best mode during the application process, and (2) eliminate best mode as a defense in litigation. This option will minimize best mode related litigation costs, maximize disclosure and innovation, and discourage strategic behavior by accused infringers and patentees alike.

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