MENDING THE FENCE: COMMERCIAL SUCCESS AND THE BLOCKING PATENT DEFENSE IN PHARMACEUTICAL LITIGATION[1]

John Jarosz, Andrea Hugill, Anna Gumen, Michael Chapman, and Joshua Rothman

I. INTRODUCTION

Commercial success often is a crucial after-the-fact consideration in litigations assessing whether a patent was nonobvious or not. Its evaluation usually entails assessing whether a patented invention (often, product) has achieved success in the marketplace and whether that success is due to the patented features. If the answer to both questions is "yes", then the implication is that the at-issue patent was not obvious because if it was obvious, others would have had the incentive to develop the invention instead of the patent owner. Conversely, if the invention practicing the at-issue patent is either unsuccessful or the marketplace success is unrelated to the at-issue patent, then the evidence may weigh against a finding of non-obviousness.

In pharmaceutical litigation, the blocking patent defense increasingly has been invoked to counter a patent owner's reliance on a showing of commercial success.[2] The core blocking patent argument is that the success of the patented invention stems not from the at-issue patent being considered for obviousness, but instead from the preclusive effect of an earlier, pre-existing "blocking" patent that prevented third parties from pursuing inventions that led to the at-issue patent. In other words, the blocking patent argument is that the success of a patented product is likely due to the restrictive barrier (or fence) created by the blocking patent – effectively keeping competitors out – rather than the inherent advantages of the patented invention at issue.

Patent owners often respond to the blocking patent defense by arguing that the alleged blocking patent(s) did not or could not have prevented earlier invention. By countering the blocking patent argument, patent owners seek to show that the success of the patent-practicing product reflects the technical merits of the patent at issue, not the exclusivity afforded it by the earlier patent that is claimed to be blocking.[3] While sometimes blocking patent arguments have successfully been countered, the Court of Appeals for the Federal Circuit ("Federal Circuit") increasingly has embraced the blocking patent defense in

---

[1] John Jarosz, B.A., J.D., M.A. is a Managing Principal at Analysis Group, Inc.; Andrea Hugill, B.A., M.A., Ph.D., is a Vice President at Analysis Group, Inc.; Anna Gumen, B.S., Ph.D., is a Vice President at Analysis Group, Inc.; Michael Chapman, B.A., Ph.D., J.D., is a founder of Envision Economics; Joshua Rothman, B.S., M.S., J.D., is a Partner at Venable LLP. We would like to thank Evie Goryshina, Nicolas Campana, and Xinyu Ni for extraordinary research assistance. We would like to thank Mark Lemley, Ryan O'Quinn, Paul Browning, Justin Hasford, Andrew Danford, and Soojin Kim for countless insights and pushback. Mr. Jarosz has been involved in two of the lawsuits mentioned in this paper: *Galderma Labs, L.P. v. Tolmar, Inc.*, and *Otsuka Pharmaceuticals Co., Ltd., v. Lupin Limited and Lupin Pharmaceuticals, Inc*. Dr. Hugill and Mr. Rothman have been involved in *Otsuka Pharmaceuticals Co., Ltd., v. Lupin Limited and Lupin Pharmaceuticals, Inc.* The views expressed here are those of the authors. We are solely responsible for any errors or oversights.

[2] *See, e.g.*, UCB, Inc. v. Actavis Labs. UT, Inc., 65 F.4th 679 (Fed. Cir. 2023); Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 97 F.4th 915 (Fed. Cir. 2024).

[3] *See, e.g.*, ViiV Healthcare UK Ltd. v. Lupin Ltd., 6 F. Supp. 3d 461, 481 (D. Del 2013); Pfizer Inc. v. Teva Pharms, 460 F. Supp 2d. 650 (D.N.J. 2006).

pharmaceutical cases involving claims of commercial success.[4] From 2003 to 2013, the Federal Circuit issued opinions in four (4) pharmaceutical cases involving the defense, finding a blocking patent in two (2) instances.[5] Over that period, there were sixteen (16) published district court opinions in pharmaceutical cases that addressed, in part, the blocking patent defense. From 2014 to 2024, the Federal Circuit decided eleven (11) such pharmaceutical cases, finding a block in seven (7) instances.[6] For that period, the number of published district court opinions doubled to 32. The blocking patent defense appears to be increasingly invoked, and much of the time, has succeeded.

Despite its growing use and acceptance, the foundations (or footers) of the blocking patent defense are less solid than they may seem. Legally, the defense cannot be applied categorically and universally to explain the commercial success of an at-issue patent. Courts repeatedly have emphasized that determining whether a patent blocks earlier invention is a fact-specific inquiry that must be resolved on a case-by-case basis.[7] Empirically, patents rarely block *all* forms of innovative activity. Promising (and often potentially lucrative) research and development efforts and associated commercial endeavors are seldom abandoned altogether due to the existence of a supposed blocking patent. Logically, determining whether a patent qualifies as blocking involves consideration of numerous factors, many of which courts already have identified explicitly. Critical to that inquiry is a description of what has been blocked and when. From an economic perspective, commercial success reflects the impact of marketplace dynamics. A blocking patent rarely eliminates all forms of competitive activity.

In most blocking patent cases, the issue has been addressed without any, or with minimal, real-world evidence that anyone or anything was blocked. While commercial success is valuable in a nonobviousness analysis because it is intended to be rooted in real-world evidence, courts often discount this evidence in the context of a blocking patent defense and instead base their conclusions solely on an expert's opinion that blocking *may* have occurred. Particularly troubling is when courts overlook or fail to consider real-

---

[4] *See, e.g.*, Sanofi-Aventis Deutschland GMBH v. Mylan Pharms. Inc., 791 Fed. Appx. 916, 927-928 (Fed. Cir. 2019); UCB v. Actavis, 65 F.4th at 695-697.

[5] The four cases in which the Federal Circuit issued opinions are *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364 (Fed. Cir. 2005); *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008); *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280 (Fed. Cir. 2012); *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731 (Fed. Cir. 2013). The two cases in which the Federal Circuit found a blocking patent are *Merck v. Teva*, 395 F.3d 1364, and *Galderma v. Tolmar*, 737 F.3d 731.

[6] The 11 cases in which the Federal Circuit issued opinions are *ViiV Healthcare UK Ltd. v. Lupin Ltd.*, 594 Fed. Appx. 686 (Fed. Cir. 2015); *UCB, Inc. v. Accord Healthcare, Inc*., 890 F.3d 1313 (Fed. Cir. 2018); *Allergan, Inc. v. Teva Pharm USA, Inc*., 742 Fed. Appx. 511 (Fed. Cir. 2018); *Merck Sharp & Dohme Corp. v. Hospira, Inc*., 874 F.3d 724 (Fed. Cir. 2017); *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310 (Fed. Cir. 2018); *Hospira, Inc. v. Amneal Pharms., LLC*, 748 Fed. Appx. 1024 (Fed. Cir. 2019); *BTG Int'l Ltd. v. Amneal Pharms., LLC*, 923 F.3d 1063 (Fed. Cir. 2019); *Sanofi-Aventis Deutschland GMBH v. Mylan Pharms., Inc.*, 791 Fed. Appx. 916 (Fed. Cir. 2019); *Amgen, Inc. v. Sandoz, Inc*., 66 F.4th 952 (Fed. Cir. 2023); *UCB, Inc. v. Actavis Labs. UT, Inc.*, 65 F.4th 679 (Fed. Cir. 2023); *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.,* 97 F.4th 915 (Fed. Cir. 2024). The seven cases in which they found a blocking patent are *Allergan v. Teva* 742 Fed. Appx. 511; *Merck v. Hospira*, 874 F.3d 724; *Hospira v. Amneal*, 748 Fed. Appx. 1024; *Acorda v. Roxane*, 903 F.3d 1310; *BTG v. Amneal*, 923 F.3d 1063; and *Sanofi-Aventis v. Mylan*, 791 Fed. Appx. 916; *UCB v. Actavis*, 65 F.4th 679. Although the Federal Circuit sided with the Defendant in *Janssen v. Teva,* 97 F.4th 915, finding that the blocking patent analysis rested on faulty premises, and remanded the district court to conduct its analysis of secondary considerations consistent with the opinion of the Federal Circuit, in November 2024, the district court issued another ruling, finding that the claimed blocking patents were not in fact blocking. *Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 2024 U.S. Dist. LEXIS 227696 (D.N.J. Nov. 21, 2024)*.

[7] *See, e.g*., Merck Sharp & Dohme Corp. v. Hospira, Inc. (*Merck II)*, 874 F.3d 724, 731 (Fed. Cir. 2017).

world evidence showing that others were actively working in the field of the claimed invention. This approach risks undervaluing certain patented inventions by relying on speculative assertions that a blocking patent deterred others, even when real world evidence suggests otherwise—namely, that the blocking patent did not block competitive R&D, and that the patented invention succeeded because it was genuinely innovative and nonobvious.

II. OBVIOUSNESS DEFENSE

To be patentable, an invention must not have been obvious to a person skilled in the relevant field at the time of the invention.[8] This standard ensures that patents are not granted for incremental changes or developments that would be obvious to a knowledgeable person in the relevant industry or area of technology.

The U.S. Supreme Court's decision in *Graham v. John Deere Co*., 383 U.S. 1 (1966), established the key factors for assessing obviousness:

- the scope and content of prior art (existing knowledge in the field);
- the level of ordinary skill in the art;
- differences between the claimed invention and the prior art; and
- whether those differences would have been obvious to a person skilled in the art.[9]

The fourth factor – whether differences between the claimed invention and prior art would have been obvious – often is evaluated considering six key "secondary considerations" or "objective indicia of nonobviousness:"[10]

- commercial success,
- long-felt but unmet need,
- failure of others,
- copying by others,
- unexpected results, and
- licensing and industry recognition.[11]

---

[8] *See* Graham v. John Deere Co., 383 U.S. 1, 35 (1966) (citing Richard Robbins, *Subtests of "Nonobviousness": A Nontechnical Approach to Patent Validity*, 112 U. PA. L. REV. 1169, 1175 (1964)). *See also* Daralyn J. Durie and Mark A. Lemley, *A Realistic Approach to the Obviousness of Inventions*, 50 WM. & MARY L. REV. 989, 990 (2008) ("Obviousness is the ultimate condition of patentability. The nonobviousness requirement-that inventions must, to qualify for a patent, be not simply new but sufficiently different that they would not have been obvious to the ordinarily skilled scientist-is in dispute in almost every case, and it is responsible for invalidating more patents than any other patent rule. It is also perhaps the most vexing doctrine to apply because the ultimate question of obviousness has an "I know it when I see it" quality that is hard to break down into objective elements.")

[9] *Graham*, 383 U.S. 2 (1966).

[10] While the burden of proof with regard to invalidity rests with the challenger of the patent, it is the patent owner's burden to come forward with evidence of secondary considerations, and the required nexus to the patent, to respond an invalidity challenge. *See* Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988).

[11] *Graham*, 383 U.S. 2 (1966).

These objective indicia of nonobviousness rely on real-world evidence and serve as a check against hindsight bias. Alongside other criteria for patentability (such as novelty and utility), these factors inform an evaluation of obviousness and decisions about whether a patent should be granted or deemed valid.

While objective indicia of nonobviousness, or secondary considerations, are just some of the factors considered to determine patent validity, they are often critical. The Federal Circuit has emphasized the importance of secondary considerations in evaluating patent validity, noting that such evidence "may often be the most probative and cogent evidence in the record," and that secondary considerations must always be considered ...[12] Further, the Federal Circuit has "emphasized that consideration of the objective indicia is part of the whole obviousness analysis, not just an afterthought."[13] Even though court decisions "have used the 'prima facie' and 'rebuttal' language, [the decisions] generally have made clear that a fact finder must consider *all* evidence of obviousness and nonobviousness before reaching a determination."[14]

III. COMMERCIAL SUCCESS ARGUMENT

An evaluation of commercial success typically considers whether a product that practices the at-issue patent has been successful, and whether that success has a nexus with the at-issue patent.[15] Significant marketplace success with a nexus to the at-issue patent often suggests that an invention provided something valuable and nonobvious that others in the field had not previously achieved or anticipated. In other words, commercial success may indicate that the invention solved a problem or fulfilled a market need that had not been addressed adequately.

The Federal Circuit explained in *Merck v. Teva (Merck I)* that "[c]ommercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art."[16] In *Merck v. Hospira* (*Merck II*), the Federal Circuit explained further that "… evidence of commercial success of a product or process... speaks to the *merits of the invention*."[17]

Analysis of commercial success is reasonably straight-forward when the invention and commercialization dates are close in time. The pharmaceutical industry presents unique challenges, however, because the time between invention and commercialization can be quite long – often a decade or more – in large part due to extensive regulatory requirements of the U.S. Food and Drug Administration (FDA). Because

---

12 Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1538-39 (Fed. Cir. 1983).

13 Leo Pharm. Prod., Ltd. v. Rea, 726 F.3d 1346, 1357 (Fed. Cir. 2013).

14 In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1077 (Fed. Cir. 2012) (emphasis in the original).

15 *See* John Jarosz and Robert Vigil, *Assessing Commercial Success at the U.S. Patent Trial and Appeal Board*, 8 INTERNATIONAL IN-HOUSE COUNSEL JOURNAL 32 (2015). *See also* Merck & Co. v. Teva Pharms. USA, Inc. (*Merck I)*, 395 F.3d 1364, 1376 (Fed. Cir. 2005)(citing *Graham,* 383 U.S. at 17-18); UCB, Inc. v. Actavis Labs. UT, Inc., 65 F.4th at 695 ("there must be 'a legally and factually sufficient connection' between the evidence [of commercial success] and the patent claims," citing Fox Factory, Inc. v. SRAM, LLC, 944 F.3d 1366, 1373 (Fed. Cir. 2019); Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311-12 (Fed. Cir. 2006); J.T. Eaton & Co. v. Atlantic Paste & Glue Co., 106 F.3d 1563, 1571 (Fed. Cir. 1997); Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 2017 U.S. Dist. LEXIS 48479, at *104-105 (D. Del. March 31, 2017).

16 *Merck I*, 395 F.3d at 1376.

17 *Merck Sharp & Dohme Corp. v. Hospira, Inc*. (*Merck II)*, 874 F.3d 724, 731 (Fed. Cir. 2017).

obviousness is evaluated as of the time of invention, not commercialization,[18] pharmaceutical cases allow for (and encourage) consideration of a large set of historical events from which to draw reasonable inferences about motivations to invent.

To evaluate the first step of the commercial success inquiry – whether the patented invention has achieved marketplace success – courts in pharmaceutical cases often consider a patent-practicing product's sales, shipments, prescriptions, prices, profits, performance relative to forecast, trends, and/or shares in the relevant marketplace. Critically, a drug (or any patent-practicing product) does not need to be the most successful one in the business to be deemed a marketplace success. As the federal district court of Delaware in *ViiV v. Lupin* wrote, "the fact that a commercial embodiment is not the most popular product on the market, however, does not dictate that the embodiment is not a … success. Although [it] did not capture the greatest share of the market, [it is] solidly in the top half of [the relevant class of drugs] through [its] sales history … [it] has consistently outperformed the majority of other [drugs] on the market and [] did as well during the peak years of [its] life cycle."[19]

For analysis of the nexus between the asserted marketplace success and the patented invention, courts consider whether the patented invention, as opposed to other factors, has been a driver of marketplace success. Those other factors that may have driven success include the patent owner's marketing efforts, favorable pricing, a first-mover advantage, or other business strategies. The existence of other factors does not negate the existence of a sufficient causal nexus, but an appropriate analysis often does (and should) consider the importance of the at-issue patent versus those other factors. In *Acorda v. Roxane*, the court recognized that while success may result from multiple features (some patented, others not), it was enough that the patented invention meaningfully contributed to that success: "[T]he proffered evidence regarding the importance of the drug's efficacy [taught by the patents] … to its sales is sufficient for establishing a nexus between the Acorda Patents and [the drug's] success."[20] In short, even though other factors were present, in that case, there was deemed to be a nexus to the asserted claims of the at-issue patents.

The view that there can be multiple factors driving success is consistent with the economic reality that every product offered and sold is a combination of attributes and characteristics. Together, those attributes and characteristics lead to marketplace demand for a product or service.[21] No single factor or attribute, whether covered by a patent or not, is ever the only driver of marketplace demand.

---

[18] *See, e.g.*, "2141 Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 [R-01.2024]," Department of Commerce, Patent and Trademark Office (USPTO), https://www.uspto.gov/web/offices/pac/mpep/s2141.html# ("This MPEP section is applicable regardless of whether an application is examined under AIA or under pre-AIA law. For applications subject to the first inventor to file (FITF) provisions of the AIA, the relevant time is 'before the effective filing date of the claimed invention'. For applications subject to pre-AIA 35 U.S.C. 102…, the relevant time is 'at the time of invention'."); Raytheon Techs. Corp. v. General Electric Co., 993 F.3d 1374, 1376 (Fed. Cir. 2021) ("We have explained that there is no absolute requirement for a relied-upon reference to be self-enabling in the § 103 context so long as the overall evidence for what was known at the time of invention establishes that a skilled artisan could have made and used the claimed invention.").

[19] ViiV Healthcare UK Ltd. v. Lupin Ltd., 6. F. Supp. 3d 461, 502 (D. Del. 2013).

[20] Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 2017 U.S. Dist. LEXIS 48479, at *111 (D. Del. March 31, 2017).

[21] Kelvin Lancaster, *A New Approach to Consumer Theory*, 74 J. OF POLIT. ECON. 2, 132-157 (1966).

While drawing a conclusion about nexus can be complex given that a host of factors often drive product success, in the pharmaceutical industry the analysis of what drives success differs, not surprisingly, from other industries. Largely because of regulatory requirements, pharmaceutical products must satisfy essential criteria to be approved --namely safety and efficacy, and must satisfy other essential criteria to be marketed successfully – such as acceptable bioavailability, formulation, and dosage regimen. Unlike other products – such as cell phones, which are often a collection of distinct and optional features (*e.g.*, camera quality, processor speed, or screen resolution) – a drug cannot be sold unless all necessary qualities are present. A cell phone with an older processor or screen can still be sold, albeit at a lower price, because its features are not interdependent. In contrast, a drug that lacks any of the essential qualities noted above, like acceptable safety or efficacy, cannot be sold at all.

Commercial success is rarely evaluated in isolation, and it should not be. Commercial success generally correlates with other objective indicia of nonobviousness, such as long-felt but unmet need, failure of others, and unexpected results. These factors often strengthen the argument that the invention was not obvious and represented a significant advancement in the field.

Patent owners frequently rely on evidence of commercial success to counter challenges to patent obviousness, and more generally, validity. This evidence can be a powerful tool in litigation, patent prosecution, licensing negotiations, and enforcement actions. When well-supported, this evidence can demonstrate persuasively that an invention was not only novel but also nonobvious.

IV. BLOCKING PATENT RESPONSE

A. Overview

A blocking patent defense is used to counter the value of commercial success in proving nonobviousness.[22] In invoking this defense, the alleged infringer argues that the patented invention's success was not driven by the value or teachings of the at-issue patent, but rather by the existence of an earlier blocking patent that prevented others from pursuing the at-issue invention.[23] As a result, according to the blocking patent

[22] In fact, a blocking patent defense is rarely invoked in non-pharmaceutical cases. *See* Melissa Brand & Hans Sauer, *Expansion of the Blocking Patent Doctrine: Trading Logic for Gremlins*, IP WATCHDOG (Oct. 12, 2018, 10:50 AM), https://ipwatchdog.com/2018/10/12/expansion-blocking-patent-doctrine-trading-logic-gremlins/id=102260/; David Manspeizer, *'Blocking Patent' Doctrine May Now Apply to All Technologies*, LAW360, (Dec. 6, 2019, 1:20 PM), https://www.law360.com/articles/1224918. Examples of non-pharmaceutical cases analyzing blocking patents include *Carpet Seaming Tape Licensing Corporation v. Best Seam Incorporated, Vectron Industries, Inc.,* 616 F.2d 1133 (9th Cir. 1980); *Int'l Mfg. Co. v. Landon, Inc.,* 336 F.2d 723(9th Cir. 1964); *Chemours Co. FC, LLC v. Daikin Industries, Ltd.,* 4 F.4th 1370 (Fed. Cir. 2021). This may be due to the inherent unpredictability of pharmaceutical science, which can create fact patterns that may appear to support a blocking patent defense. A lack of activity, however, may suggest substantial uncertainty rather than a block. Moreover, because of the uncertainty, relatively few inventions may be obvious to pursue. The defense may also be more applicable in pharmaceutical cases because such products typically involve a smaller number of patents—so a single strong patent may have a greater deterrent effect than in fields like consumer electronics, where numerous overlapping patents are common. Finally, the slower pace of innovation in the pharmaceutical sector—driven largely by extensive regulatory requirements—may make the absence of competing R&D appear more consistent with blocking, even when that may not be the case.

[23] In pharmaceutical litigations, a compound patent often is represented to be a blocking patent. As described below, a compound patent can and does block certain activity, but not all inventive activity, and only for the period in which it is in force.

argument, the patent-practicing invention succeeded, assuming it did, because the blocking patent prevented others from earlier invention. Accordingly, by the argument, there is no nexus (or causal connection) between the patent-practicing invention's success and the at-issue patent.[24]

In its 2005 opinion in *Merck I*, the Federal Circuit wrote that when "others were legally barred from commercially testing" the ideas of the claimed invention, "[f]inancial success is not significantly probative of [the commercial success] question."[25] In its 2018 opinion in *Acorda v. Roxane*, the Federal Circuit was more expansive in its explanation of the doctrine:

> A patent has been called a 'blocking patent' where practice of a later invention would infringe the earlier patent. The existence of such a blocking patent may deter non-owners and non-licensees from investing the resources needed to make, develop, and market such a later 'blocked' invention, because of the risk of infringement liability and associated monetary or injunctive remedies. If the later invention is eventually patented by an owner or licensee of the blocking patent, that potential deterrent effect is relevant to understanding why others had not made, developed, or marketed that 'blocked' invention and, hence, to evaluating objective indicia of the obviousness of the later patent.[26]

In *Acorda*, the Federal Circuit provided new context and structure to the blocking patent defense when it identified considerations that are relevant in evaluating whether a patent was blocking.[27] It offered a helpful set of factors for analyzing whether a prior patent may have deterred or prevented others—aside from the patent holder—from developing the claimed invention:

- **challenging the blocking patent** – whether others believed the "blocking patent" could be successfully challenged;
- **costliness of the project** – the financial resources needed for successful research and development;
- **risk of research failure** – the likelihood that the project might fail scientifically or commercially;

---

[24] The growing reliance on the blocking patent defense may be an attempt to fight presumed evergreening, which is said to be a business strategy used by companies to extend the life of their patents. *See, e.g.*, Ali A. Alkhfaji, et al., *Impact of Evergreening on Patients and Health Insurance: A Meta Analysis and Reimbursement Cost Analysis of Citalopram/Escitalapram Antidepressants*, 10 BMC MEDICINE 142, 1 (2012) ("Evergreening refers to owners of pharmaceutical products using numerous strategies, such as patent laws and minor drug modifications, to extend their monopoly privileges with their products."). This practice is said to include taking out new patents, buying out competitors, or making minor modifications to existing patents. The presumed goal is for a patent owner to maintain its market share and/or high prices. *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590 (2018). Of course, there is great debate about the existence, extent, and merits of patent evergreening.

[25] Merck & Co. v. Teva Pharms. USA, Inc. (*Merck I)*, 395 F.3d 1364, 1377 (Fed. Cir. 2005). *See also* Hospira, Inc. v. Amneal Pharms., 285 F. Supp. 3d 776, 797 (the existence of a blocking patent means that evidence of commercial success of the product embodying the invention has little probative value.)

[26] Acorda Therapeutics, Inc. v. Roxane Labs., Inc*.,* 903 F.3d 1310, 1337, 1342 (Fed. Cir. 2018) (citing Richard Robbins, *Subtests of 'Nonobviousness': A Nontechnical Approach to Patent Validity*, 112, U. PA. L. REV. 1169, 1177 (1964)). Zhu's definition is that "'blocking patents' occur when a dominating patent with a broader scope encompasses a part of an improvement patent with a narrower scope." Jasmine Zhu, *Are Blocking Patents Blocking Innovations? A Changing Landscape of Nonobviousness Analysis and a Survival Guide for Inventors*, 29 FED. CIR. B.J. 317, 324 (2019).

[27] DeForest McDuff, Noah Brennan & Mickey Ferri, *Thinking Economically About Blocking Patents: Did Acorda Create a New Paradigm?*, 12 LANDSLIDE 42, 43 (2020).

- **nature of potential improvements** – whether the potential improvements are outside the coverage of the blocking patent;
- **market opportunities** – the size of the market anticipated for the potential improvements;
- **costs of development and commercialization** – the expenses required to develop the improvements and bring them to market;
- **risk of losing the invention race** – the possibility that the blocking patent owner or licensee might beat the potential innovator to the market with the at-issue improvements;
- **license availability and terms** – the risk that the blocking-patent owner might refuse to license the improvement or demand terms so burdensome that the project becomes economically unviable; and
- **other investment opportunities** – the weight of the above factors in relation to alternative opportunities for investment available to the innovator.[28]

While asserted pharmaceutical blocking patents typically are compound patents, blocking patents can take many forms, as new pharmaceutical products often benefit from multiple innovations. As the Federal Circuit noted in *Merck II*, "developers of new compounds often obtain a package of patents protecting the product, including compound, formulation, use, and process patents."[29] The pursuit of multiple patents and different types of patents is due to "Patent Office restriction requirements relating to the technicalities of patent classifications and rulings that various aspects of claiming an invention cannot be claimed in the same patent. Or they may result from continuing improvements in a product or process."[30]

While the Federal Circuit has accepted the blocking patent defense in pharmaceutical cases since at least *Merck I* in 2005, academic scholarship has embraced the defense since well before then.[31] As noted above, the use and acceptance of the blocking patent defense at the Federal Circuit has accelerated over time. From 2014 through 2024, the Federal Circuit heard three times as many cases where a blocking patent defense was argued, and it found that a block existed in over three times as many cases, as it did in the prior 10 years.[32]

The growing use of the blocking patent defense in patent litigation has raised concerns among legal scholars and commentators about its potential downstream implications. Jasmine Zhu warns that "unduly harsh" or heightened standards resulting from an increasingly robust blocking patent defense in commercial success cases may lead to a 'slippery slope' for all secondary considerations, undermining the importance of other secondary considerations such as long-felt need and unexpected results. Over time this trend could "'stifle innovation' or 'disincentivize[]' innovation in the pharmaceutical industry."[33]

---

28 *Acorda,* 903 F.3d at 1338.

29 Merck Sharp & Dohme Corp. v. Hospira, Inc. (*Merck II)*, 874 F.3d 724, 730 (Fed. Cir. 2017).

30 *Id.* at 730-31.

31 *See, e.g.*, Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents*, 62 TENN. L. REV. 75 (1994).

32 *See supra* notes 5-6 and accompanying text.

33 Zhu, *supra* note 26, at 329-330 (citing Daniel Winston Daniel & Bryana McGillycuddy, *A New Framework for 'Blocking Patents' and Obviousness?* LAW360 (Oct. 18, 2018, 3:56 PM), https://www.law360.com/articles/1092370; Matthew Bultman, *Fed. Circ. Ruling Takes 'Blocking Patents' to New Places*, LAW360 (Sept. 18, 2018, 7:07 PM), https://www.law360.com/articles/1083942/fed-circ-ruling-takes-blocking-patents-to-new-places).

Perhaps not surprisingly, the pharmaceutical industry has pushed back against the growing acceptance of the blocking patent defense, arguing that it could deter innovation by effectively "devalu[ing] pharmaceutical innovation."[34]

B. Brief History

In *Merck I*,[35] the Federal Circuit addressed the nonobviousness of a patent embodied in the once-weekly dosing regimen of Merck's osteoporosis drug Fosamax™.[36] Although the court acknowledged the success of the drug and its dosing regimen, it concluded that such evidence was "not significantly probative" of nonobviousness of the patent at issue.[37] In its opinion, the court pointed to an earlier-issued patent covering administration of the active pharmaceutical ingredient, which gave Merck the exclusive right to the relevant compound used in Fosamax™. This indicated to the court that Merck blocked others from research and commercialization in that domain.[38] As a result, the Federal Circuit concluded that "the inference of nonobviousness of weekly-dosing, from evidence of [product] success, is weak."[39] Importantly, the *Merck I* court did not address alternative ways, beyond testing in the U.S., in which inventive activities could have occurred.[40]

In *Galderma v. Tolmar* (2013), the Federal Circuit echoed this reasoning in its analysis of the success of Galderma's product Differin Gel 0.3%, writing that the existence of other Galderma patents "blocked the market entry of 0.3% adapalene products until their expiration in 2010, long after Galderma invented 0.3% adapalene compositions of the asserted claims. As a result, no entity other than Galderma could have successfully brought [0.3% adapalene] to market prior to 2010."[41] The court concluded, consistent with *Merck I*, that the success of Differin Gel, 0.3%, was of "minimal probative value" in demonstrating nonobviousness.[42]

The Federal Circuit has continued to endorse the use of the blocking patent defense.[43] In *UCB v. Actavis* (2023),[44] the Federal Circuit upheld a district court finding that UCB's extensive patent portfolio weakened the inference of nonobviousness based on commercial success, noting that other UCB patents had

---

[34] *See, e.g.,* Brief for Allergan, Inc et al. as Amici Curiae Supporting Petitioner at 18, *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.,* No. 18-1280 (U.S. May 8, 2019).

[35] Merck & Co. v. Teva Pharms. USA, Inc. (*Merck I)*, 395 F.3d 1364 (Fed. Cir. 2005).

[36] *Id.* at 1364-1367. The patent at issue in this case, U.S. Patent No. 5,994,329, was entitled "Method for Inhibiting Bone Resorption," taught a "method of treating and preventing osteoporosis through less-than-daily administration of certain compounds." *Id.* at 1366.

[37] *Id.* at 1377.

[38] *Id*.

[39] *Id*.

[40] *Id.* at 1371-1377.

[41] Galderma Labs., L.P. v. Tolmar, Inc*.,* 737 F.3d 731, 741 (Fed. Cir. 2013).

[42] *Id*. at 740-41. Notably, the dissent in *Galderma v. Tolmar* wrote that success was asserted based on market share comparisons with other dosage strengths, which were not blocked by the earlier Galderma patents. *Id.* at 797 (Newman, J., dissenting). This raises the question of whether the majority gave sufficient weight to evidence of commercial performance in a competitive landscape.

[43] Allergan, Inc. v. Teva Pharm USA, Inc., 742 Fed. Appx. 511 (Fed. Cir. 2018); Merck Sharp & Dohme Corp. v. Hospira, Inc., 874 F.3d 724 (Fed. Cir. 2017); Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310 (Fed. Cir. 2018); Hospira Inc. v. Amneal Pharms LLC, 748 Fed. Appx. 1024 (Fed. Cir. 2019); BTG Int'l Ltd. v. Amneal Pharms. LLC, 923 F.3d 1063 (Fed. Cir. 2019); Sanofi-Aventis Deutschland GMBH v. Mylan Pharms. Inc., 791 Fed. Appx. 916 (Fed. Cir. 2019); UCB, Inc. v. Actavis Labs. UT, Inc., 65 F.4th 679 (Fed. Cir. 2023).

[44] *UCB v. Actavis,* 65 F.4th 679.

"operated as blocking patents dissuading competitors from developing" comparable delivery systems for the active pharmaceutical ingredient.[45] UCB argued that the lower court's ruling "would effectively brand all co-owned patents as 'blocking.'"[46] The Federal Circuit disagreed, relying, in part, on the fact that UCB's expert had not analyzed whether UCB's other patents were responsible for the product's success. The court wrote that "[t]he district court, in determining that UCB's extensive patent rights reduced the weight of the evidence of commercial success, did not impermissibly create a bright-line rule; instead, it limited its analysis to the specific facts in the record."[47] The Federal Circuit declined to reconsider UCB's argument that the incentive for a third-party to negotiate a license agreement might "'expand[] the pie,'" and opted to not reweigh the evidence.[48]

In April 2024, the Federal Circuit issued an opinion in *Janssen v. Teva,* involving the potential sale of a generic version of Janssen's Invega Sustenna™, which embodied a patent relating to dosing regimens of paliperidone palmitate indicated for the treatment of schizophrenia.[49] While the lower court did not find blocking patent arguments persuasive, on appeal, Teva argued that the lower court improperly disregarded the impact of blocking patents and the disincentives that they created for non-owners and non-licensees to invest in activities that might be found to infringe.[50] The Federal Circuit initially agreed with Teva, writing that Janssen's arguments were based on two faulty premises.[51] First, Janssen's analysis of blocking patents focused broadly on the "blocked space" rather than on the specific invention at issue.[52] The court noted that even if a different formulation of paliperidone palmitate was not blocked, it was not relevant to the case at hand.[53] Second, the Federal Circuit rejected Janssen's broad argument that the FDA safe harbor provision allows for inventive activity and therefore defeats the blocking patent defense. The Federal Circuit emphasized that the safe harbor provision is merely one aspect of the regulatory process and does not negate the need for a fact-specific inquiry into commercial success.[54] Moreover, the safe harbor protection is eliminated once FDA submissions are complete because the safe harbor provision no longer protects activity after that point.[55]

Following these findings, the Federal Circuit in *Janssen v. Teva* remanded the case to the district court to re-evaluate secondary considerations of nonobviousness in light of the Federal Circuit's opinion.[56] However, in November 2024, the district court issued an opinion reaffirming its previous findings relating to Invega Sustenna™'s commercial success and long-felt need.[57] Rejecting Teva's claims that blocking patents had discouraged competitors from developing alternatives, the district court pointed to evidence that there were, in fact, incentives for research and development related to paliperidone palmitate.[58] The

---

45 *Id.* at 696.

46 *Id*.

47 *Id.* at 696-697.

48 *Id.* at 697.

49 Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 97 F.4th 915 (Fed. Cir. 2024).

50 *Id.* at 935-936.

51 *Id.* at 936.

52 *Id.*

53 *Id.*

54 *Id.*

55 *Id.*

56 *Id.* at 937.

57 Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 2024 U.S. Dist. LEXIS 227696, at *84-86 (D.N.J. Nov. 21, 2024).

58 *Id*.

district court emphasized that Teva itself had filed a patent application concerning the preparation and purification of paliperidone palmitate in January 2008, prior to the expiration of the asserted blocking patents.[59]

V. PROBLEMS WITH THE BLOCKING PATENT DEFENSE

A. Not Often Relevant for Commercial Success

The focus of the blocking patent defense in a commercial success case is whether inventive activity before the priority (invention) date of the patent at issue in the litigation was discouraged or prevented by the claimed blocking patent. In commercial success cases, whether or not a blocking patent defense is raised, some of the measures of success commonly evaluated in pharmaceutical cases are a product's sales, shipments, prescriptions, prices, profits, performance relative to forecast, trends, and market shares over time. These metrics are evaluated *ex post*, after the product has been commercialized and well after the priority (invention) date of the patent at issue.[60] This raises a fundamental question: what role can commercial success play in assessing nonobviousness given that no such success existed at the time of invention (because there was no commercialization at that point)?[61] That is particularly true in pharmaceutical contexts, where the path from invention to market may span a decade or more. In this context, commercial success may be best understood as *ex post* evidence of possible *ex ante* expectations of success. If others had expected success, they likely would have pursued the invention themselves. However, no court has framed commercial success in these terms.

In commercial success cases, marketplace performance of a patent-practicing product typically is (and usually needs to be) evaluated in *relative* terms. Revenue figures alone, such as $100,000, are meaningless without context. That same amount could represent a dominant market share in one therapeutic area and a negligible share in another. In this regard, it is important to note that defining the relevant market too narrowly—perhaps limiting the market to only products embodying the patented invention when other treatments are available for the same indication—renders commercial success nearly tautological. A product will always dominate a market composed solely of itself,[62] thereby rendering commercial success uninformative on the obviousness question.

The appropriateness of a narrow relevant market was addressed by the dissent in the Federal Circuit's *Acorda v. Roxane* case. The dissent wrote that "[c]ommercial success is measured against the products available for the same purpose, not against infringing copies of the patented product… [t]he objective indicia of unobviousness are measured against the state of the science and in the commercial context."[63] That broader view aligns with sound economic principles. Zhu (2020) observed that

---

59 *Id*.

60 In some cases, pre-launch forecasts (*i.e*., *ex ante* expectations) are available and can be used to assess *ex post* performance.

61 Commercial success, and indeed all secondary considerations, are real world surrogates of the *ex ante* assessments at issue. They can only come after the fact, so they end up being used in court, but not at the USPTO.

62 An exception will be in instances in which there has been licensing of the patented invention. But in those instances, the patented invention may have a 100 percent share of the technology market.

63 *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.,* 903 F.3d 1310, 1353-1354 (Newman, J., dissenting).

> [T]here are often many solutions for one technical problem, one single dominating patent is unlikely to encompass all of the solutions to one problem… there are usually options to get around the existing technology of the dominating patent… The extent of how much 'blocking' has occurred can be helpful for courts to determine when a blocking patent situation exists and thereby to evaluate the evidence of objective indicia... If there were reasonable alternatives, the technological advancement was not actually blocked and other competitors, including non-licensees of the existing patent, were not actually out of options.[64]

At the same time, if the relevant market is defined to include all potential solutions to a problem—rather than just the specific patented invention—the blocking patent defense often is of no moment. Because a blocking patent is one that is said to have blocked the path to a particular product or process, it usually does not block the path to other products or processes.[65] Further, many of those other non-covered products (and processes), whether in the same drug class or not, are competitors in the relevant market and should be used for assessing the performance of the patent-practicing product. A blocking patent often does not block that competition.

The issue of the relevant market arose in *Sanofi-Aventis v. Mylan*, where the patented product at issue was Lantus, a long-acting insulin formulation.[66] In its rebuttal to the blocking patent defense, Sanofi-Aventis argued that the development of the asserted patented technology practiced by Lantus™ was not blocked "because the glargine compound patents [the claimed blocking patents] did not block all long-acting insulins from entering the market."[67] Although Sanofi-Aventis' argument has economic appeal, the Federal Circuit ultimately rejected this argument, pointing to Sanofi-Aventis' previous argument that the relevant market encompassed the "claimed glargine-surfactant combination," not insulin-surfactant combinations generally, nor insulin even more generally.[68]

Another view of market definition appeared in *ViiV v. Lupin*,[69] where the federal district court of f Delaware evaluated two relevant market options: a market confined to a certain class of drugs (broader than just a single compound) and a much broader market encompassing all therapies capable of treating HIV.[70] The court concluded that the appropriate market was the more narrow one (a certain class of drugs), though still broader than a single compound.[71] The court rejected the idea of broadening the market to include all possible drug classes, finding that the relevant market should include just the drug class at issue.[72] With regard to the blocking patent defense, the court found that the commercial success of the patented

---

64 Zhu, *supra* note 26 at 342.

65 There appears to be little agreement among defendants, their experts, and courts on whether a patent can be deemed to be blocking if it disincentives just some invention in an area or all invention in that area. As discussed below, the degree of the block matters, and is one input to determining the direction of the secondary considerations.

66 Sanofi-Aventis Deutschland GMBH v. Mylan Pharms, Inc., 791 Fed. Appx. 916, 919 (Fed. Cir. 2019).

67 *Id.* at 928.

68 *Id*.

69 ViiV Healthcare UK Ltd. v. Lupin Ltd., 6 F. Supp. 3d 461, 501 (D. Del. 2013).

70 *Id.*

71 *Id.*

72 *Id.* at 501-502 ("The Court must first define the relevant market. ViiV argues that the relevant market is limited to drug products in the NRTI class. Defendants argue that the relevant market is all classes of anti-HIV drugs… The market for Epzicom and Trizivir is the NRTI market.")

combination therapies at issue in *ViiV v. Lupin* could not be completely attributed to the existence of blocking patents. It wrote that "[t]his is not a situation where a patentee was able to 'block' others…."[73] Further, it wrote that the patentee was not able to block others "attempting to make the claimed inventions for many years – they were formulated a matter of months into [one of the blocking patents'] exclusivity period."[74] That is, the effectiveness of the at-issue combination therapies was shown only a few months after the rights to one of the blocking patents were obtained.[75]

In narrow markets—limited to products that practice the patented invention—commercial success becomes a weak indicator of nonobviousness because the "relative" success of the patent practicing product (*i.e.*, market share dominance) is almost assured. In broad markets—encompassing all therapies for the underlying condition—the blocking patent defense may likewise lose relevance, as most competitors remain unaffected by the blocking patent.

A blocking patent defense, however, can matter when considering other nonobviousness factors beyond commercial success, such as long-felt but unmet need, failure of others, and unexpected results.[76] According to David Manspeizer's reading of *Acorda*, the blocking patent doctrine applies to each of the six nonobviousness considerations.[77] Indeed, the blocking patent defense does call for an evaluation of incentives (and impediments) well prior to commercialization of a product.

While a blocking patent may discourage certain (sometimes many) inventive and commercial activities, thereby enhancing the success of the patent practicing product, understanding the relevant market, the scope of the blocking patent, and the timing of the blocking patent is critical. Understanding these and other nuances may explain why, as shown below, widespread and effective blocking remains the exception, not the rule.

B. Not a Theoretical Construct

The Federal Circuit consistently has emphasized that determining whether a blocking patent is the reason for an invention's commercial success is a question of fact, dependent upon the specific circumstances of each case.[78]

In *Merck II* in 2017,[79] the district court had considered the preclusive effect of a prior patent when assessing the success of Merck's Invanz™ product. On appeal, the Federal Circuit cautioned that "Merck's evidence of commercial success should not have been discounted simply because of the existence of another patent of which Merck was the exclusive licensee,"[80] and emphasized that commercial success remains a "fact-specific inquiry."[81] It noted that the mere existence of one or many blocking patents does

---

73 *Id.* at 503.

74 *Id.* at 503.

75 *Id.*

76 *See* Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 97 F.4th 915, 936 (Fed. Cir. 2024).

77 David Manspeizer, *'Blocking Patent' Doctrine May Now Apply to All Technologies*, LAW360 (Dec. 6, 2019, 1:20 PM), https://www.law360.com/articles/1224918.

78 *See, e.g.*, Galderma Labs., L.P. v. Tolmar, Inc., 737 F.3d 731 (Fed. Cir. 2013).

79 Merck Sharp & Dohme Corp. v. Hospira, Inc. (*Merck II)*, 874 F.3d 724, 730-31 (Fed. Cir. 2017).

80 *Id.* at 730.

81 *Id.* at 731.

not, by itself, "necessarily detract from the evidence of commercial success of a product or process, which speaks to the merits of the invention, not to how many patents are owned by a patentee."[82]

In *UCB v. Actavis* in 2023, the Federal Circuit again rejected the broad proposition that all co-owned patents automatically qualify as "blocking patents."[83] The Court pointed out that UCB's expert economist failed to analyze whether UCB's multiple patents were responsible for the asserted commercial success.[84] While it affirmed the lower court's holding that "UCB's extensive patent rights reduced the weight of the evidence of commercial success," in rendering its decision, the court emphasized that its determination was based on the specific factual record—not a reflection of the existence of a bright-line rule. [85]

Despite the Federal Circuit's repeated emphasis on fact-specific analysis, many defendants in Abbreviated New Drug Application ("ANDA") cases continue to advance (and some courts continue to accept) the broad argument that if a prior patent exists, in particular one related to the compound used in the product that practices the at-issue patent, the nexus chain between commercial success and the patented invention is broken. For example, in *Merck II*, the federal district court of Delaware wrote that "[t]he weight of the commercial success evidence is, however, discounted by the blocking effect of the '820 patent… Since the '820 patent blocked anyone other than Zeneca and Plaintiff from commercially exploiting ertapenem, no other industry players and the many persons of skill in the art employed by them had any incentive to develop alternative formulations for ertapenem."[86] The court, however, provided no evidence, or argument, about what specifically was blocked and when. The mere existence of a legal "fence" appeared sufficient to negate the probative value of commercial success, contrary to the Federal Circuit's directive for a more nuanced, fact-driven inquiry.[87]

Although a patent can indeed discourage (or block) certain innovative activity beyond what has already been patented, the significance of that block depends on the facts, particularly what was blocked and when. A blocking patent defense that is not grounded in specific evidence is neither persuasive nor consistent with Federal Circuit precedent. In *Acorda v. Roxanne*, the plaintiff argued on appeal "that the court improperly applied a categorical rule that a blocking patent (the Elan patent) negates any findings in favor of Acorda on the objective indicia of commercial success, failure of others, and long felt but unmet need."[88] The Federal Circuit rejected this argument, writing "[w]e think, however, that the district court's opinion is best read not as invoking a categorical rule, but as drawing conclusions on the limited factual

---

82 *Id.* (emphasis in original). *See also* Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310, 1338 (Fed. Cir. 2018) ("as a theoretical matter, a blocking patent may or may not deter innovation in the blocked space.")

83 UCB, Inc. v. Actavis Labs. UT, Inc., 65 F.4th 679. 696 (Fed. Cir. 2023).

84 *Id.* at 696-97.

85 *Id*.

86 Merck Sharp & Dohme Corp. v. Hospira Inc., 221 F. Supp. 3d 497, 512-13 (D. Del. 2016). Selling a commercial product, of course, is not the only way to generate value from a patented invention. Among other things, rights to a patented invention can be licensed, sold, and/or enforced in litigation.

87 In *Otsuka v. Sandoz*, defendant's chemistry expert offered a blocking patent defense in response to plaintiff's assertion of commercial success of its patent-practicing product. When cross examined about several patent applications, including one filed by a named defendant in the lawsuit, that actually cited the claimed blocking patent, the expert testified that he did not consider any of the patent applications citing the blocking patent in forming his opinions. His basis for claiming that there was a block was "I lived through blocking patents, so my opinion as a medicinal chemist is based on my own experience." Otsuka Pharm. Co. v. Sandoz, Inc., No. 3:07-cv-01000, Trial Tr. 307-318, ECF No. 346 (D. N.J. Aug. 6, 2010).

88 Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310, 1328-29 (Fed. Cir. 2018).

record created in this case bearing on the effect of a blocking patent."[89] The ruling here underscores that the blocking patent argument is not a categorical rule and should not be applied as such when analyzing the nonobviousness factors.

C. Not Dispositive as to Nonobviousness

A showing of commercial success typically is insufficient on its own to support a finding of nonobviousness. The blocking patent defense typically is insufficient on its own to undercut a finding of nonobviousness. Commercial success and the possible existence of a blocking patent represent some of the evidence that often is considered.

The Federal Circuit repeatedly has emphasized that blocking patent evidence, or the lack of it, should serve to strengthen or weaken the weight of all secondary consideration evidence. This flexible, case-specific approach ensures that the defense is not treated as a categorical rebuttal to evidence of nonobviousness but is, instead, carefully tailored to the facts of each case and put in context.

In *Acorda v. Roxane*, the Federal Circuit described its 2013 decision in *Galderma v. Tolmar*:

> Because earlier patents owned by Galderma may have 'blocked' competition to market the FDA-approved product by any entity other than Galderma, we reasoned that the commercial success of the product was 'of 'minimal probative value'' and not sufficient to justify a conclusion of nonobviousness in light of the other evidence supporting obviousness.[90]

According to the Federal Circuit in *Merck II,* "[w]e have previously held that where 'market entry was precluded' by another patent and by exclusive statutory rights stemming from FDA marketing approvals, the 'inference of nonobviousness... from evidence of commercial success[] is weak.'"[91] Similarly, in *UCB v. Actavis*, the Federal Circuit found that the presence of blocking patents "weakened [the] evidence of commercial success."[92]

The interplay between commercial success and the preclusive effect of a blocking patent does not exist in isolation; instead, it must be evaluated within the broader context of all nonobviousness considerations. A blocking patent and the commercial success argument to which it responds can either strengthen or weaken a case for nonobviousness – but is not dispositive on its own.[93] The Federal Circuit confirmed this in *Merck II*, writing "… we do not discern clear error in the district court's determination that Merck's evidence of commercial success could not overcome the weight of the evidence that the claimed process was substantially described in the prior art and required only improvement by the use of established variations."[94]

---

89 *Id.* at 1337.

90 *Id.* at 1337-1338 (quoting *Merck I*).

91 *Merck II*, 874 F.3d at 730 (quoting *Merck* I).

92 UCB, Inc. v. Actavis Labs. UT, Inc., 65 F.4th 679. 696 (Fed. Cir. 2023).

93 *See, e.g., Merck I*, 395 F.3d at 1377 (because entry was as a result of Merck's right to a blocking patent, "the inference of nonobviousness of weekly-dosing, from evidence of commercial success, is weak.")

94 *Merck II*, 874 F.3d at 731.

This underscores that the ultimate determination of nonobviousness rests on a thorough, fact-specific analysis relevant facts—not on any single consideration in isolation.

D. Not a Block to Many Forms of Activity

1. Substantive Block

A patent is granted for a specific invention, and its scope or coverage is limited to what is explicitly claimed. The claimed invention may pertain to a pharmaceutical compound, a composition of matter, a method of treatment, or a process for manufacturing.[95] Patent rights confer a *right to exclude*—allowing the patent holder to prevent others from making, using, offering for sale, or selling the invention within a specific country, or importing it into the country.

In pharmaceutical litigations, an asserted blocking patent often refers to one that covers the underlying pharmaceutical compound or genus of compounds. As shown in Table 1 below, in 5 of the 9 Federal Circuit pharmaceutical cases since 2005 in which the Court has found there to be a blocking patent, at least one of the blocking patents was a compound patent; one more case involved a composition of matter patent.[96]

[95] For the analyses undertaken and described below, patent "type" was determined by Sagacious IP, the data vendor. According to correspondence with Sagacious' representative, "[the t]ype of Patent field has been populated based on Claim focus. [e.g.,] For US4621077A, there is one claim… method of treatment of urolithiasis and inhibiting bone reabsorption which consists of administering to a patient in need thereof an effective amount of 4-amino-1-hydroxybutane-1,1-biphosphonic acid. Details like composition and process are not claimed. Since the focus is on method of treatment, patent type has been indicated accordingly."

[96] Merck & Co. v. Teva Pharms. USA, Inc., 395 F.3d 1364 (F3d. Cir. 2005); Pfizer Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364 (Fed. Cir. 2008); Otsuka Pharm. Co. v. Sandoz, Inc., 678 F.3d 1280 (Fed. Cir. 2012); Galderma Labs., L.P. v. Tolmar, Inc., 737 F.3d 731 (Fed. Cir. 2013); ViiV Healthcare UK Ltd. v. Lupin Ltd., 594 Fed. Appx. 686 (Fed. Cir. 2015); UCB, Inc. v. Accord Healthcare, Inc., 890 F.3d 1313 (Fed. Cir. 2018); Allergan, Inc. v. Teva Pharm USA, Inc., No. 742 Fed. Appx. 511 (Fed. Cir. 2018); Merck Sharp & Dohme Corp. v. Hospira, Inc., 874 F.3d 724 (Fed. Cir. 2017); Hospira Inc. v. Amneal Pharms LLC, 748 Fed. Appx. 1024 (Fed. Cir. 2019); Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310 (Fed. Cir. 2018); BTG Int'l Ltd. v. Amneal Pharms. LLC, 923 F.3d 1063 (Fed. Cir. 2019); Sanofi-Aventis Deutschland GMBH v. Mylan Pharms. Inc., 791 Fed. Appx. 916 (Fed. Cir. 2019); UCB, Inc. v. Actavis Labs. UT, Inc., 65 F.4th 679 (Fed. Cir. 2023); Amgen, Inc. v. Sandoz Inc., 66 F.4th 952 (Fed. Cir. 2023); Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 97 F.4th 915 (Fed. Cir. 2024).

Table 1: Federal Circuit Pharmaceutical Blocking Patent Cases

	At-Issue Patent					Blocking Patent			
1) Case Name	**2) Patent Number**	**3) Priority Date**	**4) Grant Date**	**5) Expiration Date**	**6) At-Issue Compound**	**7) Patent Number**	**8) Grant Date**	**9) Expiration Date**	**10) Patent Type**
Merck v. Teva (2005)	5,994,329	08/14/1998	11/30/1999	07/17/2018	Alendronate monosodium trihydrate	4,621,077	11/04/1986	08/06/2007	Method of Treatment
Galderma Labs v. Tolmar (2013)	7,579,377	09/10/2004	08/25/2009	02/25/2025	Adapalene	RE 34,440	11/09/1993	01/16/2012	Composition, Method of Treatment
	7,737,181	07/28/2006	06/15/2010	08/29/2024					
	7,834,060	05/07/2009	11/16/2010	05/16/2023					
	7,838,558	04/15/2008	11/23/2010	03/12/2023		4,717,720	01/05/1988	05/31/2010	Compound
	7,868,044	05/03/2010	01/11/2011	03/12/2023					
Allergen, Inc. v. Teva Pharm. (2017)	8,629,111	08/14/2013	01/14/2014	08/27/2024	Cyclosporin	4,839,342	06/13/1989	08/02/2009	Method of Treatment
	8,648,048	08/14/2013	02/11/2014	08/27/2024					
	8,685,930	08/07/2013	04/01/2014	08/27/2024		5,474,979	12/12/1995	05/17/2014	Composition
	9,248,191	03/21/2014	02/02/2016	08/27/2024					
Merck Sharp & Dohme Corp. v. Hospira (2017)	6,486,150	04/27/2001	11/26/2002	10/27/2020	Ertapenem	5,478,820	12/26/1995	11/21/2015	Compound
Hospira, Inc. v. Amneal Pharm. (2018)	8,242,158	01/04/2012	08/14/2012	01/04/2032	Dexmedetomidine	4,910,214	03/20/1990	07/15/2013	Compound
	8,338,470	07/03/2012	12/25/2012	01/04/2032					
	8,455,527	11/15/2012	06/04/2013	01/04/2032					
	8,648,106	04/22/2013	02/11/2014	01/04/2032					
Acorda Therapeutics, v. Roxane Labs. (2018)	8,007,826	12/13/2004	08/30/2011	05/26/2027	4-aminopyridine	5,540,938	07/30/1996	10/24/2019	Compound
	8,663,685	07/20/2011	03/04/2014	01/18/2025					
	8,354,437	04/08/2005	01/15/2013	12/22/2026					
	8,440,703	11/18/2011	05/14/2013	04/08/2025					
BTG Int'l Ltd. V. Amneal Pharm. (2019)	8,822,438	02/24/2011	09/02/2014	08/24/2027	Abiraterone	5,604,213	02/18/1997	07/25/2017	Methods of Use
Sanofi-Aventis Deutschland GMBH v. Mylan Pharm. (2017)	7,476,652	03/25/2005	01/13/2009	07/23/2023	Insulin glargine	5,656,722	08/12/1997	09/12/2014	System, Method of Manufacture
	7,713,930	12/04/2008	05/11/2010	06/13/2023		6,100,376	08/08/2000	09/03/2012	Compound
UCB, Inc. v. Actavis Labs. (2023)	10,130,589	01/31/2018	11/20/2018	12/22/2030	Rotigotine	6,884,434	04/26/2005	03/31/2021	System
						7,413,747	08/19/2008	09/21/2020	System

Compound patents block others from making, using, offering for sale, and selling that compound. They do not block others from making, using, or selling other compounds. Some purported blocking patents cover a method of treatment or a process for manufacturing. They do not block others from making, using, offering for sale, or selling the compound outside the claimed confines. For example, in *Otsuka v. Lupin,* Lupin claimed that two patents were blocking: U.S. Patent Nos. 5,258,510 ("the '510 Patent") and 5,753,677 ("the '677 Patent"). The '510 Patent covered the active pharmaceutical ingredient, tolvaptan, in the relevant patent-practicing product, Jynarque™; while the '677 Patent covered the use of tolvaptan to treat a specific condition.[97]

In the pharmaceutical industry, innovation typically proceeds through a series of resource-intensive[98] activities that can be grouped into three general phases: (1) research, (2) development, and (3) marketing.[99] It is rare for a so-called blocking patent to hinder work in all three of these phases. In fact, as described below, considerable activity often occurs *after* the issuance of a claimed blocking patent.

Further, while existing patents do have the power to exclude use of certain inventions in future products, the act of patenting an invention also opens that technology up to further innovation. Patent publication is, by law, a process of divulging inventors' proprietary knowledge publicly, to the world.[100] The U.S. Supreme Court pointed to this goal of patent publication, clarifying that "the publication requirement seeks to inform the work of follow-on inventors and reduce duplicative research and development (R&D)."[101] By restricting the use of a particular invention, a blocking patent may encourage competitors and researchers to explore alternative approaches, develop workaround solutions, or advance related compounds and methods of treatment. Academic research has found that "accelerated patent publication [has] had substantial effects on patenting, R&D, and citations by follow-on inventors," and that the mechanism behind these outcomes is "enhanced knowledge diffusion."[102] This dynamic accelerates progress by fostering diversification of research efforts, ultimately resulting in additional innovation.

Regulatory protections for research also mute the power of a blocking patent. The safe harbor provision in 35 U.S.C. §271(e)(1) plays a critical role in limiting the impact of blocking patents in the pharmaceutical industry. The provision provides that "[i]t shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention... solely for uses reasonably related to the development and submission of information under a federal law which regulates

---

97 Otsuka Pharm. Co. v. Lupin Ltd., 2024 U.S. Dist. LEXIS 135251, *19, *35-39 (D. Del. July 31, 2024).

98 *See* McDuff et al., *supra* note 27 at 45 ("In the pharmaceutical industry... it is often the case that third-party research does not occur without freedom to operate from competing patent protection and enforcement") citing Hirotaka Nonaka, FTO (FREEDOM TO OPERATE) IN THE PHARMACEUTICAL INDUSTRY, 2018; Carlos Maria Correa, *Ownership of Knowledge-The Role of Patents in Pharmaceutical R&D*, 82 BULL. OF THE WORLD HEALTH ORG. 784 (2004); Clarisa Long, *Patents and Cumulative Innovation*, 2 WASH. U. J.L. & POL'Y 229 (2000); Fiona Murray et al., *Of Mice and Academics: Examining the Effect of Openness on Innovation*, 8 AM. ECON. J.: ECON. POL'Y212 (2016); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERS.1, at 29 (1991); Stoyan A. Radkov, *Freedom to Operate (FTO) from a Large Company's Perspective* (Oct. 11, 2010), https://www.rsc.org/images/stoyanradkov_tem18-192425.pdf).

99 There are rarely clean lines of demarcation between these phases. Moreover, invention can and does occur at all phases, particularly during research and development.

100 Deepak Hedge, Kyle Herkenhoff & Chenqi Zhu, *Patent Publication and Innovation*, 131 J. OF POLIT. ECON. 7, at 1845-1903 (2023).

101 *Id.* at 1846.

102 *Id.* at 1898.

the manufacture, use, or sale of drugs or veterinary biological products."[103] As a result, many research activities by third parties are not—and legally cannot be—blocked by an existing patent.

Under this provision, many research activities conducted by third parties—such as studies aimed at developing data for FDA submissions—are not considered infringing, even if they involve the use, for example, of a patented compound or manufacturing method. As a result, the existence of such patents does not block all research and development activities, and courts must (and sometimes do) consider this nuance when evaluating a blocking patent defense.

Moreover, the Federal Circuit has clarified that the mere act of filing a patent application based on an approved drug or compound does not constitute patent infringement, as it does not amount to "commercializing an invention:"

> Filing a patent application... is not the making, using, offering to sell, selling, or importing of an invention. It is the act of approaching an agency of the government in order to obtain a limited privilege and to fulfill a public goal of making knowledge of an invention available to the public. It is not commercializing an invention which requires introducing an invention into commerce, or making preparations to do so.[104]

In practice, third parties frequently obtain patents on subject matter related to previously patented inventions. This is especially common in the pharmaceutical industry, where inventors and associated companies routinely secure patents on solid state forms, formulations, and methods of manufacture related to active pharmaceutical ingredients originally patented by branded pharmaceutical companies.

A U.S. patent also does not prevent others from practicing the invention outside the United States. In the context of the blocking patent analysis, a U.S. patent cannot preclude foreign entities from conducting research activities aimed at improving upon a blocking patent. In fact, a U.S. patent may serve as a motivator for innovation abroad, where entities are free to explore and build upon the technology without infringing.

2. Temporal Block

The timing of the at-issue patent, the blocking patent, and the period during which innovation can occur is paramount to a blocking patent analysis. A patentee can only prevent others from performing prohibited activities from the point at which the patent issues until the point at which the patent expires.

Because of the prolonged nature of pharmaceutical development, product and market-oriented activities often are undertaken many years before a new product's introduction. According to estimates published by the National Academies of Sciences, Engineering, and Medicine, the drug development process can take up to 15 years, with drug discovery and preclinical testing (in animals) taking between 3 and 6 years, and clinical testing (in humans) and FDA evaluation requiring an additional 6.5 to 9 years.[105] Given this

---

103 35 U.S.C. § 271(e)(1) (2025), available at: https://www.law.cornell.edu/uscode/text/35/271.

104 Classen Immunotherapeutics, Inc. v. Elan Pharms., Inc., 786 F.3d 892, 898-99 (Fed. Cir. 2015).

105 Nat'l Acads. Of Scis., Eng'g & Med., *Complexity in Action*, National Academies of Sciences, Engineering, and Medicine, in MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 37 (Norman R. Augustine, Guru Madhavan & Sharyl J. Nass eds., Nat'l Acads. Press 2018).

long timeline, because of the limited lifespan of any patent, including a blocking patent, and the safe harbor provision discussed above, it usually would be imprudent for pharmaceutical companies to wait until the expiration of a so-called blocking patent to begin development activities associated with a promising drug.[106]

The federal district court of Delaware in *Janssen v. Teva* recognized this practical reality, writing

> Both parties' economic experts further agreed that the drug development process can take many years, even up to a decade or longer… Given this drug development timeline and the fact that the last alleged blocking patent expired in November 2018, the Court finds that these patents created little, if any, disincentives to innovate as of the claimed December 19, 2007, priority date or the December 5, 2008, application date.[107]

3. Activity Block

While marketplace success often is assessed based on the performance of a patent-practicing product, there are many other ways for an invention to succeed.[108] These include 1) licensing,[109] 2) cross-licensing,[110] 3) patent pooling, 4) sale of patent rights, and 5) enforcement/litigation.[111] Such outcomes often are the fruits of many years of prior work, and that work generally is not pre-empted altogether by the existence of a blocking patent. In fact, the prospect of engaging in those efforts by research institutions and (often) operating companies may motivate much related and extending work. Sharing the fruits of that work with the blocking patent owner may be a strong motivator for third party inventive activity. If third-party work actually was done after the issuance of the blocking patent but before the priority date of the at-issue patent, the opportunity and motivation to invent the at-issue patent might have existed, but the wherewithal (or perhaps scientific knowledge) did not.

4. Real World Evidence

Because of the constraints on the reach of a blocking (or any) patent, it is not surprising that blocking patents rarely preclude all inventive activities. As shown below, an evaluation of some of the recent Federal Circuit commercial success cases where a blocking patent argument was considered shows that there is a wide variation of activities related to the inventions covered by the claimed blocking patent(s). While some blocking inventions are never expanded upon or extended, which is consistent with evidence of a block,

---

106 Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 2024 U.S. Dist. LEXIS 227696, at *84-86 (D.N.J. Nov. 21, 2024).

107 Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 571 F. Supp. 3d 281, 324-25 (D.N.J. 2021), *aff'd in part, vacated in part, remanded*, 97 F.4th 915 (Fed. Cir. 2024).

108 Rahul Guha, Jian Li & Andrea L. Scott, *The Economics of Commercial Success in Pharmaceutical Patent Litigation*, 1 LANDSLIDE 8, 9 (2009).

109 McDuff et al., *supra* note 27, at 44.

110 *Id.* Citing its opinion in *Merck II*, the Federal Circuit in *Acorda* recognized that potential innovators may seek a license to the blocking patent, challenge the blocking patent, and/or research in the blocked space (regardless of whether such research is within the safe harbor), and then negotiate for a cross-license. Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310, 1338 (Fed. Cir. 2018).

111 McDuff et al., *supra* note 27, at 44.

that is quite different for others, which may suggest that the blocking patent did not block all inventive activities.

While not dispositive, this kind of evidence can provide insight into what was blocked, when, and how much of a block the claimed blocking patent provided.

a) Forward Citations

Forward citation evidence is one form of real-world data that can be used to evaluate whether a blocking patent actually deterred inventive activity. When third-party patent applications (*i.e*., patent applications filed by parties that are unrelated to the party that owns rights to the blocking patent) cite a purported blocking patent, it may indicate that the earlier invention was used as a foundation for further, independent R&D. In other words, forward citations can signal that third-party inventive activity was not halted, and may, in fact, have been encouraged, by the claimed blocking patent. Work being done in the area, either before the blocking patent or after, may suggest that others (perhaps many) were motivated and positioned to invent the at-issue patent, but were unable or unwilling to do that for reasons unrelated to any legal barrier. Conversely, when third-party patent applications do not cite the purported blocking patent, that evidence might provide support for the belief of an effective block..

The timing of forward citations can also provide useful insights. Third-party forward citations appearing soon after the blocking patent's issuance and/or well in advance of the expiration of the blocking patent may provide evidence of little or no block considering that work likely was done many years in advance. That research likely began before the blocking patent issued. Third-party forward citations issued much later in time, on the other hand, likely began after the blocking patent issued. Those later forward citations may undermine a claim of early innovative activity or may suggest anticipation of soon-to-occur expiration of the blocking patent.

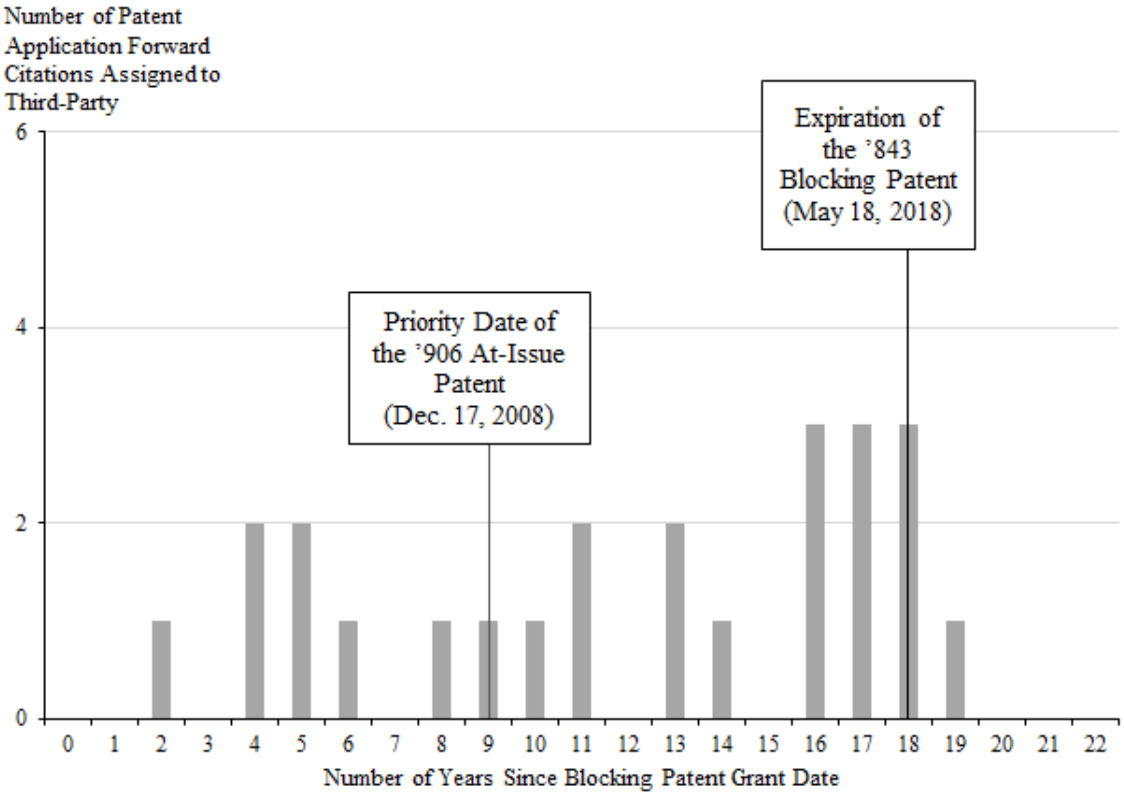
In *Janssen v. Teva,* U.S. Patent No. 6,077,843 ("the '843 Patent"), which covers a composition of matter, was one of the alleged blocking patents that, according to Teva, prevented others from innovating, and thereby undermined the evidence of long-felt need or commercial success of the at-issue patent. Figure 1 below, which is based on information from Sagacious IP,[112] shows that 20 U.S. patent applications that were filed by third parties not affiliated with Janssen cited the '843 Patent during the life of the patent.[113] Four additional third party U.S. patent applications citing the '843 Patent were filed in the five years after the patent expired. This forward citation activity suggests that, rather than deterring innovation, the '843 Patent may have served as a foundation or motivator for ongoing R&D in the field.

---

[112] All forward citation data were provided by Sagacious IP, which provides technology research to law firms, companies, and other institutions. *See* https://sagaciousresearch.com/. Sagacious IP provided data on all forward citations of the 13 blocking patents identified in Table 1. Forward citation data provided by Sagacious IP include forward citation patent numbers, application numbers, titles, type of patent, whether the patent was a continuation, whether there was a prior patent application, the priority date, the filing date, the grant date, the expiration date, the current assignee(s), the first assignee(s), the inventor, and whether the forward citation patent is expired or lapsed.

[113] In *Janssen v. Teva*, the three alleged blocking patents were U.S. Patent No. 6,555,544 (the "'544 Patent"), U.S. Patent No. 5,254,556 (the "'556 Patent"), and U.S. Patent No. 6,077,843 (the "'843 Patent"). All three patents were directed towards paliperidone palmitate. Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 571 F. Supp. 3d 281, 323 (D.N.J. Oct. 21, 2021).

Figure 1: Third-Party Forward Citations of the '843 Blocking Patent (*Janssen v. Teva*)



Further, seven (7) forward citations of the '843 Patent by third parties occurred before the priority date of the '906 Patent—the patent whose obviousness was at issue in *Janssen v. Teva*.

Third-party entities that filed patent applications citing the '843 Patent included large pharmaceutical companies and research entities. Third-party patent application filers included, among others,

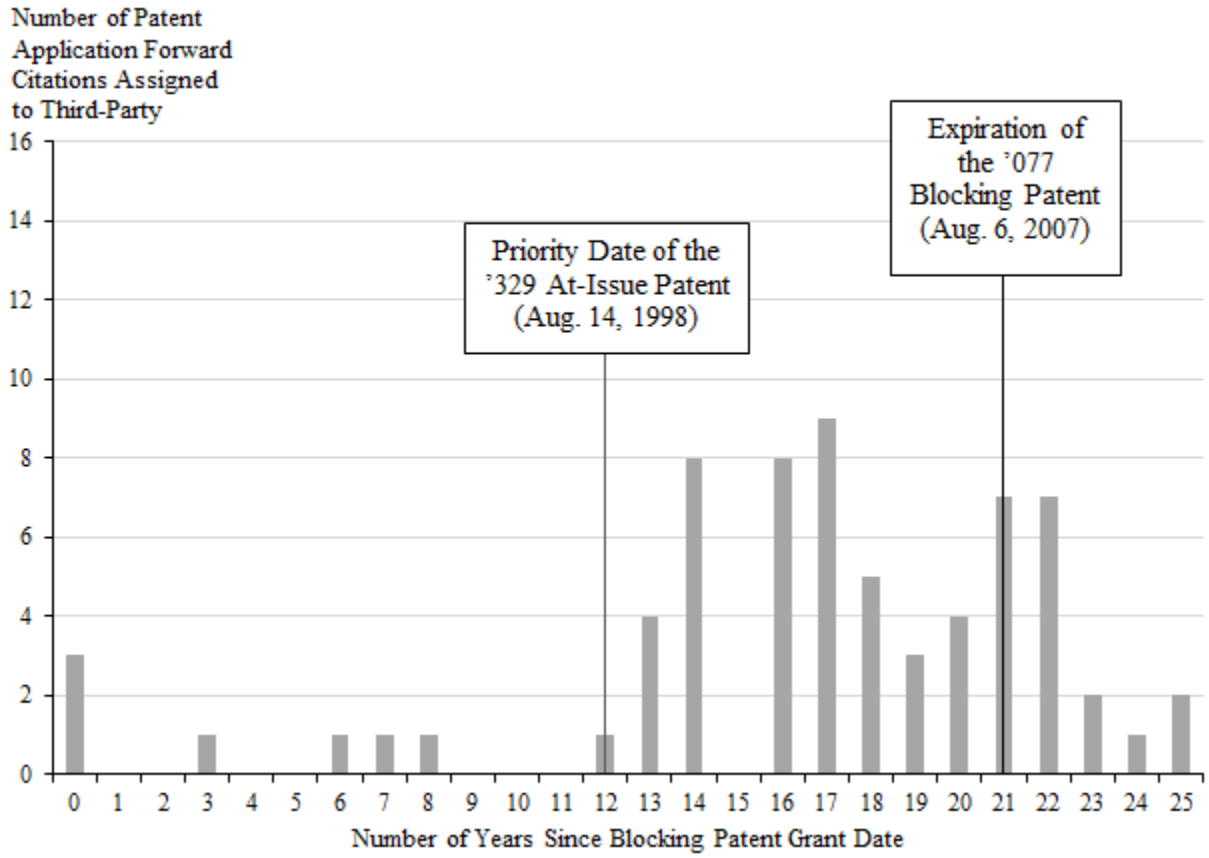
- Johns Hopkins University;
- Protia LLC;
- Sepracor Inc.;
- Sumitomo Dainippon Pharma Co. Ltd.;
- The University of Pennsylvania;
- Vanda Pharmaceuticals Inc.; and
- ViiV Healthcare Co.

Also as shown in Figure 1, the patent applications citing the '843 Patent occurred throughout the life of the '843 Patent, seemingly not changing in volume regardless of the remaining life of the '843 Patent. This pattern suggests that the '843 Patent did not discourage inventive activity by others—many of whom are major participants in pharmaceutical R&D. Rather than serving as a deterrent, the claimed blocking patent appears to have coexisted with (or perhaps incentivized) sustained third-party innovation in the field,

further supporting the ultimate district court opinion in November 2024 that the alleged blocking patents, including the '843 Patent, did not deter the development of paliperidone palmitate products.[114]

Forward citation evidence may be less conclusive in other cases. For example, U.S. Patent No. 4,621,077 ("the '077 Patent")—a method of treatment patent deemed blocking in *Merck I*—shows a different pattern of citation activity.[115] As shown below in Figure 2 below, 49 U.S. patents applications that cited the '077 Patent were filed by third party entities that did not have intellectual property rights to the '077 Patent during the life of the '077 Patent. In the five years following the expiration of the '077 Patent, an additional 19 patent applications were filed by third parties that cited the '077 Patent, resulting in a total of 68 patent applications by third parties from the grant date of the '077 Patent through five years after the expiration date of the patent.

Figure 2: Third-Party Forward Citations to the '077 Blocking Patent (*Merck I*)



Entities other than Merck that filed patent applications citing the '077 Patent included, among others,

- Hoffmann-La Roche Inc.;
- Warner Chilcott Company;

[114] Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 2024 U.S. Dist. LEXIS 227696, *84-86 (D.N.J. Nov. 21, 2024).

[115] Merck & Co. v. Teva Pharms. USA, Inc. (*Merck I*), 395 F.3d 1364, 1377 (Fed. Cir. 2005).

- Boehringer Mannheim Gmbh;
- Elizanor Biopharmaceuticals Inc.;
- Norwich Eaton Pharmaceuticals Inc.;
- Novartis Corporation;
- Oy Leiras Finland AB; and
- Procter & Gamble.

Of the 68 total third-party patent applications citing the ’077 Patent from its issuance through five years post-expiration, the majority were filed during the final seven years of the ‘077 Patent’s life. Only seven applications were filed in the first decade, while the remaining 61 were filed within the nine years leading up to the patent’s expiration or during the five years that followed. This evidence suggests that the ’077 Patent may have discouraged inventive activity in the early years following its issuance, and in particular, before the priority date of the at-issue patent. However, the ’077 Patent did not fully prevent inventive activity by third parties in the area, including major pharmaceutical developers, especially during the second decade of the life of the ’077 Patent.

While the forward citation evidence may bear on the issue of whether there was a block, again, this fact should not be taken in isolation as proof that there was or was not a block. These forward citation data can often be used to assess whether a blocking patent, in fact, blocked large swaths of inventive activity. To better assess whether the ’077 Patent, for example, functioned as a true blocking patent, further analysis may be warranted. Relevant considerations may include whether other factors explain the limited early citation activity—such as lack of recognition of the patent’s significance or slower scientific uptake.[116] Additional insight may come from examining the timelines of research programs that culminated in late-stage patent filings, or from other indicators of inventive activity.

b) Clinical Trials

Analysis of clinical trials involving claimed blocking patent technology is another form of real-world evidence that can provide insight into whether a patent actually blocked the at-issue invention. Like forward citations, clinical trial data may reveal that, despite the existence of patent(s) alleged to be blocking, research related to the blocked technology forged ahead.

Clinical trials involving patented technology generally are permissible under the FDA’s safe harbor provision, which protects R&D conducted in anticipation of FDA approval from infringement liability, as discussed above.[117] While the strength of evidence from clinical trials likely depends on who was conducting the research (whether it was an organization with rights to the blocking patent), when they were conducting the research (whether it was within a few years of the expiration of the blocking patent), and why that research was conducted (whether it was for the purpose of competing after the blocking patent expired), pursuit of that work may undermine the hypothesis of a block.

In *Sanofi-Aventis v. Mylan,* the Federal Circuit found that U.S. Patent Nos. 5,656,722 (“the ’722 Patent”) and 6,100,376 (“the ’376 Patent”) (both related to glargine, a form of insulin) were blocking patents.

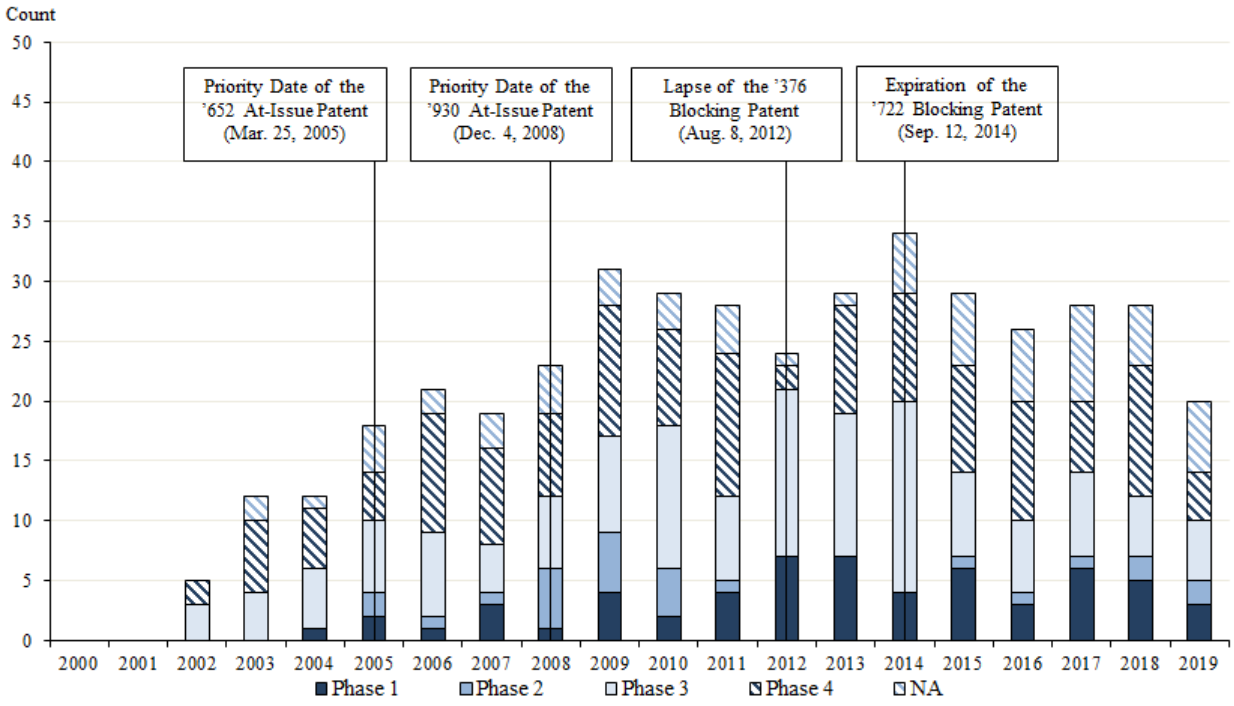
---

116 This may be tested by evaluating the extent to which the subject matter of the patent was published contemporaneously in the scientific literature.

117 35 U.S. Code § 271(e)(1) (2025), available at: https://www.law.cornell.edu/uscode/text/35/271.

However, clinical trial data maintained by the U.S. National Library of Medicine from clinicaltrials.gov suggest that these patents did not block all research related to the allegedly blocked compound glargine. The '722 Patent issued in August 1997, and the '376 Patent followed in August 2000. As shown below in Figure 3, 281 third-party clinical trials involving glargine were initiated between 2000 (the first-year clinical trial data became available) and September 2014 (when the '722 Patent expired). An additional 135 third-party clinical trials involving glargine began in the five years after the '722 Patent expired, for a total of 416 third-party clinical trials involving glargine from 2000 through September 2019.

Figure 3: Third-Party Glargine Clinical Trials (*Sanofi-Aventis v. Mylan*)[118]
2000-2019



The clinical trials investigating development and use of glargine spanned all phases of R&D. While many studies were later stage trials (*i.e.*, Phases 2-4), early-stage trials (*i.e.*, Phase 1) were conducted in every year from 2004 through 2014, the expiration year of the '722 Patent. Such trials signal new or beginning research programs. Thus, based on the clinical trials evidence, it appears that the '376 Patent and the '722 Patent did not block all third-party inventive activity involving glargine. In fact, there was substantial research involving the glargine compound, including work done in advance of the priority dates at issue (2005 and 2008). Absent other evidence, this activity casts doubt on whether the '376 and '722 Patents functioned as true blocking patents.

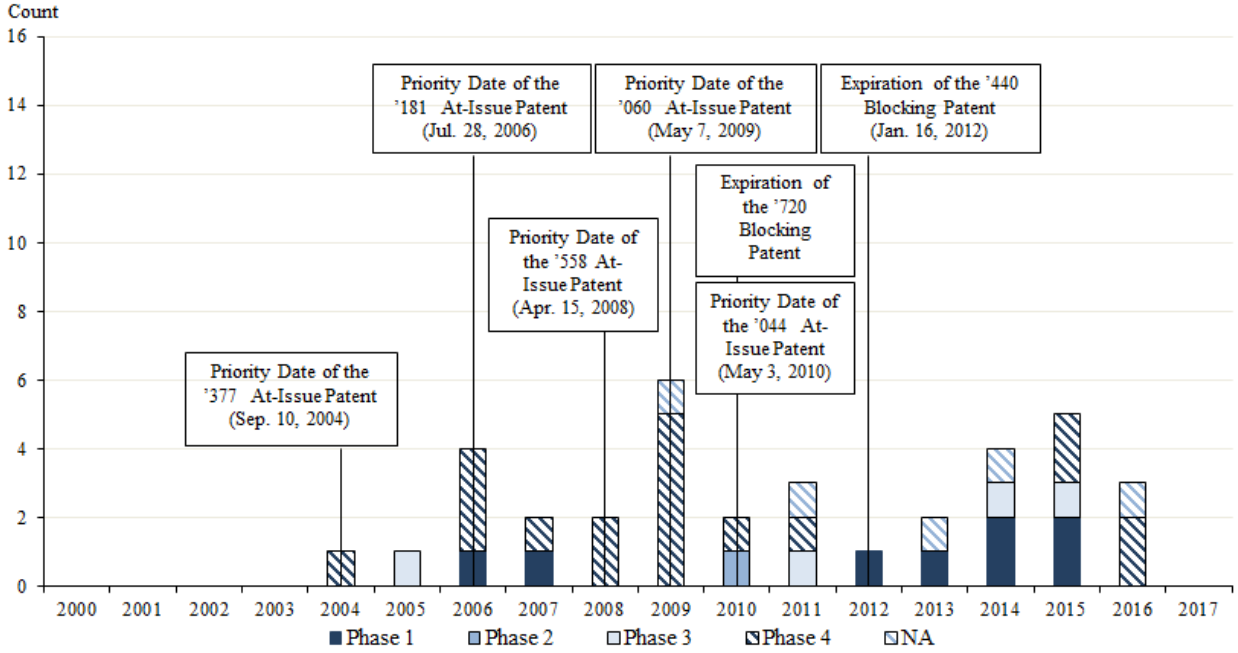
Clinical trial activity for other compounds covered by patents that the Federal Circuit determined were blocking was somewhat less informative. For example, in 2013 in *Galderma v. Tolmar,* the Federal Circuit found that the U.S. Patent No. 4,717,720 (the "'720 Patent") and the Reissue 34,440 Patent ("the '440

[118] https://clinicaltrials.gov/search?intr=Glargine%20insulin. One trial began in September 1999. This trial is not shown in Figure 3 as the 1999 data are likely incomplete.

Patent"), both of which are related to the compound adapalene, were blocking. The '720 Patent issued in January 1988 and the '440 patent issued in November 1993. Although data on clinical trial activity involving adapalene are unavailable prior to 2000, clinicaltrials.gov data over the period 2000 to 2017—covering up to five years after the expiration of the second-to-expire blocking patent—indicate that 36 clinical trials were sponsored by third parties during this period.

As shown below in Figure 4, although the clinical trials data involving adapalene suggest that some research activity did occur during the life of the '720 and '440 Patents, the number of clinical trials conducted by third parties were fewer than those involving glargine, for example, and many of the trials occurred in the six years prior to expiration of the last to expire blocking patents, from 2006 through 2012.[119]

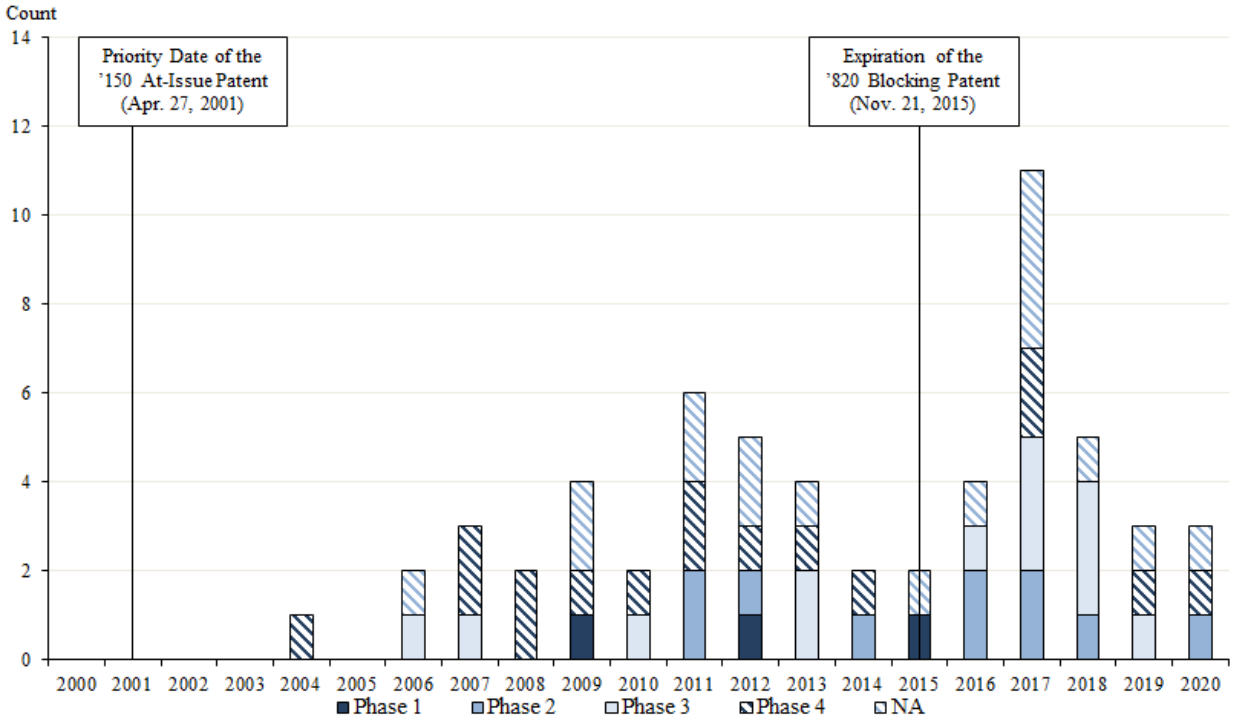
Figure 4: Third-Party Clinical Trials Involving Adapalene (*Galderma v. Tolmar*) 2000-2017



A similar pattern appears in *Merck II,* where the Federal Circuit found that the '820 Patent covering the compound ertapenem was blocking. Issued in December 1995, the '820 Patent expired in 2015. As shown below in Figure 5, clinical trials data from 2000, when data were first available, through 2020, indicate that while there was some third-party inventive activity involving ertapenem, it occurred just a few years before the expiration of the '820 Patent in 2015. For example, only three Phase 1 clinical trials that may signal the beginning of new research programs began from 2000 through expiration of the '820 Patent, and all were conducted within six years of the patent's expiration.

[119] An absence of clinical trial evidence is far from dispositive on the issue of the existence of a blocking patent. Some treatment areas attract substantial research, development, and clinical trial efforts. Others, for many reasons, do not.

Figure 5: Third-Party Clinical Trials Involving Ertapenem (*Merck II*) 2000-2020



While the relatively low volume of clinical research involving ertapenem may, in isolation, suggest that the '820 Patent blocked some inventive activity, other contextual factors must be considered. For example, the treatment population for the compound likely plays a significant role in determining the level of clinical research activity. For glargine, cited above, the treatment population is diabetes, which affects over 38 million people in the U.S., according to the U.S. Centers for Disease Control and Prevention.[120] A substantial number of clinical trials for a compound that treats a large patient population is expected. Ertapenem, in contrast, is an antibiotic biologic treatment that is delivered via intravenous or intramuscular injection in the event of certain complicated or serious infections, resulting in a much smaller target patient population and more limited, one-time use.[121] Given these differences, fewer clinical trials involving ertapenem may simply be the result of its narrower clinical application rather than any blocking effects caused by the '820 Patent. Additional evidence may be necessary to determine whether the '820 Patent functioned as a true barrier to innovation.

Though often informative, like forward citation data, clinical trial data are not conclusive. They do not capture research efforts that never progressed to the clinical trial stage or were ultimately abandoned. The FDA rules on which clinical trials must be registered and reported generally exclude Phase 1 trials of investigational drug or biological products and noninterventional (observational) clinical research.[122] In fact, clinical study sponsors may not report results when their results are negative, when the sponsor does

---

120 Ctrs. for Disease Control & Prevention, *Data, Trends, and Maps*, CDC: Diabetes Public Health Resource, https://www.cdc.gov/diabetes/php/data-research/index.html.

121 U.S. Food & Drug Admin., *Ertapenem (NDA 21-337/S-018) Clinical BPCA Review* (Aug. 9, 2007), https://www.fda.gov/files/drugs/published/N21-337S018-Ertapenem-Clinical-BPCA.pdf.

122 *FDAAA 801 and the Final Rule*, U.S. Nat'l Libr. of Med., https://clinicaltrials.gov/policy/fdaaa-801-final-rule.

not have sufficient resources to support publication, or when a company ceases to exist because of negative study results.[123] Similarly, many failed clinical trials do not come to the FDA for review and, therefore, will not be observable.[124] While the precise number of these abandoned research programs may not be knowable, the realities of pharmaceutical research suggest that that this number is significant. If the number of studies for inventions covered by blocking patents could be known, it would provide another important indicator of inventive activity.

In the pharmaceutical industry, R&D efforts are dictated by the projected net benefits of a project rather than by the mere existence of an asserted blocking patent. It is rare for R&D to be categorically deterred by the mere presence of a patent.[125] The above real-world evidence shows that.

E. A Fact-Based Issue

Undoubtedly, a patent can contribute to blocking further inventive activity. In practice, however, it appears that a patent *alone* rarely serves as a complete barrier. The Federal Circuit has emphasized that specific facts—not generalized assertions about a blocking patent's preclusive effect—must guide the analysis.

As noted above, in 2018, the Federal Circuit issued its opinion in *Acorda v. Roxane.*[126] Roxane (along with others) submitted an ANDA seeking approval to sell a generic version of Ampyra™, a prescription medication for patients with multiple sclerosis.[127] The lower court found that the asserted claims of Acorda's patents were invalid because of obviousness.[128]

Central to the case was U.S. Patent No. 5,540,938, ("the '938 Patent") originally owned by Elan Corporation and later exclusively licensed to Acorda. The Federal Circuit deemed the '938 Patent to be a blocking patent,[129] explaining that it covered the methods claimed in the Acorda patents being evaluated for commercial success, making it necessary for any developer of a drug practicing those methods to obtain a license to the '938 Patent.[130] Acorda had held an exclusive license to the Elan patent for 8 years prior to the 2004 priority date of the at-issue Acorda patents.[131]

An assessment of the forward citation data, however, suggests that inventive activity may not have been blocked by the '938 Patent. As shown in Figure 6 below, the forward citation evidence indicates that the '938 Patent was cited by third parties, suggesting notable use well before the expiration of the '938 Patent.

---

123 Arthur M. Feldman, *Publishing "Invisible" and "Abandoned" Clinical Trials: A Commitment for CTS*, 6 CLIN. & TRANSLATIONAL SCI. 251 (2013)

124 *Id.*

125 *See, e.g.*, Michael A. Klein & Yibai Yang, *The Blocking Patents, Rent Protection and Economic Growth*, 52 REV. ECON. DYNAMICS 2, 3 (2024), developing a dynamic growth model in which R&D investment decisions are guided by expected returns rather than the mere existence of blocking patents, and finding that forward protection mechanisms can preserve incentives for follow-on innovation by securing a share of future rents.

126 Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310 (Fed. Cir. 2018).

127 *Id.* at 1327.

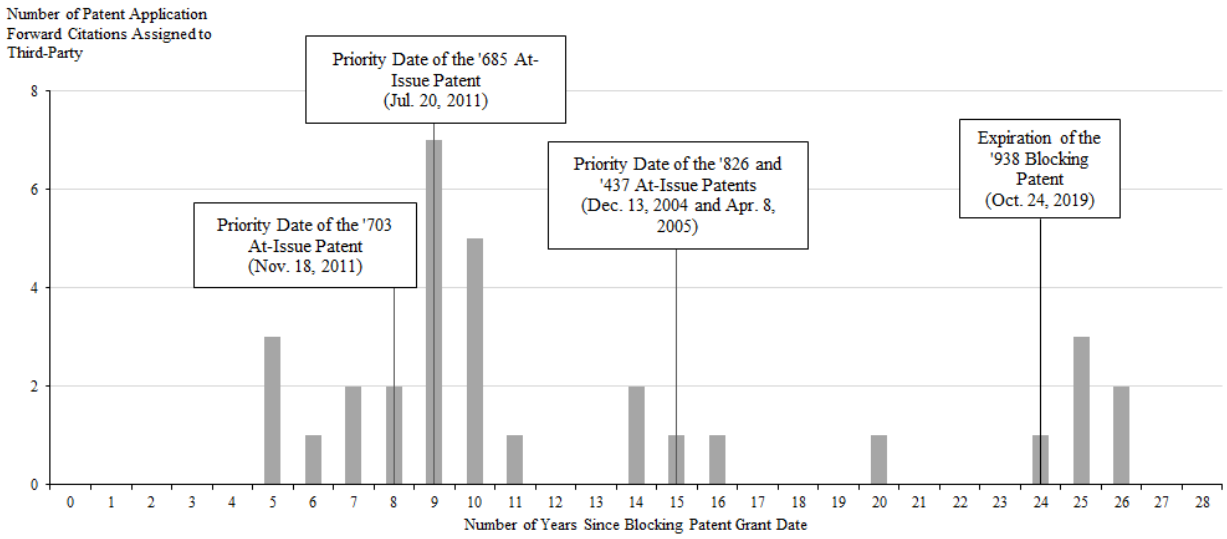
128 *Id*..

129 *Id*. at 1339-40.

130 *Id*. at 1327.

131 U.S. Patent No. 5,540,938 (issued July 30, 1996).

Figure 6: Third-Party Forward Citations of the ’938 Blocking Patent (*Acorda v. Roxane*)



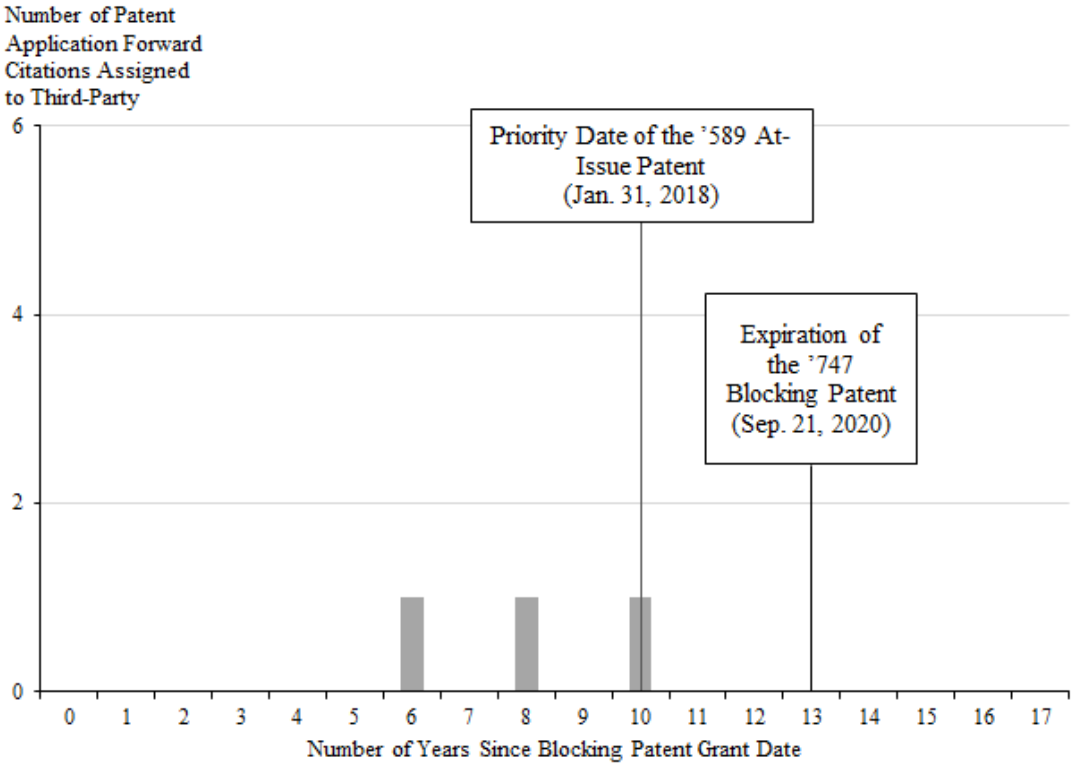
During the life of the ’938 Patent, 26 patent applications citing the ’938 Patent were filed by third parties other than Alkermes and Acorda, which had rights to use it.[132] In the five years after the expiration of the ’938 Patent, an additional six (6) patent applications citing the ’938 Patent were filed by third parties. Third-party entities attempting to build upon the inventions claimed by the ’938 Patent included Merck & Co., Purdue Research Foundation, the National Institutes of Health, and Emory University. These forward citation data suggest that the ’938 Patent did not fully suppress, or perhaps even suppress at all, inventive activity in the field.

There can be little dispute about the fact that not all forward citation data support the conclusion that a blocking patent failed to restrict innovation. In *Galderma v. Tolmar,* the Federal Circuit found that Galderma’s ’440 Patent was a blocking patent. Forward citation data for the ’440 Patent reveal that, while U.S. patent applications citing the blocking patent were filed during the life of the blocking patent, *all* of these patent applications were owned by Galderma. No third parties cited the ’440 Patent in any U.S. patent applications during the life of the patent. This lack of third-party engagement may reflect a more substantial blocking effect in this case, though that alone is not dispositive as to the effect of a blocking patent.

In *UCB v. Actavis,* the Federal Circuit found that U.S. Patent Nos. 6,884,434 (“the ’434 Patent”) and 7,413,747 (“the ’747 Patent”) were blocking. Forward citation data for the ’747 Patent indicate minimal inventive activity by third parties during the life of the ’747 Patent, as shown below in Figure 7.

[132] Acorda licensed the ’938 Patent from Alkermes to sell the covered product Ampyra®. *See* Alkermes Public Limited Company, SEC Form 8-K, October 13, 2022.

Figure 7: Third-Party Forward Citations of the '747 Blocking Patent (*UCB v. Actavis*)



In isolation, third-party forward citation data for the '747 Patent may suggest some blocking effect. However, it is not clear from this evidence alone whether the other blocking patent in the case – the '434 Patent – which issued three years before the '747 Patent was responsible for deterring inventive activity that might otherwise have built on the disclosures in the '747 Patent. A more complete understanding would require deeper factual investigation and consideration of other indicators of inventive activity.

Though the lower court and Federal Circuit in *Acorda v. Roxane* did not appear to consider forward citation evidence, the Federal Circuit in *Acorda* recognized that the existence of a blocking patent may deter investment due to fears of liability and monetary or other remedies.[133] The Federal Circuit there emphasized that such a deterrent is "relevant to understanding why others had not made, developed, or marketed th[e] 'blocked' invention."[134] Importantly, it wrote that determining whether a patent is truly blocking is a factual inquiry—one that must be grounded in evidence rather than assumption.

While categorical use of a blocking patent defense is unacceptable, so too is its categorical dismissal. The Federal Circuit in *Janssen v. Teva* held that the existence of the FDA's safe harbor provision, which permits certain inventive activities, does not mean that no patent can serve as a blocking patent with respect to the marketing of a product.[135] The court noted that the safe harbor provision is just one aspect of a

133 *Acorda*, 903 F.3d at 1337.

134 *Id*.

135 Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 97 F.4th 915, 936 (Fed. Cir. 2024).

nonobviousness determination, and is present in all ANDA cases.[136] It does not override the Federal Circuit's directive to conduct a fact-specific investigation into commercial success.[137] Facts matter.

F. Not a Binary Choice

To date, litigants and courts in pharmaceutical commercial success cases typically have framed the key inquiry as: "Did a particular patent block invention in the area covered by an at-issue patent?" But this question, in its binary form, is largely unhelpful.

The reality is that every patent blocks some inventive activity, and no patent blocks all inventive activity.

At the same time, as illustrated above, substantial inventive activity routinely occurs even in areas subject to so-called blocking patents. Activity is rarely shut down altogether.

The relevant and useful question in addressing the nexus requirement in a commercial success case is: "To what degree did a particular patent block invention in the area covered by an at-issue patent?" The blocking inquiry should not be answered with a simple "yes" or "no," but rather through a fact-specific evaluation of the extent to which the patent in question deterred or limited innovation.

VI. APPROPRIATE ASSESSMENT OF THE BLOCKING PATENT DEFENSE

Despite its limitations, a blocking patent defense may be appropriate in some pharmaceutical commercial success cases. Depending on the facts, it can weaken (or even break) the asserted nexus link between the patented invention and the marketplace success of the at-issue invention. However, merely asserting that a pre-existing patent blocked inventive activity, and therefore led to patent owner success, is not sufficient.

The three-factor framework outlined below provides valuable guideposts for determining the degree to which the facts of a particular case support a blocking patent defense. It focuses on assessing evidence related to 1) actual inventive activity; 2) actual blocking effects; and 3) potential blocking effects.

Together, these factors help determine the appropriate weight to assign to the blocking patent defense, while also reinforcing that commercial success is just one of several secondary considerations in assessing nonobviousness.

A. Evidence of Actual Inventive Activity

The first element for evaluating a blocking patent defense is an assessment of whether actual work by one or more third parties in the field of the at-issue patent was conducted before the invention date of the at-issue patent.[138] If such work occurred, it may become difficult to argue that the claimed blocking patent fully deterred innovation. While the claimed blocking patent may have impeded some inventive activity, it certainly did not prevent *all* inventive activity in the relevant space. Importantly, the analysis should focus on the degree to which the blocking patent actually impeded innovation.

---

136 *Id*.

137 *Id*.

138 This issue is important, and may be close to dispositive, for many of the nonobviousness factors, including long felt but unmet need, failure by others, and unexpected results.

In *Janssen v. Teva*, the '843 Patent did not block further inventive activity by entities such as Alza, Johns Hopkins, Sepracor, Sumitomo Dainippon, the University of Pennsylvania, or ViiV. As discussed above, third parties engaged in research and development throughout the life of the asserted blocking patent that covered the underlying compound, including prior to the priority date of the at-issue patent in that case. In *Merck I*, however, forward citation evidence demonstrated that while follow-on innovative activity by such pharmaceutical manufacturers as Hoffman-LaRoche, Warner-Chilcott, and Novartis did occur, such activity mostly took place in the decade leading up to the expiration of the '077 Patent, which covered a specific method of treatment rather than the underlying compound and was claimed to be blocking.

In *Otsuka v. Lupin*, the federal district court of Delaware wrote that the "relevant inquiry is whether the [blocking] patent caused a deterrent effect, not whether all others were dissuaded from resource investment."[139] The court noted that there were two third parties that worked in the area around the time of the priority date. However, other research and commercialization work was done in the area "close to a decade after the priority date of the asserted patents and three years after the [blocking] patent expired."[140] Further, the court wrote that substantial research and commercialization work were done in earnest near the expiration of the blocking patent, and it ultimately concluded that the deterring effect of the blocking patents contributed to its finding that the success of the [product at issue] had only a "small" connection to the claimed invention at issue.[141] The perceived quantity and timing of the inventive work by others appeared to matter to the *Otsuka* court.[142]

Limited evidence of inventive activity also mattered in the federal district court of Delaware's 2024 case *Exelixis v. MSN*, where MSN pointed to a blocking patent and a blocking patent application that covered the underlying compound and uses of the compound, respectively.[143] The federal district court of Delaware found that only two groups investigated the compound during the blocked period. This, to the court, was sufficient evidence of the deterring or disincentive effect of the blocking patents.[144] MSN did not need to prove that "all others were dissuaded,"[145] only that there was minimal inventive activity. Further, MSN was able to argue that there was a disincentive associated with a mere patent application.

However, the mere fact that a limited number of competitors have engaged in inventive activity is not necessarily indicative of blocking impact. In *Janssen v. Teva, t*he federal district court of New Jersey pointed to the activity of a single competitor to support its conclusion that inventive activity had not been deterred by the existence of the alleged blocking patents. In that case, Teva, the defendant in the proceeding, had engaged in substantial inventive activity and invested significant resources to develop a competing product with the underlying compound covered by the patent-at-issue during the "allegedly blocked period."[146] In fact, Teva's work led it to file a patent application prior to the expiration of the blocking patents.[147] The

---

139 Otsuka Pharm. Co. v. Lupin Ltd., 2024 U.S. Dist. LEXIS 135251, *52-53 (D. Del. July 31, 2024).

140 *Id.* at *53.

141 *Id.* at *55.

142 The court did not appear to evaluate whether the timing of third-party actions may have been driven in whole or part by other considerations.

143 Exelixis, Inc. v. MSN Labs. Priv. Ltd., 2024 U.S. Dist. LEXIS 187077, *91-92 (D. Del. Oct. 15, 2024).

144 *Id.* at *47.

145 *Id.* at *95.

146 Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 571 F. Supp. 3d 281, 284-85 (D.N.J. 2021), *aff'd in part, vacated in part, remanded*, 97 F.4th 915 (Fed. Cir. 2024).

147 *Id*.

district court there held that, contrary to Teva's expert opinion that "'[n]o one would have an economic motivation to try and research and discover [ ] the alleged novelties of the '906 patent because of Janssen's 'patent fortress around paliperidone palmitate for the treatment of schizophrenia'," Teva "itself filed a provisional patent application involving the purification and preparation of paliperidone palmitate on January 10, 2008."[148] Based on this fact and Teva's admission that there was an incentive to research and develop as of December 2007, the district court found that Janssen's "evidence of commercial success and long-felt unmet need should not be discounted."[149] While Teva argued on appeal that only it was motivated to develop the patents-at-issue because of internal clinical trial results, the Federal Circuit disagreed, stating that "although identifying a recognized problem or need in the prior art is one way to demonstrate motivation, Teva was not required to demonstrate that there was an explicit problem."[150]

The above opinions reinforce the idea that evidence of some work in the field is important, but it may not necessarily be dispositive. Such evidence is one of several factors to be weighed in the commercial success and broader nonobviousness analyses.[151]

The blocking patent argument fundamentally asks, "Did the asserted blocking patent actually prevent others from inventing the claimed invention?" This inquiry aligns with the Federal Circuit's reasoning in *Acorda,* where it explained that "if all other variables are held constant, a blocking patent diminishes possible rewards from a nonowner's or non-licensee's investment activity aimed at an invention whose commercial exploitation would be infringing, therefore reducing incentives for innovations in the blocked space by non-owners and non-licensees of the blocking patent."[152]

The presence of actual work in a field is a critical consideration when evaluating the strength of a blocking patent defense. Such evidence provides concrete insight into whether the blocking patent in question truly hindered innovation or whether it actually encouraged ongoing inventive activity. In short, real-world evidence, some of which is reflected above, rather than conjecture, should guide the analysis of whether a blocking patent meaningfully affected the incentives for innovation.

Importantly, such activity often reflects the culmination of years of prior research and development. Patent applications and clinical trials are rarely spontaneous responses to patent expiration; they typically build on longstanding scientific inquiry and planning. Further, patent rights limit commercial exploitation, but they do not bar research, the pursuit of patent protection, or the initiation of clinical trials related to the patented invention. Some of that work predates the priority date of an at-issue patent—further underscoring the need for a fact-specific, evidence-based analysis.

Even commercial activity that occurs after the point of invention may be relevant when evaluating the impact of a blocking patent. While an issued patent may prevent third parties from making, using, offering for sale, or selling patent practicing product, it does not preclude all forms of commercialization. As noted

148 *Id.* at 325.

149 *Id*.

150 Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 97 F.4th 915. 929 (Fed. Cir. 2024)

151 *See* Otsuka Pharm. Co. v. Lupin Ltd., 2024 U.S. Dist. LEXIS 135251, *54 (D. Del. July 31, 2024) ("… the claimed invention has a weak nexus to [the product's] commercial success.").

152 Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310, 1339 (Fed. Cir. 2018).

above, these forms include licensing,[153] cross-licensing,[154] patent pooling, sale of patent rights, and enforcement/litigation.[155] Those strategies usually reflect the culmination of years of research and development, and their viability is not eliminated by the existence of a blocking patent. In fact, the prospect of engaging in these non-product commercialization efforts may drive the research behind patent applications and clinical trials. Sharing the fruits of that work with the blocking patent owner may be a strong motivator for third party inventive activity.

In *Ferring v. Fresenius Kabi*, the Defendant claimed the existence of a blocking patent prevented invention of the at-issue patent.[156] The court rejected that claim, citing testimony from Ferring's expert, who explained that although Ferring held rights to the alleged blocking patent, it relied on contract manufacturers for the synthesis of peptide drugs. [157] Those manufacturers, the expert noted, would be incentivized—not blocked—to develop improved methods of synthesis and offer them to Ferring under commercial contract.[158] This practical dynamic undercut the defendant's blocking patent argument.

Evidence of activity in a therapeutic area may also be reflected in Drug Master File (DMF) applications. DMFs are FDA submissions that "provide confidential, detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drug products."[159] Because DMFs are the product of extensive prior research and development, their submission often signals significant earlier work in the field.

In *Otsuka v. Lupin,* Otsuka identified ten companies that had submitted DMFs for the active ingredient in the product practicing the at-issue patent.[160] The federal district court of Delaware considered two blocking patents, and noted that the DMFs were submitted in 2013 or later, three years after the first blocking patent expired, but during the life of the second alleged blocking patent.[161] Though it did not explicitly address the significance of the DMF evidence, the court found that the first blocking patent did indeed block invention, while the second patent did not.[162]

The examples discussed above illustrate that the actual work reflected in patent applications, clinical trials, and DMF submissions can serve as important evidence that inventive activity continued despite the existence of an asserted blocking patent. While the timing of that work may coincide with the expiration of the alleged blocking patent, correlation does not imply causation, and the observed activity may have been driven by other factors.

---

153 McDuff et al., *supra* note 27, at 44.

154 *Id. See also* Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310, 1338 (Fed. Cir. 2018).

155 McDuff et al., *supra* note 27, at 44.

156 Ferring Pharms. Inc. v. Fresenius Kabi United States LLC, 645 F. Supp. 3d 335, 371 (D. Del. 2022).

157 *Id.* at 372-73.

158 *Id*. at 371.

159 U.S. Food & Drug Admin., *Drug Master Files (DMFs)* (Jan. 7, 2025), https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs.

160 Otsuka Pharm. Co. v. Lupin Ltd., 2024 U.S. Dist. LEXIS 135251, *52 (D. Del. July 31, 2024).

161 *Id.* at *53.

162 *Id*.

B. Evidence of Actual Blocking

A second critical factor in evaluating a blocking patent defense is whether there is affirmative evidence that any particular entity was dissuaded from inventive or commercial activity prior to the expiration of the blocking patent. In other words, is there evidence of an actual block? Such evidence, if it exists, may be found in internal business documents, internal or external business correspondence, or R&D documentation, and this evidence may show that a company abandoned or delayed a project due to concerns about patent infringement. However, access to this type of information is rare. Confidentiality concerns, limited disclosure obligations, and the general absence of documentation for "what did not happen" often prevent such evidence from surfacing.

Importantly, the absence of evidence is not proof of a blocking effect. Nor does it rebut it. Courts have made clear that bald assertions certainly prove nothing.[163]

In *Allergan v. Teva,* the federal district court for the Eastern District of Texas, Marshall Division found that Allergan's alleged blocking patents covered "the field of cyclosporin-based emulsions with higher fatty acid glycerides, including castor oil, even though the benefits of castor oil and the combination of castor oil and cyclosporin in treating dry eye were known well before the priority date" of the at-issue patents.[164] Further, the district court noted that the blocking patents issued approximately 20 years before the at-issue patents, and that this indicated that commercial success of the product at-issue "is attributable mainly to the patent protection Allergan enjoyed."[165] The district court also found that the blocking patents weighed on the long-felt, but unmet need, which existed, but could not be addressed because of Allergan's patents.[166] Allergan's expert sought to counter the blocking patent defense with evidence that others had sought to develop treatments for the same condition – dry eye disease – but the court found that evidence unconvincing because, among other reasons, Allergan's expert did not consider when in time the other development programs occurred relative to the blocking patents and the at-issue patents.[167] The Federal Circuit affirmed this decision.[168] While the failure of others to develop competing products is not, again, dispositive that the blocking patents prevented innovation and competition, it does provide some evidence.

In *Exelixis v. MSN*, the federal district court of Delaware concluded that the blocking patent defense was strong, in part, because "there would have been concerns of losing the invention race to Exelixis and its partners... And there was low economic opportunity for others in light of the blocking patent."[169] While these observations describe *potential* consequences of a blocking patent, they do not establish that innovation was, in fact, stifled. As with all elements of the blocking patent inquiry, broad factual evidence is required to assess whether the patent meaningfully constrained inventive activity.

---

163 Hospira, Inc. v. Amneal Pharms., LLC, 285 F. Supp. 3d 776, 797 (D. Del. 2018) ("Defendant submits that Plaintiff has not adequately addressed the '214 blocking patent, because Plaintiff "simply asserts without citing any evidence that the blocking patent did not prevent competition.").

164 Allergan, Inc. v. Teva Pharms. USA, Inc., 2017 U.S. Dist. LEXIS 225897, *153-54 (E.D. Tex. Oct. 16, 2017).

165 *Id.* at*154-55.

166 *Id.*

167 *Id.* at *155-56.

168 Allergan, Inc. v. Teva Pharms. USA, Inc., 742 Fed. Appx. 511 (Fed. Cir. 2018).

169 Exelixis, Inc. v. MSN Labs. Priv. Ltd., 2024 U.S. Dist. LEXIS 187077, *93 (D. Del. Oct. 15, 2024).

The inclusion of a blocking patent in the FDA Orange Book serves as circumstantial evidence that the blocking patent was known within the industry and *may* have prevented others from engaging in inventive activity.[170] However, whether a specific party had knowledge of the blocking patent and whether that knowledge influenced its actions are factual questions that require a case specific inquiry.

The Federal Circuit has clarified that the at-issue patents in a case cannot themselves serve as blocking patents. While *Chemours v. Daikin Industries* arose outside of the pharmaceutical context, the court's ruling in the case is instructive. There, the Federal Circuit reversed the district court's determination that the challenged (at-issue) patents were blocking. The court wrote, the Patent Trial and Appeal Board "erred by misapplying the 'blocking patents' doctrine to the challenged patents themselves."[171] This decision confirms that the blocking patent doctrine applies only to distinct, pre-existing patents that could deter innovation, not to the patents being litigated. However, when trying to determine why third parties began performing their work, depending on the timing, the presence of the at-issue patents themselves may provide, with adequate evidence, a deterrent effect, as opposed to the asserted blocking patents.

C. Evidence of Potential Blocking

The third element in evaluating the strength of a blocking patent defense is an assessment of the degree to which the allegedly blocking patent had the potential to deter inventive activity by third parties. This inquiry focuses on the economic incentives—or disincentives—facing entities that might otherwise consider pursuing innovation in the area covered by the patent.

In the real-world, business decisions, including those involving the pursuit of a research project that may lead to a commercial product, are assessed based on the projected net present value ("NPV") of that opportunity. That is, projects with a negative NPV, where projected costs exceed projected benefits, should not be (and usually are not) pursued, while projects with a positive NPV should be (and often are) pursued.[172]

In cases involving a blocking patent defense, the challenger implicitly argues that the absence of earlier invention indicates that 1) third parties viewed the project as NPV-negative and 2) the project was NPV-negative because of the existence of a blocking patent.

NPV evaluations are forward-looking. They are conducted as of the time of the potential project (invention) viewed through the eyes of the potential investor. Projections of future benefits and costs are, by their nature, estimates, with some more informed than others. *Ex post* information often is relied upon in litigation settings to inform *ex ante* projections.

Constructing a precise, formal, and elegant NPV model is undoubtedly challenging. But, for current purposes, that is not required to determine if a projected invention was deemed to be NPV negative

---

170 McDuff et al., *supra* note 27, at 44.

171 Chemours Co. FC, LLC v. Daikin Indus., 4 F.4th 1370, 1379 (Fed. Cir. 2021).

172 CFI Team, *Net Present Value Rule*, https://corporatefinanceinstitute.com/resources/valuation/net-present-value-rule/ ("a positive NPV indicates that a project or investment is profitable when discounting the cash flows by a certain discount rate, whereas a negative NPV indicates that a project or investment is unprofitable… A negative NPV project or investment shows that the costs exceed the cash flows generated, and it is said to 'destroy value'"). As a practical matter, companies and investors do not pursue all NPV-positive projects because resources are limited, and some projects with a positive NPV may be deprioritized if other opportunities offer superior projected net returns.

because of the existence of a blocking patent. Assessing the underlying building blocks is important. Careful analysis, as described below, will ensure that the blocking patent defense is grounded in factual, economic reasoning.

In many regards, the approach here is quite simple. To determine whether a blocking patent could (and perhaps did) drive a project NPV-negative, it is important to evaluate the **nature of the opportunity** and the **nature of the potential block**. Evaluation of those building blocks, which incorporate the useful considerations identified by the Federal Circuit in *Acorda*, can (and should) form the foundation for assessing whether a blocking patent *could* have materially discouraged innovation.

1. Nature of the Opportunity

Evaluation of the nature of the opportunity calls for an assessment of the likely benefits and costs of the opportunity, assuming no blocking patent stands in the way. Opportunities whose net benefits are either negative or fairly insignificant likely are or were not pursued because of a blocking patent.

a) Opportunity Benefits

Inventive (or any) activity tends to be more attractive when the size of the potential opportunity is large. In the pharmaceutical context, this often is driven by the large patient population, favorable reimbursement terms, and/or substantial clinical demand. It is unsurprising that branded manufacturers tend to seek to limit generic competition when the marketplace opportunity is one worth protecting. However, the exact size of the market opportunity varies by context and depends on the therapeutic area, the specific drug, the competitive landscape, and the remaining life of relevant patents.

Large opportunities are rarely ignored by those conducting R&D—and arguably should not be. For instance, prior to the entry of biosimilar competition in 2023, AbbVie's biologic blockbuster Humira™ generated $20 billion in annual revenue and was referred to, after the fact, as "a moneymaking juggernaut."[173] Between 2012 and 2018 alone, Humira™ generated more than $56 billion in sales in the U.S. alone.[174] Holding all else constant, any profit-maximizing firm would and should invest in such an opportunity, even if only a fraction of the actual performance could have been predicted in advance.

Conversely, small opportunities are often foregone. For many of those opportunities, the associated costs outweigh projected revenues. For still others, the investor has more attractive opportunities available.

Almost needless to say, not all opportunities are in the feasible set for all potential investors (inventors). Companies and individuals tend to focus their attention on the endeavors in which they have comparative advantage or interest. Opportunities can be unattractive for various reasons, including having a negative NPV or falling outside the strategic focus (or "strike zone") of the potential investor.

In cases where the predicted profits are substantial, a blocking patent may, depending on the facts, have played a role in discouraging third party invention. But that deterrent effect is difficult to accept at face value, as substantial opportunities usually are not foregone, particularly by entities operating in that technology space. Conversely, when predicted profits are modest, a project may be abandoned for a range

---

173 Ben Adams, *Biosimilars making inroads into Humira sales, but docs still cautious on switching: Spherix*, FIERCE PHARMA (Sept. 19, 2023, 9:35 AM), https://www.fiercepharma.com/marketing/biosimilars-making-inroads-humira-sales-docs-still-cautious-switching-spherix.

174 In re Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811. 820 (N.D. Ill. 2020).

of reasons, including resource constraints, technical hurdles, and the presence of more promising alternatives. In such cases, attributing the lack of innovation solely to a blocking patent might be speculative, at best.

b) Opportunity Costs

Product development, particularly in the pharmaceutical sector, is an inherently costly endeavor. Branded manufacturers should, and generally do, pursue only those projects that are projected to be profitable after accounting for all relevant costs. In short, the net present value ("NPV") of the project must be projected to be positive.[175]

A proper (complete project) NPV analysis must consider all relevant costs, both upfront and ongoing. These include capital investments, research and development expenditures, regulatory approval costs, manufacturing infrastructure, and long-term commercialization expenses. Both direct and indirect costs associated with the project must be included in the analysis. Only when the present value of the projected benefits exceeds the present value of the total anticipated costs can a project be deemed worth pursuing.

However, cost projections are inherently uncertain. Research timelines may stretch, clinical trials can fail, regulatory delays may arise, and manufacturing challenges can increase expenses well beyond initial forecasts. These uncertainties introduce additional risk into the NPV calculation and may discourage the pursuit of otherwise promising projects.

Importantly, not all positive-NPV projects are equally attractive. A project with a projected NPV of $5 may technically be worth pursuing, but it differs significantly in strategic value from one with a projected NPV of $50 million. Though both may be worth pursuing, natural estimation uncertainties and the existence of other opportunities may make the former much less attractive than the latter. Thus, when analyzing whether a blocking patent deterred innovation, it is essential to consider the scale of the expected returns and the relative attractiveness of the opportunity in a real-world business context.

c) Net Present Value

Assessing whether the benefits of a project (investment/invention) exceed the costs of the project involves careful consideration of two additional factors.

The first factor is the probability of success, or probability-adjusted benefits versus probability-adjusted costs. Probability adjustments are central in any evaluation of whether a research and development project, particularly in the pharmaceutical sector, is worth pursuing. Drug development is inherently uncertain, marked by high failure rates, long timelines, and multiple points of attrition. These risks must be incorporated into any NPV analysis.

---

[175] According to the revealed preference principle of economics, that means that all projects that have been pursued must have been deemed to be profitable projects. *See* Paul A. Samuelson, *A Note on the Pure Theory of Consumer's Behaviour*, 5 ECONOMICA 17, 61-71 (1938); Hendrik S. Houthakker, *Revealed Preference and the Utility Function*, 17 ECONOMICA 66, 159-174 (1950).

Historically, the probability of a drug successfully progressing from discovery through FDA approval is low.[176] At each stage of the development process, there are substantial technical, scientific, and regulatory hurdles. Failure at any stage can eliminate years of investment.

Moreover, even successful clinical development does not guarantee commercial success.[177] Market dynamics, pricing pressures, payer reimbursement decisions, and competition from existing therapies can all affect whether an approved drug is economically viable.

The second factor that needs to be considered is the time value of money. In short, a dollar tomorrow is not worth the same as a dollar today. The time value of money is widely accepted in corporate finance. Discounting is the specific process of calculating the present value of a future cash flow.[178] A discount factor, or discount rate, is often applied to future revenues as a way to convert that future value into value today. Discount rates reflect the rate of return on investments made today and the probability of receiving that return, among other factors.[179] For example, $100 in two years may be worth $85 today. That is, an individual or organization like a pharmaceutical company may be indifferent between receiving $85 today and $100 in two years. Assessing the projected value (or NPV) of a project necessarily involves converting all the benefits and costs into current year dollars.

Calculating the free-standing net present value of a project (investment/invention) is an important first step in assessing whether a blocking patent could have been, or was, the reason why a project was not pursued. Many times, a project was not pursued because it was not identified, or was NPV negative, or was not sufficiently NPV positive. A blocking patent may not have been the reason. There may be some instances, however, in which a patent blocked, in whole or in part, further pursuit of a worthwhile project, and was one of or the primary reason why an NPV calculation was determined to be negative or insufficiently large to warrant an investment in inventive activity.

2. Nature of the Potential Block

Evaluation of a blocking patent defense should consider how the uncertainties created by an alleged blocking patent would realistically impact an innovator's decision-making process, covering an otherwise attractive and positive NPV project. In making this assessment, key considerations include 1) the strength of the alleged blocking patent; 2) the scope of the alleged blocking patent; 3) the remaining life of the alleged blocking patent; and (4) the patent owner's willingness to share its intellectual property (IP).

a) Strength of the Blocking Patent

A blocking patent that is strong or perceived-to-be-strong is one that may discourage competing inventive activity by signaling a high risk of infringement litigation. Competitors facing such a patent may conclude

---

176 U.S. Food & Drug Admin., *The Drug Development Process Step 3: Clinical Research,* https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last visited June 8, 2025).

177 Arlene Weintraub, *Failure to launch? Half of drugs rolled out since 2004 didn't live up to sales forecasts: report,* FIERCE PHARMA (Jan. 20, 2021, 10:20 AM), https://www.fiercepharma.com/pharma/half-drugs-launched-last-15-years-failed-to-meet-wall-street-s-expectations-report.

178 CORPORATE FINANCE 97-98 (Stephen A. Ross, Randolph W. Westerfield & Jeffrey Jaffe eds. McGraw-Hill Irwin 2008).

179 *Id*.

that the legal and financial risks of pursuing research or development in the covered area are simply too high to justify the investment.

Whether a competitor believes it could successfully challenge the blocking patent plays a central role in evaluating the impact of the blocking patent. Some patents labeled as "blocking" may, in fact, be vulnerable to invalidation based on prior art, lack of enablement, or on other grounds. If a competitor assesses that the patent is likely to be invalidated, it may proceed with development activities under the assumption that, if necessary, it can litigate and invalidate the patent with minimal risk.

Conversely, a patent perceived as legally robust presents a more formidable barrier. In such cases, potential innovators may decide not to pursue overlapping inventions at all, not because the science is unworkable or the opportunity is unattractive, but because the perceived legal risk outweighs the potential reward.

In *Exelixis v. MSN*, the federal district court of Delaware found the blocking patent defense to be meaningful, in part, because "there were no successful challenges to the [blocking patent]."[180] Though important, that observation cannot be dispositive. That "evidence," however, does not address the issue of whether there were any unsuccessful challenges, or whether there were reasonable beliefs that the blocking patent could be challenged successfully.

One valuable source of evidence here may be patent office rejections. Cotropia and Schwartz (2024) have written that examiner rejections based on prior patents serve as an independent and significant indicator of patent value, suggesting that rejections tied to a blocking patent may reflect its real-world influence on subsequent innovation. Based on data from the U.S. Patent and Trademark Office (USPTO) covering examiner rejections from 2008 through mid-2017, none of the patents identified above in Table 1 that were found to be blocking were cited for "novelty" or "obviousness" reasons as a basis for patent application examiner rejections.

Further, Paragraph IV certifications and the subsequent notices provided to branded pharmaceutical manufacturers may contain statements that generic companies believe a blocking patent is invalid or unenforceable. These certifications provide evidence that third parties view the blocking patent as subject to validity challenges.

Patent invalidations may provide further insight into whether a patent blocked inventive activity. Those can be observed through the outcomes of litigation or administrative proceedings such as inter partes review, particularly where a patent asserted as blocking is ultimately held invalid or narrowed.

Many studies have shown that patents, whether blocking or not, ultimately are deemed to be not valid, unenforceable, or not infringed. According to Allison and Lemley (1998), which analyzed patent validity decisions issued by the federal courts between 1989 and 1996, 46 percent of patents litigated to a final judgment, including decisions on appeal and summary judgment, are held to be invalid.[181] According to Tu (2015), of all patents that were litigated to a final judgment between 2010 and 2011, approximately one-third were found invalid, with invalidity rates varying by technology area.[182] According to other statistics,

---

180 Exelixis, Inc. v. MSN Labs. Priv. Ltd., 2024 U.S. Dist. LEXIS 187077, *93 (D. Del. Oct. 15, 2024).

181 John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q. J., 185, 205-207 (1998).

182 Shine Tu, *Invalidated Patents and Associated Patent Examiners*, 18 VAND. J. ENT. & TECH. L. 1, 135 (2015).

out of all patents that were challenged in an America Invents Act (AIA) proceeding like an inter partes review (IPR) in 2024, 71 percent were determined to be invalid.[183]

In evaluating the strength of a blocking patent defense, consideration should be given to not only the existence of a patent, but also how it may have been perceived at the time the relevant innovation decisions were made. This includes assessments of perceptions of patent validity, enforceability, and the likelihood of a successful challenge, all of which inform whether a patent could plausibly have deterred inventive activity.

b) Scope of the Blocking Patent

A patent's potential blocking ability depends significantly on what it covers, *i.e.*, the scope of the alleged patent. A patent prohibits certain activities, and the nature of the activity covered (such as a method of use, compound, composition of matter, or process) affects the blocking potential of a patent.

When the subject matter of the alleged blocking patent is a *method of use*, the patent prohibits others from using, offering for sale, selling, or importing a product for the claimed method. In *Otsuka v. Lupin*, the defendant identified two patents as potentially blocking.[184] The federal district court of Delaware agreed as to the blocking nature of the first patent, covering the tolvaptan compound.[185] However, it disagreed as to the blocking nature of the second patent, which covered a method of treatment. The court explained that this method patent did not block work on the synthesis process, which was the subject of the patent-in-suit.[186]

When the subject matter is a *formulation*, the patent prohibits the commercialization of products containing that specific formulation. In *Vifor v. Teva*, the federal district court of Delaware found that the blocking patent was limited to the beta form of the active ingredient, whereas the at-issue patent included other forms, including alpha and gamma.[187] The court further noted that there was no evidence that any competitor was precluded from practicing the at-issue patent because of the blocking patent.[188]

Where the blocking patent claims a *process*, the prohibited activities include making, using, selling, offering to sell, or importing a product made by that patented process. However, unless the process is essential to creating the claimed invention, third-party activity may continue in adjacent or alternative areas.

In short, courts have made it clear that covered activities, and therefore blocked activities, are limited to those that are specifically claimed in the asserted blocking patent.

As discussed above, there is a safe harbor provision that permits research and development work, without fear of infringement, on a product that may be submitted for FDA approval. A patent cannot and does not

---

183 Stephen Schreiner, *Recent Statistics Show PTAB Invalidation Rates Continue to Climb,* IPWATCHDOG (June 25, 2024, 12:15 PM), https://ipwatchdog.com/2024/06/25/recent-statistics-show-ptab-invalidation-rates-continue-climb/id=178226/.

184 Otsuka Pharm. Co. v. Lupin Ltd., 2024 U.S. Dist. LEXIS 135251, *51 (D. Del. July 31, 2024).

185 *Id.*

186 *Id.*

187 Vifor Fresenius Med. Care Renal Pharma Ltd. v. Teva Pharms. USA, Inc., 623 F. Supp. 3d 389, 411 (D. Del. 2022)

188 *Id.*

block that activity. Nevertheless, the existence of the safe harbor provision, as noted above, does not categorically negate a blocking patent defense. In *Janssen v. Teva*, the Federal Circuit noted that a "potential innovator might or might not be willing to research in the blocked space without a license to a blocking patent—even if the research itself is within the safe harbor."[189] The court clarified that the safe harbor provision is merely one factor—always present in the ANDA context—among the broader commercial realities that influence whether a blocking patent deters innovation.[190]

Courts consistently have emphasized the need for clear evidence linking a blocking patent to the alleged deterrence. In *Ferring v. Fresenius Kabi*, the federal district court of Delaware criticized Ferring's failure to specify what the claims of the blocking patent covered.[191] The court found it "unclear" and, therefore, unconvincing that the alleged blocking patent even related to the Ferring patent in suit.[192] Simply asserting that a blocking patent existed was insufficient. Similarly, in *Janssen v. Teva*, the federal district court of New Jersey highlighted that Teva's economic expert acknowledged that none of the so-called blocking patents could have prevented competitors from commercializing the dosing regimens claimed in the patent in suit.[193] This lack of evidence as to the scope of the block undermined the blocking patent argument.

c) Life of the Blocking Patent

A patent protects an invention for a limited period, that is, for the life of the patent. Absent an extension, patents issued before 1995 had a life of 17 years from the patent grant date.[194] Patents issued since 1995 have a life of 20 years from the patent filing, or application date, again, absent an extension.[195]

Understanding the timing of a blocking patent in relation to an at-issue patent is critical when assessing its impact. A blocking patent that was granted after the priority date of the at-issue patent cannot, by definition, block inventive activity that occurred before the priority date. Conversely, a patent that was granted before the priority date of the at-issue patent might have blocked third-party work, depending on the nature of other evidence of a block.

As well, a blocking patent that issued close to the priority date of the at-issue patent, or one that expired well in advance of the at-issue patent, likely had little to no deterrent effect on third-party innovation. A blocking patent issued many years before the at-issue priority date, or one that expired close in time to the at-issue patent, is likely to have had a very different effect. Of course, what constitutes "close," "many years before," or "well in advance" are critical, and factual inquiries.

---

189 Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 97 F.4th 915, 936 (Fed. Cir. 2024) (citing *Acorda*, 903 F.3d at 1338).

190 *Id.*

191 Ferring Pharms. Inc. v. Fresenius Kabi United States LLC, 645 F. Supp. 3d 335, 371 (D. Del. 2022).

192 *Id*.

193 Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 571 F. Supp. 3d 281, 324 (D.N.J. 2021), aff'd in part, vacated in part, remanded, 97 F.4th 915 (Fed. Cir. 2024).

194 U.S. Food & Drug Admin., *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program (last visited Feb. 12, 2025).

195 U.S. Patent & Trademark Office, *Manual of Patent Examining Procedure* § 2701, https://www.uspto.gov/web/offices/pac/mpep/s2701.html#.

In *ViiV v. Lupin*, the Defendant's economic expert argued that other researchers were precluded from engaging in inventive work due to the existence of a blocking patent.[196] However, the federal district court of Delaware disagreed, highlighting key facts about the timing of the alleged block:

> It is true that Burroughs Welcome had the right to exclude others from working on all three drug compounds as of the effective filing date. Burroughs Welcome only had the right of exclusivity for a short period of time, however. The rights to market 3TC were gained in March 1994, and […] performed her tests [in …] June 1994. This is not a situation where the patentee was able to block others from attempting to make the claimed inventions for many years - they were formulated a matter of months in the Burroughs Welcomes exclusivity period.[197]

In the pharmaceutical industry, as noted above, it is crucial to consider the long timelines associated with drug development and commercialization. For example, the period from drug synthesis to initial trials averages 52 months,[198] while the time from initial clinical trials to commercialization spans even longer—often several additional years.[199] As discussed above, these extended timelines and the industry's familiarity with safe harbor provisions suggest that a blocking patent is unlikely to completely stifle inventive activity. For instance, a blocking patent set to expire in four years is unlikely to deter much innovation, as research, clinical trials, and the filing of Drug Master Files (DMFs) often occur during the life of a blocking patent. This demonstrates that the existence of a blocking patent cannot categorically, and often does not practically, dissuade much inventive activity.

In *Otsuka v. Lupin*, the court addressed the timing issue and noted that patent applications, publications, ANDAs, and DMFs were submitted nearly three years *after* the blocking patent expired.[200] While some research (and inventive activity) undoubtedly took place during the pendency of the blocking patent, the court wrote "[t]hat only two groups investigated methods of synthesizing tolvaptan close to the priority date of [one of the at-issue patents] [,suggesting that] Otsuka's competitors experienced disincentives in investing resources into this area."[201] The court did not appear to treat the existence of a blocking patent as dispositive. Instead, it focused on the nature and extent of actual activity in the field.

There is a second dimension to the timing issue that bears directly on the evaluation of marketplace success evidence in a nonobviousness analysis. When evaluating marketplace success evidence, the

---

196 ViiV Healthcare UK Ltd. v. Lupin Ltd., 6 F. Supp. 3d 461, 503 (D. Del. 2013).

197 *Id*.

198 Patricia R. Robuck & John I. Wurzelmann, *Understanding the Drug Development Process*, 11 INFLAMMATORY BOWEL DISEASES 1 (2005), S13-S16, at p. S14, Figure 1 (Showing stage 1, drug discovery, and stage 2, preclinical, the two stages before a drug reaches clinical trials, take 6.5 years); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. OF HEALTH ECON. 151, 166 (2003) ("We estimated the average time from synthesis of a compound to initial human testing for self-originated drugs to be 52.0 months").

199 The FDA estimates that clinical trials last several years, and then that FDA approval can take several additional months. *See* U.S. Food & Drug Admin., *The Drug Development Process Step 3: Clinical Research* https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last visited June 8, 2025); U.S. Food & Drug Admin., *Drug Approval Process*, https://www.fda.gov/media/82381/download (last visited June 8, 2025).

200 Otsuka Pharm. Co. v. Lupin Ltd., 2024 U.S. Dist. LEXIS 135251, *53 (D. Del. July 31, 2024).

201 *Id*.

relative success of competing therapies usually is a critical factor. The timing of a blocking patent is irrelevant to the entry or lack of entry of therapies that are not taught by the blocking patent. However, timing becomes significant when considering the entry or absence of therapies that are covered by the blocking patent. If a blocking patent remains in force after the commercialization of a product, it may help explain that product's success by limiting competition in the area. Critical, however, is the definition of the relevant market. And again, a factual, case-specific inquiry is necessary to address that issue.

d) Patent Owner's Willingness to Share its IP

As a practical matter, the impact of an alleged blocking patent on third-party innovation depends not only on the strength, scope, and timing of the blocking patent, but also on whether—and how—the patent holder is expected to exercise its rights. A patent may confer the legal authority to exclude, but the extent to which it actually deters inventive activity often hinges on the patent holder's strategic posture.

Many owners or licensees of patented ventures seek to hold tightly to their rights, while others take a more collaborative approach.[202] According to a Harvard Business School working paper, the licensing market generally is "sizable" and "continuously growing," reaching $57 billion in the pharmaceutical industry based on U.S. and European-based licensing deals in 2016.[203] A JP Morgan 2023 Annual Biopharma Licensing and Venture Report noted that there were 108 deals signed in Q4, 2023 alone, valued at $63.0 billion.[204] Motivations for licensing include reducing development costs, receiving royalty payments, sharing development risks, streamlining a path to profitability, and benefitting from shelved projects.[205]

This reality has important implications for the blocking patent defense. If a patent holder is known to license its IP broadly, or has a history of collaborative agreements, the existence of the patent may not meaningfully deter innovation. Conversely, if the patent holder is known to enforce its rights aggressively and refuses to license, third parties may be more likely to view the patent as a credible block to commercialization. As with other aspects of this inquiry, the analysis must be fact-specific and grounded in real-world behavior, not merely the theoretical rights conferred by a patent.

In *Exelixis v. MSN*, the federal district court of Delaware concluded that the blocking patent defense was strong, in part, because there was "no evidence of a good licensing opportunity."[206] However, the court did not define what constitutes a "good" opportunity. This lack of clarity raises concerns, particularly if the bar is set so high that a generic entrant can prevail on a blocking patent defense merely by pointing to the patent owner's failure to proactively seek out licensees. In fact, of the 9 cases where blocking patents were found, identified above in Table 1, the patent owner licensed rights to all or some of the blocking patents in at least three instances, specifically, *Acorda v. Roxane*, *Allergan v. Teva,* and *Merck II.* Perhaps evidence

---

202 *See* ViiV Healthcare UK Ltd. v. Lupin Ltd., 6 F. Supp. 3d 461, 503 (D. Del. 2013) (the federal district court of Delaware, in rejecting a claim of the existence of a blocking patent, noted that, in this space, researchers frequently shared compounds with other companies in the field to help create new therapies).

203 Mosab Hammoudeh, Joshua L. Kreiger, and Jiajie Xu, *Dusting Off the Old Ones: Drug Licensing to Startups, Innovation Success and Efficiency* 10 (Harvard Business School, Working Paper No. 24-067, 2024).

204 J.P. Morgan, 2023 Annual Biopharma Licensing and Venture Report 2 (Dec. 2023).

205 Hammoudeh et al., *supra* note 203, at 10-11.

206 Exelixis, Inc. v. MSN Labs. Priv. Ltd., 2024 U.S. Dist. LEXIS 187077, *92 (D. Del. Oct. 15, 2024).

of willingness (or steps) to license can best be thought of as case-specific facts to consider in determining the weight of the commercial success evidence.

Courts have recognized the relevance of collaborative practices. In *Ferring v. Fresenius Kabi*, the federal district court of Delaware highlighted an example of a collaborative approach. The court wrote that Ferring had rights to the blocking patent, but it relied on contract manufacturers for synthesis of the drug at issue.[207] This reliance, the court observed, encouraged rather than blocked inventive activity. Specifically, the court wrote that "a contract manufacturer would be encouraged [not blocked] to try to develop a better synthesis… and then offer that to the patent owner."[208]

Similarly, in *UCB v. Accord,* the federal district court of Delaware found that the owners of the claimed blocking patents offered licenses to those patents, and "[t]he availability of a license meant that companies had the opportunity to pursue" the covered class of compounds.[209] The availability of a license and the opportunity to pursue the covered compounds contradicted defendants' assertions that those patents blocked competitors from inventive activity.[210]

Further, in *ViiV v. Lupin*, the federal district court of Delaware noted that at the time of the alleged block, "researchers [in the HIV field] frequently shared compounds with other companies… to help create new HIV [combination] therapies," suggesting that other companies in the industry besides ViiV were unlikely to have been fully disincentivized from pursuing the combinations covered by the at-issue patents.[211]

In *Ferring v. Fresenius Kabi*, the court also pointed to Ferring's lack of in-house process development capabilities during the relevant time period, writing "during the period 2009, up to 2015, [Ferring] didn't have laboratories for process development. So, there was no, what we call 'wet chemistry' ongoing in [its] labs... The 'wet chemistry' was done at PPL but not exclusively at PPL and, at the time of the invention, Ferring was working with at least Dr. Reddy's Laboratories and Lonza in Switzerland around the process chemistry for [the drug]."[212] Based on these facts, the court concluded that there was no block.[213] In fact, there was encouragement to invent.

Together, these cases reaffirm that facts—not generalizations—must drive the analysis. The mere existence of a patent does not establish a block. Courts must examine how the patent was exercised, whether licenses were offered or accepted, and whether the patent holder's conduct fostered or discouraged third-party inventive activity. Licensing behavior, in particular, is best understood as one factor among many in evaluating the weight of commercial success evidence and the viability of a blocking patent defense.

VII. CONCLUSION

Although the blocking patent defense has gained traction in pharmaceutical litigation involving commercial success allegations in recent years, its application and success should not be painted with a

---

207 Ferring Pharms. Inc. v. Fresenius Kabi United States LLC, 645 F. Supp. 3d 335, 371 (D. Del. 2022).

208 *Id*.

209 *UCB, Inc. v. Accord Healthcare, Inc*., 201 F. Supp. 3d 491, 539 (Fed. Cir. 2023).

210 *Id*.

211 ViiV Healthcare UK Ltd. v. Lupin Ltd., 6 F. Supp. 3d 461, 503 (D. Del. 2013).

212 Ferring Pharms. Inc. v. Fresenius Kabi U.S., LLC, 645 F. Supp. 3d 335, 371-72 (D. Del. 2022).

213 *Id.*

broad brush. The application and success are fact dependent. Courts have recognized that the existence of a blocking patent alone is not dispositive; rather, establishing whether a blocking patent meaningfully constrained innovation requires a case-specific inquiry supported by concrete evidence.

That evidence requires an identification of what allegedly was blocked, when the blocking occurred, and how it influenced third-party decision-making. While some blocking patents may deter certain forms of research and development, they rarely create an absolute barrier to inventive activity. Analysis of forward citation data, patent rejections, as well as clinical trials and drug master file applications, if available, often offer valuable insights into whether a blocking patent truly restricted innovation or merely shaped the trajectory of research in a given field.

Evaluating commercial success in light of a blocking patent requires careful consideration of marketplace realities, including competition from alternative products and the extent to which a blocking patent actually limited entry. The Federal Circuit consistently has emphasized that the weight of commercial success as an indicator of nonobviousness should be assessed in the broader context of all relevant evidence. And a blocking patent defense, which is not amenable to a simple binary choice of either existing or not, is just one component of a nonobviousness evaluation.

Further, a blocking patent defense is not a categorical bar to findings of commercial success. Its viability depends on a detailed, fact-specific analysis. As courts continue to refine their approach to this defense, economic and empirical evidence should play an increasingly critical role in shaping its application.