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ABSTRACT

Patents are necessary to incentivize innovation because they grant owners the right to protect inventions. To be patentable, an invention must be useful, it must be novel, and it must not be obvious. But the judiciary has struggled to apply the latter requirement, non-obviousness, particularly for highly technical innovations subject to FDA regulations. For these innovations, the progression through the regulatory jungle can take ten to twenty years and millions of dollars (2.6 billion for a pharmaceutical drug). The complexities of the regulatory process can also render an innovation unprotected by patent rights because, by the end of the process, the patent office may determine that the invention is "obvious" as a direct consequence of the process itself. But rendering inventions unpatentable merely because they show a reasonable expectation for success goes against the public interest. Because of the changing landscape of the path to the public domain and significant disincentives in regulated technologies, incentivizing innovation requires a reinterpretation of the obviousness standard.

AUTHOR'S NOTE

Natalie M. Peters, received her B.S., from Southern Illinois University and expects to receive her J.D. from the University of Massachusetts School of Law in 2023. The author would like to give special thanks to Professor of Patent Law and experienced practitioner, Jerry Cohen, for whose course this Note was developed and for his expert feedback, edits, and perspective. Thanks to Professor Jeremiah Ho, for his inspiration and instruction during the writing of this Note, and to Professor Ralph Clifford for his advice, support, and guidance in its creation. The author would also like to express deep gratitude to the editors of the University of Massachusetts Law Review, especially Managing Editor Emily Dillan and Lead Editor Danielle Gilbert, to whom this Note owes its polish and clarity.

INTRODUCTION

Imagine you are a chemist who has discovered a potentially world-changing cure for cancer. You've applied for a patent to protect your invention and embarked on the ten-to-twenty years-long process of gaining approval from the Food and Drug Administration (FDA) to offer your world-changing cure to the public.[1] The protection offered by a patent will be important to you because, in addition to the time commitment involved, completing the clinical trials and compiling the volume of research required by the FDA could cost up to 2.6 billion dollars before you are allowed to market your cure to the public.[2] That's just over seven hundred thousand dollars per day, if it only takes you ten years (and you count weekends).[3] Nonetheless, your chances of surviving through the process with a marketable product could be as low as three percent.[4] Despite the astronomical costs of time and money, you face up to a ninety-seven percent chance of rejection by the FDA.[5] That

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1 *See* Richard C. Mohs & Nigel H. Greig, *Drug Discovery and Development: Role of Basic Biological Research*, 3 ALZHEIMER'S & DEMENTIA: TRANSLATIONAL RSCH. & CLINICAL INTERVENTIONS 651, 651–54 (2017) (discussing the process of discovery and development of completely new medicines, including the time involved, the cost, the risk of failure, and the uncertainty); Steven M. Paul, et al., *How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge*, 9 NATURE REV. DRUG DISCOVERY 203, 205, 211 (2010) (observing that the discovery and development of a new drug may take between 11.4 and 13.5 years, which doesn't factor in the additional time required to develop a drug target).

2 *See* Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 31 (2016) (research study estimating "total out-of-pocket and capitalized R&D cost per new drug to be $1395 million and $2558 million in 2013 dollars, respectively."). *But see* Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 163 n.45 (2016) (showing that cost estimates vary and can also be a source of controversy).

3 $2558 million divided by ten (for ten years), divided by 365 (for 365 days per year) equals $700,821.92 per day.

4 Chi Heem Wong, Kien Wei Siah & Andrew W. Lo, *Estimation of Clinical Trial Success Rates and Related Parameters*, 20 BIOSTATISTICS 273, 277, 279 (2019) (showing a 3.4% success rate for oncology).

5 *See id.*; *Unapproved Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs [https://perma.cc/4LVD-99A6] (last updated June 2, 2021) (explaining that FDA approval is required by law before a new drug product may be marketed to the public).

rejection would prevent you from marketing your invention to the public and from recovering your investment.[6]

In addition, to receive and maintain patent protection, you must defend each claim of the patent covering the invention as useful, new, and not obvious against attacks to the contrary.[7] Of the three requirements, the obviousness standard is the most difficult to define and apply, partially because most things appear obvious in hindsight.[8] Think of the last time you heard the answer to a riddle and, after hearing it, thought that the answer should have been obvious.[9] It is the same with inventions; because a problem solved often appears obvious in hindsight, hindsight bias is a constant, pernicious, and unavoidable issue with the obviousness standard.[10] Yet, this is just one of the difficulties associated with an obviousness analysis.

The obviousness standard is anything but obvious; both Congress and the courts have wrestled with the question of what should constitute a requisite level of invention since the United States' first Patent Act in 1790.[11] Judge Learned Hand called the inventive concept behind the

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6 *See Unapproved Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs [https://perma.cc/4LVD-99A6] (last updated June 2, 2021) (explaining that FDA approval is required by law before a new drug product may be marketed to the public).

7 *See* 35 U.S.C. §§ 101-103 (2011).

8 *See* Gregory N. Mandel, *Patently Non-Obvious: Empirical Demonstration that the Hindsight Bias Renders Patent Decisions Irrational*, 67 OHIO ST. L.J. 1391, 1393-94 (2006) ("Individuals are intellectually incapable of preventing hindsight information from impacting their judgments about the past."); Gregory Mandel, *Patently Non-Obvious II: Experimental Study on the Hindsight Issue Before the Supreme Court in* KSR v. Teleflex, 9 YALE J.L. & TECH. 1, 3 (2006) [hereinafter *Patently Non-Obvious II*] ("[O]nce outcome information is known, people are cognitively incapable of preventing that information from influencing their understanding of past events.").

9 *See* Mandel, *supra* note 8, at 1394 (explaining that "common wisdom" recognizes the pervasiveness of hindsight bias in phrases such as "hindsight is 20/20" and "Monday morning quarterback"). "These sayings are based on a now well-proven fact: once outcome information is known, people are cognitively incapable of preventing that information from influencing their understanding of past events." *Patently Non-Obvious II*, *supra* note 8, at 3.

10 In fact, inventions likely face even greater hindsight bias. *See* Mandel, *supra* note 8, at 1393-94 ("The results presented here indicate that there is a greater hindsight effect for non-obvious determinations than for other legal judgments."); *Patently Non-Obvious II*, *supra* note 8, at 3, 5, 7, 8.

11 *See* Fernando Fernández, *The Non-Obviousness Requirement in the Chilean Patent Law: A Critical Assessment*, 38 REVISTA CHILENA DE DERECHO 487, 493

nonobvious requirement the most "fugitive, impalpable, wayward, and vague a phantom as [exists] in the whole paraphernalia of legal concepts."[12] Justice Scalia more recently called the case law on the obviousness standard "irrational," "meaningless," "gobbledygook."[13] Judge Posner succinctly captured the problem of applying the obviousness standard to the shifting landscape of innovation when he said, "[l]aw lags science; it does not lead it."[14] The amorphous nature of the obviousness standard and how to apply it to innovations of increasing complexity has been a challenge for both the Federal Circuit and the Supreme Court.[15]

However, the variability associated with the application of the obviousness standard likely has little to do with an innovation's complexity.[16] The largest variable determining how the obviousness standard is applied most likely involves differing perspectives on the role that patents should play in encouraging innovation.[17] The question

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(2011) ("[T]here is a divergence of the criterion applied by patent offices and courts around the world in how to measure [obviousness]."). *See generally* Jessie Kratz, *Inventing in Congress: Patent Law Since 1790*, NAT'L ARCHIVE (Mar. 11, 2015), https://prologue.blogs.archives.gov/2015/03/11/inventing-in-congress-patent-law-since-1790/ [https://perma.cc/E6TZ-MTJH] (tracing the evolution of the Patent Act from 1790 through the present and the "inefficiency and inconsistency" that has motivated Congress to revisit the patent examination process in 1793, 1849, and 2014).

12 Harries v. Air King Prods. Co., 183 F.2d 158, 162 (2d Cir. 1950).

13 Transcript of Oral Argument at 36, 41, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2006) (No. 04-1350) (referring to the Federal Circuit's "teaching, suggestion, and motivation" test to determine obviousness).

14 Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996) (wherein the defendant was a manufacturer of the nicotine patch that was patented in 1989).

15 *See id.* (noting that "the courtroom is not the place for scientific guesswork"). "The Federal Circuit — and later, the Supreme Court in KSR — ambiguously implied either that the object of inquiry is only conception, or that it is some unexplained combination of conception and reduction to practice." Jeanne C. Fromer, *The Layers of Obviousness in Patent Law*, 22 HARVARD J. L. AND TECH. 75, 82.

16 Further, patentability is not to be "negated by the manner in which the invention was made." 35 U.S.C. § 103 (2011).

17 *See* Ryan T. Holte & Ted Sichelman, *Cycles of Obviousness*, 105 IOWA L. REV. 107, 115 (2019) (differences in applications of the nonobviousness standard are most likely the result of "different judicial attitudes regarding the precise role patents–and, hence, the nonobviousness bar–should play in spurring innovative activity."); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1578 (2003) (stating that differences in the "application of patent

is deceptively simple.[18] It is the issue at the core of the obviousness standard itself, and different perspectives on the answer appear to set courts and their decisions apart.[19] The answer is elusive because patent policy is caught in a tug-of-war tension between the public's competing desires for public domain access to innovations and for new innovation development.[20] These competing desires are sometimes called a paradox, which is "inherent in a system where *social* benefits via technological progress are achieved by means of *private* rewards."[21] Thus, although the public desires public domain access to affordable drugs, biotherapies, and complex medical devices, it is the protection of the patent system that creates the incentive for the development of these innovations.[22]

A patent grants monopolistic control over an invention for a limited amount of time in exchange for the intellectual knowledge behind that invention.[23] If an invention is already in the public domain, it cannot be

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standards to different industries correlates with . . . radically different ideas for interpreting patent law . . . .").

18 "[T]he apparent simplicity of the [nonobvious] requirement belies the complexities and difficulties that have historically bedeviled the doctrine." Michael Abramowicz & John F. Duffy, *The Inducement Standard of Patentability*, 120 YALE L.J., 1590, 1593-94, 1597 (2011).

19 *See* Holte & Sichelman, *supra* note 17; *see also* Burk & Lemley, *supra* note 17.

20 *See* Diane Christine Renbarger, *Putting the Brakes on Drugs: The Impact of* KSR v. Teleflex *on Pharmaceutical Patenting Strategies*, 42 GA. L. REV. 905, 906 (2008) (discussing how the debate surrounding the strength of patents "focuses on the best way to maximize public benefits" and "[w]hich will better aid society: more public access to existing innovations or greater private rewards to spur future innovations[.]"). Renbarger further notes that "[t]his conflict is particularly pronounced in the pharmaceutical industry, where the drug companies' use of monopoly profits from patents to fund research for future products clashes with the public's present need for affordable medications."). *Id.*

21 ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 2 (8th ed. 2021) (emphasis in original).

22 "[T]he case for the patent system is at its strongest in the pharmaceutical industry: innovation in the field is incredibly valuable to society and most of it would not occur without the patent system." Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 515 (2009) (citation omitted).

23 *Id.* at 507-08 (observing that "[t]he purpose of the patent system is to encourage socially valuable investments in R&D," and that "[w]ith strong patent protection . . . firms can expect to enjoy a lengthy monopoly over their drugs . . . .").

patented.[24] But if a granted patent is enforceable, the holder can exclude others from making, using, selling, and perhaps even importing, the invention.[25] The rights to the patented material may also be licensed or sold.[26] Consequently, a patent is more than a valuable property right,[27] it is a necessary tool to incentivize innovation because some inventions, such as pharmaceutical drugs, would not be produced without strong incentives.[28]

But not all inventions deserve patent protection.[29] For example, it would not make sense to grant a patent for the invention of a chickpea-butter and jelly sandwich because the invention is already constructively within the public domain.[30] Although it has utility and has not already been patented, the public has no interest in obtaining the intellectual

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[24] SRI Int'l, Inc. v. Internet Sec. Sys., 511 F.3d 1186, 1194 (Fed. Cir. 2008) ("[O]nce an invention is in the public domain, it is no longer patentable by anyone.") (quoting Application of Bayer, 568 F.2d 1357, 1361 (C.C.P.A 1978)); 35 U.S.C. § 102 (2011).

[25] Herman v. Youngstown Car Mfg. Co., 191 F. 579, 584–85 (6th Cir. 1911) ("A patent . . . grants only the right to exclude others . . . and cannot be practiced unless by license thereunder.").

[26] 35 U.S.C. § 261 (2012).

[27] "The constitution and law . . . give to the inventor . . . an inchoate property therein, which is completed by suing out a patent. This inchoate right is exclusive. It can be invaded or impaired by no person. No person can, without the consent of the inventor, acquire a property in the invention." Evans v Jordan, 8 F.Cas. 872, 873 (1813). *See also* 35 U.S.C. § 261 (2012) ("[P]atents . . . have the attributes of personal property.").

[28] *See, e.g.*, Roin, *supra* note 22, at 507-08 (noting that innovators refuse to sink enormous investments into clinical trials without patent protections because they would be unable to recover their losses); Burk & Lemley, *supra* note 17, at 1576-77 (discussing the application of the patent system to the biotechnology industry); Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIVITY 783, 793-97 (1987) (summarizing a study that analyzed survey responses from 650 R&D managers in 130 lines of business and whose responses illustrated that patents are particularly important for pharmaceutical drugs).

[29] A patent is not warranted when "the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains." 35 U.S.C. § 103 (2011). The statute also notes that "[p]atentability shall not be negated by the manner in which the invention was made." *Id*.

[30] The difference between a chickpea-butter-and-jelly sandwich and the prior art of a peanut butter-and-jelly sandwich would be obvious to a person having ordinary skill in the art of sandwich-making. *See id.*

knowledge and design materials behind the making of a chickpea-butter and jelly sandwich.[31] The "invention" does not pass the scrutiny of the obviousness standard because the knowledge gained in return for the granted patent would offer minimal value to the public.[32] Patentable material must be useful, new, and not obvious because these standards maintain a level of integrity in the patent system.[33] They also maintain a balance between the value the public gains in exchange for the monopoly rights granted.[34]

Limiting patentable inventions by excluding those that are "obvious" is generally beneficial to the public.[35] But attempting to uniformly apply the current obviousness standard to all industries is not in the public's interest because the processes of innovation across all industries are not uniform.[36] Not only do industries have vastly different

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31 Since there is very little difference between a chickpea-butter-and-jelly sandwich and the prior art of a peanut butter-and-jelly sandwich, the public gains little to no knowledge due to the obviousness of the invention; any member of the public with ordinary skill has the knowledge and resources to access it at any time. *See id*.

32 *See, e.g.*, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007) (citing U.S. CONST. art.1, § 8, cl. 8) (noting that achievements expected in the "normal course" of development are ordinary innovations and granting patents to those inventions that would have naturally arrived in the public domain could "stifle, rather than promote, the progress of useful arts.").

33 *See* Abramowicz & Duffy, supra note 18, at 1593-94, 1597. *See generally* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007); Graham v. John Deere Co., 383 U.S. 1 (1966).

34 *See* EDWARD C. WALTERSCHEID, THE NATURE OF THE INTELLECTUAL PROPERTY CLAUSE: A STUDY IN HISTORICAL PERSPECTIVE 143 (2002) (discussing how the quid pro quo rationale for patents incentivizes the disclosure of information that the public might not receive otherwise); Sean B. Seymore, *Symposium: The Disclosure Function of the Patent System*, 69 *VAND. L. REV.* 1455, 1456 (2016) (citation omitted) (noting that "[t]he law must also strike a delicate balance between the public's interest in disclosure and the inventor's incentive to disclose."); John H. Barton, *Non-Obviousness*, 43 IDEA 475, 491 (2003) (citing Rebecca S. Eisenberg, *Symposium, Taking Stock: The Law and Economics of Intellectual Property Rights: Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2092 (2000)) (remarking that "[o]nly research beyond that done as part of normal product design and development should be rewarded with a patent. Routine redesign should not be enough, for there is no need for monopolies as an incentive for such research.").

35 *See* Barton, *supra* note 34, at 494 (discussing the costs of unneeded patents).

36 Burk & Lemley, *supra* note 17, at 1577 (discussing the differences among technologies and the structural differences in their innovative processes, including

innovative processes, but obviousness should also be considered in the context of an invention's industry, because some industries have many other disincentivizing factors working against the incentives of a patent.[37]

Patent protections for heavily regulated industries with strong disincentivizing factors would benefit greatly from a different interpretation of the obviousness standard.[38] For example, promising pharmaceutical drugs, biologics, and therapeutics that are novel, beneficial, and show a reasonable expectation of inventive success should not be denied patent protections.[39] A reasonable expectation of success should not be considered in the obviousness calculus for these innovations because patent policy should encourage innovators to pursue promising innovations.[40] Moreover, allowing a reasonable

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the speed and cost of research, the cost of development, the factor of competing products, and the portion of innovation covered by patents).

37 FDA regulations and health insurer reimbursement decisions are two of the pharmaceutical industry's disincentivizing factors. W. Nicholson Price II, *The Cost of Novelty*, 120 COLUM. L. REV. 769, 812, 827 (2020) ("Patents act in context. Innovation incentives do not exist in a vacuum. For biomedical technologies, in particular, a wide set of additional incentive mechanisms shape the direction of innovation.").

38 "But even though the judiciary recognizes the unique challenges that inventions in the unpredictable arts bring to the patent system, it has struggled to adapt the old doctrinal framework of the patent laws to meet these challenges." Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 137-39 (2008).

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> The rationale to support a conclusion that the claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art.

U.S. PAT. AND TRADEMARK OFF., MANUAL OF PAT. EXAMINING PROC., *Reasonable Expectation of Success is Required*, ch. 2100, § 2143(I.A) (2020). *See also* Roin, *supra* note 22, at 531 (stating "[a] new drug with beneficial therapeutic properties is therefore considered obvious if those properties would have been reasonably expected at the time it was invented."). *See generally* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007).

40 "The problem of obvious–and thus patentable–drugs promises to grow worse over time because the nonobviousness requirement . . . turns progress in the pharmaceutical sciences against itself . . . it denies patent protection to new drugs based on the very advances in science that led to their discovery." *See* Roin, *supra* note 22, at 542; discussion *infra* Section IV.

expectation of success to be sufficient to show obviousness also results from a lack of understanding of how science and the useful arts progress.[41]

Part I of this Comment discusses the background of patent law, exploring the purpose of patents and the origins of the obviousness standard. Part II explores how the obviousness standard has developed through Congressional legislation and various Supreme Court decisions such as *KSR International Co. v. Teleflex*. Part III addresses critical errors resulting from the interpretation of the obviousness standard, and Part IV explores the impact of these errors on innovation and the scientific process. Part V then concludes by suggesting policy changes to the way the obviousness standard is applied that better recognize the realities of modern scientific progress.

I. PATENT LAW BACKGROUND

The United States Constitution gives Congress the ability to grant patents "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[42] Consequently, the power to grant patents is the Constitution's only enumerated power with a specific purpose.[43] The importance and necessity of a patent system

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41 "In an industry like pharmaceuticals . . . the nonobviousness requirement . . . denies patent protection to the drugs that appear most likely to succeed at the time they are invented and that have expected beneficial properties . . . ." *See* Roin, *supra* note 22, at 536. *See also* Jacob S. Sherkow, *Inventive Steps: The CRISPR Patent Dispute and Scientific Progress*, 18 EMBO REP. 1047, 1047-49 (2017) (discussing how the application of the obvious standard to biological research "highlights a long-standing division between science and patent law concerning how biological research is actually conducted–a division that is likely to widen as research in molecular biology advances.").

42 U.S. CONST. art.1, § 8, cl. 8.

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> The Copyright and Patent Clause . . . is unique among Congress' enumerated powers. While it shares with the Taxing Clause . . . the Bankruptcy Clause . . . and the Standing Army Clause . . . an express limitation on its reach, it is the only enumerated power that expressly states the purpose of its enumeration: to "promote the Progress of Science."

Opening Brief of Appellant at 8-9, Eldred v. Reno, 239 F.3d 372, No. 99-5430 (D.C. Cir. May 22, 2000) (citing E. C. Walterscheid, *Conforming the General Welfare Clause and the Intellectual Property Clause*, 13 HARV. J. L. & TECH. 87, 92 (1999)). *See generally* U.S. CONST. art.1, § 8.

featured so prominently for the Founding Fathers that the Patent Act of 1790 was one of the earliest Acts Congress passed following its establishment in 1789.[44]

A. The Purpose of Patents

Although the Constitutional purpose of patents might seem simple and straightforward, there are disagreements about what policies promote progress.[45] For example, one policy interpretation might focus on the value of an invention based on market forces involved, whereas another might focus on the quality of creation; supporters of each likely believe their interpretation best promotes progress.[46] Policymakers are not the only ones who disagree as this confusion can also be seen in the courts: when determining whether an invention is obvious, one court may depend on commercialization factors and another may focus on invention.[47] Thomas Jefferson, one of the nation's first patent agents, stated that he was well-acquainted with the difficulty of finding the line between patentable and unpatentable material.[48] This line-drawing difficulty still plagues the courts with uncertainty.[49] As referenced *supra*, it is also the question at the core of the obviousness standard dilemma and is likely the most significant variable in determining how the obviousness standard is applied.[50] However, before discussing how the obviousness standard is being applied, the requisite background to

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44 Patent Act of 1790, ch. 7, 1 Stat. 109-112 (1790).

45 *See* U.S. CONST. art.1, § 8, cl. 8.; Roin, *supra* note 22, at 504 (opining that encouraging investments in the research and development of socially valuable inventions promotes progress). *See generally* Price II, *supra* note 37 (opining that policy should focus on promoting innovations that are not already known to the public).

46 *See* Price II, *supra* note 37, at 779 (discussing the different theories that justify patent law).

47 *See id.* at 779-780 & n. 40, 786 n. 84 & n. 88.

48 In a letter to Isaac McPherson, Jefferson said that he knew how difficult it would be to make a distinction between patentable and unpatentable material because the exclusive rights that a patent grants are not based on natural rights, but are instead given for the benefit of society. INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE, VOL. 2: PATENTS AND TRADE SECRETS, 5-6 (Peter K. Yu ed., 6th ed. 2007).

49 "But even though the judiciary recognizes the unique challenges that inventions in the unpredictable arts bring to the patent system, it has struggled to adapt the old doctrinal framework of the patent laws to meet these challenges." Seymore, *supra* note 38, at 139.

50 *See generally* Holte & Sichelman, *supra* note 17.

its development, including the need for inventions to display an acceptable threshold of ingenuity or inventiveness, will be helpful.

B. Origins of Obviousness: Developments in the Law

After struggling with the difficulty of finding the line between patentable and unpatentable material since the enactment of the First Patent Act, the Supreme Court attempted to clarify the analysis in the 1851 case *Hotchkiss v. Greenwood*.[51] The Court determined that a doorknob made with porcelain was not a significant enough improvement.[52] Although the doorknob improvement was "the work of the skillful mechanic," it lacked a requisite level of ingenuity and skill because it was not the work "of the inventor."[53] Therefore, substituting porcelain as a doorknob material, as opposed to wood or metal, was insufficient to warrant a patent.[54] The *Hotchkiss* Court's new "skill and ingenuity" requirement attempted to articulate the line between patentable and unpatentable material by setting a new standard, which granted patents "only when there is significant ingenuity at the time of conception."[55] Nevertheless, subsequent courts had difficulty defining "significant ingenuity."[56]

Consequently, by 1948, requiring an inventor to prove that an invention possessed the kind of ingenuity that courts and the patent office were looking for had made it increasingly difficult for innovators to obtain patent protections for their inventions.[57] During hearings before the House of Representatives Subcommittee on Patents, Trademarks, and Copyrights, Giles Rich testified that "[t]he general feeling . . . is that . . . the standard of invention [is] so high that it is getting harder and harder for the people that would ordinarily be considered inventors to get over it."[58]

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51 *See generally* Hotchkiss v. Greenwood, 52 U.S. 248 (1851).

52 The improvement was to "the superiority of the material . . . which is not new." *Id.* at 266.

53 *Id.* at 267.

54 *Id.*

55 Holte & Sichelman, *supra* note 17, at 111 (internal citations omitted).

56 *Id.*

57 *Contributory Infringement in Patents, Definition of Invention: Hearings Before the Subcomm. on Pats., Trade-Marks, and Copyrights of the H. Comm. On the Judiciary*, 80th Cong. 40, 46-48, 94-95 (1948).

58 *Id.* at 46 (statement of Giles Rich, New York Patent Law Association). Giles Rich was then the head of the New York Patent Law Association. He and P.J. Federico were part of the two-person committee to re-write the patent statute in 1942, which

The "general feeling" was that the standard of invention was a disaster.[59] Congress responded to the mounting confusion by passing the Patent Act on July 19, 1952, thereby creating the obviousness standard.[60] In addition to imposing requirements of usefulness and novelty, the Patent Act stated that if the differences between the prior art and the invention would be obvious to a person having ordinary skill in the art (PHOSITA) at the time the invention was made, then the invention is unpatentable.[61] According to the Act's primary author, P. J. Federico,[62] the legislative intent behind both the requirement for non-

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President Truman signed into law in 1952. Rich sat on the committee while continuing to practice law full time. President Eisenhower nominated him to sit as a judge on the U.S. Court of Customs and Patent Appeals in 1956. He later sat on the U.S. Court of Appeals for the Federal Circuit. When he died at age ninety-five, he was still working full time and never took a reduced workload. His work and legacy are much honored, some of his writings considered to be classics. The Hon. Giles Rich was the expert and the man at the center of patent law as it developed at that time. *See generally* Philip C. Swain, *A Brief Biography of Giles Sutherland Rich*, 3 J. FED. CIR. HIST. SOC'Y 9 (2009).

59 Although there were many reasons for this sentiment, much of it can be traced to a case decided in1941, where the Court interpreted the inventiveness standard to require a "flash of creative genius." Cuno Engineering Corp. v. Automatic Devices Corp., 314 U.S. 84, 91 (1941). Following this decision, "policymakers and the patent bar [became] increasingly concerned with the Supreme Court's standard of invention." MERGES & DUFFY, *supra* note 21, at 344. In December of 1941, just one month after the *Cuno* decision, President Roosevelt issued an Executive Order establishing a commission to study the patent system. The result of this study was a criticism of the invention standard and a call for legislative action. NAT. PAT. PLAN. COMM'N, THE AMERICAN PATENT SYSTEM, REPORT OF THE NATIONAL PATENT PLANNING COMMISSION, *reprinted in* 25 J. PAT. OFF. SOC'Y 455, 456, 462-63 (1943). This sentiment reverberated throughout academia as well. *See, e.g.* Otto Raymond Barnett, *The "Flash of Genius" Fallacy*, 25 J. PAT. OFF. SOC'Y 785, 787, 789 (1943) (determining that legislation was required because the standard of invention had become increasingly difficult to evaluate); Anthony W. Deller, *The Problem of Invention in the Law of Patents*, 28 J. Pat. Off. Soc'y 797, 797, 804-06 (1951) (discussing the difficulty with the inventiveness standard, that "a great controversy raged" following the *Cuno decision*, and that Congress would need to pass legislation to help alleviate the difficulties).

60 Under 35 U.S.C. §§ 101-103, an invention must be useful, novel, and not obvious. 35 U.S.C. §§ 101-103 (2011). *See also* Holte & Sichelman, *supra* note 17, at 124-25; Fromer, *supra* note 15, at 79.

61 35 U.S.C. § 103 (2011).

62 The 1952 Patent Act was authored by a small "nucleus" of people including the original drafter, P.J. Federico. Giles S. Rich, *Congressional Intent – or, Who Wrote The Patent Act of 1952?*, *in* PATENT PROCUREMENT AND EXPLOITATION: PROTECTING INTELLECTUAL RIGHTS 68-69 (Southwest Legal Foundation

obviousness and the presumption of patent validity,[63] was to provide an "objective standard" that would stabilize the standard of invention.[64] The new non-obviousness requirement, which was meant to be merely a "limitation" on the section 102 requirement for novelty, should have been a subset of section 102 but was instead given its own section to prevent 102 from being too cumbersome.[65] But, as one reviewer presciently warned at the time, the non-obviousness standard would prove to be an ineffective method to measure inventiveness because it was "a broad, negative test," and the concept of inventiveness itself was too elusive for obviousness alone to provide an adequate "touchstone of invention."[66]

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ed.,1963). P.J. Federico was a U.S. Patent Office Examiner at the time. Hon. Giles S. Rich, *Why and How Section 103 Came to Be*, *in* NON OBVIOUSNESS–THE ULTIMATE CONDITION OF PATENTABILITY 1:201 (John F. Witherspoon ed., 1978).

63 "When . . . seeking to interpret the language of the Act . . . to ascertain the 'intent of Congress' . . . look to the writings of . . . Federico . . . [who], far more than any member of the House or Senate, knew and understood what was intended by the language used." Hon. S.J. Crumpacker, *The Patent Act of 1962–A Congressional Perspective*, *in* APPENDIX B: SYMPOSIA, 1962 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. PROC. 108, 143 (1962).

64 "That provision paraphrases language which has often been used in decisions of the courts, and the section is added to the statute for uniformity and definiteness. This section should have a stabilizing effect and minimize great departures which have appeared in some cases." H.R. REP. NO. 1923, at 7 (1952).

65 "In form . . . section [103] is a limitation on section 102 and it should more logically have been made part of section 102, but it was made a separate section to prevent 102 from becoming too long and involved and because of its importance." P.J. Federico, *Commentary on the New Patent Act*, 73 J. PAT. AND TRADEMARK OFF. SOC'Y 161, 180 (1954). *See also* P.J. Federico, *Furthering Comments and Observations on the Origin of Section 103*, *in* NON OBVIOUSNESS–THE ULTIMATE CONDITION OF PATENTABILITY 1:304 (John F. Witherspoon ed., 1978).

66 "Since in the words of Mr. Justice Jackson 'the concept of invention is inherently elusive' the broad negative test of 'non-obviousness' can do little to afford a touchstone of invention." Stefan A. Riesenfeld, *The New United States Patent Act in the Light of Comparative Law I*, 102 U. PA. L. REV. 291, 309 (1954) (quoting Great A. & P. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 154 (1950)). Predictability considerations are improved if made with careful attention to the statutory text. All too often, parts of the statutory text are overlooked. *See, e.g.*, Christopher A. Cotropia, *Predictability and Nonobviousness in Patent Law After* KSR, 20 MICH. TELECOMM. & TECH. L. REV 391, 394 (2014) (discussing the two types of predictability, their respective analyses promulgated by the USPTO and the courts, and citing cases illustrating the application of the analyses). Another relevant statute is 35 USC § 282, requiring that a defendant accused of

Following the 1952 Patent Act, courts developed different interpretations of what would be obvious to a person having ordinary skill in the art.[67] This seemingly objective standard proved challenging to apply, even to linear feats of engineering.[68] In 1966, the Supreme Court sought to resolve these different interpretations in *Graham v. John Deere*, an ostensibly straightforward case about shock absorbers attached to a plow.[69] Under the resulting *Graham* test, a court must determine the "scope and content of the prior art," the "differences between the prior art and the claims at issue," the "level of ordinary skill" in the field, and other objective considerations.[70] The *Graham* test is still the seminal case for the obviousness standard,[71] and "forms the basis of all nonobviousness doctrine today."[72] However, notwithstanding this attempt to clarify the law on the obviousness standard, inconsistencies in patent law remained.[73]

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infringement has the burden of showing unpredictability of a claim. *See* 35 U.S.C. § 282 (2011).

67 *See infra* note 70; *infra* note 83. However, recognize that a mixed procedural and substantive approach is applied. Courts and the United States Patent Office (now the USPTO) are instructed procedurally to evaluate claims one-by-one. *See* MERGES & DUFFY, *supra* note 21, at 49-55 (discussing the handling of patent prosecution and enforcement by the courts); U.S. PAT. AND TRADEMARK OFF., MANUAL OF PAT. EXAMINING PROC., EXAMINATION OF APPLICATIONS: ORDER OF EXAMINATION, ch. 0700, § 708 (2020) (emphasis in original) (enumerating the order of examination of patent applications by patent examiners, including that "[e]ach examiner will give priority to that application in his or her docket, whether amended or new, which has the *oldest effective U.S. filing date*.").

68 *See infra* note 70-73; *infra* note 82.

69 Graham v. John Deere Co., 383 U.S. 1, 4 (1966). *Graham* was a keystone case, heard and decided along with other cases involving two other patents. The other cases were Calmar, Inc. v. Cook Chem. Co. and Colgate-Palmolive Co. v. Cook Chem. Co. (reported together with *Graham*) and United States v. Adams. Together they are known as the "Graham Trilogy" and form the "foundation of the modern nonobviousness requirement." Dmitry Karshtedt, *Nonobviousness: Before and After*, 106 IOWA L. REV. 1609, 1623 n.96 (2021) (citing United States v. Adams, 383 U.S. 39 (1966).

70 *Graham*, 383 U.S. at 17.

71 Abramowicz & Duffy, *supra* note 18, at 1593.

72 Holte & Sichelman, *supra* note 17, at 125 (citation omitted). *See also* Karshtedt, *supra* note 69, at 1623 (citation omitted) (noting the *Graham* decision "constitute[s] the foundation of the modern nonobviousness requirement.").

73 Holte & Sichelman, *supra* note 17, at 125.

In yet another attempt to bring stability to patent doctrine following *Graham*, the Federal Circuit was created on October 1, 1982.[74] With exclusive appellate jurisdiction in cases involving patents, the Federal Circuit's Appellate Court has a high level of specialization compared to the average district court.[75] Realizing the difficulties in applying the obviousness standard, the Federal Circuit created the teaching, suggestion, or motivation ("TSM") test to prove obviousness, which required that "'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."[76]

TSM, however, was criticized by some in academia as setting the bar for obviousness too high.[77] For example, the members of academia who reported to the Federal Trade Commission ("FTC") Hearings on Competition and Intellectual Property took issue with the Federal

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74 *Id.* at 126. *See also* MERGES & DUFFY, *supra* note 21, at 13 ("[T]he Federal Circuit was ostensibly formed strictly to unify patent doctrine.").

75 *See* 28 U.S.C. § 1295(a) (2011). "At the appellate level, the U.S. Court of Appeals for the Federal Circuit is legally specialized, with patent cases accounting for sixty-three percent of its docket and roughly eighty percent of its time." Sapna Kumar, *Judging Patents*, 62 WM. & MARY L. REV. 871, 875 (2021) (citation omitted). *See also* Arti K. Rai, *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1097 (2003) (noting the "significant limitations" of generalist trial judges hearing patent law cases); Timothy B. Dyk, *Thoughts on the Relationship Between the Supreme Court and the Federal Circuit*, 16 CHICAGO-KENT J. INTELL. PROP., 67, 77 (2016) (citation omitted) (noting the thirty percent increase in patent cases on the Federal Circuit's docket in the span of sixteen years). However, there are some exceptions, largely due to a bad construction of venue in patent cases and forum shopping. The Eastern District of Texas recently had this problem until the venue issue was resolved. *See* Samantha Handler, *Patent Plaintiffs Scrambling After Texas Court Cools Hotspot*, BLOOMBERG L. (July 27, 2022, 5:05 AM), https://news.bloomberglaw.com/us-law-week/patent-plaintiffs-scrambling-after-texas-court-cools-hotspot [https://perma.cc/98EY-HLNV].

76 "[T]he reason, suggestion, or motivation could technically emanate from the 'nature of [the] problem to be solved' or the mere 'knowledge of one having ordinary skill in the art . . . .'" Holte & Sichelman, *supra* note 17, at 127 (citation omitted).

77 "In biotechnology cases, the Federal Circuit has gone to inordinate lengths to find biotechnological inventions nonobvious, even if the prior art demonstrates a clear plan for producing the invention." *See* Burk & Lemley, *supra* note 17, at 1593. *See also* Holte & Sichelman, *supra* note 17, at 127-28 (noting the "significant criticism" of the TSM test promoted by academics, large corporations, startups, and policymakers).

Circuit's case law on TSM.[78] They suggested that the non-obviousness standard needed reformation because the Federal Circuit's application of the TSM test had made it too difficult to show that an invention was obvious.[79] In general, the critics of the Federal Circuit's case law on the obviousness standard considered it a weakening of the nonobviousness standard that required attention and re-strengthening.[80]

Accordingly, the Supreme Court granted certiorari in *KSR International Co. v. Teleflex* to clarify the obviousness standard once again.[81] Like *Graham*, *KSR* addressed another innovation involving linear concepts and mechanical engineering, this time centered around a patent for a sensor attached to a car's gas pedal.[82] Rejecting what it referred to as a "rigid" application of the TSM test, the Court insisted on flexibility in findings of obviousness.[83]

In *KSR*, the Court was concerned with promoting legitimate innovation, not the "results of ordinary innovation."[84] However, it does not appear that innovations which must satisfy regulatory demands involve the "ordinary" innovation that the Court had in mind.[85] This is

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78 *See* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PAT. L. AND POL'Y, ch. 4 at 11 (2003) (alteration in original) (quoting Q. Todd Dickinson's Feb. 6, 2002 contribution to FTC/DOJ Hearing), www.ftc.gov/os/2003/10/innovationrpt.pdf [https://perma.cc/Q5R5-CAU7] (noting that participants "disagreed with the Federal Circuit's recent applications of the test, which seem to require 'specific and definitive [prior] art references with clear motivation of how to combine those references.'").

79 *Id.* at 11-12.

80 *See, e.g.*, *Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, FED. TRADE COMM'N 102-03 (Feb. 6, 2002) (statement of then-President of Yale University Richard C. Levin) (remarking on the nonobviousness standard's "diluted" nature and the risks associated with same); *Hearings on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy*, FED. TRADE COMM'N 67-68 (Feb. 20, 2002) (statement of Professor Edmund W. Kitch) (opining that the Federal Circuit has "seemed to soften the non-obviousness test . . . .").

81 KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 405-07 (2007); *see also* Holte & Sichelman, *supra* note 17, at 127-29.

82 *KSR*, 550 U.S. at 405-07.

83 *Id.* at 415. *See also* Holte & Sichelman, *supra* note 17, at 128-29.

84 *KSR*, 550 U.S. at 427.

85 *See KSR*, 550 U.S. at 416 (indicating that combination inventions are often referred to as ordinary inventions because they utilize older, or previously discovered elements, that are then combined and yield predictable results); Sachs, *supra* note 2, at 170. *See generally* Mohs & Greig, *supra* note 1; DiMasi, Grabowski & Hansen, *supra* note 2.

illustrated by the extreme costs of research and development, the highly unfavorable odds of surviving the FDA approval process, the time required to carry an invention all the way to the marketplace, and the difficulty of procuring insurance reimbursement payment procedures.[86]

Nonetheless, the Court did recognize that evaluating obviousness could still pose challenges when evaluating inventions because other technologies do not employ techniques as relatively straightforward as a sensor attached to a vehicle's gas pedal assembly.[87] This appears to be accurate, as there seem to be vastly different results in the application of the obviousness standard when it is applied to different technologies.[88]

However, the definition of "obvious" indicates that a court's determination of obviousness should be straightforward.[89] One potential reason for the increasingly difficult application of the obviousness standard to inventions in the unpredictable arts could be the changes in some industries' innovative landscape.[90] Nonetheless, an obviousness standard that has been adequately defined should at least be able to state the obvious.

II. THAT WHICH IS OBVIOUS SHOULD BE OBVIOUS

When the Court in *KSR* stated that "[w]e build and create by bringing to the tangible and palpable reality around us new works . . . " the process of invention that the Court had in mind was a direct path from concept to "tangible and palpable reality."[91] This is the innovative

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86 *See* Mohs & Greig, *supra* note 1; DiMasi, Grabowski & Hansen, *supra* note 2; Sachs, *supra* note 2, at 170.

87 "Following these principles may be more difficult" for other technologies. KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 417 (2007).

88 *See* Burk & Lemley, *supra* note 17, at 1577 ("The best examples of such divergence are found in biotechnology and computer software cases, where the courts have applied the common legal standards of obviousness, enablement, and written description to reach radically different results . . . although patent law is technology-neutral in theory, it is technology-specific in application.").

89 WEBSTER'S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE, UNABRIDGED, 1683 (William Neilson, Thomas A. Knott & Paul W. Carhart, eds., 2nd ed. 1950) ("Ob/vi*ous . . . 1. That is in the way or in front; opposite; fronting . . . . 2. Easily discovered, seen, or understood; plain; evident; as, an *obvious* meaning, remark, defect. 3 . . . . a. Presenting itself in the way; occurring often. b. Exposed; subject; open; liable."). *See* discussion *infra* Section II.B.

90 Seymore, *supra* note 38, at 137-39.

91 KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 427 (2007).

atmosphere in which the *Hotchkiss* doorknob was invented in 1851, and it was also the atmosphere in which a chemist would have advanced technologies before the first Food and Drug Act in 1906.[92] In mechanical industries with innovations such as door knobs and plow shocks, the atmosphere remains the same today. But for other industries, such as pharmacology, the path from concept to "tangible and palpable reality" has been dramatically altered by other mechanisms.[93]

To maintain the integrity of the patent system, it is essential for patent law not to lose track of the original purpose of the obviousness standard, especially in the midst of such tremendous alterations to some innovative landscapes. Remember that the original purpose under the Patent Act was to promote scientific progress while granting patents only to deserving innovations. This requires inventions to necessarily satisfy a threshold level of inventiveness. However, although the obviousness standard "has undergone wildly shifting, often cycling, meanings throughout the history of patent law[,]"[94] if that which is obvious is to remain obvious, it is important not to obscure the original purpose of the obviousness standard: to encourage further innovation.

A. Inventiveness Was (and Technically Still Is) The Goal

One difficulty with the *Hotchkiss* "significant ingenuity" requirement was defining what was significant; sometimes, the most significant discoveries happen on the most miniscule scale.[95] Consider

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92 *See* CLAYTON A. COPPIN & JACK HIGH, THE POLITICS OF PURITY: HARVEY WASHINGTON WILEY AND THE ORIGINS OF FEDERAL FOOD POLICY, 18-20 (1999) (discussing the evolution of the American food industry as contributing to the production of the Pure Food and Drugs Act of 1906 and further discussing the evolution of American life from "an agrarian to an industrial society"). This evolution would have great impact on society, including on the innovative landscape.

93 Price II, *supra* note 37, at 812 (stating that biomedical technologies experience many other disincentives, such as those resulting from the FDA and insurance payment reimbursement strategies, which "shape the direction of innovation.").

94 Holte & Sichelman, *supra* note 17, at 109 (citations omitted).

95 *See generally* Curt Suplee, *Studies of Matter at Smallest Scale Yield Biggest Prizes in Science*, WASH. POST (Oct. 14, 1998), https://www.washingtonpost.com/archive/politics/1998/10/14/studies-of-matter-at-smallest-scale-yield-biggest-prizes-in-science/b7b2adad-a6a9-416b-b2b4-513ac6d745b2/ [https://perma.cc/949T-P25Q**]** (describing how five universities won Nobel Prizes in Physics and Chemistry for "investigations of the behavior of matter at the smallest scale.").

too that progress in science and applied science is more often incremental, rather than breakthrough.[96]

Scientific innovations and discoveries don't just broaden our horizons, they change what we already know.[97] For example, although science has made tremendous advances in the realm of cosmology and astrophysics, "[m]ore is unknown than is known."[98] The Hubble Space Telescope has traveled farther and farther into outer space, teaching astrophysicists more and more about space's outer limits, while *changing* mankind's fundamental understanding of the universe.[99] Biophysics has done the same, but on an inverse scale.[100] Each human cell is a universe unto itself, and as science teaches us more and more about protein structures, protein intercalation behaviors,[101] molecular interactions, and countless other discoveries as plentiful as the starry

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96 Harvey Brooks, *The Relationship Between Science and Technology*, 23 RSCH. POL'Y 477, 477-78 (1994) (describing how the "pipeline model" of innovation conflates technological and scientific progress and places "excessive emphasis on originality in the sense of newness to the universe as opposed to newness in context.").

97 Of the many examples given, one notable, highlighted discovery is the way Einstein's theory of general relativity changed our perspective on gravity. *See generally* Martin Rees, *How Astronomers Revolutionized Our View of the Cosmos*, SCI. AM. (Sep. 1, 2020), https://www.scientificamerican.com/article/how-astronomers-revolutionized-our-view-of-the-cosmos/ [https://perma.cc/8L6Q-DNRV].

98 Dana Bolles, *Dark Energy, Dark Matter*, NASA, https://science.nasa.gov/astrophysics/focus-areas/what-is-dark-energy [https://perma.cc/U6GG-USRM] (last updated Oct. 13, 2022).

99 Brian Dunbar, *About the Hubble Space Telescope*, NASA, https://www.nasa.gov/mission_pages/hubble/about [https://perma.cc/79WF-V86A] (last updated May 26, 2022).

100 "[N]early *all* that *exists* in the macrouniverse is mirrored in a *biological* cell as a *microuniverse*. *Simply put, the universe can be pictured as a cell."* Seyed Hadi Anjamrooz, Douglas J. McConnell & Hassan Azari, *The Cellular Universe: A New Cosmological Model Based on the Holographic Principle*, 6 INT'L J. PHYSICAL SCI. 2175, 2175 (2011).

101 When proteins interact with DNA, they will sometimes intercalate the DNA, meaning the side chains will insert into the DNA between pairs and to various degrees. This mechanism has been successfully used to battle cancer. *See generally* William B. Peters, Stephen P. Edmondson & John W. Shriver, *Thermodynamics of DNA Binding and Distortion by the Hyperthermophile Chromatin Protein Sac7d*, 343 J. MOLECULAR BIOLOGY 339, 339-41 (2004). *See also* Cecilia Martini et al., *Intercalation of Bioactive Molecules into Nanosized ZnAl Hydrotalcites for Combined Chemo and Photo Cancer Treatment*, 1 ACS APPLIED NANO MATERIALS 6387, 6387-95 (2018).

hosts, discoveries become successively smaller,[102] leading to new tools for engineering improvements and other forms of applied science.[103]

In 1952, Congress took a dramatically different approach from *Hotchkiss* because "significant ingenuity" was becoming more and more difficult for innovators to defend against spirited attacks by defendants accused of infringement.[104] In taking this dramatically different approach, Congress transitioned from "significant ingenuity" to the non-obviousness standard, which spun the innovative focus in the opposite direction.[105] It is likely that Congress did not intend to make a significant change to the inventiveness standard itself given the language of the 1952 Patent Act and the tenor of the comments following it.[106] The understanding was that the non-obvious

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102 *See* Matt Clancy, *Science Is Getting Harder: Evidence That Discoveries Are Getting Smaller on Average*, NEW THINGS UNDER THE SUN (June 1, 2022) https://mattsclancy.substack.com/p/science-is-getting-harder?utm_source=profile&utm_medium=reader2 [https://perma.cc/Q649-X9CY] (discussing the declining "size" of discoveries); Nicholas Bloom et al., *Are Ideas Getting Harder to Find?*, 110 AM. ECON. REV. 1104, 1004-1138 (2020) (showing that more and more R&D effort is necessary to sustain the present rates of technological progress); Deller, *supra* note 59, at 797. "In the different arts, the increment [of knowledge] varies and as any particular art becomes more and more crowded, the increment changes and becomes progressively smaller." *Id.*

103 Suplee, *supra* note 95 **(**discussing how studies of matter at the smallest scales "open[] doors to faster discoveries of new medical treatments and high-tech materials . . . .").

104 Irving Kayton, *Nonobviousness of the Novel Invention –35 U.S.C. § 103*, *in* NON OBVIOUSNESS–THE ULTIMATE CONDITION OF PATENTABILITY 2:104 (John F. Witherspoon ed., 1978). *See also* P.J. Federico, *Furthering Comments and Observations on the Origin of Section 103*, *in* NON OBVIOUSNESS–THE ULTIMATE CONDITION OF PATENTABILITY 1:302 (John F. Witherspoon ed., 1978) (discussing "six or seven cases" where lower courts found that an innovation did not meet the "significant ingenuity" standard for patentability). *See supra* note 59 and accompanying text.

105 "[Nonobviousness] is not a ridiculously low standard of patentability; the standard still requires a fairly substantial contribution. But it was designed to end the Court's search for a distinction between ordinary and extraordinary ingenuity and to focus the inquiry solely on obviousness." John F. Duffy, *Inventing Invention: A Case Study of Legal Innovation*, 86 TEX. L. REV. 1, 43 (2007). *See also* 35 U.S.C. § 103 (2011); Fromer, *supra* note 15, at , 79 (discussing the Supreme Court's shift from the significant ingenuity standard to the obviousness standard).

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> While it is not believed that Congress intended any radical change in the level of invention or patentable novelty . . . it is believed that some modification was intended in the direction of moderating the extreme degrees of strictness exhibited by a number of judicial

requirement was intended to moderate the extreme positions taken by the courts and to achieve a more favorable attitude toward patents.[107] However, instead of looking forward at what constituted inventiveness, Congress turned around and started walking backwards by describing what didn't.[108]

B. Definition and Meaning Of "Obvious" As It Relates To "Inventiveness" Indicates That Obvious Inventions Already Exist In the Public Domain

As stated *supra*, the general requirement for non-obviousness is a "broad, negative test" that is inadequate to provide "a touchstone of invention";[109] accordingly, it is unsurprising that the courts have struggled to apply the obviousness standard.[110] Moreover, considering the fact that the non-obvious requirement was only intended to be a limitation placed on the requirement for novelty, it appears that Congress intended to widen the door for patentable material and broaden inventors' access to patents by shifting the focus from "significant ingenuity" to "not obvious."[111]

However, the obviousness standard itself has grown from a subsection of the section 102 novelty requirement to completely

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> opinions . . . some change of attitude more favorable to patents was hoped for.

P. J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 183 (1993).

107 *Id.*

108 Describing what constitutes a requisite level of inventiveness is like describing where you want to go as you move forward towards the goal. Requiring that something be nonobvious is like turning around and describing where you don't want to go; it describes the surroundings but not where you're headed. Inventiveness is saying what ought to be. Nonobviousness is describing what ought not to be. One could say it's very Shakespearean. "To be, or not to be- that is the question . . . ." WILLIAM SHAKESPEARE, HAMLET act 3, sc. 1, l. 1750 (OpenSource Shakespeare ed.2003), https://www.opensourceshakespeare.org/views/plays/play_view.php?WorkID=hamlet&Act=3&Scene=1&Scope=scene [https://perma.cc/72AC-CJED].

109 " [T]he broad negative test of 'non-obviousness' can do little to afford a touchstone of invention." Riesenfeld, *supra* note 66, at 309 (citation omitted).

110 *See generally* Fernández, *supra* note 11 (noting the difficulties faced by academics and judges in identifying a uniform application of the nonobviousness requirement).

111 P. J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 180 (1993).

dominating the patent scene.[112] Nonobviousness is currently presented as "the most important" patent requirement,[113] described as "central" to a determination of patentability,[114] and is suggested to be "the key to defining . . . patentable invention[s]."[115] Furthermore, nonobviousness is given the blanket description of "the ultimate condition of patentability."[116] Far from being merely a limitation on an invention's novelty, obviousness has become the line in the sand between patentable and unpatentable material.[117]

At the time the 1952 Patent Act was passed, "obvious" was defined as being "easily discovered, seen, or understood; plain; evident; as, an *obvious* meaning, remark, defect."[118] It was something "[p]resenting itself in the way; occurring often[,]" or "[e]xposed; subject; open; liable."[119] When considering this definition of "obvious" in light of the fact that it was to be a limitation on section 102's novelty requirement,

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112 "In form . . . section [103] is a limitation on section 102 and it should more logically have been made a part of section 102, but it was made a separate section to prevent 102 from becoming too long and involved . . . ." *Id. See* P.J. Federico, *Furthering Comments and Observations on the Origin of Section 103*, *in* NON OBVIOUSNESS–THE ULTIMATE CONDITION OF PATENTABILITY 1:301 (John F. Witherspoon ed., 1978) ("[Obviousness] represents the latest stage in the evolution of a basic principle in patent law: that something which is actually new in fact cannot be patented unless a certain degree . . . of novelty is present."). *See generally* Abramowicz & Duffy, *supra* note 18.

113 MERGES & DUFFY, *supra* note 21, at 327.

114 Michael J. Meurer & Katherine J. Strandburg, *Patent Carrots and Sticks: A Model of Nonobviousness*, 12 LEWIS & CLARK L. REV. 547, 548 (2008).

115 Alan L. Durham, *Patent Symmetry*, 87 B.U. L. REV. 969, 970 (2007).

116 *See generally* NONOBVIOUSNESS: THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1978).

117 *See* P.J. Federico, *Furthering Comments and Observations on the Origin of Section 103*, *in* NON OBVIOUSNESS -
THE ULTIMATE CONDITION OF PATENTABILITY 1:304 (John F. Witherspoon ed., 1978); Hon. Giles S. Rich, *Laying the Ghost of the "Invention" Requirement*, *in* NON OBVIOUSNESS–THE ULTIMATE CONDITION OF PATENTABILITY 1:512 (John F. Witherspoon ed., 1978); Irving Kayton, *Nonobviousness of the Novel Invention–35 U.S.C. § 103*, *in* NON OBVIOUSNESS–THE ULTIMATE CONDITION OF PATENTABILITY 2:114 (John F. Witherspoon ed., 1978).

118 WEBSTER'S NEW INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE, UNABRIDGED, 1683 (William Neilson, Thomas A. Knott & Paul W. Carhart, eds., 2nd ed. 1950) (emphasis in original).

119 *Id.*

the intended meaning behind the concept becomes even clearer.[120] The novelty requirement means that if an invention is already in the public domain, it cannot be patented.[121] But an invention that may not yet be in the public domain is still not patentable if it is a thing already openly exposed to the public.[122] That is, an invention was not to be patentable if it was already in the public domain actually *or constructively*.[123] Considering that the 1952 Patent Act also elevated a presumption of validity to a statutory mandate, it seems that Congress intended the non-obvious requirement to broaden inventors' access to patents, not to narrow it.[124]

Current legislation seems to support this view, as the current section 103 states that, even though an "identically disclosed" product or process may not already exist, if the differences between pre-existing products and processes and of the claimed invention "are such that the claimed invention *as a whole* would have been *obvious*" to the skilled artisan, then the invention is not patentable (emphasis added).[125] Per the common definition of "obvious" at the time the Patent Act was passed in 1952, if an invention and its anticipated use is openly exposed to the public as a whole, then the invention is unpatentable because the public can already access the invention and can already anticipate its use.[126]

As things generally appear obvious in hindsight, it seems that *"*not obvious" has not had quite the impact on patentability that the legislature intended.

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120 P. J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 180, 183 (1993).

121 *See* 35 U.S.C. § 102 (2011).

122 *See id*.

123 *See id. See also* P. J. Federico, *Commentary on the New Patent Act*, 75 J. PAT. & TRADEMARK OFF. SOC'Y 161, 178, 181 (1993).

124 35 U.S.C. § 282 (2022).

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> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102 [35 U.S.C. § 102], if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious[.]

35 U.S.C. § 103 (2011).

126 H.R. REP. NO. 1923, at 7 (1952).

C. KSR Addressed Obviousness, But Not The Issue

Although the discussion and debate surrounding the obviousness standard is extensive, the issue at the core of it remains unsettled. The Court addressed the obviousness standard in *KSR* and highlighted how important it is for patent law to encourage innovation.[127] However, it did not settle the question of what, exactly, the obviousness standard was meant to analyze.[128] Moreover, because the object that the obviousness standard analyzes is unclear, the standard is difficult to apply with uniformity, and results may vary from case to case.[129]

The controlling statute, 35 U.S.C.S. § 103, states that a patent should not be granted for an invention, even if the invention has not already been patented, "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . ."[130] The words "as a whole" appear to cast the most light on the object that should be analyzed by the obviousness standard.[131] According to the statute, the object to be analyzed by the obviousness standard is a fully completed invention *as a whole*, not the *process* of invention or the elements that contributed to it.[132] Because the process of invention could be different for every technology, or every invention within a particular technology, applying the obviousness standard to the

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127 *See* KSR Int'l Co. v. Teleflex Inc., 550 U.S. 538, 427 (2007) ("Application of the [obviousness] bar must not be confined within a test or formulation too constrained to serve its purpose.").

128 Fromer, *supra* note 15, at 76 (discussing the proper object of the nonobviousness inquiry and stating that "[d]espite this overarching purpose [of encouraging innovation] highlighted in *KSR*, neither courts nor scholars have analyzed or settled on the obviousness inquiry's object, that is, the thing which must be nonobvious.").

129 *Id. See infra* note 211.

130 35 U.S.C. §§ 103 (2011) ("A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102 [35 U.S.C § 102], if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . .").

131 *See* U.S. PAT. AND TRADEMARK OFF., MANUAL OF PAT. EXAMINING PROC., EXAMINATION GUIDELINES FOR DETERMINING OBVIOUSNESS UNDER 35 U.S.C. 103, ch. 2100, § 2141 (2020) ("Ascertaining the differences between the claimed invention and the prior art requires interpreting the claim language . . . and considering both the invention and the prior art as a whole.").

132 *Id.*

process of invention is not a reliable determiner of results.[133] Looking backward at the process of invention is also what creates hindsight bias.[134] Nonetheless, understanding the process of invention is necessary to maintain the patent system's incentive structure.[135]

Restricting the application of the obviousness standard to the product of an inventive process and not to the process itself might bring some stability to the obviousness standard.[136] But even if the object of the obviousness standard is clarified, the standard still has other issues that need to be addressed.

III. CRITICAL ERRORS THAT RESULT FROM THE COURTS' INTERPRETATIONS

The FTC hearings that contributed to the Supreme Court's decision to hear *KSR* revealed two things: commentators disagreed with the Federal Circuit's attempt to deal with the obviousness problem with the TSM test, and some felt that the most significant effects of the Federal Circuit's TSM test manifested more prominently in the chemical sciences.[137] Instead of considering the factors that might have contributed to this disparity, the commentators seemed inclined to view these effects as detrimental developments that needed attention.[138] However, when effects are observed, it is generally because there is

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133 *See generally* Mandel, *supra* note 8; *Patently Non-Obvious II supra* note 8 (discussing the hindsight bias's effect on obviousness and how it may cloud the decision makers' ability to conceive the obviousness of an invention).

134 Mandel, *supra* note 8, at 1399, 1402.

135 Amy L. Landers, *Ordinary Creativity in Patent Law: The Artist Within the Scientist*, 75 MO. L. REV. 1, 5 (2010) ("Understanding the process of invention assists, or at a minimum refrains from impeding, the incentive structure that the patent system was intended to create.").

136 *See, e.g.*, Mandel, *supra* note 8; *Patently Non-Obvious II supra* note 8.

137 *See* FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 4, at 8 (2003), http://www.ftc.gov/os/2003/10/innovationrpt.pdf [https://perma.cc/7YW9-2Y2B] (noting that "[p]articipants generally perceived a trend since the advent of the Federal Circuit toward reducing the size of the step required for patentability–that is, reducing the rigor of the nonobviousness standard."); *Id.* at n.45 ("Some . . . panelists found the trend toward a less rigorous nonobviousness standard particularly pronounced in biotechnology contexts . . . . [A] lot of the watering down on nonobviousness has come in the chemical field.").

138 *See id.* at 4-5, 7-9.

"something" causing those effects which might not yet be recognized.[139] When scientists discovered black holes, it was not because they could see black holes.[140] They could not see them, but their presence was known long before the first picture of a black hole was released in 2019.[141] When light is bent and impacted in strange ways, it is because something is affecting it.[142] As scientists had predicted, that unknown object might be the gravitational pull associated with the presence of a black hole.[143] In the case of the obviousness standard, as the courts struggle to apply it to the regulated sciences and useful arts, the source of the disparity might be the presence of some critical errors with the courts' interpretation of the obviousness standard.

A. The Court's Concept of a PHOSITA Is a Phantasm

Far from being a person having ordinary skill in any art, the courts' concept of a PHOSITA is "a rather *extraordinary* creature, an idiot savant with extraordinary knowledge and virtually no creativity."[144] In addition to the rigors of a PHOSITA's discipline, such as the years of study and research necessary to obtain a doctorate, and also the subsequent years of developing research hypotheses, creating research plans, collecting and analyzing data, publishing research results, and

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139 *See generally* Mandel, *supra* note 8; *Patently Non-Obvious II supra* note 8 (discussing the inability of human beings to objectively understand events prior once they have learned the outcome).

140 UNSOLVED PROBLEMS IN ASTROPHYSICS 94 (John N. Bahcall & Jeremiah P. Ostriker eds., 1997) ("Gravitational lensing was predicted theoretically by Eddington, Lodge, Zwicky, Einstein and others, long before the first convincing example of this phenomenon . . . was discovered."). *Gravitational Lensing*, HARV. & SMITHSONIAN CTR. FOR ASTROPHYSICS, https://pweb.cfa.harvard.edu/research/topic/gravitational-lensing [https://perma.cc/4FWK-TQ7G] ("The light-bending effect was first demonstrated for the Sun during a solar eclipse in 1919. Since then, astronomers have used gravitational lensing from galaxy clusters to discover far-off galaxies, and identified exoplanets from the tiny amount of lensing they produce.").

141 Mike Wall, *Eureka! Scientists Photograph a Black Hole for the 1st Time*, SPACE.COM (Apr. 10, 2019), https://www.space.com/first-black-hole-photo-by-event-horizon-telescope.html [https://perma.cc/Q5YT-MBD4].

142 Nola Taylor Tillman, Meghan Bartels & Scott Dutfield, *Einstein's Theory of General Relativity*, SPACE.COM (Jan. 5, 2022), https://www.space.com/17661-theory-general-relativity.html [https://perma.cc/S47D-B6D5] ("Light bends around a massive object, such as a black hole, causing it to act as a lens for the things that lie behind it.").

143 *Id.*

144 Abramowicz & Duffy, *supra* note 18, at 1606 (emphasis in original).

seeking grants and funding to support these efforts, a PHOSITA apparently has also developed knowledge and awareness of all prior art that is legally pertinent to his inventions, no matter how obscure.[145] Regardless of the Federal Circuit's definition of a skilled person as "one who thinks along the line of conventional wisdom in the art and is *not one who undertakes to innovate*,"[146] the courts have not placed any limitations on this supposed knowledge. Under the courts' interpretation, a PHOSITA is not only aware of extremely obscure prior art that would be exceedingly difficult to locate,[147] but he is also aware of that which is physically impossible to know, such as patent applications held in secret by the Patent Office,[148] inventions held in secret by other inventors,[149] and sales occurring under the cloak of secrecy.[150]

Although the Federal Circuit attempted to apply some reasonableness to these expectations with its development of the TSM test, which required a common-sense showing that the prior art "connect the dots . . . very, very clearly,"[151] these attempts did not survive the

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145 *See, e.g.*, MERGES & DUFFY, *supra* note 21, at 442 (recognizing that the extent of knowledge credited to a PHOSITA makes him a "superperson").

146 Std. Oil Co. v. Am. Cyanamid Co., 774 F.2d 448, 454 (Fed. Cir. 1985) (emphasis added).

147 *See* In re Hall, 781 F.2d 897, 898 (Fed. Cir. 1986) (holding that prior art included an uncatalogued, unshelved thesis indexed in the library of a foreign country).

148 *See* Hazeltine Rsch., Inc, v. Brenner, 382 U.S. 252, 255-56 (1965) (holding that § 102 patent applications are a source of prior art for purposes of § 103 requirements for non-obviousness).

149 *See* In re Bass, 474 F.2d 1276, 1286-87 (C.C.P.A. 1973) (an earlier invention that was not abandoned, suppressed, or concealed was prior art even though the invention was not available to the public at the relevant time). *See also* 35 U.S.C. § 102 (2011). *But see First Inventor to File (FITF) Resources*, U.S. PAT. AND TRADMARK OFF. (FEB. 5, 2016), https://www.uspto.gov/patents/first-inventor-file-fitf-resources, [https://perma.cc/EP4S-2MFY] ("The first inventor to file (FITF) provision of the America Invents Act transitions the U.S. to a first-inventor-to-file system from a first-to-invent system and became effective on March 16, 2013. The provision introduced changes to 35 U.S.C. § 102 that impact patent prosecution directly.").

150 Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628, 634 (2019) (holding an inventor's secret sale of an invention constituted prior art).

151 FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 4, at 11 (2003), www.ftc.gov/os/2003/10/innovationrpt.pdf [https://perma.cc/7YW9-2Y2B] (recounting the 2002 testimony of Stephen Kunin, then-Deputy Commissioner for

Court's 2007 *KSR* decision.[152] The Federal Circuit's attempts to combat hindsight bias and maintain a logical method of showing that an invention was "obvious" while preserving the concept of a person having "ordinary" skill in the art were a valiant effort. Nevertheless, Justice Scalia called the TSM test "gobbledygook."[153] The Court in *KSR* held that TSM could not be applied rigidly, but it still allowed courts to consider TSM as an element of a flexible analysis.[154] Regardless, following the *KSR* decision, any concept of "ordinary" skill was lost.[155]

B. Differences Between Case Law and The Unpredictable Arts

Although the statute's wording requiring nonobviousness is expansive enough to cover all innovation,[156] the Supreme Court's case law on the obviousness standard has developed within a very narrow category of innovation, one focused on easy-to-grasp, straightforward, linear concepts.[157] The narrowness of this category of innovation can be

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Patent Examination Policy at the U.S. Patent and Trademark Office, describing the Federal Circuit's case law on obviousness).

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

153 Transcript of Oral Argument at 41, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2006) (No. 04-1350) (referring to the Federal Circuit's teaching, suggestion, motivation test to determine obviousness during 2007 oral argument).

154 OSRAM Sylvania, Inc. v. Am. Induction Techs., Inc., 701 F.3d 698, 707 (Fed. Cir. 2012) (citing KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 415, 419 (2007)) ("The Supreme Court has warned, however, that, while an analysis of any teaching, suggestion, or motivation to combine known elements is useful to an obviousness analysis, the overall obviousness inquiry must be expansive and flexible."). *See generally KSR*, 550 U.S. at 427.

155 Abramowicz & Duffy, *supra* note 18, at 1607 (noting that following the *KSR* decision, "[w]hatever administrability benefit the courts once derived from their textually implausible construction of 'ordinary" was lost).

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> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102 [35 U.S.C. § 102], if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

35 U.S.C. § 103 (2011).

157 *See, e.g.*, KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007) (invention at issue was a sensor attached to a car's gas pedal); Graham v. John Deere Co., 383 U.S.

seen in the wording the Court used when it described this type of innovation:

> We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius. These advances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws. Were it otherwise patents might stifle, rather than promote, the progress of useful arts.[158]

In the category of innovation to which the Court refers, progress is a two-dimensional climb on a ladder, and as progress moves upward, all that lays below the "threshold" exists in the realm of what is already known; thus, what is below is no longer patentable.[159] While the two-dimensional climb might be true for innovation involving doorknobs, plow shocks, and gas pedals, the rest of the inventive universe is a three-dimensional, inter-stellar wonderland with an infinity of interacting parts, constantly changing dynamics, and an unpredictable rearrangement of understandings.[160] Although the Court recognizes that patent law applies to all technologies, patent law must reflect the reality that innovation does not work the same way in all technologies.[161] Some critics indicated that the Federal Circuit's interpretation of the obviousness standard set the bar too high because it allowed patents on

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1 (1966) (shock absorbers on a plow); Hotchkiss v. Greenwood, 52 U.S. 248, 267 (1850) (doorknob).

158 *KSR*, 550 U.S. at 427.

159 *Id.* (indicating that only progress reaching "higher levels" would be subject to patent rights).

160 *See generally* DAVID L. NELSON, MICHAEL M. COX, & AARON A. HOSKINS, PRINCIPLES OF BIOCHEMISTRY (8th ed. 2021) (showing the interactions that occur when the fields of biology, chemistry, and physics intersect); BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL (6th ed. 2014) (illustrating that every cellular discovery illuminates more that remains unknown); FRANCIS LEBLANC, AN INTRODUCTION TO STELLAR ASTROPHYSICS (2010) (illustrating the intersections between astrophysics and other fields of physics); NOUREDINE ZETTILI, QUANTUM MECHANICS: CONCEPTS AND APPLICATIONS (2d ed. 2009) (showing how scientists believed that all that could be known had already been discovered until it was discovered that physical laws alter at very fast speeds and on very small scales).

161 Burk & Lemley, *supra* note 17, at 1696.

relatively small variations of known biopharmaceutical products.[162] However, even the critics will note that a small chemical or physical change in a molecular structure can dramatically change its properties.[163] Miniscule changes to molecules can have dramatic effects, which are not (and should not) be found to be obvious either explicitly or inherently.[164]

C. Negative Impact of Reasonable to Try & Reasonable Expectation of Success

The United States Patent and Trademark Office manual has seven guidelines for establishing a prima facie case of obviousness.[165] In the

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[162] *See, e.g.*, Price II, *supra* note 37, at 786-87 (stating that the Federal Circuit has made obviousness "very hard to show" for pharmaceuticals, calling it a "weaker requirement"); Rebecca S. Eisenberg, *Pharma's Nonobvious Problem*, 12 LEWIS & CLARK L. REV. 375, 378 (2008) (claiming that for pharmaceutical companies hindsight bias has an opposite effect, making some chemical and pharmaceutical inventions "appear less obvious in hindsight"); Amir A. Naini, *Convergent Technologies and Divergent Patent Validity Doctrines: Obviousness and Disclosure Analyses in Software and Biotechnology*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 541, 544-60 (2004) (describing what appears to be the effects of "a relatively low nonobviousness barrier").

[163] Just like a stick figure drawing of a person is wholly inadequate to convey all the nuances of a person's character, the two-dimensional chemical structures depicted on paper cannot convey the full range of a molecule's characteristics. Eisenberg, *supra* note 162, at 396-97. "[E]ven in small molecules, the three-dimensional complexity arising from what appear on paper to be slight changes in structure may give rise to radically different properties in apparently related molecules." Burk & Lemley, *supra* note 17, at 1684-86.

[164] *See, e.g.*, Millennium Pharm., Inc. v. Sandoz Inc., 862 F.3d 1356 (Fed. Cir. 2017) (determining that a pharmaceutically active chemical compound was not inherently obvious because it was not disclosed or recognized in prior art); Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075 (Fed. Cir. 2008) (finding that the disclosure of a racemic compound did not explicitly or inherently disclose its enantiomers). *See generally* Christopher M. Holman, *Inherency in the Patenting of Biotechnology and Pharmaceutical Innovation*, 39 BIOTECHNOLOGY L. REP. 79, 99 (2020) (discussing the doctrine of inherency in the context of the nonobviousness requirement and the different outcomes that may result "in the hands of policy-minded judges").

[165] According to the United States Patent and Trademark Office, there are factors that may support a conclusion of obviousness, including:

> (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device

pharmaceutical industry, the nonobviousness standard is currently being applied to prevent patents from being granted to inventions that are produced using routine procedures that produce predictable results.[166] If a court finds that an invention produced in this manner had a reasonable expectation of success, this presents a prima facie case of obviousness that the inventor may overcome by showing that the results were unexpected.[167] The Federal Circuit has recognized the difficulty the courts face when considering obviousness in this context; unless the inventor was surprised by the invention's success, the obviousness standard as it is currently being applied would prevent the invention from being patented.[168] Denying patents to innovations, regardless of the type of predictability that caused an invention's development, has a detrimental impact on innovation as a whole.[169] Looking back to see that all elements of a discovery existed in the prior art should not be sufficient for a finding of obviousness because of all elements of the

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> (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

U.S. PAT. AND TRADEMARK OFF., MANUAL OF PAT. EXAMINING PROC., *Reasonable Expectation of Success is Required*, ch. 2100, § 2143(I) (2020).

166 The rationale to support a conclusion that claims are obvious is that "a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and whether there would have been a reasonable expectation of success in doing so." DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co., 464 F.3d 1356, 1360 (Fed. Cir. 2006) (citing Brown & Williamson Tobacco Corp. v. Philip Morris, Inc. 229 F.3d 1120, 1124 (Fed. Cir. 2000)). *See also* Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1365-69 (Fed. Cir. 2007).

167 *See Pfizer*, 480 F.3d at 1368-69.

168 "The evaluation of the choices made by a skilled scientist, when such choices lead to the desired result, is a challenge to judicial understanding of how technical advance is achieved in the particular field of science or technology." Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1351-52 (Fed. Cir. 2008). *See also* Roin, *supra* note 22, at 533.

169 "The primary problem with Type II predictability, particularly when used by itself to render a patent claim obvious, is that the standard runs counter to patent law and patent policy." Cotropia, *supra* note 66, at 394.

things that could have existed since the dawn of time; it's finding ways that those things can make new things that is the very nature of innovation.[170]

Denying patent protection to an invention based on an inventor's reasonable predictions of inventive success does not also automatically satisfy the regulatory requirements of the FDA.[171] Consequently, there is a disconnect between the obviousness standard's assumption that an invention is obvious on the basis that the public already has access to it, and the fact that the public has prevented public access to inventions that do not pass certain regulatory procedures.[172]

This creates an innovative conundrum, wherein the public will deny a patent for an invention because the invention can already be obtained because it is "obvious," but then the public cannot obtain that invention because the inventor likely has no motivation or incentive to produce it.[173]

D. Some Inventions Deemed Obvious Are Not, and Consequently May Never Be Accessible to The Public

Determining if an invention passes the non-obviousness bar is an essential part of obtaining a patent.[174] This is because, as shown, the obviousness bar prevents the issuance of patent protections for ordinary inventions which could, and do, pass easily into the realm of the public domain.[175] The consequences of misapplication of the nonobvious standard can be dire, because if patent protections are denied to pharmaceutical drugs and biotherapies on the basis that they are obvious when in fact they are not, then those inventions may never be accessible to the public.[176]

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170 In overturning the Patent Trial and Appeal Board's finding of obviousness based on the inherency of a chemical's trait, the Federal Circuit stated: "[a]ll properties of a composition are inherent in that composition, but unexpected properties may cause what may appear to be an obvious composition to be nonobvious." Honeywell Int'l Inc. v. Mexichem Amanco Holding S.A. de C.V., 865 F.3d 1348, 1355 (Fed. Cir. 2017) (citing In re Papesch, 315 F.2d 381, 391 (C.C.P.A. 1963)).

171 *See* DiMasi, *supra* note 2, at 29-30; Sachs, *supra* note 2, at 173-75.

172 Roin, *supra* note 22, at 534.

173 *Id.*

174 *See* 35 U.S.C. §§ 101-103 (2011).

175 KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 427 (2007).

176 "Conventional economic actors will only produce a good when they can appropriate sufficient returns to recoup the capitalized costs of providing the

Drugs denied patent protection do not simply end up within the grasp of the public in the "tangible and palpable" reality of the public domain,[177] but are instead effectively blocked from entry by the FDA's regulatory process.[178] The FDA doesn't just regulate the process of bringing pharmaceutical drugs to the market; it can deny marketing approval to drugs that do not meet its standards.[179] An invention cannot reach the public without gaining FDA approval, and a product is not worth the time, cost, and risk of venturing the FDA approval process without strong patent protections.[180] For industries governed by FDA regulatory procedures, a finding of obviousness effectively relegates an invention *outside* the grasp of the public domain.[181] For example, "[a]ccording to academic researchers, industry insiders, and medicinal-chemistry textbooks, pharmaceutical companies systematically screen

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good." Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L. J. 1900, 1908 (2013).

177 "We build and create by bringing to the tangible and palpable reality around us new works based on instinct, simple logic, ordinary inferences, extraordinary ideas, and sometimes even genius." *KSR*, 550 U.S. at 427.

178 *See generally* 21 U.S.C. § 355 (2012) (elucidating the requirements to file an application for FDA approval prior to introducing a new drug to interstate commerce).

179 *Unapproved Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs [https://perma.cc/4LVD-99A6] (last updated June 2, 2021) (explaining that FDA approval is required by law before a new drug product may be marketed to the public).

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> [P]atent protection is indispensable in promoting pharmaceutical innovation for drug products containing new chemical entities. The sunk cost of engaging in research projects aimed toward the development of these drugs is extremely high . . . . The discovery of a chemical molecule that is both efficacious and safe for human usage can result in a totally new drug product. Such discoveries typically require significant amounts of pioneering research, and both fixed costs and risks of failing to develop a marketable product, consequently, are very high.

FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3, at 4-5 (2003) http://www.ftc.gov/os/2003/10/innovationrpt.pdf [https://perma.cc/7YW9-2Y2B].

181 Roin, *supra* note 22, at 545 (discussing how the public's access to new drugs can be limited).

their drug candidates to exclude the ones lacking strong patent protection."[182]

IV. PROMOTING SCIENTIFIC PROGRESS REQUIRES UNDERSTANDING HOW SCIENCE PROGRESSES

Science is a process of discovery that progresses through the formulation of hypotheses followed by the testing of those hypothesis to discover if the hypotheses are true or false.[183] This process–of predicting results followed by attempts at falsification–is what makes science different from other industries.[184] Science is not encyclopedic; it does not get laid down in concrete concepts as it moves forward.[185] The entire field is dynamic, constantly changing as hypotheses previously shown to be true are revised, developed, partially falsified, or seen in a new light.[186] Moreover, neither are hypotheses that are shown to be false a setback, for these, too, advance the realm of understanding.[187] Like the Hubble Space Telescope, our current understanding of the entire universe changes as scientific progress moves forward, revealing to us more of the unknown.[188]

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182 *Id.*

183 "'[Science] represents a *process* for proposing and refining theoretical explanations about the world that are subject to further testing and refinement.'" Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 590 (1993) (emphasis in original) (quoting Brief for Am. Ass'n for the Advancement of Sci. et al. as *Amici Curae* 7-8).

184 "'Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry.'" *Id.* at 593 (quoting E. Green & C. Nesson, PROBLEMS, CASES, AND MATERIALS ON EVIDENCE 649 (1983)).

185 "'Science is not an encyclopedic body of knowledge about the universe.'" *Id.* at 590 (quoting Brief for Am. Ass'n for the Advancement of Sci. et al. as *Amici Curae* 7-8).

186 "Scientific conclusions are subject to perpetual revision." *Id.* at 597.

187 "The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance." *Id.*

188 Brian Dunbar, *About the Hubble Space Telescope*, NASA, https://www.nasa.gov/mission_pages/hubble/about [https://perma.cc/79WF-V86A] (last updated May 26, 2022); *Scientific Ideas Lead to Ongoing Research*, UNDERSTANDING SCI., https://undsci.berkeley.edu/understanding-science-101/what-is-science/scientific-ideas-lead-to-ongoing-research/ [https://perma.cc/V5WM-6RLG] ("[I]n a sense, the more we know, the more we

A. Prediction is Part of the Scientific Method

Some have interpreted the *KSR* decision to imply that "[p]redictability is the touchstone of obviousness . . . ."[189] But this is quite problematic for the sciences because "the essence of science is prediction."[190] If predictability really were the touchstone of obviousness, then all scientific discoveries resulting from the scientific method would be considered obvious because they follow predictions.[191] The Federal Circuit attempted to rectify this precarious situation for pharmaceutical drugs by requiring both "'that a skilled artisan would have been motivated to combine the teachings of the prior art . . . and that the skilled artisan would have had a reasonable expectation of success in doing so.'"[192] Although this is a clear indication that the current obviousness standard does not hinge on predictability alone, this determination of obviousness still manages to describe almost all scientific endeavors to date.[193]

B. Science Cannot Progress Without Reasonable Expectations of Success

Science cannot advance if it does not build upon the knowledge and understanding that came before, and there is generally no motivation to

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know what we don't yet know. As our knowledge expands, so too does our awareness of what we don't yet understand.").

189 Price II, *supra* note 37, at 786 (citations omitted). *See generally* KSR Int'l Co. v. Teleflex Inc. 550 U.S. 398 (2007).

190 Bernard L. Diamond, *The Scientific Method and the Law*, 19 HASTINGS L. J. 179, 181 (1967).

191 *Id.* at 189.

192 Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd., 821 F.3d 1359, 1367-68 (Fed. Cir. 2016) (first citing Kinetic Concepts, Inc. v. Smith & Nephew, Inc., 688 F.3d 1342, 1360 (Fed. Cir. 2012); then quoting Procter & Gamble Co. v. Teva Pharm. USA, Inc., 566 F.3d 989, 994 (Fed. Cir. 2009) (internal quotation marks omitted); and then citing In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1068-69 (Fed. Cir. 2012)).

193 "These general principles are subject to test and validation . . . . [U]sing further inductive logic, and sometimes deductive logic, to make predictions about reality. These predictions are then subject to further empirical observation and if these observations correspond to expectations, the general principle (theory) is . . . an *approximation* of the truth." Diamond, *supra* note 190, at 189 (emphasis in original) (discussing how the scientific method begins with empirical observations to make inferences about general principles using inductive logic).

research a prospect that shows no reasonable expectation of success.[194] Moreover, a research plan that shows no reason to combine prior understandings and proposes no reasonable expectation of success is a fool's errand; scientists cannot get funding for endeavors based on mere happenstance, fantasy, or hope for a positive outcome that cannot be predicted.[195] This would not be science. Promoting only those inventions that result from random accidents or magic would not be in the public interest.

Scientific advancement and progress are predicated on predicting what might happen and then finding out if these predictions are true.[196] Predictability is insufficient to make an invention obvious, nor is it a guarantee of experimental success or FDA approval.[197] Therefore, predictions are insufficient to make an innovation accessible to the public, either actually or constructively.[198] Moreover, to conclude that the obviousness standard hinges on predictability is to conclude that patentable scientific discoveries are those that result from surprise or accident. Yet this not how science progresses, nor is it the way to promote scientific progress. As stated *supra*, according to the United States Constitution, the purpose of patent law is to "promote progress," not to promote the invalidation of inventions developed with the scientific method.[199]

A thorough comprehension of scientific concepts is not necessary to promote scientific progress. As Justice Rehnquist stated, "definitions of scientific knowledge, scientific method, scientific validity, and peer review . . . [are] matters far afield from the expertise of judges," and, therefore, judges should "proceed with great caution in deciding" more

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194 Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 29, 29 (1991).

195 Gene Quinn, *When is an Invention Obvious?* IPWATCHDOG (Feb. 1, 2014, 6:05 PM), https://www.ipwatchdog.com/2014/02/01/when-is-an-invention-obvious/id=47709/ [https://perma.cc/6FA2-7V3Y].

196 "[W]e are trying to prove ourselves wrong as quickly as possible, because only in that way can we find progress." RICHARD FEYNMAN, THE CHARACTER OF PHYSICAL LAW 158 (1st ed. 1965).

197 *See generally* 35 U.S.C. § 103 (2011); *Unapproved Drugs*, U.S. FOOD & DRUG ADMIN, https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs [https://perma.cc/4LVD-99A6] (last updated June 2, 2021).

198 *See generally* 35 U.S.C. § 103 (2011); *Unapproved Drugs*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/enforcement-activities-fda/unapproved-drugs [https://perma.cc/4LVD-99A6](last updated June 2, 2021).

199 U.S. CONST. art. 1, § 8, cl. 8.

than what is necessary to avoid exceeding their grasp.[200] The promotion of progress, however, merely requires understanding what constitutes progress, what promotes that progress, and what does not promote that progress. A reasonable expectation of success is exactly what the public wants (or should want) to encourage innovators to pursue.

C. Symptoms of Faltering Innovation are Indicative of the Need

If the purpose of the patent system is to promote scientific progress and innovation, then it follows that the obviousness standard's purpose is to prevent inventions that lack scientific advancement from being granted a patent.[201] But an overly aggressive application of the obviousness standard or a mis-application of it, will have the opposite effect, resulting in the suppression of innovation by denying patents to inventions that should qualify,[202] and by making it too easy for third parties to claim obviousness.[203] Discussing the unpredictability of an invention's patentability, the retired Chief Judge of the Federal Circuit, Hon. Paul R. Michel stated:

> I've spent twenty-two years on the Federal Circuit and nine years since [retirement] dealing with patent cases and I cannot predict in a given case whether eligibility will be found or not found. If I can't do it, how can bankers, venture capitalists [and] business executives and all of the other players in the system make reliable predictions and sensible decisions? [204]

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200 "[D]efinitions of scientific knowledge, scientific method, scientific validity, and peer review . . . [are] matters far afield from the expertise of judges . . . . [T]he unusual subject matter should cause us to proceed with great caution in deciding more than we have to, because our reach can so easily exceed our grasp." Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 599 (1993).

201 U.S. CONST. art. 1, § 8, cl. 8; MERGES & DUFFY, *supra* note 21, at 327.

202 *See, e.g.*, Roin, *supra* note 22, at 507-08 (noting that innovators won't sink enormous investments into clinical trials without patent protections because they would be unable to recover their losses); Burk & Lemley, *supra* note 17, at 1576-77 (discussing how the patent system is essential for the promotion of innovation in biotechnology).

203 Jason Lief & Peter Schuyler, *Pharmaceutical Patents After* KSR*: What is Not Obvious?* 15 J. COM. BIOTECH. 44, 45 (2009).

204 Steve Brachmann & Eileen McDermott, *First Senate Hearing on 101 Underscores That 'There's More Work to Be Done'*, IPWATCHDOG (June 4, 2019, 10:23 PM), https://www.ipwatchdog.com/2019/06/04/first-senate-hearing-on-

Without the strong protection afforded by patents, innovators limit the disclosure of information to prevent the theft of their ideas.[205] Although entrepreneurs are generally less averse to risk than others,[206] reducing uncertainty through predictable patent results is important for encouraging innovation because uncertainty poses a tremendous barrier.[207] It is difficult to get the funding that an entrepreneur needs to get an invention in the hands of the public if that invention cannot be protected by an enforceable patent.[208] Patents essentially enable the market of ideas in the sciences.[209] Therefore, both the object and

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101-underscores-that-theres-more-work-to-be-done/id=110003/ [https://perma.cc/CY9J-X8PK]. *See also The State of Patent Eligibility in America: Part I: Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary*, U.S. S. (2019) (testimony of Judge Paul R. Michel [Ret.], United States Court of Appeals for the Federal Circuit), https://www.judiciary.senate.gov/meetings/the-state-of-patent-eligibility-in-america-part-i [https://perma.cc/CX9E-B74Y] ("If I, as a judge with 22 years of experience deciding patent cases on the Federal Circuit's bench, cannot predict outcomes based on case law, how can we expect patent examiners, trial judges, inventors and investors to do so?"); Senate Judiciary Committee Subcommittee on Intellectual Property, *Hearings to Examine the State of Patent Eligibility in America*, C-SPAN (2019) (testimony of Judge Paul R. Michel [Ret.]), https://www.c-span.org/video/?461419-1/judiciary-intellectual-property [https://perma.cc/B7C9-Z69U].

205 James J. Anton & Dennis A. Yao., *Expropriation and Inventions: Appropriable Rents in the Absence of Property Rights*, 84 AM. ECON. REV. 190, 190-91 (1994) (noting that licensors limit the disclosure of information to prevent partners from expropriating information, thereby significantly reducing the gains from technological trade).

206 *See* Richard A. Posner, *Keynes and Coase*, 54 J. L. & ECON. S31, S37 (2011) (discussing empirical evidence that entrepreneurs are more willing to take "noncalculable risks" compared to others of equal intelligence, and remarking that "economic growth is indeed . . . positively correlated with tolerance for uncertainty (low uncertainty aversion) and . . . that entrepreneurs are less averse to uncertainty than are other persons.").

207 "Despite the inherent risks in innovation, participants in the system count on some predictability and certainty in legal structures to justify their investments." Daniel R. Cahoy, *Patently Uncertain*, 17 NW. J. TECH. & INTELL. PROP. 1, 8 (2019).

208 *Id.*

209 "[P]rivate sector innovators are causally influenced by the receipt of IP rights . . . [p]atent allowance reduces the uncertainty of patent scope, [and so reduces] . . . imperfections in the market for ideas." This reality "highlights the value of grappling with the operational details of the patent system." Joshua S. Gans, David H. Hsu & Scott Stern, *The Impact of Uncertain Intellectual Property Rights on the Market for Ideas: Evidence from Patent Grant Delays*, 54 MGMT. SCI. 982, 996 (2008).

application of the obviousness standard need to be clarified, because both are having negative impacts on the public's access to innovation.[210]

In its report to the White House Competition Council, the United States Department of Health and Human Services stated that its "overall goal . . . is to foster innovation, increase competition, and improve the market environment, all in pursuit of reduced drug spending for consumers and throughout the health care system."[211] To address the high costs of pharmaceutical drugs which all Americans bear, [212] the report identified three guiding principles for drug pricing reform, one of which was fostering scientific innovation.[213] Although the report's main focus centered on the desire to approve competing generics and biosimilars, the report acknowledged the strong need for innovative products that are new to the market, particularly because current policies discourage innovation and therefore cause innovators to avoid the risks of new products, opting instead for variations of known therapies. [214] Fostering innovation requires strengthening the patent system, which

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[210] *See, e.g.* Price II, *supra* note 37, at 831 (urging policymakers to understand that, although patent policy encourages invention, other policies are pushing back, disincentivizing invention, causing innovators to avoid exploring new, different technologies); *see also* Sachs, *supra* note 2, at 160.

> But too often, these two systems [the FDA and the patent system] fail to encourage the production of important, socially valuable pharmaceutical interventions. These invisible interventions are often difficult to spot—by definition, they are missing precisely because the current innovation ecosystem has distorted inventive behavior away from what might be socially optimal.

Id.

[211] U.S. DEP'T OF HEALTH AND HUM. SERVS., COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES: A REPORT IN RESPONSE TO THE EXECUTIVE ORDER ON COMPETITION IN THE AMERICAN ECONOMY 3 (2021).

[212] "All Americans pay for higher drug spending through insurance premiums and taxes to pay for drug costs in programs including Medicare, Medicaid, the Children's Health Insurance Program (CHIP), the Veterans Health Administration (VA), and the Indian Health Service." *Id.* at 6.

[213] The other two principles included making "drug prices more affordable and equitable for all consumers and throughout the health care system" and improving and promoting "competition throughout the prescription drug industry." *Id.* at 2.

[214] *Id.* at 11-12. "Empirical evidence tends to support the effectiveness of patents in *encouraging innovation* . . . patents [are] . . . extremely important in protecting . . . competitive advantage in a few industries, notably biotechnology, drugs, chemicals and, to a certain extent, machinery and computers." ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, PATENTS AND INNOVATION: TRENDS AND POLICY CHALLENGES 9 (2004) (emphasis in original).

will reduce the cost of pharmaceutical drugs by encouraging new market entrants to invest in the research and development of new treatments.[215]

Behind both the *Hotchkiss* inventiveness requirement and the non-obviousness requirement is an attempt to define inventions that possess a quality of inventiveness.[216] This is the minimum value that the invention should possess, the minimum value that the public should receive in exchange for the grant of a patent's monopoly rights.[217] An evaluation of the value given in exchange for a patent cannot ignore the impact of regulatory requirements on innovation in the pharmaceutical and biomedical therapies and devices industries.[218] In sum, it is as equally true today as it was in 1943, that "[i]t is inconsistent with sound national policy to continue to grant patents with existing uncertainty as to their validity, and unfair to the inventors of this country and to manufacturers and investors who have proceeded on the basis of a protective security in the form of a patent . . . ."[219]

V. CONCLUSION

Born in 1952, the obviousness standard has become an outdated and unrealistic measure of modern scientific inventiveness, as the judiciary has "struggled to adapt the old doctrinal framework" of the obviousness standard to meet the needs of innovation.[220] Vastly outdated by the current innovative landscape, it is time, again, for Congress to act. Some of the difficulty in application could be clarified by specifying what the object of the obviousness standard is meant to analyze, but this will

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215 "Drug prices in the U.S. are too high because multiple factors stifle competition. The prescription drug industry is characterized by multiple market failures including lack of new entrants . . . [and] research and development spending that goes toward me-too drugs instead of new treatments and cures . . . ." U.S. DEP'T OF HEALTH AND HUM. SERVS., COMPREHENSIVE PLAN FOR ADDRESSING HIGH DRUG PRICES: A REPORT IN RESPONSE TO THE EXECUTIVE ORDER ON COMPETITION IN THE AMERICAN ECONOMY 4 (2021).

216 *See* Holte & Sichelman, *supra* note 17; *see also* Burk & Lemley, *supra* note 17.

217 *See generally* Abramowicz & Duffy, *supra* note 18.

218 Price II, *supra* note 37, at 831 (urging policymakers to understand that, although patent policy encourages invention, other policies are pushing back, disincentivizing invention, causing innovators to avoid exploring new, different technologies).

219 NAT. PAT. PLAN. COMM'N, THE AMERICAN PATENT SYSTEM, REPORT OF THE NATIONAL PATENT PLANNING COMMISSION, *as reprinted in* 25 J. PAT. OFF. SOC'Y 455, 463 (1943).

220 Seymore, *supra* note 38, at 139.

likely be insufficient to correct the confusion. The obviousness standard needs to be reinterpreted because there are multiple difficulties that have been created by the Court's interpretation of a person having ordinary skill in the art; as illustrated by the case law that has impacted the interpretation of the standard that did not address science within the unpredictable arts. Moreover, the consequences of denying patent protections to the regulated industries–of finding obviousness when in fact there is none–will ultimately prevent beneficial pharmaceutical drugs and therapeutics from being developed. As it currently operates, the obviousness standard is simply too blunt a tool to perform the task that it was designed to do. The purpose of the patent system is to promote progress, but in order to promote scientific progress, policies must be built around an understanding that science is dynamic. What is known may change, and therefore, what is obvious may too. Nonobviousness is not an appropriate, modern measure of inventiveness and it has landed us in a place of innovative stagnation and confusion. If a policy is going the wrong direction, then sometimes progress means going back the way we've come in order to find our way.[221]

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> We all want progress. But progress means getting nearer to the place you want to be. And if you have taken a wrong [turn], then to go forward does not get you any nearer. If you are on the wrong road, progress means doing an about-turn and walking back to the right road; and in that case, the man who turns back soonest is the most progressive man . . . . There is nothing progressive about being pigheaded and refusing to admit a mistake.

C.S. LEWIS, MERE CHRISTIANITY 33 (1952).