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MENDING THE FENCE:
COMMERCIAL SUCCESS & THE BLOCKING PATENT DEFENSE IN PHARMACEUTICAL LITIGATION

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I. INTRODUCTION

Commercial success often is a crucial after-the-fact consideration in litigations assessing whether a patent was non-obvious. Its evaluation usually entails assessing whether a patented invention (often, a product that incorporates an at-issue patent) 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 were obvious, others beyond the patent owner would have had the incentive to develop the invention before the priority date of the at-issue patent. Conversely, if the invention practicing the at-issue patent is either unsuccessful or the marketplace success is unrelated to the at-issue patent, then that evidence does not support 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.[1] 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.[2] 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 pharmaceutical cases involving claims of commercial success.[3] 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.[4] Over that period, there were sixteen

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1 *See, e.g.*, UCB, Inc. v. Actavis Labs. UT, Inc., 65 F.4th 679, 695–96 (Fed. Cir. 2023) [hereinafter *Actavis Labs. II*]; Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 97 F.4th 915, 934 (Fed. Cir. 2024) [hereinafter *Janssen Pharms. III*].

2 *See, e.g.*, ViiV Healthcare UK Ltd. v. Lupin Ltd., 6 F. Supp. 3d 461, 502–03 (D. Del. 2013) [hereinafter *ViiV Healthcare I*].

3 *See, e.g.*, Sanofi-Aventis Deutschland GmbH v. Mylan Pharm., Inc., 791 Fed. App'x 916, 927–928 (Fed. Cir. 2019); *Actavis Labs. II*, 65 F.4th at 695–697.

4 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 Pharm. USA, Inc., 518 F.3d 1353 (Fed. Cir. 2008) [hereinafter *Pfizer II*]; Otsuka Pharm. Co. v. Sandoz, Inc., 678 F.3d 1280 (Fed. Cir. 2012) [hereinafter *Otsuka Pharm. Fed. Cir.*]; and Galderma Labs., L.P. v. Tolmar, Inc., 737 F.3d 731, 740

(16) published district court opinions in pharmaceutical cases that addressed, in part, the blocking patent defense.[5] 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 thirty-two.[7] The blocking patent defense appears to be increasingly invoked, and much of the time, it has succeeded.

Despite its growing use and acceptance, the foundations 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 an earlier invention is a fact-specific inquiry that must be resolved

(Fed. Cir. 2013). The two cases in which the Federal Circuit found a blocking patent are *Merck & Co.*, 395 F.3d at 1377, and *Galderma Labs.*, 737 F.3d at 740.

5 Westlaw search for (pharmaceutical or drug) & ((block*! /s patent)) & "commercial success" (conducted July 24, 2025). When the court addressed the same allegation of blocking multiple times, repeat results were combined and deduplicated so that only the most up-to-date opinions were counted. This yielded a total of 16 cases during this timeframe.

6 The 11 cases in which the Federal Circuit issued opinions are ViiV Healthcare UK Ltd. v. Lupin Ltd., 594 Fed. App'x 686 (Fed. Cir. 2015) [hereinafter ViiV Healthcare II]; UCB, Inc. v. Accord Healthcare, Inc., 890 F.3d 1313 (Fed. Cir. 2018) [hereinafter Accord Healthcare II]; Allergan, Inc. v. Teva Pharm. USA, Inc., 742 Fed. App'x. 511 (Fed. Cir. 2018) [hereinafter Allergan II]; Merck Sharp & Dohme Corp. v. Hospira, Inc., 874 F.3d 724 (Fed. Cir. 2017) [hereinafter Merck II]; Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 903 F.3d 1310 (Fed. Cir. 2018) [hereinafter *Acorda Therapeutics II*]; Hospira, Inc. v. Amneal Pharms. LLC, 748 Fed. App'x 1024 (Fed. Cir. 2019) [hereinafter Hospira II]; BTG Int'l Ltd. v. Amneal Pharms. LLC, 923 F.3d 1063 (Fed. Cir. 2019); Sanofi-Aventis Deutschland GmbH v. Mylan Pharm., Inc., 791 Fed. App'x 916 (Fed. Cir. 2019); Amgen, Inc. v. Sandoz, Inc., 66 F.4th 952 (Fed. Cir. 2023); Actavis Labs. II, 65 F.4th at 696; Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 760 F. Supp. 3d 184, 223 (D.N.J. 2024) [hereinafter Janssen Pharms. II]. The seven cases in which they found a blocking patent are Allergan II, 742 Fed. Appx. at 511; Merck II, 874 F.3d at 730; Hospira II, 748 Fed. App'x at 1024; *Acorda Therapeutics II*, 903 F.3d at 1138–40; BTG Int'l, 923 F.3d at 1076; and Sanofi-Aventis, 791 Fed. App'x at 938; and Actavis Labs. II, 65 F.4th at 696. Although the Federal Circuit sided with the defendant in Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 97 F.4th 915, 936 (Fed. Cir. 2024) [hereinafter Janssen Pharms. III], 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., 760 F. Supp. 3d 184, 223 (D.N.J. 2024) [hereinafter Janssen Pharms. II].

7 Westlaw search for (pharmaceutical or drug) & ((block*! /s patent)) & "commercial success" (conducted July 24, 2025). When the court addressed the same allegation of blocking multiple times, repeat results were combined and deduplicated so that count only the most up-to-date opinions. This yielded a total of 32 cases during this timeframe.

on a case-by-case basis.[8] 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.

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 non-obviousness 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.[9] Particularly troubling is when courts overlook or fail to consider real-world evidence showing that others were actively working in the field of the claimed invention.[10] 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 non-obvious.

In Part II of this Article, we briefly describe the legal framework governing the non-obviousness argument, focusing on the role of commercial success as a secondary consideration. In Part III, we analyze how courts evaluate claims of commercial success in pharmaceutical cases, including how they determine the nexus between marketplace success and the patented invention. Part IV examines the development and increasing use of the blocking patent defense as a response to a commercial success argument, highlighting recent Federal Circuit decisions that have shaped the doctrine. In Part V, we explain that the blocking patent defense often is applied with limited care, undermining its reliability. In response to its often-questionable application, in Part VI, we offer a framework for properly evaluating and applying the blocking patent defense, grounded in real-world evidence and economic principles. Finally, in Part VII, we conclude by emphasizing the need for a nuanced, fact-specific approach to assessing the blocking patent defense in pharmaceutical litigation.

II. NON-OBVIOUSNESS ARGUMENT

To be patentable, an invention must not have been obvious to a person skilled in the relevant field at the time of the invention.[11] This standard ensures

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[8] *See, e.g.*, *Merck II*, 874 F.3d at 731.

[9] *See, e.g.*, UCB, Inc. v. Actavis Labs. UT, Inc., No. CV 19-474-KAJ, 2021 WL 1880993, at *19 (D. Del. Mar. 26, 2021), *aff'd,* 65 F.4th 679 (Fed. Cir. 2023) [hereinafter *Actavis Labs. I*], *affirmed by Actavis Labs. II*, 65 F.4th at 695–96.

[10] *See, e.g.*, Merck Sharp & Dohme Corp. v. Hospira Inc., 221 F. Supp. 3d 497, 512–13 (D. Del. 2016) [hereinafter *Merck I*].

[11] *See* Graham v. John Deere Co., 383 U.S. 1, 36-37 (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 & Mark A. Lemley, *A*

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.[12]

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 non-obviousness:"[13]

- commercial success,
- long-felt but unmet need,
- failure of others,
- copying by others,
- unexpected results, and
- licensing and industry recognition.[14]

These objective indicia of non-obviousness 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 val*id.*

While objective indicia of non-obviousness, 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

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Realistic Approach to the Obviousness of Inventions, 50 WM. & MARY L. REV. 989, 990 (2008).

12 *Graham*, 383 U.S. at 2.

13 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 to an invalidity challenge. *See* Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 1392 (Fed. Cir. 1988).

14 *Graham*, 383 U.S. at 2.

considerations must always be considered.[15] Further, the Federal Circuit has "emphasized that consideration of the objective indicia is part of the whole obviousness analysis, not just an afterthought."[16] The decisions "generally have made clear that a fact finder must consider *all* evidence of obviousness and non-obviousness before reaching a determination."[17]

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.[18] Significant marketplace success with a nexus to the at-issue patent often suggests that an invention provided something valuable and non-obvious that others in the field had not previously achieved or anticipated.[19] In other words, commercial success may indicate that the invention solved a problem or fulfilled a marketplace 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."[20] 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*."[21]

Analysis of commercial success is reasonably straightforward 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 – largely due to the U.S. Food and Drug Administration (FDA) regulatory

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

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

17 *In re* Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063, 1077 (Fed. Cir. 2012).

18 *See* John Jarosz & Robert Vigil, *Assessing Commercial Success at the U.S. Patent Trial and Appeal Board*, 8 INT'L IN-HOUSE COUNS. J. 32, 5 (2015); *see also Merck I*, 221 F. Supp. 3d at 512 (citing *Graham*, 383 U.S. at 17–18); *Actavis Labs. II*, 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., No. 14-882-LPS, 2017 WL 1184207, at *79 (D. Del. Mar. 31, 2017) [hereinafter *Acorda Therapeutics I*].

19 *See, e.g.*, *Merck I*, 221 F. Supp. 3d at 511–12.

20 *Merck & Co.*, 395 F.3d at 1376.

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

requirements.[22] Because obviousness is evaluated as of the time of invention, not commercialization,[23] 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.[24] 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.[25] Courts have held that a drug may qualify as a commercial success if it outperforms a majority of peers in its class; it need not outperform all.[26]

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.[27] Those other factors that may have driven success include the patent owner's marketing efforts, favorable pricing, switching costs, physician prescribing patterns, patient inertia, a first-mover advantage, or other business strategies.[28] The existence of other factors does not negate the existence of a sufficient causal nexus, but an

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22 NORMAN R. AUGUSTINE ET AL., MAKING MEDICINE AFFORDABLE: A NATIONAL IMPERATIVE 34 (Nat'l Acad. Press 2018).

23 *See, e.g.*, *2141 Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 [R-01.2024]*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/web/offices/pac/mpep/s2141.html# [perma.cc/2LPZ-CMES] [hereinafter *2141 Examination Guidelines for Determining Obviousness*] ("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 Tech. 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.").

24 *See, e.g.*, Chemours Co. FC, LLC v. Daikin Indus., Ltd., 4 F.4th 1370, 1378 (Fed. Cir. 2021).

25 *See, e.g.*, *ViiV Healthcare I*, 6 F. Supp. 3d at 502 ("The fact that a commercial embodiment is not the most popular product on the market . . . does not dictate that the embodiment is not a commercial success.").

26 *See id.*

27 *See Acorda Therapeutics I*, 2017 WL 1184207 at *110.

28 *See, e.g.*, *Acorda Therapeutics I*, 2017 WL 1184207 at *110–11; Janssen Pharms., Inc. v. Teva Pharms. USA, Inc., 571 F. Supp. 3d 281, 322–23 (D.N.J. 2021) [hereinafter *Janssen Pharms. I*].

appropriate analysis often does (and should) consider the importance of the at-issue patent versus those other factors.[29]

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."[30] 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.

Every product reflects a bundle of features/attributes, and no single feature/attribute fully explains demand for any product.[31] Further, the drivers of success in the pharmaceutical industry differ from those in other industries. To obtain approval, drugs must satisfy essential thresholds of safety and efficacy;[32] to be marketable, they must also meet requirements such as bioavailability, formulation, and dosage regimen.[33] Unlike consumer products, which can succeed in the face of numerous tradeoffs, a drug that fails to meet any of these essential criteria cannot be sold at all.[34]

In pharmaceutical commercial success cases, whether or not a blocking patent defense is raised, the measures of success are evaluated *ex post*, after the product has been commercialized and well after the priority (invention) date of the patent at issue.[35] This raises a fundamental question: what role can commercial success play in assessing non-obviousness, given that no such success existed at

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29 *See Acorda Therapeutics I*, 2017 WL 1184207 at *110–11.

30 *Id.* at *111.

31 Kelvin Lancaster, *A New Approach to Consumer Theory*, 74 J. POLIT. ECON. 2, 132–157 (1966).

32 *See The Drug Development Process Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-3-clinical-research [perma.cc/7NJF-W7KN] [hereinafter *The Drug Development Process Step 3*].

33 *See* Ningfeng Fiona Li, *The Art and Science of Drug Formulation*, DRUG TARGET REVIEW (Aug. 9, 2024), https://www.drugtargetreview.com/article/152120/the-art-and-science-of-drug-formulation/ [perma.cc/27FC-R74F].

34 *See* Duxin Sun et al., *Why 90% of Clinical Drug Development Fails and How to Improve It?*, 12 ACTA PHARMACEUTICA SINICA B 3049, 3049 (2022).

35 An *ex post* analysis of success is an inherent feature of commercial success in pharmaceutical cases, where the patent challenger is a generic company seeking to invalidate a brand drug manufacturer's patent. The generic only seeks to compete with the brand drug after it has been on the market for some time, typically several years. *See, e.g., Acorda Therapeutics II*, 903 F.3d at 1313. In some cases, pre-launch forecasts (*i.e.*, *ex ante* expectations) are available and can be used to assess *ex post* performance in that one can compare how the product performed in reality relative to its expected performance at the time of launch. For products that sold more than expected, this is another signal of success.

the time of invention (because there was no commercialization at that point)?[36] That is particularly true in pharmaceutical contexts, where the path from invention to market may span a decade or more.[37] 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, the marketplace performance of a patent-practicing product typically is (and usually needs to be) evaluated in *relative* terms. Revenue figures alone often are meaningless without context. That same amount could represent a dominant market share in one therapeutic area and a negligible share in another.[38] 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,[39] thereby rendering commercial success uninformative for 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."[40] That broader view aligns with sound economic principles. Zhu (2020) observed that

[36] 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.

[37] AUGUSTINE ET AL., *supra* note 22, at 34.

[38] For example, Slynd® is a progestin-only oral contraceptive, which accounts for a larger market share of the small progestin-only oral contraceptive market, but a smaller share of the broader oral contraceptive market more generally. *See Have Questions About Slynd?*, SLYND, https://slynd.com/faqs/ [perma.cc/65HS-6TDM]; Exeltis USA, Inc. v. Lupin Ltd., No. 22-434-RGA, 2024 WL 4040470, at *32 (D. Del. Sep. 4, 2024).

[39] 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.

[40] *Acorda Therapeutics II*, 903 F.3d at 1353–54.

> [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.[41]

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.[42] 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.[43] 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."[44] 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.[45]

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41 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, 341–42 (2019).

42 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. For example, in the District Court opinion in *Janssen v. Teva*, the court cited *Merck II* for the understanding that "'the mere existence' of blocking patents alone is not necessarily enough to undermine evidence of long-felt need and commercial success," and wrote that "In this case, a competitor was incentivized to and did invest the resources to develop a competing paliperidone product during the allegedly blocked period." *See Janssen Pharms. II*, 760 F. Supp. 3d at 223.

43 *Sanofi-Aventis*, 791 Fed. App'x at 919.

44 *Id.* at 928.

45 *Id.*

Another view of market definition appeared in *ViiV v. Lupin*,[46] where the federal district court of 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.[47] The court concluded that the appropriate market for purposes of determining commercial success was the more narrow one (a certain class of drugs), though still broader than a single compound.[48] 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.[49]

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

A blocking patent defense, however, can matter when considering other non-obviousness factors beyond commercial success, such as long-felt but unmet need, failure of others, and unexpected results.[50] According to David Manspeizer's reading of *Acorda*, the blocking patent doctrine applies to each of the six non-obviousness considerations.[51] 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 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 are critical, as discussed below.

IV. BLOCKING PATENT RESPONSE

The blocking patent defense has been argued increasingly in pharmaceutical litigation, particularly as a response to commercial success arguments. This section outlines how courts—especially the Federal Circuit—have

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46 *ViiV Healthcare I*, 6 F. Supp. 3d at 501.

47 *Id.*

48 *Id.*

49 *Id.* at 501–02 ("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.").

50 *See Janssen Pharms. III*, 97 F.4th at 935.

51 David Manspeizer, *'Blocking Patent' Doctrine May Now Apply to All Technologies*, LAW360 (Dec. 6, 2019), https://www.law360.com/articles/1224918 [perma.cc/X62R-28CX].

framed and applied the defense, and it traces its development through key cases to show how its role in non-obviousness analyses has evolved over time.

A. OVERVIEW

A blocking patent defense is used to counter the value of commercial success in proving non-obviousness.[52] 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. In other words, the success of the patent-practicing product—if it was successful at all—stemmed not from innovation, but from the lack of competition caused by the blocking patent. As a result, the argument goes, there is no nexus (or causal connection) between the invention's marketplace success and the at-issue patent itself.[53]

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]

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[52] 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*, IPWATCHDOG (Oct. 12, 2018), https://ipwatchdog.com/2018/10/12/expansion-blocking-patent-doctrine-trading-logic-gremlins/id=102260/ [perma.cc/64CT-2UL8]; David Manspeizer, *'Blocking Patent' Doctrine May Now Apply to All Technologies*, LAW360 (Dec. 6, 2019), https://www.law360.com/articles/1224918 [perma.cc/X62R-28CX]. Examples of non-pharmaceutical cases analyzing blocking patents include *Carpet Seaming Tape Licensing Corp. v. Best Seam Inc.*, 616 F.2d 1133 (9th Cir. 1980); *Int'l Mfg. Co. v. Landon, Inc.*, 336 F.2d 723 (9th Cir. 1964); and *Chemours Co.*, 4 F.4th 1370. This may be due to the inherent unpredictability of pharmaceutical science, which can create fact patterns that 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 overlapping patents—so a single patent may have a greater deterrent effect than in fields like consumer electronics. Finally, the slower pace of innovation in the pharmaceutical sector—largely due to regulatory hurdles—may make the absence of competing R&D appear more consistent with blocking, even when that is not the case.

[53] The growing reliance on the blocking patent defense may be an attempt to fight presumed evergreening—a strategy used by companies to extend the life of their patents through new filings, minor drug modifications, or acquisitions. *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 MED. 142, 1 (2012). 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. BIOSCI. 590 (2018). Of course, there is great debate about the existence, extent, and merits of patent evergreening.

question."[54] 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.[55]

In *Acorda*, the Federal Circuit provided new context and structure to the blocking patent defense by identifying a set of factors to evaluate 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;
- **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;

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[54] *Merck & Co.*, 395 F.3d at 1377; *see also* Hospira, Inc. v. Amneal Pharms. LLC, 285 F. Supp. 3d 776, 796 (D. Del. 2018) [hereinafter *Hospira I*].

[55] *Acorda Therapeutics II*, 903 F.3d at 1337 (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).

- **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.[56]

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."[57] 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."[58]

The impact of blocking patents in commercial success analyses can vary significantly by claim type. Compound claims, which cover the active ingredient, tend to be the most restrictive, often conferring some de facto exclusivity until expiration.[59] In contrast, method-of-use and dosage regimen claims may leave more room for inventive and commercial activity due to available alternative approaches or narrower infringement risk.[60] Treating all patents alike risks overstating the strength of the blocking defense.

While the Federal Circuit has accepted the blocking patent defense in pharmaceutical cases since at least *Merck I* in 2005, academic scholarship identified blocking patents as a potential impediment to innovation well before then.[61] 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

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[56] *Acorda Therapeutics II*, 903 F.3d at 1338; DeForest McDuff et al., *Thinking Economically About Blocking Patents: Did Acorda Create a New Paradigm?*, 12 LANDSLIDE 42, 43 (2020).

[57] *Merck II*, 874 F.3d at 730.

[58] *Id.*

[59] Timothy R. Holbrook, *Method of Patent Exceptionalism*, 102 IOWA L. REV. 1001, 1011 (2017).

[60] *Id.* at 1005.

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

it found that a block existed in over three times as many cases as it did in the prior ten years.[62]

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.[63] Over time, this trend could "'stifle innovation' or 'disincentivize[]' innovation in the pharmaceutical industry."[64]

Perhaps not surprisingly, the branded 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."[65]

B. BRIEF HISTORY

In *Merck I*, the Federal Circuit addressed the non-obviousness of a patent embodied in the once-weekly dosing regimen of Merck's osteoporosis drug Fosamax™.[66] Although the court acknowledged the success of the drug and its dosing regimen, it concluded that such evidence was "not significantly probative" of the non-obviousness of the patent at issue.[67] 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™.[68] This indicated to the court that Merck blocked others from research and commercialization in that domain.[69] As a result, the Federal Circuit concluded that "the inference of non-obviousness of weekly-dosing, from evidence of [product] success, is weak."[70] Importantly, the *Merck I* court did not

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62 *See supra* notes 4, 6, and accompanying text.

63 Zhu, *supra* note 41, at 328–30.

64 *Id.*; Matthew Bultman, *Fed. Circ. Ruling Takes 'Blocking Patents' to New Places*, LAW360 (Sept. 18, 2018), https://www.law360.com/articles/1083942/fed-circ-ruling-takes-blocking-patents-to-new-places [perma.cc/U6R3-BSBD].

65 *See, e.g.*, Brief for Allergan, Inc. et al. as Amici Curiae Supporting Petitioner at 18, Acorda Therapeutics, Inc. v. Roxane Labs., Inc., 140 S. Ct. 111 (2019) (No. 18-1280) [hereinafter Allergan Amicus Br.].

66 *Merck & Co.*, 395 F.3d at 1366. 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."

67 *Id.* at 1377.

68 *Id.*

69 *Id.*

70 *Id.*

address alternative ways, beyond testing in the U.S., in which inventive activities could have occurred.[71]

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."[72] The court concluded, consistent with *Merck I*, that the success of Differin Gel, 0.3%, was of "minimal probative value" in demonstrating non-obviousness.[73]

The Federal Circuit has continued to endorse the use of the blocking patent defense.[74] In *UCB v. Actavis* (2023),[75] the Federal Circuit upheld a district court finding that UCB's extensive patent portfolio weakened the inference of non-obviousness based on commercial success, noting that other UCB patents had "operated as blocking patents dissuading competitors from developing" comparable delivery systems for the active pharmaceutical ingredient.[76] UCB argued that the lower court's ruling "would effectively brand all co-owned patents as 'blocking.'"[77] 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.[78] 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."[79] 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.[80]

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

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71 *Id.* at 1371–77.

72 *Galderma Labs*., 737 F.3d at 741.

73 *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.

74 *Allergan II*, 742 Fed. App'x at 511; *Merck II*, 874 F.3d at 730; *Acorda Therapeutics II*, 903 F.3d at 1342; *Hospira II*, 748 Fed. App'x at 1024; *BTG Int'l*, 923 F.3d at 25; *Sanofi-Aventis*, 791 Fed. App'x at 928; *Actavis Labs. II*, 65 F.4th at 696.

75 *Actavis Labs. II*, 65 F.4th at 679.

76 *Id.* at 696.

77 *Id.*

78 *Id.*

79 *Id.* at 696–97.

80 *Id.* at 697.

indicated for the treatment of schizophrenia.[81] 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.[82] The Federal Circuit initially agreed with Teva, writing that Janssen's arguments were based on two faulty premises.[83] First, Janssen's analysis of blocking patents focused broadly on the "blocked space" rather than on the specific invention at issue.[84] The court noted that even if a different formulation of paliperidone palmitate was not blocked, it was not relevant to the case at hand.[85] 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.[86] 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.[87] Moreover, the safe harbor protection is eliminated once FDA submissions are complete because the safe harbor provision no longer protects activity after that point.[88]

Following these findings, the Federal Circuit in *Janssen v. Teva* remanded the case to the district court to re-evaluate secondary considerations of non-obviousness in light of the Federal Circuit's opinion.[89] 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.[90] 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.[91] The 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.[92]

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81 *Janssen Pharms. III*, 97 F.4th at 918.

82 *Id.* at 935–36.

83 *Id.* at 936.

84 *Id.*

85 *Id.*

86 *Id.*

87 *Janssen Pharms. III*, 97 F.4th at 936.

88 *Id.*

89 *Id.* at 937.

90 *Janssen Pharms. II*, 760 F. Supp. 3d at 224.

91 *Id.* at 223–24.

92 *Id.*

V. PROBLEMS WITH THE BLOCKING PATENT DEFENSE

Although increasingly successful in pharmaceutical cases, the blocking patent defense is often applied superficially and without sufficient evidentiary support. As discussed below, it should not be treated as a binary inquiry or categorical rule. Even when a prior patent exists, its relevance and the degree to which it blocked future development depend on specific facts—what was blocked, when, and how—and should be evaluated alongside other evidence, grounded in real-world, not theoretical, considerations, whenever possible.

A. NOT A BINARY ISSUE

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?"93 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. In fact, as described below, substantial inventive activity often occurs even in areas subject to so-called blocking patents.

Instead, 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 an evaluation of the extent to which the patent in question deterred or limited innovation.

B. NOT DISPOSITIVE

A showing of commercial success typically is insufficient on its own to support a finding of non-obviousness. The blocking patent defense typically is insufficient on its own to undercut a finding of non-obviousness. 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.[94] 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 non-obviousness... from evidence of commercial success[] is weak.'"[95] Similarly, in *UCB v. Actavis*, the Federal Circuit found that the presence of blocking patents "weakened [the] evidence of commercial success."[96] The Federal Circuit's flexible, case-specific approach ensures that the defense is not treated as a categorical rebuttal to evidence of non-obviousness.

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93 *See, e.g.*, *ViiV Healthcare I*, 6 F. Supp. 3d at 502–03.

94 *See, e.g.*, *Acorda Therapeutics II*, 903 F.3d at 1337–38.

95 *Merck II*, 874 F.3d at 730.

96 *Actavis Labs. II,* 65 F.4th at 696.

The effect of a blocking patent on commercial success generally should be considered in the broader context of all non-obviousness factors. It may strengthen or weaken a case, but it is not dispositive.[97] 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."[98]

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

C. 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.[99]

In *Merck II* in 2017,[100] 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,"[101] and emphasized that commercial success remains a "fact-specific inquiry."[102] It noted that the mere existence of one or many blocking patents does 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."[103]

In *UCB v. Actavis* in 2023, the Federal Circuit again rejected the broad proposition that all co-owned patents automatically qualify as "blocking patents."[104] The Court pointed out that UCB's expert economist failed to analyze whether UCB's multiple patents were responsible for the asserted commercial success.[105] 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

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97 *See, e.g.*, *Merck & Co.*, 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.").

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

99 *See, e.g.*, *Galderma Labs.*, 737 F.3d at 740.

100 *Merck II*, 874 F.3d at 724, 730–31.

101 *Id.* at 730.

102 *Id.* at 731.

103 *Id.* (emphasis in original); *see also Acorda Therapeutics II*, 903 F.3d at 1310, 1338 ("[A]s a theoretical matter, a blocking patent may or may not deter innovation in the blocked space.").

104 *Actavis Labs. II*, 65 F.4th at 696.

105 *Id.* at 696–97.

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. [106]

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, the nexus chain between commercial success and the patented invention is broken.[107] For example, in *Merck II*, the district court broadly discounted commercial success evidence based on the blocking effect of the '820 patent, asserting it left no incentive for others to develop alternative formulations for ertapenem.[108] However, the court offered no evidence of what was actually blocked or when, treating the patent's existence as sufficient—contrary to the Federal Circuit's directive for a fact-specific inquiry.[109]

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 categorical blocking patent defense that is not grounded in specific evidence is neither persuasive nor consistent with Federal Circuit precedent.[110]

D. NOT A CATEGORICAL DEFENSE

The blocking patent defense cannot be applied as a blanket rule. Its significance should be based on a detailed, fact-specific analysis that considers the scope of the alleged block, the timing of the claimed blocking patent relative to the at-issue invention, and the existence of and nature of any inventive activity that may have occurred despite the alleged block. Rather than assuming that the mere existence of a prior patent nullifies evidence of commercial success, courts should evaluate whether and to what extent the earlier patent actually deterred innovation that might have predated the priority date of the at-issue patent.

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106 *Id.*

107 *See, e.g.*, *Merck I*, 221 F. Supp. 3d at 512–13.

108 *Id.*

109 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." Transcript of Tr. at 313:5–6, Otsuka Pharm. Co. v. Sandoz, Inc., No. 3:07-cv-01000 (D.N.J. Aug. 6, 2010), ECF No. 346.

110 *Acorda Therapeutics II*, 903 F.3d at 1328–29, 1337.

1. Substantive Block

A patent is granted for a specific invention, and its scope or coverage is limited to what is explicitly claimed.[111] The claimed invention may pertain to a pharmaceutical compound, a composition of matter, a method of treatment, or a process for manufacturing.[112] 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.[113]

In pharmaceutical litigations, an asserted blocking patent often refers to one that covers the underlying pharmaceutical compound or genus of compounds.[114] 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.[115]

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111 *Patent Essentials*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/essentials#questions [perma.cc/5ZBR-VSWD] [hereinafter *Patent Essentials*]; *Scope of Patent Protection Under Federal Law*, JUSTIA (Oct 2024), https://www.justia.com/intellectual-property/patents/scope-of-patent-protection/ [perma.cc/L7UP-DTP2].

112 *2106 Patent Subject Matter Eligibility*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/web/offices/pac/mpep/s2106.html [https://perma.cc/TZ7P-VHWJ]; SAGACIOUS IP, https://sagaciousresearch.com/ [perma.cc/VM5Y-W4LF]. 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."

113 *Patent Essentials*, *supra* note 111.

114 *See infra* Table 1.1; Table 1.2.

115 *Merck & Co.*, 395 F.3d at 1366; *Pfizer II*, 518 F.3d at 1355-56; *Otsuka Pharm. Fed. Cir.*, 678 F.3d at 1280; *Galderma Labs.*, 737 F.3d at 734; *ViiV Healthcare II*, 594 Fed. App'x at 686; *Accord Healthcare II*, 890 F.3d at 1321–22; *Allergan II*, 742 Fed. App'x at 511; *Merck II*, 874 F.3d at 724–25; *Hospira II*, 748 Fed. App'x at 1024; *Acorda Therapeutics II*, 903 F.3d at 1336; 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. App'x 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 1.1: Federal Circuit Pharmaceutical Blocking Patent Cases (1 of 2)

	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	8/14/98	11/30/99	7/17/18	Alendronate monosodium trihydrate	4,621,077	11/4/86	8/6/07	Method of Treatment
Galderma Labs v. Tolmar (2013)	7,579,377	9/10/04	8/25/09	2/25/25	Adapalene	RE 34,440	11/9/93	1/16/12	Composition, Method of Treatment
	7,737,181	7/28/06	6/15/10	8/29/24					
	7,834,060	5/7/09	11/16/10	5/16/23					
	7,838,558	4/15/08	11/23/10	3/12/23		4,717,720	1/5/88	5/31/10	Compound
	7,868,044	5/3/10	1/11/11	3/12/23					
Allergen, Inc. v. Teva Pharm. (2017)	8,629,111	8/14/13	1/14/14	8/27/24	Cyclosporin	4,839,342	6/13/89	8/2/09	Method of Treatment
	8,648,048	8/14/13	2/11/14	8/27/24					
	8,685,930	8/7/13	4/1/14	8/27/24		5,474,979	12/12/95	5/17/14	Composition
	9,248,191	3/21/14	2/2/16	8/27/24					
Merck Sharp & Dohme Corp. v. Hospira (2017)	6,486,150	4/27/01	11/26/02	10/27/20	Ertapenem	5,478,820	12/26/95	11/21/15	Compound

Table 1.2 : Federal Circuit Pharmaceutical Blocking Patent Cases (2 of 2)

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
Hospira, Inc. v. Amneal Pharm. (2018)	8,242,158	1/4/12	8/14/12	1/4/32	Dexmedetomidine	4,910,214	3/20/90	7/15/13	Compound
	8,338,470	7/3/12	12/25/12	1/4/32					
	8,455,527	11/15/12	6/4/13	1/4/32					
	8,648,106	4/22/13	2/11/14	1/4/32					
Acorda Therapeutics, v. Roxane Labs. (2018)	8,007,826	12/13/04	8/30/11	5/26/27	4-aminopyridine	5,540,938	7/30/96	10/24/19	Compound
	8,663,685	7/20/11	3/4/14	1/18/25					
	8,354,437	4/8/05	1/15/13	12/22/26					
	8,440,703	11/18/11	5/14/13	4/8/25					
BTG Int'l Ltd. V. Amneal Pharm. (2019)	8,822,438	2/24/11	9/2/14	8/24/27	Abiraterone	5,604,213	2/18/97	7/25/17	Methods of Use
Sanofi-Aventis Deutschland GMBH v. Mylan Pharm. (2017)	7,476,652	3/25/05	1/13/09	7/23/23	Insulin glargine	5,656,722	8/12/97	9/12/14	System, Method of Manufacture
	7,713,930	12/4/08	5/11/10	6/13/23		6,100,376	8/8/00	9/3/12	Compound
UCB, Inc. v. Actavis Labs. (2023)	10,130,589	1/31/18	11/20/18	12/22/30	Rotigotine	6,884,434	4/26/05	3/31/21	System
						7,413,747	8/19/08	9/21/20	System

Compound patents block others from making, using, offering for sale, and selling that compound.[116] 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").[117] 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.[118]

In the pharmaceutical industry, innovation typically proceeds through a series of resource-intensive[119] activities that can be roughly grouped into three general phases: (1) research, (2) development, and (3) commercialization. It is rare for a so-called blocking patent to hinder work in all three of these phases, and, in fact, considerable activity often occurs *after* the issuance of a claimed blocking patent.

Further, while existing patents do have the power to exclude the use of certain inventions in future products, the act of patenting an invention also opens up that technology to further innovation. Patent publication is, by law, a process of divulging inventors' proprietary knowledge publicly to the world.[120] The U.S. Supreme Court pointed to this goal of patent publication, clarifying that "the

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116 Michael A. Carrier & S. Sean Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 TEX. INTELL. PROP. L.J. 79, 82 (2024) (describing various types of pharmaceutical patents); Barbara J. Williams, *A Prescription for Anxiety: An Analysis of Three Brand-Name Drug Companies and Delayed Generic Drug Market Entry*, 40 NEW ENG. L. REV. 1, 66 (2005) (discussing the difference between compound patents and formulation patents).

117 Otsuka Pharm. Co. v. Lupin Ltd., No. CV 21-900-RGA, 2024 WL 3618123, at *19 (D. Del. July 31, 2024) (referencing Benzoheterocyclic compounds, U.S. Patent No. 5,258,510 (issued Nov. 2, 1993) and Benzoheterocyclic compounds, U.S. Patent No. 5,753,677 (issued May 19, 1998)).

118 *Id.* at *35.

119 *See* McDuff et al., *supra* note 56, 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 (1st ed. 2018))); Carlos Maria Correa, *Ownership of Knowledge—The Role of Patents in Pharmaceutical R&D*, 82 BULL. 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'Y 212 (2016); Suzanne Scotchmer, *Standing on the Shoulders of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERS. 1, 29 (1991); Stoyan A. Radkov, *Freedom to Operate (FTO) from a Large Company's Perspective,* ROYAL SOCIETY OF CHEMISTRY (Oct. 11, 2010), https://www.rsc.org/images/stoyanradkov_tem18-192425.pdf [perma.cc/ZHG2-NDPU].

120 Deepak Hedge et al., *Patent Publication and Innovation*, 131 J. POLIT. ECON. 1845, 1845–1903 (2023).

publication requirement seeks to inform the work of follow-on inventors and reduce duplicative research and development (R&D)."[121] 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.[122] 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."[123] 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.[124] 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 the manufacture, use, or sale of drugs or veterinary biological products.[125]

As a result, many third-party research activities—such as studies aimed at generating data for FDA submissions— are protected under the safe harbor provision and are not blocked by existing patents.[126] 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."[127]

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

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121 *Id.* at 1846.

122 *See, e.g.*, J.P. WALSH ET AL., EFFECTS OF RESEARCH TOOL PATENTS AND LICENSING ON BIOMEDICAL INNOVATION, IN PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285–86 (Wesley M. Cohen & Stephen A. Merrill eds., Nat'l Research Council 2003).

123 Hedge et al., *supra* note 120, at 1872, 1898.

124 35 U.S.C. § 271(e)(1).

125 *Id.*

126 Alicia A. Russo & Jason Johnson, *Research Use Exemptions to Patent Infringement for Drug Discovery and Development in the United States*, 5 COLD SPRING HARB. PERSP. MED. 1, 7 (2015).

127 Immunotherapies, Inc. v. Elan Pharms., Inc., 786 F.3d 892, 898–99 (Fed. Cir. 2015).

related to active pharmaceutical ingredients originally patented by branded pharmaceutical companies.[128]

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.[129] 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.[130]

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.[131]

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 fifteen years, with drug discovery and preclinical testing (in animals) taking between three and six years, and clinical testing (in humans) and FDA evaluation requiring an additional 6.5 to nine years.[132] Given this long timeline, because of the limited lifespan of any 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.[133] Courts have also recognized this practical reality.[134]

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128 Caroline Horrow et at., *Patent Portfolios Protecting 10-Selling Prescription Drugs*, 184 JAMA INTERN MED. 810, 811 (2024).

129 *See generally* Melissa Feeney Wasserman, *Divided Infringement: Expanding the Extraterritorial Scope of Patent Law*, N.Y.U. L. REV. 82 (2007).

130 *Id.* at 304–06.

131 *Duration of Patent Protection Under Federal Law*, JUSTIA, https://www.justia.com/intellectual-property/patents/duration-of-patent-protection/ [perma.cc/58AV-JJUW].

132 NAT'L ACADS. OF SCIS., ENG'G & MED., *Complexity in Action, in* MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 37 (Sharyl J. Nass, Guru Madhavan & Norman R. Augustine eds., 2018).

133 *Janssen Pharms. II*, 760 F. Supp. 3d at 184–86.

134 *See, e.g.*, *Janssen Pharms. I*, 571 F. Supp. 3d at 324–25, *aff'd in part, vacated in part, remanded*, *Janssen Pharms. III*, 97 F.4th at 916.

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.[135] These include 1) licensing,[136] 2) cross-licensing,[137] 3) patent pooling, 4) sale of patent rights, and 5) enforcement/litigation.[138] 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 do not 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).[139] While some blocking patents show little or no follow-on activity, perhaps suggesting a block, many others do, suggesting that the blocking patent did not block all inventive activities. Though not dispositive, such evidence can provide insight into what was blocked, when, and how much of a block the claimed blocking patent provided.

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135 Rahul Guha et al, *The Economics of Commercial Success in Pharmaceutical Patent Litigation*, 1 LANDSLIDE 2 (2009).

136 McDuff et al., *supra* note 56, at 4.

137 *Id.*; *Acorda Therapeutics II*, 903 F.3d at 1338 (recognizing 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, citing its opinion in *Merck II*).

138 McDuff et al., *supra* note 56, at 4.

139 *See infra* Section V.D.4.a.

a. Forward Citations

Forward citation evidence—that is, references to a patent in patent applications filed at a later date — is one form of empirical evidence that can help one understand whether a purported blocking patent in fact deterred inventive activity.[140]

If there were a substantial number of forward citations in third-party patent applications (*i.e.*, applications filed by entities unrelated to the patentee), this evidence may suggest that research activity in the relevant technological area predated or existed despite, or may have been spurred by, the existence of the allegedly blocking patent. When third parties cite a purported blocking patent in their own applications, the earlier patent may have served as a foundation for further independent research. More broadly, evidence of continued work in the field may suggest that others were motivated and positioned to pursue the patented advance but failed to do so for reasons unrelated to any legal barrier. One reason may have been the non-obviousness of the invention at issue.

The timing of forward citations can also provide useful insights. Third-party citations that appear shortly after the issuance of a purported blocking patent—or well before its expiration—may suggest that the patent did not operate as a meaningful barrier, since the underlying research likely began years earlier. By contrast, forward citations that arise much later in the life of the patent are more plausibly linked to research initiated after issuance.

While the forward citation patterns can be informative, they should be considered in the broader context of the technology, market conditions, and the specific record in a given case. The absence of forward citations may be consistent with a blocking effect, but it can also stem from other factors—such as narrow scope, niche application, limited commercial uptake, or lack of awareness. Likewise, forward citations that appear late in a patent's life may reflect responses to the patented technology, but they can also arise from unrelated dynamics such as long development timelines, shifting market priorities, or examiner practices. In short, citation timing and frequency can offer meaningful evidence, but they are not necessarily dispositive.

In *Janssen v. Teva,* Teva argued that the U.S. Patent No. 6,077,843 ("the '843 Patent"), which covers a composition of matter, blocked innovation and weakened evidence of long-felt need or commercial success of the at-issue patent.[141] However, as shown in Figure 1 below, data from Sagacious IP[142] show that twenty

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[140] Forward citation analysis can be a noisy proxy for inventive activity; citation lags, examiner practices, and field-specific variation can all limit the extent to which they can be taken as reliable indicators. *See* ADAM B. JAFFE & MANUEL TRAJTENBERG, PATENTS, CITATIONS, AND INNOVATIONS: A WINDOW ON THE KNOWLEDGE ECONOMY 28-35 (MIT Press 2002).

[141] *Janssen Pharms. I*, 571 F. Supp. 3d at 323 n. 44 (referencing Aqueous suspensions of 9-hydroxyrisperidone fatty acid esters, U.S. Patent No. 6,077,843 (issued June 20, 2000)).

[142] All forward citation data were provided by Sagacious IP, which provides technology research to law firms, companies, and other institutions. *See* SAGACIOUS IP, *supra* note 112. Sagacious IP provided data on all forward citations of the 13 blocking patents identified in Table 1.1 and 1.2. Forward

U.S. patent applications that were filed by third parties not affiliated with Janssen cited the '843 Patent during its life,[143] and four more did so in the five years after the patent expired.[144]

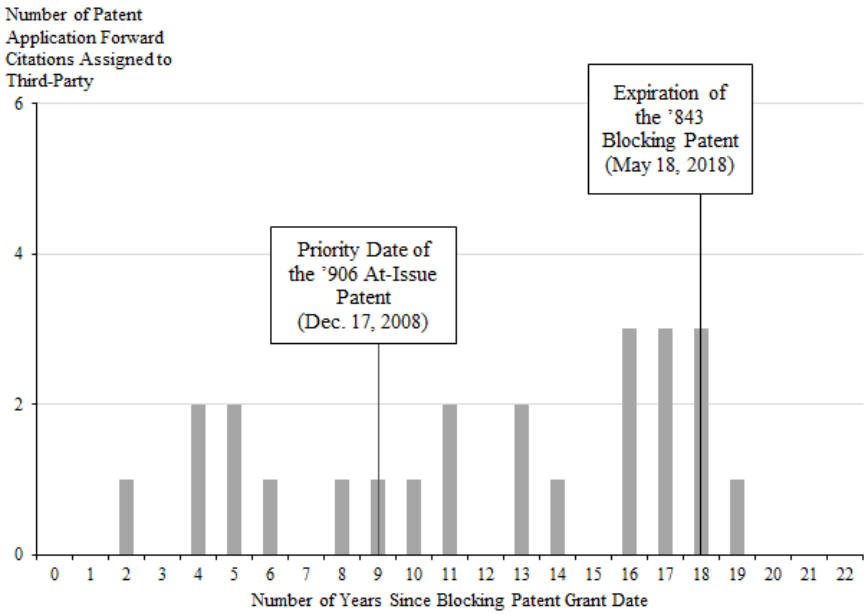

Figure 1: Third-Party Forward Citations of the '843 Blocking Patent (*Janssen v. Teva*)

Third-party entities citing the '843 Patent included major pharmaceutical companies and research institutions such as Johns Hopkins University,[145] The

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.

143 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. I*, 571 F. Supp. 3d at 323.

144 *See infra* Figure 1.

145 Methods and Compositions for Treating Schizophrenia, U.S. Patent No. 10,154,988 (issued Dec. 18, 2018).

University of Pennsylvania,[146] Sepracor,[147] Sumitomo Dainippon Pharma,[148] ViiV Healthcare,[149] and others.[150]

As shown in Figure 1, third-party citations to the '843 Patent occurred consistently throughout its life, suggesting it did not deter innovation. Instead, 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's November 2024 opinion that the alleged blocking patents, including the '843 Patent, did not deter the development of paliperidone palmitate products.[151]

As another example, in 2018, the Federal Circuit issued its opinion in *Acorda v. Roxane*.[152] Roxane (along with others) submitted an ANDA seeking approval to sell a generic version of Ampyra™, a prescription medication for patients with multiple sclerosis.[153] The lower court found that the asserted claims of Acorda's patents were invalid because of obviousness.[154]

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.[155] The Federal Circuit deemed the '938 Patent to be a blocking patent,[156] 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.[157] 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.[158]

An assessment of the forward citation data, however, suggests that the '938 Patent did not block innovation.[159] As shown in Figure 2 below, 26 third-party

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146 Long-Term Delivery Formulations and Methods of Use Thereof, U.S. Patent Application No. 2008/0305140 (filed Jan. 12, 2005) (pub. Dec. 11, 2008).

147 Hydroxyrisperidone Compositions and Methods, U.S. Patent Application No. 2004/0266792 (filed Jul. 13, 2004) (pub. Dec. 30, 2004).

148 Sustained-Release Formulation for Injection, U.S. Patent No. 9,469,630 (filed Oct. 18, 2011) (issued Oct. 18, 2016).

149 Pharmaceutical Compositions, U.S. Patent No. 11,224,597 (filed Oct. 13, 2016) (issued Jan. 18, 2022).

150 *See e.g.*, Aqueous Suspensions of 9-Hydroxyrisperidone Fatty Acid Esters, U.S. Patent No. 6,077,843 (filed May 12, 1997) (issued June 20, 2000).

151 *Janssen Pharms. II*, 760 F. Supp. 3d at 184–86.

152 *Acorda Therapeutics II*, 903 F.3d at 1310.

153 *Id.* at 1326.

154 *Id.* at 1327.

155 *Id.* at 1313.

156 *Id.* at 1339–40.

157 *Id.* at 1327.

158 *Acorda Therapeutics II*, 903 F.3d at 1320, 1327; *see generally* U.S. Patent No. 5,540,938 (filed Oct. 24, 1994) (issued July 30, 1996).

159 *See infra* Figure 3.

patent applications cited the '938 Patent during its term, and six more followed within five years of expiration. Third-party entities attempting to build upon the inventions claimed by the '938 Patent included Merck,[160] Purdue Research Foundation,[161] and Emory University,[162] indicating ongoing research and development despite the existence of the '938 Patent. Again, third parties were positioned and motivated but failed to invent before the at-issue priority date.

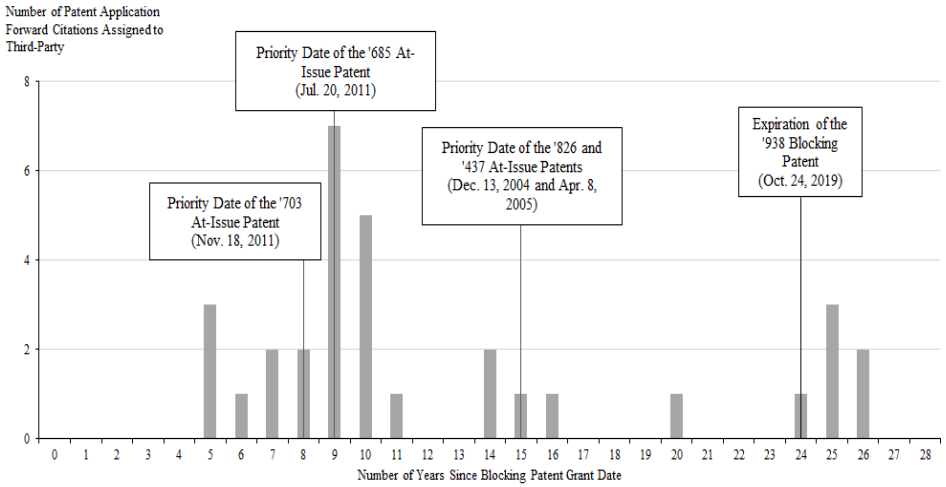

Figure 2: Third-Party Forward Citations of the '938 Blocking Patent (*Acorda v. Roxane*)

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.[163] As shown below in Figure 3, the '077 Patent was cited by forty-nine third-party U.S. patent applications during its life and nineteen more in the five years after expiration, totaling sixty-eight third-party patent applications from the grant date of the '077 Patent through five years after the expiration date of the patent.[164] And while the third-party filers included such major pharmaceutical companies as Novartis, Hoffman-La Roche, and Boehringer Mannheim, the majority of the sixty-eight third-party applications were filed during the final seven years of the '077 Patent's life.[165] Only seven applications were filed in the first decade after issuance, with the remaining 61 filed in the final nine years of the patent's life or shortly

160 2-Aminopyridine Compounds Useful as Beta-Secretase Inhibitors for the Treatment of Alzheimer's Disease, WO2,006,060,109 (filed Oct. 25, 2005).

161 Pyridines for Treating Injured Mammalian Nerve Tissue, U.S. Patent Application No. US 2011/0130429 (filed Sep. 9, 2010) (pub. June 2, 2011).

162 Antiviral Jak Inhibitors Useful in Treating or Preventing Retroviral and Other Viral Infections, WO2,013,082,476 (filed Nov. 30, 2012).

163 *Merck & Co.*, 395 F.3d at 1377.

164 *See infra* Figure 3.

165 *See infra* Figure 3.

after expiration.[166] This pattern suggests the '077 Patent may have discouraged early inventive activity, particularly before the priority date of the at-issue patent, but did not fully prevent third-party innovation, especially during the second decade of the life of the '077 Patent.

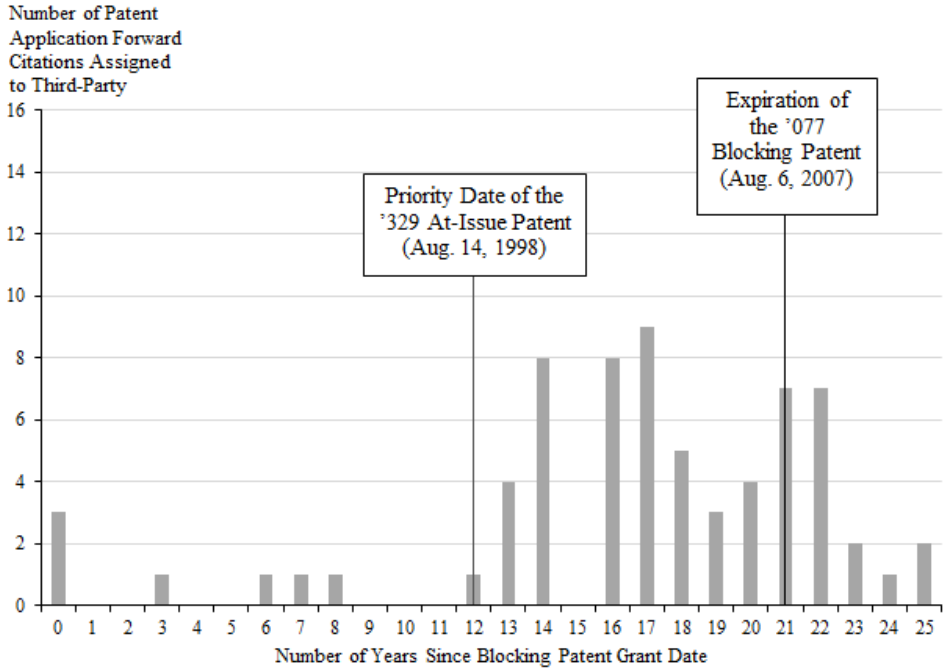

Figure 3: Third-Party Forward Citations of the '077 Blocking Patent (*Merck I*)

Forward citation data in other cases likewise show that not all such evidence supports 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.[167] 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. 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 general, while the forward citation evidence may bear on the issue of whether there was a block, it should not be viewed in isolation as proof that there was or was not a block. Limited citations may reflect factors like delayed recognition of the patent's significance or slow scientific uptake. A fuller assessment would potentially include examining research timelines that culminated in late-stage patent filings and other indicators of inventive activity through deeper factual analysis.

Though the lower court and Federal Circuit in *Acorda v. Roxane* did not appear to consider forward citation evidence, the Federal Circuit in *Acorda*

[166] *See infra* Figure 3.

[167] *Galderma Labs.*, 737 F.3d at 740.

recognized that the existence of a blocking patent may deter investment due to fears of liability and monetary or other remedies.[168] 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."[169] 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.[170]

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 an at-issue invention. Like forward citations, clinical trial data may show that research on the alleged blocked technology continued despite the patent's existence, and likely predated the priority of the at-issue patent.

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.[171] 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.[172] 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.[173] The '722 Patent issued in August 1997, and the '376 Patent followed in August 2000. As shown below in Figure 4, between 2000 (the first year clinical trial data became available) and the '722 Patent's expiration in 2014, 281 third-party clinical trials involving glargine were initiated, with another

168 *Acorda Therapeutics II*, 903 F.3d at 1337.

169 *Id.*

170 *Id.* at 1339.

171 35 U.S.C. § 271(e)(1).

172 *Sanofi-Aventis*, 791 Fed. App'x at 927–29; *Mylan Pharm.*, 2018 WL 6584915, at *19–20.

173 *See* CLINICALTRIALS.GOV, NIH, https://clinicaltrials.gov/ [perma.cc/KW2H-355E]. On February 13, 2025, the database was searched for the "Insulin Glargine" compound in the "Intervention/treatment" field. The raw data were then filtered to include only clinical trials conducted by parties unaffiliated with Sanofi or Aventis within five years of the expiration of the last-expiring alleged blocking patent.

135 launched in the following five years—totaling 416 trials through September 2019.[174]

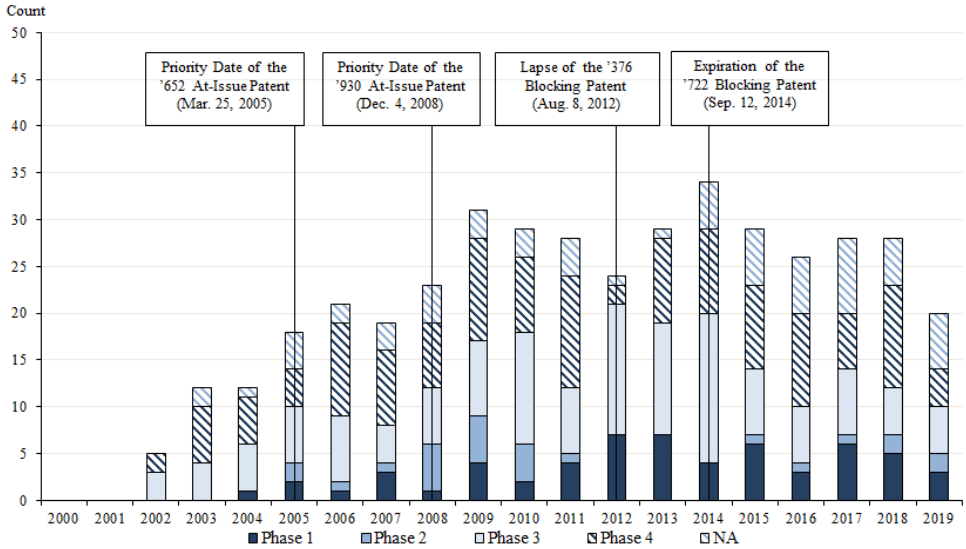

Figure 4: Third-Party Glargine Clinical Trials (*Sanofi-Aventis v. Mylan*) 2000-2019

The clinical trials investigating the development and use of glargine spanned all phases of R&D.[175] While many studies were later-stage trials (*i.e.*, Phases 2-4), early-stage trials (*i.e.*, Phase 1) were conducted every year from 2004 through 2014.[176] Such trials signal new or beginning research programs. Thus, clinical trial data suggest that the '376 and the '722 Patents did not block all third-party inventive activity involving glargine. Substantial research involving the glargine compound occurred, including before the priority dates at issue (2005 and 2008),[177] casting doubt—absent other evidence—on whether these patents truly functioned as blocking.

Clinical trial data for other compounds tied to blocking patents were 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 Patent"), both of which are related to the compound adapalene, were blocking.[178] The '720 Patent was issued in January 1988, and the '440 Patent was issued in November 1993.[179] 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

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174 *See infra* Figure 4.

175 *See supra* Figure 4.

176 *See supra* Figure 4.

177 *See supra* Figure 4.

178 *Galderma Labs.*, 737 F.3d at 734–35, 740.

179 U.S. Patent No. 4,717,720 (filed Apr. 10, 1996) (issued Jan. 5, 1988); U.S. Patent No. Re. 34,440 (filed Mar. 30, 1990) (reissued Nov. 9, 1993).

blocking patent—indicate that 36 clinical trials were sponsored by third parties during this period.[180]

As shown below in Figure 5, although the clinical trials data involving adapalene suggest that some research activity did occur during the life of the '720 and '440 Patents, many of the trials occurred in the six years prior to expiration of the last to expire blocking patents, and the overall volume of activity was lower than for glargine.[181]

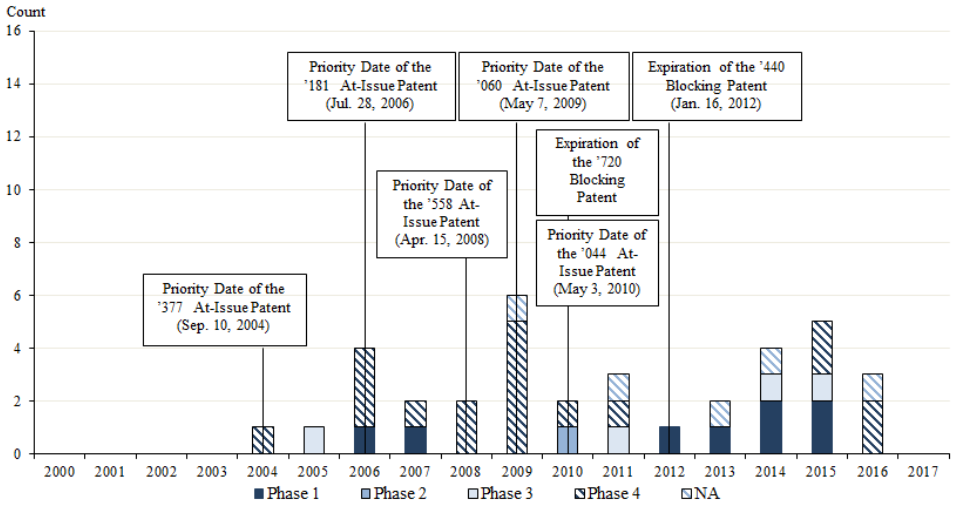

Figure 5: Third-Party Clinical Trials Involving Adapalene (*Galderma v. Tolmar*) 2000-2017

A similar pattern appears in *Merck II,* where the Federal Circuit found that the '820 Patent covering the compound ertapenem was blocking.[182] Issued in December 1995, the '820 Patent expired in 2015. As shown below in Figure 6, 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 the expiration of the '820 Patent, and all were conducted within six years of the patent's expiration.[183]

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180 *See infra* Figure 5.

181 *See infra* Figure 5 (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.).

182 *Merck II*, 874 F.3d at 730–31 (referencing Antibiotic compounds, U.S. Patent No. 5,478,820 (issued Dec. 26, 1995)).

183 *See infra* Figure 6.

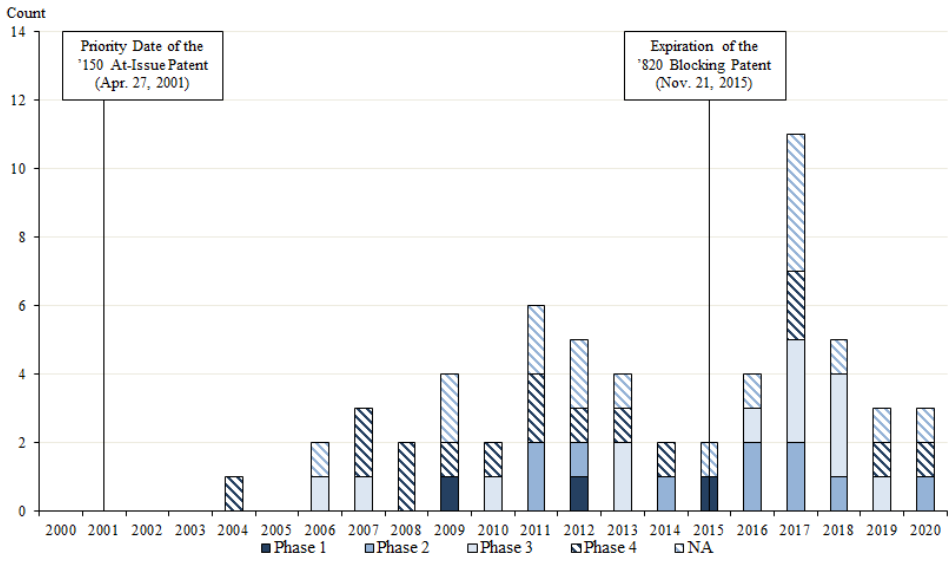

Figure 6: Third-Party Clinical Trials Involving Ertapenem (*Merck II*) 2000-2020

While the relatively low volume of clinical research involving ertapenem may, in isolation, suggest that the '820 Patent may have blocked some inventive activity, other contextual factors should be considered. For example, unlike glargine, which treats millions with diabetes, ertapenem is used for serious infections in a smaller population and administered as a one-time intravenous or intramuscular dose.[184] These differences may explain the limited research activity involving ertapenem, and further evidence may be necessary to determine whether the '820 Patent functioned as a true barrier to innovation.

Like forward citation data, clinical trial data can be informative but not conclusive. They do not capture research efforts that never progressed to the clinical trial stage or were ultimately abandoned.[185] The FDA reporting rules exclude Phase 1 trials and observational studies,[186] and sponsors may withhold negative results or fail to report due to lack of funding or dissolution.[187] While the precise number of these abandoned research programs is known, the realities of pharmaceutical research suggest that it is likely significant. If the number of

[184] *National Diabetes Statistic Report*, CDC (May 15, 2024), https://www.cdc.gov/diabetes/php/data-research/index.html [perma.cc/6PHF-UCH5]; Linda M. Forsyth, *Clinical Review Ivanz (Ertapenem Sodium)*, U.S. FOOD & DRUG ADMIN. (Aug. 9, 2007), https://www.fda.gov/files/drugs/published/N21-337S018-Ertapenem-Clinical-BPCA.pdf [perma.cc/9F3L-YQ6K].

[185] Duxin Sun et al., *Why 90% of Clinical Drug Development Fails and How to Improve It?*, 12 ACTA PHARMACEUTICA SINICA B 3049, 3049–53 (2022).

[186] *FDAAA 801 and the Final Rule*, NAT'L LIBR. MED. (Sep. 10, 2025), https://clinicaltrials.gov/policy/fdaaa-801-final-rule [perma.cc/X62R-28CX].

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

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.[188] While a patent may contribute to deterring some innovation, it rarely acts as a complete barrier.[189] As the real-world evidence shows, and the Federal Circuit has emphasized, blocking claims must be assessed based on specific facts, not broad assumptions.[190]

VI. APPROPRIATE ASSESSMENT OF THE BLOCKING PATENT DEFENSE

Despite its limitations, a blocking patent defense may be appropriate to consider, and perhaps even accept, 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—but mere assertion of a block is not enough.

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 to determine how much weight the defense should carry, reinforcing that commercial success is just one of several secondary considerations in assessing non-obviousness.

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/priority date of the at-issue patent.[191] If such work occurred, it may become difficult to argue that the claimed blocking

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188 *See Mastering Strategic Decision-Making in the Pharmaceutical R&D Portfolio*, DRUGPATENTWATCH (Aug. 20, 2025), https://www.drugpatentwatch.com/blog/decision-making-product-portfolios-pharmaceutical-research-development-managing-streams-innovation-highly-regulated-markets/ [perma.cc/SH2S-SSMB].

189 *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).

190 *Acorda Therapeutics II*, 903 F.3d at 1339 ("[A] blocking patent diminishes possible rewards from a non-owner's or non-licensee's investment activity . . . [b]ut the magnitude of the diminution in incentive . . . is 'a fact-specific inquiry.'").

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

patent fully deterred innovation. Importantly, the analysis should focus on the degree to which the blocking patent actually impeded innovation.

As discussed above, in *Janssen v. Teva*, third parties engaged in research and development throughout the life of the '843 Patent, including before the at-issue patent in that case was filed and disclosed publicly (on the priority date).[192] In *Merck I*, however, forward citation evidence demonstrated that while follow-on innovative activity did occur, such activity mostly took place in the decade leading up to the expiration of the '077 Patent, which was claimed to be blocking.[193]

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."[194] The court noted that there were two third parties who worked in the area around the time of the priority date.[195] 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."[196] Further, the court wrote that substantial research and commercialization work were done in earnest near the expiration of the blocking patent.[197] 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.[198] The perceived quantity and timing of the inventive work by others appeared to matter to the *Otsuka* court.[199]

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.[200] The federal district court of Delaware found that only two groups investigated the compound during the blocked period.[201] This, to the court, was sufficient evidence of the deterring or disincentive effect of the blocking patents.[202] MSN did not need to prove that "all others were

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192 *See supra* Figure 1 and *supra* Section V.D.4.a.

193 *See supra* Figure 2 and *supra* Section V.D.4.a.

194 Otsuka Pharm. Co. v. Lupin Ltd., No. CV 21-900-RGA, 2024 WL 3618123, at 37 (D. Del. July 31, 2024).

195 *See id.* at *37.

196 *Id.*

197 *See id.*

198 *See id.* at *39.

199 *See id.* at *19–20. 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.

200 *See* Exelixis, Inc. v. MSN Labs. Priv. Ltd., No. 22-228-RGA, 2024 WL 4491176, at *62–63 (D. Del. Oct. 15, 2024).

201 *See id.* at *62.

202 *See id.*

dissuaded,"[203] only that there was minimal inventive activity. Further, MSN was able to argue that there was a disincentive associated with a mere patent application.[204]

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.[205] In that case, Teva itself 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."[206] In fact, Teva's work led it to file a patent application prior to the expiration of the blocking patents on January 10, 2008.[207] 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."[208] 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."[209]

The above opinions reinforce the idea that evidence of some work in the field is important, but it may not necessarily be dispositive. The core question in a blocking patent defense is whether the asserted patent actually prevented others from inventing the claimed invention. As the Federal Circuit explained in *Acorda*, a blocking patent may reduce incentives for non-owners to invest in competing innovation.[210] However, evidence of actual work in the field—such as patent filings or clinical trials—can show that innovation continued, weakening the defense. These activities often result from years of prior research and planning, not a sudden response to patent expiration. While patents limit commercial use, they do not prohibit research, patent filings, or early-stage trials.

Further, 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.[211] As noted above, activities such as licensing,[212]

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203 *See id.*

204 *See id.*

205 *See Janssen Pharms. I*, 571 F. Supp. 3d at 325.

206 *See id.*

207 *See id.*

208 *See id.*

209 *Janssen Pharms. III*, 97 F.4th at 929.

210 *See Acorda Therapeutics II*, 903 F.3d at 1339.

211 *See* KEVIN RICHARDS, CONG. RSCH. SERV., IF 11561, PHARMACEUTICAL PATENTING PRACTICES: A LEGAL OVERVIEW 1 (June 1, 2020).

212 *See* McDuff et al., *supra* note 56, at 44.

cross-licensing,[213] patent pooling, and enforcement/litigation[214] often stem from years of research and development and remain viable despite a blocking patent. In some cases, the potential for these strategies may even motivate the underlying research and patent filings.

In *Ferring v. Fresenius Kabi*, the Defendant claimed the existence of a blocking patent prevented the invention of the at-issue patent.[215] 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. [216] Those manufacturers, the expert noted, would be incentivized—not blocked—to develop improved methods of synthesis and offer them to Ferring under commercial contract.[217] This practical dynamic undercut the defendant's blocking patent argument.

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.

Importantly, the absence of evidence is not proof of a blocking effect. Nor does it rebut it, as courts have made clear.[218]

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.[219] Further, the district court noted that the blocking patents issued approximately twenty years before the at-issue patents, and that this indicated that the commercial success of the product at issue "is attributable mainly to the patent protection Allergan enjoyed."[220] The district court also found

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213 *See Acorda Therapeutics II*, 903 F.3d at 1338.

214 *See* McDuff et al., *supra* note 56, at 44.

215 *See Ferring Pharms*., 645 F. Supp. 3d at 371.

216 *See id.* at 372–73.

217 *See id.* at 371.

218 *Hospira I*, 285 F. Supp. 3d at 797 ("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.'").

219 Allergan, Inc. v. Teva Pharm. USA, Inc., No. 2:15-cv-1455-WCB, 2017 U.S. Dist. LEXIS 225897, at *153–54 (E.D. Tex. Oct. 16, 2017) [hereinafter *Allergan I*].

220 *Id.* at *154–55.

that the blocking patents weighed on the long-felt, but unmet need, which existed, but could not be addressed because of Allergan's patents.[221] 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.[222] The Federal Circuit affirmed this decision.[223] 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."[224] 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 provides insight into whether the patent meaningfully constrained inventive activity.[225]

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.[226] There, the Federal Circuit reversed the district court's ruling that misapplied the blocking doctrine to the challenged patents themselves, confirming that only distinct, pre-existing patents can qualify.[227] However, depending on the timing, at-issue patents may still explain delays in third-party innovation if supported by adequate evidence.

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 practice, business decisions, including those involving R&D, are guided by the projected net present value ("NPV").[228] Projects expected to generate

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221 *Id.*

222 *Id.* at *155–56.

223 *See Allergan II*, 742 Fed. App'x at 511.

224 *Exelixis*, 2024 WL 4491176, at *93.

225 *See, e.g.*, *Acorda Therapeutics II*, 903 F.3d at 1339.

226 *See Chemours Co.*, 4 F.4th at 1373.

227 *See id.* at 1379.

228 *See Net Present Value (NPV)*, CFI Team https://corporatefinanceinstitute.com/resources/valuation/net-present-value-npv/ [perma.cc/4QD9-EN9V].

negative NPV are typically avoided, while positive NPV projects are often pursued.[229] In cases involving a blocking patent defense, the challenger effectively implies that the earlier invention did not occur because third parties viewed the project as NPV-negative due to the blocking patent.[230]

Although constructing a precise NPV model is undoubtedly challenging, as *ex post* information is often relied upon in litigation settings to inform *ex ante* projections as of the time of the potential invention,[231]a careful analysis of the key components can reveal whether the patent meaningfully deterred innovation. Specifically, it is important to evaluate the *nature of the opportunity* and the *nature of the potential block*, incorporating useful considerations identified by the Federal Circuit in *Acorda*.[232]

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 activity tends to be more attractive when the size of the potential opportunity is large. In the pharmaceutical context, this is often driven by the large patient population, favorable reimbursement terms, and/or substantial clinical demand. For example, prior to the entry of biosimilar competition in 2023, AbbVie's biologic blockbuster Humira™ generated billions of dollars in annual revenue, making it a clear R&D target for any profit-maximizing firm, all else constant.[233] In contrast, smaller opportunities may be foregone due to limited returns, technical hurdles, or better alternatives. Not all opportunities are feasible for all potential investors, as strategic focus and comparative advantage vary.

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229 *See Net Present Value Rule*, CFI TEAM https://corporatefinanceinstitute.com/resources/valuation/net-present-value-rule/ [perma.cc/V65L-WZE4]. 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.

230 *See, e.g.*, Fabian Gaessler et al., *Patents, Freedom to Operate, and Follow-on Innovation: Evidence from Post-Grant Opposition*, 71 MGMT. SCI.1315, 1334 (2025).

231 *See* Donald M. May, *Using Ex-Ante and Ex-Post Benchmarks in Estimating Damages*, VALUE EXAMINER, May–June 2012, at 15.

232 *See Acorda Therapeutics II*, 903 F.3d at 1338–39.

233 *See* Ben Adams, *Biosimilars Making Inroads into Humira Sales, but Docs Still Cautious on Switching: Spherix*, FIERCE PHARMA (Sept. 19, 2023), https://www.fiercepharma.com/marketing/biosimilars-making-inroads-humira-sales-docs-still-cautious-switching-spherix [perma.cc/28B8-7U5V]; *see also In re* Humira (Adalimumab) Antitrust Litig., 465 F. Supp. 3d 811, 820 (N.D. Ill. 2020).

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, the absence of invention in low-return markets may reflect broader economic factors, not a block. 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.[234] 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 NPV of the project normally should be projected to be positive.[235]

A proper NPV analysis considers all relevant costs, both upfront and ongoing,[236] such as capital investments, R&D expenditures, regulatory approval, and long-term commercialization expenses.[237] Both direct and indirect costs are considered.[238] A project is worth pursuing only if the present value of expected benefits exceeds total anticipated costs.[239]

However, cost projections are inherently uncertain—research delays, clinical trial failures, and regulatory or manufacturing challenges can raise expenses and risks, discouraging even the most promising projects. Importantly, not all positive-NPV projects are equally appealing: a five-dollar NPV project is far less attractive than one worth fifty 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. Evaluating whether a blocking patent deterred innovation often involves considering both the scale of expected returns and the relative appeal of competing opportunities.

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234 *See* Aylin Sertkaya et al., *Cost of Drug Development and Research and Development Intensity in the US, 2000-2018*, 7 JAMA NETWORK 1, 2 (2024).

235 According to the revealed preference principle of economics, projects that have been pursued are likely to have been deemed to be profitable. *See* Paul A. Samuelson, *A Note on the Pure Theory of Consumer's Behaviour*, 5 ECONOMICA 61, 61–71 (1938); Hendrik S. Houthakker, *Revealed Preference and the Utility Function*, 17 ECONOMICA 66, 159–74 (1950).

236 *See* RICHARD A. BREALEY ET AL., PRINCIPLES OF CORPORATE FINANCE 23 (13th ed. 2020) [hereinafter BREALEY ET AL. 13th ed.]

237 *See* DRUGPATENTWATCH, *supra* note 188.

238 *See, e.g.*, Bennett Levitan et al., *Assessing the Financial Value of Patient Engagement: A Quantitative Approach from CTTI's Patient Groups and Clinical Trials Project*, 52 THERAPEUTIC INNOVATION & REGUL. SCI. 220, 223 (2018).

239 *See* STEPHEN A. ROSS ET AL., CORPORATE FINANCE 137 (8th ed. 2008).

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.[240]

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.[241] Drug development is inherently uncertain, marked by high failure rates, long timelines, and multiple points of attrition.[242] Moreover, even successful clinical development does not guarantee commercial success.[243] Market dynamics, pricing pressures, payer reimbursement decisions, and competition from existing therapies can all affect whether an approved drug is economically viable. All these risks generally should be incorporated into any NPV analysis.

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.[244] A discount factor (rate) often is applied to future revenues as a way to convert that future value into value today.[245] Discount rates reflect the rate of return on investments made today and the probability of receiving that return, among other factors.[246] 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. Estimating the NPV of a project necessarily involves converting all the benefits and costs into current-year dollars.

Calculating the free-standing project NPV 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.

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240 *See* RICHARD A. BREALEY ET AL., PRINCIPLES OF CORPORATE FINANCE 240 (10th ed. 2011).

241 *See id* at 258.

242 *See The Drug Development Process Step 3*, *supra* note 32.

243 *See* 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), https://www.fiercepharma.com/pharma/half-drugs-launched-last-15-years-failed-to-meet-wall-street-s-expectations-report [perma.cc/4N6U-38X9].

244 *See* ROSS ET AL., *supra* note 239, at 97.

245 BREALEY ET AL. 13th ed., *supra* note 236, at 22.

246 *Id.*

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 should 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 perceived as strong may deter innovation by signaling high litigation risk, while a patent seen as vulnerable may not, as a competitor may proceed with development activities under the assumption that, if necessary, it can litigate and invalidate the patent with minimal risk. The likelihood of a successful challenge—based on prior art, lack of enablement, or other grounds—is central to this assessment.

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]."[247] Though important, that observation cannot be dispositive as it 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.

Another valuable source of evidence may include Paragraph IV certifications and the subsequent notices provided to branded pharmaceutical manufacturers containing 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.

Studies have shown that many patents, whether blocking or not, are ultimately deemed invalid, unenforceable, or not infringed. According to Allison and Lemley (1998), who analyzed patent validity decisions issued by the federal courts between 1989 and 1996, forty-six percent of patents litigated to a final judgment, including decisions on appeal and summary judgment, are held to be inval*id*.[248] 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.[249] According to other statistics, out of all patents that were challenged in an America Invents Act (AIA)

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247 *Exelixis*, 2024 WL 4491176, at *93.

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

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

proceeding, like an inter partes review (IPR) in 2024, 71 percent were determined to be invalid.[250]

Ultimately, evaluating the strength of a blocking patent defense often involves analyzing not just the patent's existence, but how it was perceived at the time—its validity, enforceability, and likelihood of successful challenge.

b. Scope of the Blocking Patent

A patent's potential blocking ability depends on its scope—whether it covers a method of use, compound, composition of matter, or process. Courts have made clear that covered activities, and therefore blocked activities, are limited to those that are specifically claimed in the asserted blocking patent.

For example, in *Otsuka v. Lupin*, the federal district court of Delaware found the patent covering the tolvaptan compound blocking, but not a method-of-treatment patent.[251] The court explained that this method patent did not block work on the synthesis process, which was the subject of the patent-in-suit.[252]

Similarly, 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.[253] 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.[254]

Courts also 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.[255] The court found it "unclear" and, therefore, unconvincing that the alleged blocking patent even related to the Ferring patent in suit.[256] 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.[257] This lack of evidence as to the scope of the block undermined the blocking patent argument.

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250 Stephen Schreiner, *Recent Statistics Show PTAB Invalidation Rates Continue to Climb*, IPWATCHDOG (June 25, 2024), https://ipwatchdog.com/2024/06/25/recent-statistics-show-ptab-invalidation-rates-continue-climb/id=178226/ [perma.cc/J9D3-CZ7H].

251 *See Lupin Ltd.*, 2024 WL 3618123, at *36.

252 *See id.*

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

254 *See id.*

255 *See Ferring Pharms.*, 645 F. Supp. 3d at 371.

256 *See id.*

257 *See Janssen Pharms. I*, 571 F. Supp. 3d at 324, *aff'd in part, vacated in part, remanded*, *Janssen Pharms. III*, 97 F.4th at 915.

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 seventeen years from the patent grant date.[258] Patents issued since 1995 have a life of twenty years from the patent filing, or application date, again, absent an extension.[259]

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 block an earlier invention. 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.

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.[260] 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.[261]

In the pharmaceutical industry, as noted above, it is crucial to consider the long timelines associated with drug development and commercialization.[262] These extended timelines and safe harbor provisions suggest that a blocking patent is

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258 *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, FOOD & DRUG ADMIN. (Aug. 15, 2025), https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program [perma.cc/8XZS-M4DR] [hereinafter *Small Business Assistance*].

259 Manual of Patent Examining Procedure § 2701 (9th ed. Rev. 8, Jan. 2018).

260 *See ViiV Healthcare I*, 6 F. Supp. 3d at 503

261 *Id.*

262 *See supra* Section V.D.2.

unlikely to completely stifle inventive activity.[263] For instance, a blocking patent set to expire in four years is unlikely to deter much innovation, as research, clinical trials, and other activities often occur during the life of a blocking patent.

In *Otsuka v. Lupin*, the court addressed the timing issue and noted that patent applications, publications, ANDAs, and Drug Master Files (DMFs)[264] were submitted nearly three years *after* the blocking patent expired.[265] While some research 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."[266] 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.[267]

Timing also affects how marketplace success is evaluated in a non-obviousness analysis. While the timing of a blocking patent is irrelevant to competing products it does not cover, it matters 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.[268] According to a Harvard Business School working paper, the licensing market generally is "sizable" and "continuously growing," reaching $57 billion in the pharmaceutical industry

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263 *See supra* Section V.D.2.

264 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." *Drug Master Files (DMFs)*, FOOD & DRUG ADMIN. (Jan. 7, 2025), https://www.fda.gov/drugs/forms-submission-requirements/drug-master-files-dmfs [perma.cc/8P3R-DTYG].

265 *See Lupin Ltd.*, 2024 WL 3618123, at *37.

266 *Id.*

267 *See id.* at *36–39 (discussing the volume of patent applications, publications, abbreviated new drug applications (ANDAs), and Drug Master Files (DMFs) submitted during the relevant time period).

268 *See, e.g.*, *ViiV Healthcare I*, 6 F. Supp. 3d at 503.

based on U.S. and European-based licensing deals in 2016.[269] Motivations for licensing include reducing development costs, receiving royalty payments, sharing development risks, and benefiting from shelved projects.[270]

This has important implications for the blocking patent defense. If a patent holder is known to license its IP 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.

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."[271] However, the court did not define what constitutes a "good" opportunity.[272] 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.

Of the nine 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 several instances.[273] For example, the '820 patent, which the court determined was blocking in *Merck II,* was filed in 1993 when the inventor, Zeneca, filed a U.S. patent application on ertapenem.[274] Also in 1993, Zeneca granted Merck an exclusive license to the '820 Patent.[275]

As another example, the '938 Patent—found to be blocking in *Acorda*—was originally assigned to Elan Corporation.[276] The '938 Patent claims "methods of treating patients having certain conditions, including multiple sclerosis, by administering a drug containing a sustained-release formulation of any of certain agents, one of them 4-AP."[277] In 1997, Elan Corporation granted Acorda an exclusive license to the '938 Patent, and Acorda conducted studies to evaluate the efficacy of a sustained-release formulation of 4-AP in patients with spinal cord injuries, but those studies failed.[278] After Acorda learned that Elon Corporation was no longer interested in using the '938 Patent for multiple sclerosis research,

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269 *See* MOSAB HAMMOUDEH ET AL., DUSTING OFF THE OLD ONES: DRUG LICENSING TO STARTUPS, INNOVATION SUCCESS AND EFFICIENCY 10 (Harvard Bus. Sch., Working Paper No. 24-067, 2024)). *See also* J.P. MORGAN, 2023 ANNUAL BIOPHARMA LICENSING AND VENTURE REPORT 2 (Dec. 2023).

270 *See* HAMMOUDEH ET AL., *supra* note 269, at 11.

271 *Exelixis*, 2024 WL 4491176, at *62.

272 *See id.*

273 *See, e.g.*, *Merck II*, 874 F.3d at 731; *Acorda Therapeutics II*, 903 F.3d at 1342.

274 *See Merck I*, 221 F. Supp. 3d at 512, *aff'd by Merck II*, 874 F.3d 724 (Fed. Cir. 2017).

275 *See id.* at 512–13.

276 *Acorda Therapeutics II*, 903 F.3d at 1313.

277 *Id.*

278 *See id.* at 1320.

Acorda expanded its license to include studies of multiple sclerosis specifically.[279] Perhaps evidence of willingness 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 *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.[280] The availability of a license and the opportunity to pursue the covered compounds contradicted defendants' assertions that those patents blocked competitors from inventive activity.[281]

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.[282]

Together, these cases reaffirm that facts—not generalizations—must drive the analysis. Courts should examine how the alleged blocking 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.

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279 *See id.*

280 *Accord Healthcare I*, 201 F. Supp. 3d at 539.

281 *Id.*

282 *ViiV Healthcare I*, 6 F. Supp. 3d at 503.

VII. CONCLUSION

Although the blocking patent defense has gained traction in pharmaceutical litigation involving commercial success allegations in recent years, its 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 often involves a case-specific inquiry supported by concrete evidence.

That evidence generally includes an identification of what was allegedly blocked, when the blocking occurred, and how it influenced third-party decision-making. Empirical indicators like forward citations, clinical trials, and licensing practices may offer useful evidence but may require careful, context-specific interpretation. While some blocking patents may deter certain forms of research and development, they rarely create an absolute barrier to inventive activity. Similarly, commercial success should not be dismissed solely on the basis of an asserted block.

Ultimately, assessing a blocking patent defense benefits from a nuanced, evidence-based approach that reflects how innovation and competition function in the pharmaceutical industry. As courts continue to refine their analysis, economic and empirical evidence should guide their application.