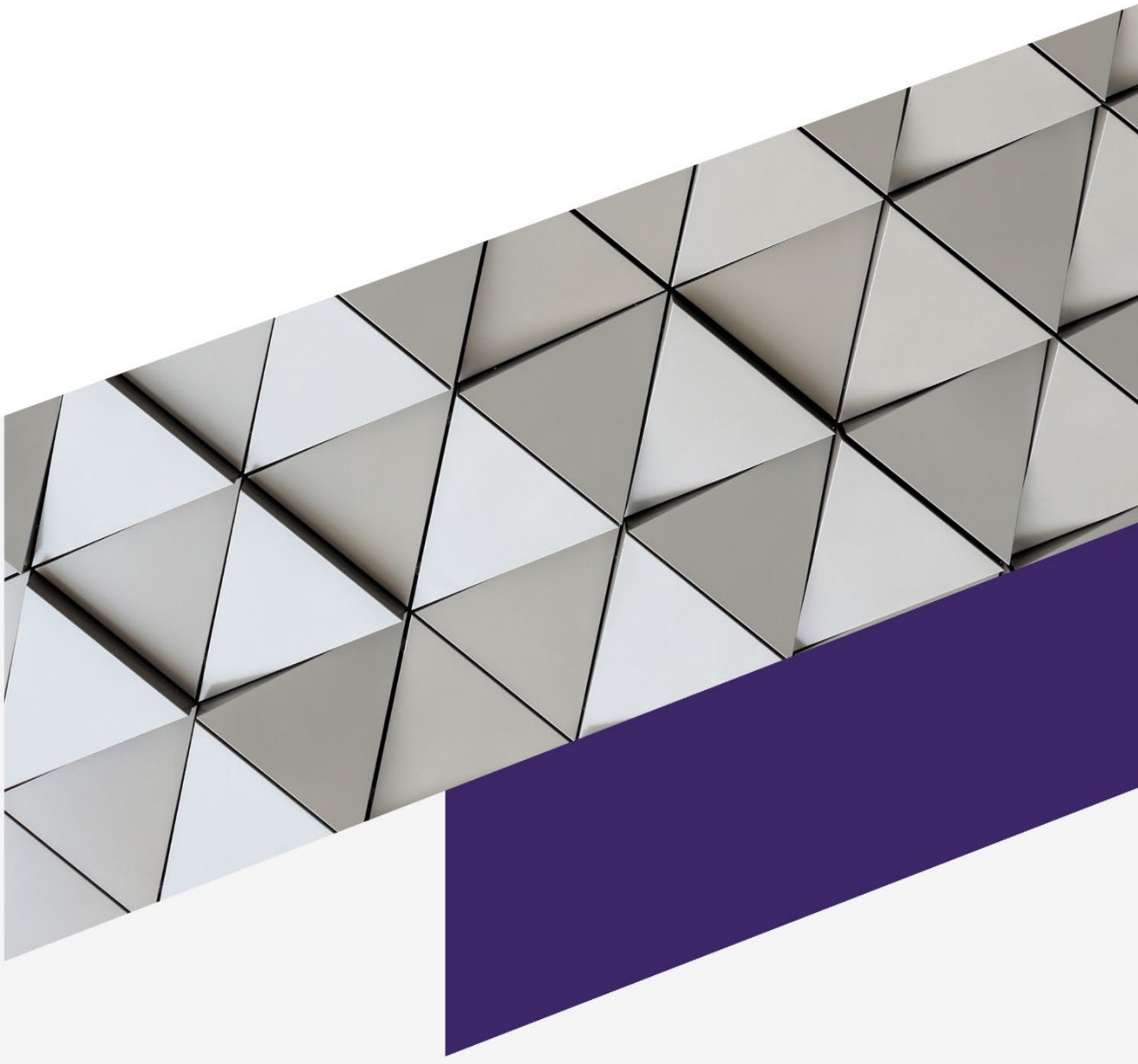
The Intersection of Antitrust and Intellectual Property: *A Practitioner's Handbook*



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This edition, *The Intersection of Antitrust and Intellectual Property: A Practitioner's Handbook*, was authored by Craig C. Martin, Chairman Americas; Aaron Hersh, Partner; Sara Tonnies Horton, Partner; Henry Thomas, Partner; Matthew Freimuth, Partner; John Goerlich, Partner; and Katrina Robson, Partner.

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Introduction: The Inherent Tension Between Patent Rights and Free Competition

Plaintiffs secured $4.3 billion from patent suits in 2024.[1] There was $8.41 billion in antitrust class action settlements in the same year.[2] With billions at stake each year, intellectual property ("IP") and antitrust litigation present the opportunity for significant recovery, or existential damage, for innovators and competitors. And while each subject is complex in its own right, their intersection can pose challenging problems.

IP and antitrust law are arguably two countervailing sources of doctrine. IP law, after all, establishes "limited monopolies."[3] A patent gives its owner the right to exclude others "from making, using, offering for sale, or selling" a specified product or process.[4] Antitrust law, meanwhile, prohibits the "monopoliz[ation], or attempt[s] to monopolize . . . any part of . . . trade or commerce."[5] It also bars "contract[s], combination[s,] or conspirac[ies] in restraint of trade or commerce."[6] In doing so, antitrust law establishes a "non-right," barring behaviors with anticompetitive effects on the market.

Yet both IP and antitrust law, perhaps counterintuitively, aim to promote harmonious ends. Patents are property rights issued to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[7] Federal antitrust law prohibits defined economic activities to codify "a policy of competition" and "yield the best allocation of the Nation's resources."[8] In that way, these two bodies of law arguably are "actually complementary, as both are aimed at encouraging innovation, industry and competition."[9] Moreover, neither explicitly grants or prohibits market monopolies: IP law authorizes exclusionary property rights over a defined innovation for a limited period of time, and antitrust law prohibits certain monopolistic behaviors.[10]

In practice, the push and pull between IP rights and antitrust can lead to complex scenarios. This Handbook explores three notable ways that these legal worlds can merge. *First*, enforcing IP rights acquired through fraud may constitute an antitrust violation, enforceable through *Walker Process* claims. In *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp*., the Supreme Court ruled that enforcing a patent obtained by fraud on the United States Patent and Trademark Office can be the basis of antitrust liability.[11] *Walker Process* claims are particularly complex

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[1] Carla Rydholm, *Lex Machina 2025 Patent Litigation Report Shows 22% Surge in Filings and Record 4.3B in Damages*, LEX MACHINA, https://www.lexisnexis.com/community/insights/legal/lex-machina/b/lex-machina/posts/lex-machina-2025-patent-litigation-report-shows-22-surge-in-filings-and-record-4-3b-in-damages (July 11, 2025).
[2] Edward Segal, *Class Action Settlements Topped $40 Billion Again In 2024: New Report*, FORBES, https://www.forbes.com/sites/edwardsegal/2025/01/07/class-action-settlements-topped-40-billion-again-in-2024-new-report/ (Jan. 7, 2025).
[3] *Impression Prod., Inc. v. Lexmark Int'l, Inc*., 137 S. Ct. 1523, 1531–32 (2017).
[4] 35 U.S.C. § 154.
[5] 15 U.S.C. § 2.
[6] *Id.* § 1.
[7] U.S. Const. Art. I. Sec. 8, Cl. 8.
[8] *Nat'l Collegiate Athletic Ass'n v. Alston*, 141 S. Ct. 2141, 2147 (2021).
[9] *Atari Games Corp. v. Nintendo of Am., Inc*., 897 F.2d 1572, 1576 (Fed. Cir. 1990).
[10] *See Verizon Commc'ns Inc. v. L. Offs. of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).
[11] 382 U.S. 172 (1965).

because they require plaintiffs to prove the given patent's invalidity, the patent holder's fraudulent intent, and an antitrust injury, all while litigating common issues of jurisdiction, discovery, and damages. At the extreme end, defending (or proving) a *Walker Process* claim potentially requires a "case within a case" analysis.

Second, IP and antitrust meet distinctively in the pharmaceutical industry. Pharmaceutical companies spend billions on research and development each year.[12] To maximize their returns on their significant investments, pharmaceutical companies rely on patents to optimize their market share. With mixed success, litigants have targeted certain strategies used to maximize the impact of pharmaceutical patents, arguing that those strategies amount to antitrust violations. Accordingly, these tactics are the subject of ongoing dialogue and litigation.

Third, there are potential antitrust implications when a patent is held over a component part that is required by other products to meet industry standards, as with standard essential patents ("SEPs"). The interoperability of those products depends on standard-setting organizations ("SSOs") to decree what technologies must appear in them. The immediate effect is pro-competitive, allowing many *competing* firms to make useful products. But, where SEPs exist for those necessary technologies, a clear problem arises: any patent holder can "hold out" to try and generate the greatest possible economic rent from its IP. To overcome potential anticompetitive holdouts, SSOs require participating SEP-owners to disclose potential patent interests in developing standards and license their IP on fair, reasonable, and nondiscriminatory terms ("FRAND"). There is significant discussion regarding when violations of FRAND agreements cross the line from a contractual issue between private parties to an antitrust violation.

This Handbook provides identification and practical analysis on the interplay between IP and antitrust law by examining in greater depth each of these three important intersections: (1) *Walker Process* claims, (2) pharmaceutical industry practices, and (3) SEPs. For each intersection, the Handbook presents the current state of the law and practical insights for industry leaders and litigators. Ultimately, it concludes that litigating at the high-stakes and complex cusp of antitrust and patent law requires special attention, expertise, and practice.

[12] *See Research and Development in the Pharmaceutical Industry*, Congressional Budget Office, available at https://www.cbo.gov/publication/57126 (last visited December 13, 2022).

***Walker Process* Litigation**

I. Introduction

IP and antitrust advocates often approach market regulation from opposing directions, creating tension between the two fields. Naturally, antitrust advocates are wary of a system that grants exclusive market rights.[13] The invalidation rate of patents was estimated to be around 71% in 2024, a stark increase from a 2019 estimate of 55%, bolstering antitrust advocates' suspicions of potential market power.[14] Advocates for a strong IP regime, meanwhile, are concerned that the pursuit of anti-monopolistic goals in the short term will diminish innovation and competition in the long term. Yet, even strong IP advocates can recognize that a scourge of invalid patents opposes the goals of innovation and productivity.

In 1965, the Supreme Court held in a landmark decision, *Walker Process Equipment Inc. v. Food Machinery & Chemical Corp.*, that enforcement of a patent can form the basis of an antitrust claim if the patent was procured by fraud on the patent office.[15] These *Walker Process* claims have two primary allegations: (1) the patent enforcer either defrauded the Patent and Trademark Office ("PTO") when they applied for the patent in question, or knew it was obtained through fraud; and (2) the patent enforcer violated Section 2 of the Sherman Antitrust Act.[16] *Walker Process* claims offer common ground between conflicting IP and antitrust doctrines in order to prevent the establishment of a monopoly through egregiously invalid patents—those obtained by fraud on the PTO. The *Walker Process* standard focuses on the enforcement of patents resulting from knowing and willful fraud.[17] In other words, only a showing of intent should expose the patent owner to antitrust liability, and *Walker Process* claims cannot address conduct falling short of fraud.[18]

In *Walker Process*, Food Machinery & Chemical Corporation sued Walker Process Equipment, Inc. to enforce its sewage treatment patent.[19] Walker Process countersued, alleging that Food Machinery had defrauded the patent office and violated Section 2 of the Sherman Antitrust Act.[20]

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[13] *See, e.g.*, *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 135 (1969) (referring to patents as a "legal monopoly"); *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964) ("The grant of a patent is the grant of a statutory monopoly.").

[14] *See* Ryan Fitzgerald, Note, *Standing Up to Bad Patents: Allowing Non-Infringing Direct Competitors to Satisfy the Article III Standing Requirements Appealing an Adverse Inter Partes Review Decision to the Federal Circuit*, 105 MINN. L. REV. 961, 968 (2020) (noting that "twenty-eight percent of currently issued patents would be declared invalid if litigated"); Christopher R. Leslie, *The Anticompetitive Effects of Unenforced Invalid Patents*, 91 MINN. L. REV. 101, 105–6 (2006) (noting that "forty-six percent of litigated patents were held invalid").

[15] *Walker Process*, 382 U.S. at 172–73 (1965).

[16] *Id.* at 179 ("We hold today that a treble-damage action for monopolization which, but for the existence of a patent, would be violative of § 2 of the Sherman Act may be maintained under § 4 of the Clayton Act if two conditions are satisfied: (1) the relevant patent is shown to have been procured by knowing and willful fraud practiced by the defendant on the Patent Office or, if the defendant was not the original patent applicant, he had been enforcing the patent with knowledge of the fraudulent manner in which it was obtained; and (2) all the elements otherwise necessary to establish a § 2 monopolization charge are proved.").

[17] *See id*.

[18] *Id*. at 179–80 (1965) (J. Harlan, concurring) (emphasizing that *Walker Process* liability attaches only to fraudulent conduct).

[19] Brief of Petitioner at 4, *Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1964) (No. 13); Leslie, *supra* note 14, at 101, 110–11.

[20] *See Walker Process*, 382 U.S. at 174–75.

Walker Process argued that Food Machinery's patent was invalid because Food Machinery had publicly used its sewage treatment product for more than a year before filing its patent application.[21] Furthermore, Walker Process asserted that the existence of the fraudulent patent deprived them of business they would have otherwise enjoyed.[22] The district court granted Food Machinery's motion to dismiss, and the Seventh Circuit affirmed.[23] The Supreme Court reversed and held that enforcement of a fraudulent patent could give rise to antitrust liability, provided other elements necessary for antitrust liability were present.[24]

In his concurrence in *Walker Process*, Justice Harlan clarified the scope of the majority's holding with regard to fraud, stating that no cause of action will exist if the plaintiff: (1) established no more than general invalidity due to, e.g., obviousness or a good-faith mistake; (2) showed fraudulent procurement but no knowledge thereof by the defendant; or (3) failed to prove the elements of a Section 2 claim even though intentional fraud existed.[25] Justice Harlan emphasized that "this private antitrust remedy should not be deemed available to reach § 2 monopolies carried on under a nonfraudulently procured patent."[26]

The original suit in *Walker Process* was an enforcement action by a patent holder against a competitor, so these claims first appeared as counterclaims to patent enforcement litigation. But *Walker Process* claims are by no means limited to counterclaims or even to parties who are active competitors.[27] Adding additional weight to these types of claims is the fact that successful civil plaintiffs may seek either treble damages, equitable relief, or both under Section 4 of the Clayton Act.[28]

The prevalence of *Walker Process* claims has consistently grown since the Supreme Court initially recognized the claim as a cause of action in 1965.[29] The market has come to rely on *Walker Process* claims and related forms of suits to ferret out invalid patents and sham litigation.[30] This section will first discuss *Walker Process* claims generally and address jurisdictional, procedural, and choice of law considerations. Next, the section will elaborate on the elements of *Walker Process* suits under both patent and antitrust law. The final section addresses other considerations,

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[21] *Id.* at 174.
[22] *Id*.
[23] *Id*.
[24] *Id.* at 178.
[25] *Id*. at 179 (Harlan, J., concurring).
[26] *Id.* at 180.
[27] *See, e.g.*, *Chandler v. Phoenix Servs. LLC*, 1 F.4th 1013, 1015 (Fed. Cir. 2021) (where a *Walker Process* claim was brought offensively by a competitor rather than as a counterclaim); *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 505 (Fed. Cir. 2012) (where a *Walker Process* claim was brought offensively by customers in the market); *Molecular Diagnostics Lab'ys v. Hoffmann-La Roche Inc.*, 402 F. Supp. 2d 276, 282 (D.D.C. 2005) (holding that direct purchasers have standing to bring a *Walker Process* claim); *Arista Recs. LLC v. Lime Grp. LLC*, 532 F. Supp. 2d 556, 573 (S.D.N.Y. 2007) (where a *Walker Process* claim was brought by a prospective competitor).
[28] Clayton Act, 15 U.S.C. §§ 15, 26; *see also* Gideon Mark & T. Leigh Anenson, *Inequitable Conduct and* Walker Process *Claims After* Therasense *and the America Invents Act*, 16 U. PA. J. BUS. L. 361, 397 n.231–32 (2014); *Walker Process*, 382 U.S. at 177–78.
[29] *See* Jeffrey J. Oelke, *Inequitable Conduct, Willful Infringement, and Antitrust Law: Navigating New Challenges in Patent Litigation*, THOMSON REUTERS, 2012 WL 6636454, at *8–9.
[30] Leslie, *supra* note 14, at 106.

including damages, timeliness and equitable tolling, and how *Walker Process* claims can be contextualized among similar claims that also seek to invalidate patents.

II. Jurisdictional, Choice of Law, and Procedural Considerations

Walker Process claims provide unique jurisdictional, choice of law, and procedural issues. While the Federal Circuit has exclusive appellate jurisdiction over cases arising under patent law, this does not necessarily mean that the Federal Circuit will have jurisdiction over a *Walker Process* claim. Rather, the Federal Circuit has held that it only has jurisdiction over cases where federal patent law creates the cause of action or cases where the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law.[31] When the Federal Circuit does have jurisdiction over a *Walker Process* case, there is a further question of what law the Federal Circuit should apply when deciding substantive or procedural issues outside the scope of its jurisdiction. While there is nuance as to when an issue is appropriately categorized as a patent issue, as a general rule, courts apply Federal Circuit law to patent issues and regional circuit law to nonpatent issues.

There are additional procedural considerations for litigants regarding when a *Walker Process* claim is compulsory versus permissive, which affects whether a party has waived their claim, and whether the antitrust and patent claims should be bifurcated at either the discovery or trial phases, which can impact the case timeline and litigation costs.

A. Jurisdiction

In order to create uniformity in patent law, the Federal Circuit was given exclusive jurisdiction over "any civil action arising under . . . any Act of Congress relating to patents."[32] However, this exclusive jurisdiction is not coextensive with *Walker Process* claims. Appeals from a district court's order on a *Walker Process* claim are often appropriately lodged in the circuit court that oversees that district because, the Federal Circuit's exclusive jurisdiction is only over cases "arising under" federal patent law.[33]

In *Christianson v. Colt Industries Operating Corp.*, the Supreme Court clarified the scope of the Federal Circuit's jurisdiction.[34] The case involved a former employee of a gun manufacturer who was subject to a nondisclosure agreement.[35] The former employee brought claims under Sections 1 and 2 of the Sherman Act, alleging in part that the employer was maintaining a monopoly by attempting to enforce invalid patents and invalid trade secrets.[36] The Supreme Court held that the Federal Circuit did not have jurisdiction over the appeal.[37] The Court explained that the Federal Circuit's jurisdiction extended "only to those cases in which a well-pleaded complaint establishes either that federal patent law creates the cause of action or that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal patent law, in that federal

[31] *Chandler*, 1 F.4th at 1015.
[32] 28 U.S.C. § 1295(a)(1).
[33] *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 807 (1988).
[34] *Id*. at 808.
[35] *Id*. at 804.
[36] *Id*. at 805.
[37] *Id*. at 819.

patent law is a necessary element of one of the well-pleaded claims."[38] Applying this rule, the Court found that plaintiff's antitrust and intentional interference claims were not created by patent law.[39] Plaintiff argued that patent law was essential to his claims because he alleged that the employer's assertions that plaintiff was violating trade secrets were false because "those trade secrets were not protected under state law because [the employer's] patents were invalid under §112."[40] However, the Court rejected this argument, stating that "just because an element that is essential to a particular theory might be governed by federal patent law does not mean that the entire monopolization claim 'arises under' patent law."[41]

The Supreme Court further addressed the jurisdiction issue in *Gunn v. Minton*.[42] Prior to *Gunn*, the Federal Circuit stated that *Walker Process* claims arose under patent law "because the determination of fraud before the PTO necessarily involves a substantial question of patent law."[43] However, in *Gunn*, the Supreme Court revisited the substantiality standard, holding that the substantiality inquiry looks "to the importance of the issue to the federal system as a whole."[44] In *Gunn*, plaintiff alleged legal malpractice claims against former counsel, arguing that his attorney's failure to raise an experimental use argument led to the invalidation of his patent.[45] The Court acknowledged that the resolution of a federal patent question, whether the experimental use exception applied, was necessary to plaintiff's case.[46] However, the Court held that it was not sufficiently substantial for the case to arise under federal patent law. "[I]t is not enough that the federal issue be significant to the particular parties in the immediate suit," the federal issue must be important to the federal system as a whole.[47] Plaintiff's issue was not important to the federal system because the resolution of plaintiff's claim would "not change the real-world result of the prior federal patent litigation."[48]

The Federal Circuit, building on *Gunn*, recently addressed the gap between jurisdiction for *Walker Process* claims and the Federal Circuit's exclusive jurisdiction for patent litigation in *Chandler v. Phoenix Services, LLC*.[49] There, the Federal Circuit rejected the Fifth Circuit's interpretation of the Federal Circuit's precedent as "mandat[ing] exclusive Federal Circuit jurisdiction over all *Walker Process* cases."[50] The court explained that *Walker Process* claims "may relate to patents in the colloquial use of the term," but the Supreme Court requires more.[51] Because the patent at issue in *Chandler* was previously deemed unenforceable, the court stated that the case "is not a patent case. Rather, this case purports to raise novel Fifth Circuit antitrust issues."[52] This was because adjudication of this case would not "alter the validity of [the patent at issue]," so any

[38] *Id*. at 809.
[39] *Id*.
[40] *Id*. at 810–11.
[41] *Id*. at 811.
[42] *See generally* 568 U.S. 251 (2013).
[43] *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1330 n.8 (Fed. Cir. 2008).
[44] *Gunn*, 568 U.S. at 260.
[45] *Id*. at 255.
[46] *Id*. at 259.
[47] *Id*. at 260.
[48] *Id*. at 261.
[49] 1 F.4th 1013, 1019 (Fed. Cir. 2021) (ordering the case be transferred to the appropriate regional circuit court).
[50] *Id*. at 1018.
[51] *Id.* at 1015 (*citing Christianson*, 486 U.S. at 801).
[52] *Id*. at 1018.

discussion was "'merely hypothetical' and 'would not change the real-world result of the prior federal patent litigation.'"[53] This "live" patent factor sufficiently distinguished *Chandler* from prior cases in which regional circuit courts transferred *Walker Process* claim cases to the Federal Circuit because those cases—unlike *Chandler*—presented a "live" patent.[54] It should be noted, however, that the Federal Circuit stopped short of creating a "live" patent requirement, stating that they "do not hold that [Federal Circuit] jurisdiction turns on whether a patent can still be asserted."[55]

B. Procedural Considerations

There are unique procedural considerations when litigating a *Walker Process* claim. Because an antitrust counterclaim to the enforcement of an allegedly invalid patent involves the same set of facts, there is often a question of whether a counterclaim is compulsory or permissive. Further, because of the complexity of both patent and antitrust law, courts often bifurcate the two issues.

i. Compulsory versus Permissive Counterclaims

There is currently a split of authority as to whether a *Walker Process* claim is a compulsory counterclaim, defined by the Federal Rules of Civil Procedure as "aris[ing] out of the transaction or occurrence that is the subject matter of the opposing party's claim [i.e., the patent infringement claim]."[56] When a court designates a counterclaim as compulsory and the party fails to plead it, the party cannot raise the claim in a subsequent lawsuit.[57]

The Second and Third Circuits have held that *Walker Process* claims are compulsory.[58] The Second Circuit, for example, found that there was a "logical relationship" between a patent infringement claim and a *Walker Process* counterclaim and that the "essential facts of the claims are so logically connected that considerations of judicial economy and fairness dictate that all the issues be resolved in one lawsuit."[59] Similarly, the Eastern District of Pennsylvania, which was affirmed by the Third Circuit, held that *Walker Process* claims are compulsory because they are "based on allegations of fraud before the Patent Office, which is an issue often raised during patent infringement suits."[60]

In contrast, the Fifth and Ninth Circuits classify *Walker Process* counterclaims as permissive.[61] The Fifth Circuit held that, even though antitrust claims based on infringement actions appear to be compulsory, they are permissive under the exception put forth by the Supreme Court in *Mercoid Corp. v. Mid-Continent Inv. Co.*, 320 U.S. 661 (1944).[62] Unlike the Second and Third Circuits,

[53] *Id*. (citing *Gunn*, 568 U.S. at 261).
[54] *Id*.
[55] *Id*. at 1016.
[56] *Ragner Tech. Corp. v. Berardi*, 324 F. Supp. 3d 491, 519 n.17 (D.N.J. 2018); Fed. R. Civ. P. 13(a).
[57] *Baker v. Gold Seal Liquors, Inc.*, 417 U.S. 467, 469 n.1 (1974).
[58] *Ragner Tech*, 324 F. Supp. 3d at 519 n.17.
[59] *Critical-Vac Filtration Corp. v. Minuteman Int'l, Inc.*, 233 F.3d 697, 699 (2d Cir. 2000).
[60] *Am. Packaging Corp. v. Golden Valley Microwave Foods, Inc.*, No. 94-1839, 1995 WL 262522, at *4 (E.D. Pa. May 1, 1995) *aff'd without opinion* by 1996 U.S. App. LEXIS 12061 (3d Cir. 1996).
[61] *Ragner Tech*, 324 F. Supp. 3d at 519 n.17.
[62] *Tank Insultation Int'l v. Insultherm, Inc.*, 104 F.3d 83, 89 (5th Cir. 1997).

which distinguished *Mercoid* based on its facts, the Fifth Circuit interpreted *Mercoid* as creating a binding rule that "antitrust counterclaims in which the gravamen is the patent infringement lawsuit initiated by the counterclaim defendant" are permissive.[63] This reasoning echoed that of the Ninth Circuit, which held that *Mercoid* left open "the possibility of raising antitrust claims as permissive counterclaims in an infringement action, or in a separate or subsequent action."[64]

ii. Case Bifurcation

The decision to bifurcate cases into separate patent and antitrust claims was historically the "exception rather than the rule."[65] However, by the 2010s, patent litigants were increasingly seeking bifurcation, usually under the reasoning that bifurcation would increase judicial efficiency and reduce juror confusion.[66] In fact, for a party to successfully obtain bifurcation under Federal Rule of Procedure 42, it must prove that "bifurcation promotes judicial economy and expediency and avoids prejudice to the non-moving party."[67] When considering a motion for bifurcation, courts generally focus on the following considerations: (1) whether economy is served because settlement may be encouraged based on the results of the first trial, (2) whether convenience and expediency are served and whether prejudice and confusion are reduced by trying the less complex IP issues first, (3) whether the claims arise out of the same transaction or occurrence and thus present common questions of law and fact, and (4) whether different witnesses, attorneys, or evidence are required for each claim.[68]

While bifurcation may, in some cases, improve judicial efficiency and reduce juror confusion, having two claims proceed in separate litigations may also result in duplicative presentation of evidence, more time to reach a resolution, and increased costs.[69] As such, courts may deny and defendants may oppose a motion for bifurcation. For example, in *Proctor & Gamble Co. v. Cao Group*, the Southern District of Ohio denied plaintiff's motion to bifurcate where "substantial overlap between the patent and antitrust claims . . . weigh[ed] strongly in favor of consolidated discovery and trial."[70] The Court held that "duplicative presentation to two separate juries would substantially delay resolution of the case" and could prejudice the defendant.[71]

C. Choice of Law

Regardless of which court ultimately adjudicates a *Walker Process* claim, the law applied will be split between the fraud and antitrust prongs. Questions regarding fraud on the patent office are

[63] *Id.* at 88.
[64] *Hydranautics v. Filmtec Corp.*, 70 F.3d 533, 536 (9th Cir. 1995).
[65] Mark A. Klapow & Staci Schweizer, *Bifurcation in Patent-Antitrust Cases*, 18 WESTLAW J. ANTITRUST 2 (2010).
[66] *Id.* at 2–3.
[67] *Id.* at 2.
[68] *See* ABA, ANTITRUST COUNTERATTACK IN INTELLECTUAL PROPERTY LITIGATION HANDBOOK 183–84 (2009).
[69] *See id.* at 184–85.
[70] No. 1:13-CV-337, 2013 WL 6061103 at *3 (S.D. Ohio Nov. 18, 2013).
[71] *Id.* at *3–4.

decided under Federal Circuit law.[72] The antitrust prong, however, is adjudicated under regional law.[73]

The Federal Circuit first announced this split in *Nobelpharma AB v. Implant Innovations, Inc.*, overruling prior contrary precedent.[74] The court held that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law. This conclusion applies equally to all antitrust claims premised on the bringing of a patent infringement suit."[75] The court reasoned that it was in the best position to create a "uniform body of federal law" and thereby avoid the "danger of confusion [that] might be enhanced if this court were to embark on an effort to interpret the laws" of the regional circuits.[76] Accordingly, the court found these claims within its exclusive jurisdiction.[77] Any issues involving other elements of antitrust law—e.g., relevant market, damages, etc.—are, however, subject to the law of the appropriate regional circuit, "as those issues are not unique to patent law."[78]

D. Elements

To prevail on a *Walker Process* claim, a plaintiff must show by clear and convincing evidence that the defendant enforced a patent that it procured by fraud on the patent office.[79] More specifically, a plaintiff must show: (1) a false representation or deliberate omission of a fact material to patentability, (2) made with the intent to deceive the patent examiner, (3) on which the examiner justifiably relied in granting the patent, (4) but for which misrepresentation or deliberate omission the patent would not have been granted, and (5) the "necessary additional elements" of an underlying antitrust violation.[80]

i. Requirements Under Patent Law

Walker Process claims require a showing of fraud and are held to a similar pleading standard as other fraud claims.[81] To establish fraud, a plaintiff must establish "more than mere invalidity through honest mistake."[82] Claimants must establish both materiality and intent in order to show

[72] *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998).
[73] *Cornucopia Prods., LLC v. Dyson, Inc.*, 881 F. Supp. 2d 1086, 1098 (D. Ariz. 2012) ("Federal Circuit law now governs the patent-specific portions of [a *Walker Process*] claim, while regional circuit law governs the antitrust-specific portion of the claim.").
[74] *Nobelpharma*, 141 F.3d at 1068.
[75] *Id*.
[76] *Id.*
[77] *Id.* at 1067.
[78] *Id.* at 1068.
[79] *Astrazeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 770 (Fed. Cir. 2009).
[80] *Xitronix Corp. v. KLA-Tencor Corp.*, No. A-14-CA-01113-SS, 2016 WL 7626575, at *4 (W.D. Tex. Aug. 26, 2016), *aff'd*, 767 F. App'x 1008 (Fed. Cir. 2019) (per curiam).
[81] *TransWeb, LLC v. 3M Innovative Props. Co.*, No. 10-4413, 2011 WL 2181189, at *12 (D.N.J. June 1, 2011) (comparing *Walker Process* claims to other fraud claims).
[82] *Minn. Mining & Mfg. Co. v. Rsch. Med., Inc.*, 691 F. Supp. 1305, 1307 (D. Utah 1988) (quoting D. Chisum, *Patents* § 19.03[6] (1987) (citing *Walker Process*, 382 U.S. 172)).

fraud on the PTO. These two elements must be shown independently of each other: fraud cannot be established by balancing the two.[83]

1. Intent

The case law for establishing intent takes a pragmatic approach. For instance, intent may be inferred from the facts and circumstances. Because direct evidence is rare, courts often accept circumstantial evidence without suspicion.[84] After all, "it would be naive to expect that someone who had sought to deceive the PTO would state in a deposition that this had been his intent."[85] Courts must consider the collective acts of a person's misconduct as a whole, not solely the individual acts of misconduct in isolation.[86] But mere failure on the part of a patent holder to cite prior art is insufficient to establish intent.[87] Ultimately, establishing intent is a fact-intensive inquiry for which minor differences between fact patterns may be dispositive.[88]

For example, the Second Circuit held that repeated omissions over a period of years were sufficient evidence to support a finding of intent.[89] In *In re DDAVP Direct Purchaser Antitrust Litigation*, the court stated that "while a false or clearly misleading statement can permit an inference of deceptive intent, a misrepresentation in the form of an omission is more likely to be innocent . . . and not trigger *Walker Process* fraud."[90] The evidence of intent must be separable from the simple fact of the omission.[91] However, in this case, because there were multiple omissions at issue that occurred repeatedly over a period of years, the court found this intent sufficient to support a finding of *Walker Process* fraud.[92]

Similarly, in *Kaiser Foundation Health Plan v. Abbott Laboratories, Inc.*, the Ninth Circuit Court of Appeals found that circumstantial evidence supported an intent to defraud the PTO by the defendant.[93] The court pointed to evidence of defendant's in-house attorney indicating on the PTO form that an English translation of a prior art reference was included in the patent application

[83] *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1347 (Fed. Cir. 2007), *cert. denied*, 552 U.S. 948 (2007) (holding that the standard for inequitable conduct was met but that the more demanding *Walker Process* standard was not).
[84] *Kaiser Foundation Health Plan Inc. v. Abbott Labs, Inc.*, 552 F.3d 1033, 1050 (9th Cir. 2009).
[85] *Id.*
[86] *Luv n' Care, Ltd. v. Laurain*, 98 F.4th 1081, 1098 (Fed. Cir. 2024).
[87] *Dippin' Dots*, 476 F.3d at 1347 (finding that "there must be evidence of intent separable from the simple fact of the omission.").
[88] *Id.* ("A false or clearly misleading prosecution statement may permit an inference that the statement was made with deceptive intent. For instance, evidence may establish that a patent applicant knew one fact and presented another, thus allowing the factfinder to conclude that the applicant intended by the misrepresentation to deceive the examiner."); *see also Giuliano v. SanDisk LLC*, 705 F. App'x 957, 961 (Fed. Cir. 2017) (affirming the district court's grant of summary judgment in favor of defendants and finding that "the mere presence of an undisclosed reference, where there was no evidence showing that the patentee had searched and found a copy of that reference during the prosecution of the patent, was not enough to show an intent to deceive for purposes of inequitable conduct, let alone the heightened standard for *Walker Process* claims.").
[89] *In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 693 (2nd Cir. 2009) (citing *Dippin' Dots*, 476 F.3d at 1347).
[90] *Id*.
[91] *See id.*
[92] *See id.*
[93] *Kaiser Found. Health Plan*, 552 F.3d at 1033, 1050.

without actually including the translation in the application.[94] The court emphasized how the English translation of the reference was the "only document in the initial application that, if fully understood by the patent examiner, would have resulted in a denial of the application."[95] This indicated a substantial incentive not to include the translation.[96] Repeated subsequent failures by the same attorney to mention relevant references to the PTO became a pattern of "inadvertent" disclosures that was sufficient circumstantial evidence to support a jury's finding of intent to defraud the PTO.[97]

The Federal Circuit further articulated intent to defraud the PTO where defendant's employees had knowledge of the prior art nature of plaintiff's products.[98] Evidence of plaintiff's production operations and sending samples of the claimed material to the defendant indicated that defendant knew about the claimed material yet proceeded to file its patent application excluding the prior art samples.[99] Delays between learning of the prior art and informing the PTO supported the court's finding of intent to defraud.[100]

However, the Federal Circuit has declined to find deceptive intent under a *Walker Process* claim for the "mere failure to cite a reference to the PTO."[101] The court emphasized the importance of weighing intent and materiality together in assessing whether the patentee's prosecution conduct is inequitable.[102] Where a party fails to prove deceptive intent independently from an omission that may otherwise be fraudulent and material, the court is unlikely to find *Walker Process* fraud.[103] Ultimately, establishing intent is a fact-intensive inquiry for which minor differences between fact patterns may be dispositive.[104]

2. *Materiality*

Materiality is a demanding requirement: a claimant must show that "the patent would not have issued but for the patent examiner's justifiable reliance on the patentee's misrepresentation or omission."[105] A plaintiff must show that, but for defendant's conduct, the patent examiner would not have issued the patent.

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[94] *Id.* at 1051.
[95] *Id.*
[96] *Id.*
[97] *Id.*
[98] *TransWeb*, 812 F.3d at 1305.
[99] *Id*. at 1306.
[100] *Id*.
[101] *Dippin' Dots*, 476 F.3d at 1347.
[102] *Id.* at 1348.
[103] *See id.*
[104] *Id.* at 1347. ("A false or clearly misleading prosecution statement may permit an inference that the statement was made with deceptive intent. For instance, evidence may establish that a patent applicant knew one fact and presented another, thus allowing the factfinder to conclude that the applicant intended by the misrepresentation to deceive the examiner."); see *Giuliano*, 705 F. App'x at 961 (affirming the district court's grant of summary judgment in favor of defendants and finding that "the mere presence of an undisclosed reference, where there was no evidence showing that the patentee had searched and found a copy of that reference during the prosecution of the patent, was not enough to show an intent to deceive for purposes of inequitable conduct, let alone the heightened standard for *Walker Process* claims.").
[105] *Id.* (citing C.*R. Bard, Inc. v. Ms Systems, Inc.*, 157 F.3d 1340, 1364 (Fed. Cir. 1998)).

For example, in *United Food & Commercial Workers Unions & Employers Midwest Benefits Fund v. Novartis Pharmaceuticals Corp.*, the First Circuit affirmed dismissal of plaintiff's *Walker Process* claims, finding that they failed to demonstrate the allegedly withheld reference was material to the asserted patent.[106] The court explained that the Board had previously reversed the patent examiner's initial rejection of the asserted patent with an assumption that the disclosure of the withheld reference was known in the art.[107] Accordingly, the court found it "difficult to conclude that, but for [defendant's] inaccurate representation that the prior art did not disclose [the feature of the withheld reference], the patent would not have issued."[108] Furthermore, defendant "eventually did submit prior art to the Patent Office" that disclosed the allegedly withheld feature, albeit "belatedly."[109] This lead the court to conclude that the reference was not material to the Patent Office's decision to issue the patent.[110]

In contrast, in *In re Loestrin 24 Fe Antitrust Litigation*, a district court in Rhode Island denied defendant's motion for summary judgment, finding that there was a genuine issue of material fact regarding whether the withheld reference was "but-for" material to the asserted patent.[111] Because defendants claimed that the study was duplicative of a previously disclosed study and that the plaintiffs had submitted evidence that the withheld reference had inconsistent findings with the previously disclosed study, the court found "a reasonable juror could conclude that the patent would not have issued had the PTO examiner known about the study."[112]

Information is not material if it is cumulative to information already of record or made of record in a patent application.[113] A patentee has no duty to disclose "an otherwise material reference if the reference is cumulative or less material than those already before the examiner." And an uncited reference is cumulative "if the most pertinent prior art in the field was . . . before the examiner."[114] A reference is cumulative if it "teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO."[115] Additionally, a reference that merely replicates references already before the examiner is cumulative.[116] Once a patent examiner becomes aware of a reference, an applicant has no obligation to emphasize its importance.[117]

In *Luv n' Care, Ltd. v. Laurain*, the Federal Circuit addressed the distinction between materiality and something being merely cumulative, albeit in the context of inequitable conduct claims.[118] The Federal Circuit reversed the district court's finding that the withheld references were not material,

[106] 902 F.3d 1, 10 (1st Cir. 2018).
[107] *Id*. at 9–10.
[108] *Id.* at 10.
[109] *Id.*
[110] *Id.*
[111] 433 F. Supp. 3d 274, 311 (D.R.I. 2019).
[112] *Id*.
[113] 37 C.F.R. § 1.56 (1995).
[114] *Halliburton Co. v. Schlumberger Tech. Corp.*, 925 F.2d 1435, 1440 (Fed. Cir. 1991).
[115] *Regents of the Univ. of Cal. v. Eli Lilly & Co*., 119 F.3d 1559, 1569,1575 (Fed. Cir. 1997).
[116] *See Halliburton*, 925 F.2d at 1440; *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573 (Fed. Cir. 1997); *Elkay Mfg. Co. v. Ebco Mfg. Co.*, No. 93 C 5106, 1998 WL 397844 (N.D. Ill. July 13, 1998); *Intermatic Inc. v. Lamson & Sessions Co.*, No. 94 C 50295, 1999 WL 181980 (N.D. Ill. Mar. 30, 1999).
[117] *Fiskars, Inc. v. Hunt Mfg. Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000).
[118] 98 F.4th 1081, 1098 (Fed. Cir. 2024).

explaining that the district court could find that those undisclosed prior art references "would have taught more than what a reasonable examiner would have considered to have been taught by the misrepresented [invention]."[119]

A district court granted summary judgement of no inequitable conduct where defendant failed to rebut plaintiff's assertion that the withheld prior art reference was merely cumulative.[120] Defendant argued that the withheld reference should have been independently submitted in an Information Disclosure Statement, as the disclosure of the purportedly cumulative reference among hundreds of other references was insufficient to render the alleged concealment of the withheld as immaterial.[121] However, the district court rejected this argument, stating that defendant's failure to rebut plaintiff's assertion that the prior art references "are merely cumulative of the disclosed [prior art] reference is fatal" to that theory.[122]

In contrast, in *Larson Manufacturing Co. of South Dakota v. Aluminart Products. Ltd.*, the Federal Circuit reversed the district court's finding that prior art references were material because they were cumulative of disclosed art.[123] The court found that expert testimony established that the allegedly withheld prior art references disclosed the same features as a disclosed reference.[124] Furthermore, the expert's testimony regarding a difference in ability of a feature between the disclosed and withheld art was "irrelevant to the claim limitations at issue and therefore could not support a finding of materiality and non-cumulativeness."[125]

3. Walker Process Claims versus Inequitable Conduct Defenses

The alignment of *Walker Process* claims and inequitable conduct defenses is another important area of development in the space. While *Walker Process* claims are affirmative claims, inequitable conduct is an equitable defense to patent infringement. In fact, the Federal Circuit has repeatedly analogized *Walker Process* claims to a "sword" and inequitable conduct defenses to a "shield."[126]

Inequitable conduct is a judge-made doctrine that evolved from the unclean hands doctrine, which was used to dismiss patent cases involving egregious misconduct.[127] An enforcement defendant pleading an inequitable conduct defense must show that the plaintiff: (1) misrepresented or omitted

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[119] *Id*.
[120] *XY, LLC v. Trans Ova Genetics, LC*, No. 17-CV-0944-WJM-MDB, 2025 WL 2549817, at *10 (D. Colo. Sept. 4, 2025).
[121] *Id*.
[122] *Id*.
[123] 559 F.3d 1317, 1320 (Fed. Cir. 2009).
[124] *Id*. at 1332.
[125] *Id*.
[126] *See e.g.*, *Korody-Colyer Corp. v. Gen. Motors Corp.*, 828 F.2d 1572, 1578 (Fed. Cir. 1987) (explaining that by arguing inequitable conduct, "a party raises a shield," while in contrast, by asserting a *Walker Process* claim "a party unsheaths a sword"); *Nobelpharma*, 141 F.3d at 1070 ("Inequitable conduct is thus an equitable defense in a patent infringement action and serves as a shield, while a more serious finding of fraud potentially exposes a patentee to antitrust liability and thus serves as a sword."); *Dippin' Dots*, 476 F.3d at 1348 (explaining the *Walker Process* claims are a "sword" to obtain antitrust damages rather than a mere "shield" against enforcement of a patent).
[127] *See Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 244 (1933); *Hazel-Atlas Glass Co. v. Hartford–Empire Co.*, 322 U.S. 238, 270 (1944), *overruled on other grounds by Standard Oil Co. of Cal. v. United States*, 429 U.S. 17 (1976); *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 815 (1945).

from the PTO information that is "but-for" material to patentability and (2) did so with specific intent to mislead or deceive the PTO.[128] Unlike *Walker Process* claims, an enforcement defendant need not show any antitrust liability. Another important distinction from *Walker Process* claims is that an inequitable conduct claim's "but-for" materiality showing has an exception for "affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit."[129] This exception has become more important since the Supreme Court aligned the materiality showing of inequitable conduct with *Walker Process* claims in *Therasense, Inc. v. Becton, Dickenson and Co.*[130]

Since *Therasense*, plaintiffs alleging inequitable conduct claims must show that a patent would not have issued "but-for" the inequitable conduct—the same showing required in *Walker Process* claims regarding fraud. Earlier Federal Circuit decisions, like *Nobelpharma* and *Dippin' Dots, Inc. v. Mosey*, required a showing of "knowing and willful fraud," which is a higher and more specific burden compared to "but-for" under inequitable conduct doctrine.[131] After *Therasense* raised the showing required for an inequitable conduct defense, the standards for inequitable conduct and the *Walker Process* fraud component became, arguably, identical.[132]

The post-*Therasense* landscape poses two concerns for *Walker Process* plaintiffs who choose to also raise an inequitable conduct affirmative defense: (1) the availability of an antitrust remedy at all and (2) the constriction of their Seventh Amendment right to a jury trial in the antitrust claim. Each of these concerns stem from the introduction of "*Therasense* sequencing," by which courts address materiality under inequitable conduct claims first, and then the *Walker Process* claims without a separate materiality analysis.[133] Sequencing claims in this order leaves opens the question of what preclusive effect, if any, a finding of inequitable conduct may have on subsequent *Walker Process* litigation. Consider, for instance, when a court decides the materiality issue in an inequitable conduct claim before addressing the materiality in a *Walker Process* claim—whether due to "*Therasense* sequencing" or because the inequitable conduct suit was brought first. If the court held for the alleged infringer regarding materiality in the inequitable conduct case, that materiality holding may preclude the patent owner from arguing lack of materiality in the *Walker Process* claim. At least one court has already suggested that such a finding is preclusive.[134] The holding also raised questions regarding *who* should adjudicate such a claim. Inequitable conduct defenses are decided by judges as claims in equity.[135] *Walker Process* claims are legal claims,

[128] *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1286 (Fed. Cir. 2011).
[129] *Id.* at 1292.
[130] *Id.*
[131] *Compare Nobelpharma*, 141 F.3d at 1068 *and Dippin' Dots*, 476 F.3d at 1346 *with id.* at 1291.
[132] *See* George G. Gordon & Stephen A. Stack, *Aligning Antitrust and Patent Law: Side Effects from the Federal Circuit's Cure for the Inequitable Conduct 'Plague' in* Therasense, 26 ANTITRUST 88, 91 (2011) (noting that the elements of proof are "now, identical" for an inequitable conduct defense and a *Walker Process* claim); Gideon Mark & T. Leigh Anenson, *Inequitable Conduct and Walker Process Claims after Therasense and the America Invents Act*, 16 U. OF PA. J. OF BUS. L. 261, 389 (2014).
[133] *See In re Loestrin*, 433 F. Supp. 3d at 274, 305; *Targus Int'l LLC v. Victorinox Swiss Army, Inc.*, No. 20-0464-RGA, 2020 WL 7264199, at *6–7 n.9–10 (D. Del. Dec. 10, 2020); *Guardant Health, Inc. v. Found. Med., Inc.*, No. 17-1616-LPS-CJB, 2020 WL 2461551, at *8–13 (D. Del. Oct. 9, 2020).
[134] *See Complete Genomics, Inc. v. Illumina, Inc.*, No. 21-CV-00217-WHO, 2021 WL 1197096, at *3 (N.D. Cal. Mar. 30, 2021).
[135] *See e.g., Katchen v. Landy*, 382 U.S. 323, 337 (1966) (holding that the right to a jury trial does not extend to cases of equity jurisdiction); *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1333 (Fed. Cir. 2011)

however, and must be decided by juries when plaintiffs assert their Seventh Amendment right to that effect.[136] This dynamic creates at least two new possible scenarios. First, as mentioned, a previous finding of inequitable conduct by a judge may have preclusive effect in a subsequent jury trial for a *Walker Process* claim, removing that analysis from the jury.[137] Second, if these matters are part of the same proceeding, a jury may hear both claims and issue an advisory verdict regarding the inequitable conduct defense.[138]

ii. Requirements under Antitrust Law

1. Overview of Section 2 Sherman Act Claims

Under Section 2 of the Sherman Act, it is illegal to "monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations[.]"[139] This section provides a brief overview of the elements needed for a monopolization or attempted monopolization claim. Joint monopolization and conspiracy claims are beyond the scope of this Handbook.

"The offense of monopoly under [Section 2] of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident."[140] The first element essentially requires proof of two subparts.[141] First, the plaintiff must prove there is a relevant market (i.e., a "group of products or services with which, and [a] geographic area within which, the defendant effectively competes").[142] Next, the plaintiff must prove that defendant has monopoly power within the relevant market, which the Supreme Court has defined as the power to "control prices *or* exclude competition."[143] The second element is satisfied if the defendant willfully "engaged in predatory or otherwise anticompetitive acts to maintain or acquire monopoly power."[144]

("Inequitable conduct is equitable in nature, with no right to a jury . . . ."); Peter S. Menell, *Patent Case Management Judicial Guide*, 4 (Lynn H. Pasahow et al. eds., 3d ed. 2016), https://www.law.berkeley.edu/wp-content/uploads/2016/05/Chapter-8-Final.pdf.

[136] *Complete Genomics, Inc.*, No. 21-CV-00217-WHO, 2021 WL 1197096, at *3 (treating *Walker Process* claims as legal claims); see also *Beacon Theaters, Inc. v. Westover*, 359 U.S. 500, 504 (1959) ("[T]he right to trial by jury applies to treble damages under the antitrust laws . . . .").

[137] *See Complete Genomics, Inc.*, No. 21-CV-00217-WHO, 2021 WL 1197096, at *3.

[138] Menell, *supra* note 135, at 6.

[139] 15 U.S.C. § 2.

[140] *United States v. Grinnell Corp.*, 348 U.S. 563, 570–71 (1966).

[141] *See* WILLIAM C. HOLMES, INTELLECTUAL PROPERTY AND ANTITRUST LAW: § 6.2 SINGLE FIRM MONOPOLIZATION – ELEMENTS AND STANDING 1 (2025).

[142] *Id.* For more detail on how to prove a relevant market, see generally *id.* at § 6.3 SINGLE FIRM MONOPOLIZATION – DEFINING THE RELEVANT MARKET.

[143] HOLMES, *supra* note 141, at § 6.4 SINGLE FIRM MONOPOLIZATION – MONOPOLY POWER 2 (citing *United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956)) (emphasis added).

[144] *Id.* at § 6.2 SINGLE FIRM MONOPOLIZATION; ELEMENTS AND STANDING 1. For more detail on how to prove willful monopolization conduct, see generally *id.* at § 6.5 SINGLE FIRM MONOPOLIZATION – MONOPOLIZING CONDUCT.

The offense of attempted monopoly under Section 2 of the Sherman Act has four basic elements.[145] The first element is the same—the plaintiff must prove a relevant market.[146] However, next a plaintiff must show (1) that the defendant engaged in predatory or anticompetitive conduct, (2) that the defendant specifically intended to acquire monopoly power (which may be inferred from the defendant's predatory or anticompetitive conduct), and (3) that the defendant's market position and actions pose a "dangerous probability" that, if left unchecked, the defendant will achieve actual monopoly power.[147]

2. Antitrust Standing

All federal court plaintiffs must have "case or controversy" standing under Article III of the Constitution.[148] Each plaintiff must establish (1) an injury in fact (2) that was materially caused by the defendant.[149] In the antitrust context, several common injuries in fact include paying higher prices, being foreclosed from the market as a competitor, and losing revenue and profits. However, plaintiffs cannot properly claim an antitrust injury if they benefit from the alleged illegal conduct that they challenge.[150] Nor may a competitor use generalized alleged consumer harm to establish standing for itself.[151]

Antitrust plaintiffs must also establish material cause; that is, they must show that the antitrust violation was a material and substantial cause—but need not be the sole cause—of their injury.[152] Incidental harm not directly caused by a defendant's alleged unlawful conduct is typically insufficient to show material cause of injury.[153] The Second Circuit's treatment of two cases dealing with inflated aluminum prices illustrate the contours of antitrust standing. In *In re Aluminum Warehousing Antitrust Litigation* ("*Aluminum III*"),[154] the court denied standing to purchasers of reconstituted aluminum because they were not in "the very market directly distorted by the antitrust violation" and because the very narrow standing exception for nonmarket participants whose injuries were "inextricably intertwined" with the injuries of the market participants did not apply.[155] In *Eastman Kodak Company v. Henry Bath LLC*, the Court clarified that *Aluminum III* does not compel dismissal of a plaintiff's claim for lack of standing merely because the plaintiff was not a participant in the relevant market.[156] While antitrust injury is

[145] *Id.* at § 6.8 ATTEMPTED MONOPOLIZATION 1.
[146] *Id.*
[147] *Id.*
[148] U.S. CONST. art. III, § 2, cl. 1.
[149] Brief of Amicus Curiae Public Citizen in Support of Appellant and Vacatur, Federal Election Commission v. Ted Cruz for Senate, et al., 596 U.S. 289 (2022) (No. 21-12).
[150] *Atlantic Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 344 (1990) (finding that non-conspiring competitors are typically unable to sue a cartel for price-fixing because they would benefit from higher market prices resulting from a conspiracy among their rivals).
[151] *Novation Ventures, LLC v. J.G. Wentworth Co., LLC*, 2017 WL 4711477, at *1 (9th Cir. 2017).
[152] *Zenith Radio Corp.*, 395 U.S. at 114 n.9.
[153] *Abbey House Media, Inc. v. Simon & Schuster, Inc.*, 869 F.3d 53 (2nd Cir. 2017); *see also Diesel eBooks, LLC v. Simon & Schuster, Inc.*, 869 F.3d 55, 56 (2nd Cir. 2017).
[154] 833 F.3d 151 (2nd Cir. 2016).
[155] *Id*. at 161 (holding that when evaluating whether the exception applies, courts usually ask whether the plaintiff was "manipulated or utilized by [the defendant] as a fulcrum, conduit or market force to injure competitors or participants in the relevant . . . markets").
[156] *Eastman Kodak Co. v. Henry Bath LLC*, 936 F.3d 86, 91 (2d Cir. 2019).

commonly suffered by plaintiffs in the relevant market, a plaintiff outside the relevant market can also have standing if his injuries are "inextricably intertwined with the injury the conspirators sought to inflict."[157] The Second Circuit thus held that, if the plaintiffs moved to file an amended complaint, the district court must consider the motion on its merits, rather than by drawing a hard-line rule based on an erroneous and overly narrow reading of *Aluminum III*.[158]

Antitrust plaintiffs, however, must also show standing under the judicially created concept of "antitrust standing." In *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, the Supreme Court explained that antitrust standing is distinct from constitutional standing: "Harm to the antitrust plaintiff is sufficient to satisfy the constitutional standing requirement of injury in fact, but the court must make a further determination whether the plaintiff is a proper party to bring a private antitrust action."[159]

To establish antitrust standing, *Walker Process* claimants must show that the following factors weigh in their favor: (1) the nature of the plaintiff's alleged injury; that is, whether it was the type the antitrust laws were intended to forestall; (2) the directness of the injury; (3) the speculative measure of the harm; (4) the risk of duplicative recovery; and (5) the complexity in apportioning damages.[160] The first factor requires would-be plaintiffs to establish an antitrust injury, and the remaining factors are typically referred to as creating the efficient enforcer requirement.[161]

The antitrust injury requirement leads to several intriguing use cases in the *Walker Process* claims realm. Nascent companies, commonly pharmaceutical companies, fall under one such use case. Under the Hatch-Waxman Act, when a pharmaceutical company files an Abbreviated New Drug Application ("ANDA") seeking to market a generic equivalent of a patented drug and a patent's owner files suit for infringement under 35 U.S.C. § 271(e)(2)(A), approval by the Food and Drug Administration (FDA) is automatically delayed until the patent in suit is declared invalid or not infringed.[162] In such a case, a "competitor" that produces/sells generic counterparts has standing to bring a *Walker Process* claim. "For [a patent owner] to insist that its generic competitors have no standing because they are not in the market, when [the patent owner] itself foreclosed their access to it, is meritless."[163]

Direct purchasers are another type of use case worth mentioning.[164] In *Ritz Camera & Image, LLC v. SanDisk Corp.*, the Federal Circuit expressed little concern for any inconvenience patentees may face from granting standing to direct purchasers: "the interest in protecting patentees from

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[157] *Id.* at 94 (quoting *Blue Shield of Va. v. McCready*, 457 U.S. 465, 479 (1982)). This language appears broader and less tied to the "relevant market" than that previous language used by the Second Circuit. Originally, the Second Circuit said the exception applies when the nonmarket participant's injuries are "inextricably intertwined" with those of the market participants. Here, the Second Circuit said the exception applies whenever the injury is "inextricably intertwined" to the injury conspirators sought to inflict.
[158] *Eastman Kodak Co.*, 936 F.3d at 98.
[159] *Associated Gen. Contractors of Cal., Inc. v. California State Council of Carpenters*, 459 U.S. 519, 535 n.31 (1983).
[160] *Id.* at 538–545.
[161] *Palmyra Park Hosp. Inc. v. Phoebe Putney Mem'l Hosp.*, 604 F.3d 1291, 1299 (11th Cir. 2010).
[162] 21 U.S.C. § 355(j)(5)(B)(iii).
[163] *Bristol-Myers Squibb Co. v. Ben Venue Labs*, 90 F. Supp. 2d 540, 545 (D. N.J. 2000).
[164] *Ritz Camera & Image, LLC v. SanDisk Corp.*, 700 F.3d 503, 503 (Fed. Cir. 2012).

'innumerable vexatious suits' [cannot] be used to frustrate the assertion of rights conferred by the antitrust laws."[165]

In *Ritz Camera*, the patentee wanted the court to apply declaratory judgment standing requirements to a *Walker Process* claim, but the Federal Circuit disagreed. There was no need, according to the court, to impute another doctrine's standing requirements because "purchasers are generally permitted to bring antitrust actions, and because the *Walker Process* decision did not preclude purchasers from bringing this particular type of antitrust claim."[166] Purchasers, therefore, may bring *Walker Process* claims even when they lack standing to bring suit for declaratory judgment. This is because the goal of *Walker Process* claims is to redress anticompetitive conduct,[167] and "[i]t would be perverse to deny standing to the main targets of [such] conduct."[168] Even though *Walker Process* claims may be "predicated on enforcement of a fraudulently obtained patent, the harm still accrues directly to consumers."[169]

Cease and desist letters present another standing issue for *Walker Process* claims as well as an obstacle to proving the substantive "enforcement" element. In *Chandler*, the Federal Circuit held that the plaintiffs had not demonstrated that they met the standing requirement[170] because they failed to show a causal link between the cease and desist letter and their alleged harm.[171] The plaintiffs failed to establish injury in fact due to the lack of substantial evidence that the cease and desist letter materially caused a party's lost profits.[172] Because injury-in-fact claims frequently surround economic harm, cease and desist letters, like in *Chandler*, may be insufficient to confer standing without being able to demonstrate that lost profits were caused by a cease and desist letter.

In *In re Lantus Direct Purchaser Antitrust Litigation*, the court considered whether a party's listing of its patent in the Orange Book was an "improper means" of maintaining power.[173] As a defense to antitrust liability, the listing party had to prove that the submission was the result of a "reasonable, good-faith attempt to comply with the Hatch-Waxman scheme."[174] In this case, consumers had sufficiently alleged antitrust injury arising out of the improper Orange Book listing by alleging that the manufacturer's conduct was material and substantial cause in the restriction of competition, without a proper defense of good faith.[175]

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[165] *Id.* at 508.
[166] *Id.*
[167] *Ritz Camera* was a standalone *Walker Process* claim and, therefore, could have been filed in a regional court (see jurisdiction discussion below).
[168] Opp. Br. at 21, *Ritz Camera*, 772 F. Supp. 2d 1100, 1104 (N.D. Cal. 2011), *aff'd*, 700 F.3d 503 (Fed. Cir. 2012).
[169] *Ritz Camera*, 772 F. Supp. 2d at 1104.
[170] *Chandler*, 1 F.4th at 1013.
[171] *Chandler*, 45 F.4th at 807. The suit could proceed as to the legal fees it incurred as a result of Phoenix Services' infringement action. Parlaying attorney's fees into significant awards in *Walker Process* claims is discussed below in the "Damages" section.
[172] *Id.* at 814.
[173] *In re Lantus Direct Purchaser Antitrust Litigation*, 950 F.3d 1, 7 (1st Cir. 2020).
[174] *Id.* at 14.
[175] *Id.*

3. Enforcement

The enforcement requirement is a preliminary showing, and often it is a court's first consideration when deciding a *Walker Process* claim. This requirement imposes a showing of some affirmative act. A *Walker Process* claim must establish that the defendant's actions created a "reasonable apprehension of suit."[176] Filing a patent infringement suffices as enforcement.[177]

In *Kroger Co. v. Sanofi-Aventis*, plaintiff asserted that defendant unlawfully monopolized a product market by, among other things, listing the fraudulently obtained patent in the FDA's Orange book.[178] Unlike *In re Lantus*, this court found that defendant's listing of its patent in the Orange Book was not done in bad faith but rather as a standard procedure under the Hatch-Waxman Act.[179] Whether actions short of actual patent litigation could serve as the predicate act was one of the first questions raised following the *Walker Process* decision. The doctrine has since evolved to clearly demonstrate that simply owning a patent procured by fraud will not suffice.[180] Rather, a claimant must show conduct on behalf of the patent enforcer that created a "reasonable apprehension of suit."[181]

Similarly, in *In re Netflix Antitrust Litigation*, the District Court for the Northern District of California declared that informing competitors of one's patent is not enough to sustain a *Walker Process* claim.[182] A putative class of Netflix subscribers brought a *Walker Process* claim against Netflix, claiming Netflix abused its patent for online DVD orders to deter Wal-Mart, Amazon, and Blockbuster from entering or remaining in the online DVD rental market. Wal-Mart briefly entered the market, but exited shortly thereafter; Amazon announced plans to enter the market, but never did; and Blockbuster entered the market two years after Wal-Mart.

As to Wal-Mart and Amazon, plaintiffs argued that Netflix caused Wal-Mart to exit from the market and Amazon to abandon its plans for entry. Plaintiffs pointed to Netflix's patent for online DVD ordering and pleaded that Netflix enforced the patent by "alerting" Wal-Mart and Amazon to it. The court held that this action was not enough to rise to the level of enforcement: "without any threat or implication at all that [Wal-Mart and Amazon] must either stop practicing the patented method or risk Netflix's filing suit," Netflix did not enforce its patent under *Walker Process* standard for enforcement.[183] Furthermore, plaintiffs had not sufficiently pleaded facts to

[176] It is an open question whether *Walker Process* claims use the "reasonable apprehension of suit" standard or the "substantial controversy test" because "*Unitherm* pegged the Walker Process standard for enforcement to the Declaratory Judgment standard, [the reasonable apprehension of suit standard,] and *MedImmune* announced the prevailing Declaratory Judgment standard [as the substantial controversy test]." *Xitronix Corp*., No. A-14-CA-1113-SS, 2015 WL 5037387, at *5.
[177] *Walker Process*, 382 U.S. at 172.
[178] *Kroger Co. v. Sanofi-Aventis*, 701 F. Supp. 2d 938, 960 (S.D. Ohio 2010).
[179] *Id.* at 964.
[180] *See*, *e.g.*, *Unitherm Food Sys. Inc. v. Swift-Eckrich, Inc.*, 375 F.3d 1341, 1355 (Fed. Cir. 2004), *rev'd on other grounds*, 546 U.S. 394 (2006).
[181] *Id.* at 1358.
[182] *In re Netflix Antitrust Litigation*, 506 F. Supp. 2d 308 (N.D. Cal. 2007).
[183] *Id.* at 318.

suggest Amazon and Wal-Mart even knew about this patent or, if they did know, that their decisions to exit and enter the market were not based on some other information.[184]

The district court rejected plaintiff's additional enforcement theory regarding a patent-infringement action Netflix filed in 2006.[185] Plaintiff alleged that Netflix delayed Blockbuster from entering the market.[186] However, the court stated this was not sufficient enforcement, as Blockbuster had entered the market two years before Netflix filed the patent-infringement action.[187] The court also rejected plaintiff's argument that Netflix's patent-infringement action deterred other competitors, as plaintiff did not plead any enforcement action against those competitors.[188]

E. Other Considerations

For potential *Walker Process* claim plaintiffs, there are a host of other considerations, including procedural concerns such as jurisdiction, tolling, and methods for calculating damages. Other considerations include choice of law issues created by the federal government's exclusive jurisdiction of patent matters and the ability of parties to bring additional suits simultaneously with, or instead of, a *Walker Process* claim.

i. Damages

Under Section 2 of the Sherman Act, it is unlawful to "monopolize" or "attempt to monopolize . . . any part of . . . trade or commerce."[189] And under Section 4 of the Clayton Act, Federal Courts are authorized to hear suits brought by a person injured by a defendant's violation of the "antitrust laws" of the United States.[190] The Clayton Act further states that the plaintiff "shall recover threefold the damages by him sustained, and the cost of suit, including a reasonable attorney's fee."[191] In its *Walker Process* opinion, the Supreme Court specifically said that "the treble damage provisions of [Section 4] of the Clayton Act [are] available to an injured party" when a patent is procured by fraud and the other elements necessary to establish a Sherman Act § 2 violation are established.[192] While the bar to obtaining treble damages is high because plaintiffs must prove antitrust injury, rather than simply any injury causally linked to the antitrust violation, the statutory availability of treble damages opens up the possibility of substantial awards for *Walker Process* claimants.[193]

Walker Process claimants can also recover trebled attorneys' fees for antitrust damages. In *TransWeb, LLC v. 3M Innovative Properties Company*, TransWeb, which was found liable for a *Walker Process* violation, argued that it should not have to pay trebled attorneys' fees because the

[184] *Id.* at 313, 317.
[185] *Id.* at 312.
[186] *Id.*
[187] *Id.* at 318.
[188] *Id.* at 318–19.
[189] 15 U.S.C. § 2.
[190] 15 U.S.C. § 15.
[191] 15 U.S.C. § 15(a).
[192] *Walker Process*, 382 U.S. at 174 (1965).
[193] *Handgards, Inc. v. Ethicon, Inc.*, 601 F.2d 986, 997 (9th Cir. 1979).

accused infringer's attorneys' fees were not an antitrust injury and so could not be a proper basis for damages.[194] A Federal Circuit panel disagreed, holding that the attorney's fees incurred in defending against the infringement suit flowed directly from the defendant's unlawful acts in obtaining its patent.[195] The district court's damages order was upheld by the Federal Circuit, awarding the *Walker Process* claimant $23 million in trebled attorney fees.[196]

ii. Walker Process Claims Compared to Noerr-Pennington Immunity and Sham Litigation

Under the *Noerr-Pennington* doctrine, lawsuits are a protected form of redress to the government and are generally protected from antitrust liability.[197] The *Noerr-Pennington* doctrine has evolved nearly contemporaneously with the *Walker Process* doctrine.[198] Yet it remains unclear how the two doctrines overlap. Some scholars see *Walker Process* claims as fitting naturally into the *Noerr-Pennington* doctrine.[199] The Federal Circuit has declined to take up the issue—twice.[200]

Sham litigation alleges that the defendant used legal or government processes for anticompetitive purposes. To succeed under a sham litigation claim, a plaintiff must show that defendant's conduct was: (1) objectively baseless and could not reasonably have been expected to succeed on the merits and (2) intended to use the petitioning process and accompanying litigation to interfere with a competitor's business, regardless of the petition's outcome.[201]

Sham litigation claims are exceptions to *Noerr-Pennginton* immunity when: (1) the petitioner engages in sham petitioning; (2) the petitioner uses misrepresentations or fraud in the petition process; and (3) the government is acting in a commercial capacity.

iii. Timeliness and Equitable Tolling

As with most claims, *Walker Process* claims are subject to statutes of limitation that require a plaintiff to bring their claim within a particular time period (typically four years[202]) of that claim accruing. "Generally, a cause of action accrues and the statute begins to run when a defendant

[194] 812 F.3d 1295, 1309 (Fed. Cir. 2016).
[195] *Id.* at 1309–10.
[196] *Id.* at 1309, 1312.
[197] *E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 143 (1961); *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965).
[198] The Supreme Court decided *Pennington* in the term directly preceding *Walker Process*. Both decisions were joined by the full Court, whose makeup had changed by only a single justice (Justice Fortas having taken the associate justice chair vacated by Justice Goldberg in 1965). Of note, Justice Clark (who authored the *Walker Process* opinion), joined a concurring opinion in *Pennington* highlighting the unlawful acts of the antitrust defendants and the legislative goals of the *Sherman* antitrust laws. *United Mine Workers v. Pennington*, 381 U.S. 657, 675 (1965) (concurring opinion).
[199] *See, e.g.*, H. Hovenkamp, *The Walker Process Doctrine: Infringement Lawsuits as Antitrust Violations*, *Faculty Scholarship at Penn Carey Law*, 1784 (2008) (categorizing fraudulent patent enforcement as in the "sham" exception to *Noerr-Pennington* doctrine).
[200] *FilmTec Corp. v. Hydranautics*, 67 F.3d 931, 939 n.2 (Fed. Cir. 1995), *cert. denied*, 519 U.S. 814 (1996); *Carroll Touch, Inc. v. Electro Mech. Sys., Inc.*, 15 F.3d 1573, 1583 n.10 (Fed. Cir. 1993).
[201] *Pro. Real Estate Investors, Inc. v. Columbia Pictures Indus, Inc.*, 508 U.S. 49 (1993).
[202] 15 U.S.C. § 15(b); *Acad. of Allergy & Asthma in Primary Care v. Quest Diagnostics, Inc.*, 998 F.3d 190, 196 (5th Cir. 2021).

commits an act that injures a plaintiff's business."[203] Note, however, that a claim may accrue without a plaintiff's knowledge, and the four-year window to file a claim could pass. For example, an antitrust plaintiff that was previously sued in an enforcement action may not have been aware that the previous action sought to enforce a fraudulently obtained patent. Or, in the case of direct purchasers, an antitrust plaintiff may not have known that the defendant even brought an enforcement action.

Luckily for antitrust plaintiffs, courts have developed various procedures to protect their claims. The discovery rule, for example, tolls the statute of limitations until the *Walker Process* plaintiff's "discovery of the alleged fraud in [defendant's] procurement of the patent-in-suit, or until such time as [the *Walker Process* plaintiff] should have discovered the fraud in the exercise of due diligence."[204] But *Korody-Colyer Corp. v. General Motors Corp.* presents an important limitation of the timing of the discovery of the fraud.[205] There, the court stayed proceedings pending the completion of a patent validity issue, but—critically—it did not preclude plaintiff from amending its complaint to include a *Walker Process* claim.[206] Therefore, plaintiff's claim was not tolled.[207] If a *Walker Process* claim is timed-barred under the discovery rule, that claim may nonetheless be live if the defendant acted to prevent the plaintiff from suing on time.[208] This is known as the equitable doctrine of fraudulent concealment. Also, courts construe each enforcement action for a fraudulently obtained patent as a new injury, so even if a claim regarding one such action is time-barred, a plaintiff may still bring a *Walker Process* claim for subsequent enforcement actions brought within the last four years.[209]

Two District Court of the District of Columbia cases illustrate how the doctrine of fraudulent concealment plays out in practice. In one case, the D.C. Circuit held that the fraudulent concealment doctrine did not apply because the defendant showed that the plaintiff was aware of sufficient facts to identify a specific, relevant cause of action.[210] In that particular case, the plaintiff had received notice of its claims by reading a published court opinion in a related case.[211] The plaintiff's argument that the decision was appealed was insufficient to persuade the Court that the plaintiff did not have appropriate notice of its potential causes of action.[212] In another D.C. Circuit case, the Court came out the other way.[213] In that case, the defendants argued that public "market trends, such as price increases and output reductions" should have put plaintiffs on notice of a price-fixing scheme.[214] The Court rejected the defendants' argument, finding that the fraudulent

[203] *Zenith Radio Corp. v. Hazeltine Research Inc.*, 401 U.S. 321, 338 (1971).
[204] *Kistler Instrumente, A.G. v. PCB Piezotronics, Inc.*, No. CIV-76-113, 1983 WL 1838, at *10 (W.D.N.Y. May 6, 1983) (citing *Holmberg v. Ambrecht*, 327 U. S. 392, 397 (1946)).
[205] 828 F.2d 1572, 1575 (Fed. Cir. 1987).
[206] *Id.*
[207] *Id.* at 1574–1575 (holding that a decision to stay proceedings pending completion of patent validity issue did not toll a potential Walker Process claim).
[208] *In re Copper Antitrust Litig.*, 436 F.3d 782, 790–91 (7th Cir. 2006).
[209] *Kistler Instrumente, A.G.*, No. CIV-76-113, 1983 WL 1838, at *10 (W.D.N.Y May 6, 1983).
[210] *Molecular Diagnostic Lab'ys v .Hoffmann-La Roche Inc.*, 402 F. Supp. 2d 276, 283–84 (D.D.C 2005).
[211] *Id.* at 284.
[212] *Id.*
[213] *In re Vitamins Antitrust Litig.*, No. MISC 99-197, 2000 WL 1475705 (D.D.C., May 9, 2000)
[214] *Id.* at *5.

concealment doctrine requires notice similar to actual notice, rather than the "kind of notice . . . based on hints, suspicions, hunches or rumors . . . ."[215]

iv. Walker Process Criminal Prosecutions

Technically, the Department of Justice can use *Walker Process* claims to criminally prosecute certain antitrust violations. Recall that the second prong of a *Walker Process* claims requires a violation of Section 2 of the Sherman Antitrust Act, which states that violators "shall be deemed guilty of a felony."[216] The DOJ has never brought such a case, but it has prosecuted fraud on the patent office under Section 1.[217] In that case, the DOJ alleged a conspiracy to enforce a patent which the patent holder knew to be invalid.[218]

[215] *Id.* (quoting *Hobson v. Wilson*, 737 F.2d 1, 35 (D.C. Cir. 1984)).
[216] 15 U.S.C. § 2.
[217] *United States v. Union Camp Corp. et al.*, Crim. Act. No. 4558 (E.D. Va. Nov. 30, 1967) (charging indictment fraud on the court in maintaining a patent infringement suit on a patent known to be invalid).
[218] *Id.*

Patents and Antitrust in the Pharmaceuticals Space

I. Settlements, Reverse Payment Agreements, and Potential Antitrust Violations

A. Background

i. Overview of the Hatch-Waxman Act

The Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act" or "Act") amended the Federal Food, Drug and Cosmetic Act ("FDCA") and the Patent Act to establish an expedited regulatory framework, enabling approval of generic drugs as equivalent products to existing brand-name drugs.[219] The Act also provided additional protection to inventors of new drugs, extending patent terms and providing periods of exclusivity.[220]

Prior to the Hatch-Waxman Act, a generic drug manufacturer was required to file its own New Drug Application ("NDA") with the Federal Drug Administration ("FDA") to gain market approval.[221] Although some could rely on published scientific literature to demonstrate safety and efficacy of the drug, published studies were not always available for all drugs.[222] Further, the FDA would sometimes request additional testing to address safety and efficacy, even following the drug's initial approval.[223] Because generic drug manufacturers were obligated to conduct the same safety and efficacy tests as brand-name drugs, it created steep financial barriers to the development of generic drugs.[224] Under the Hatch-Waxman Act, generic drug manufacturers can file an Abbreviated New Drug Application ("ANDA") gaining expedited approval if the active ingredient of the generic drug is the bioequivalent of the already approved brand-name drug.[225]

The Hatch-Waxman Act requires every approved drug product, both brand-name and generic, to be listed in a publication commonly known as the "Orange Book."[226] In accordance with the Orange Book Transparency Act, holders of an approved application must list any patents that a generic drug would infringe if marketed before the patents' expiration.[227] These "Orange Book Listings" give generic manufacturers notice of patents that application holders believe would be infringed by a generic drug—if that drug were marketed before the patents' expiration date.[228] Following Orange Book Listing, the FDA may not approve a generic product until after expiration

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[219] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355; 35 U.S.C. § 271(e)(1)); *see also* Garth Boehm et al., *Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298-299 (2013) (discussing key events of the US generic drug industry after the Hatch-Waxman Act of 1984).
[220] *See* C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 947 (2011).
[221] *See* CONG. RSCH. SERV., R44643, The Hatch-Waxman Act: A Primer 3 (2016).
[222] *See id.*
[223] *See id.*
[224] *See* Gary M. Owens, Seizing the Opportunity, 1 AM. HEALTH DRUG BENEFITS 52 (2008).
[225] *See* CONG. RSCH. SERV., *supra* note 221, at 6.
[226] Hemphill & Lemley, *supra* note 220, at 951–952.
[227] *See* Orange Book Transparency Act of 2020, Pub. L. No. 116-290 (codified as amended 21 U.S.C. § 355 (b)); *see also* CONG. RSCH. SERV., *supra* note 221, at 6–7.
[228] *See* CONG. RSCH. SERV., *supra* note 221, at 6–7.

of the listed Orange Book patents unless the generic manufacturer has a license to those patents.[229] Accordingly, an ANDA applicant must provide its reasoning that the listed Orange Book patents are not infringed.[230] An ANDA applicant may either: file a "section viii statement," or a "patent certification," to satisfy this requirement.[231] A section vii statement states that the generic drug application is only for a method-of-use not covered by the Orange Book listed patents.[232] A patent certification certifies: 1) that the brand-name manufacturer has not filed patent information; 2) that the patent already expired; 3) the date the patent will expire; or 4) that the patent is invalid or will not be infringed by the manufacture, use, or sale of the ANDA applicant's product.[233]

Filing a "Paragraph IV" certification constitutes an act of patent infringement.[234] As a result, the brand-name manufacturer/patent holder may file an infringement suit, which creates an automatic statutory stay for up to 30 months of the ANDA approval, a timeline unique to ANDA-based patent litigation.[235] If the brand-name manufacturer is successful in its litigation, it may prevent the marketing of that generic equivalent until the date the patent expires.[236] If not successful, the generic drug manufacturer may receive approval from the FDA to market its version of the drug.[237]

ii. Potential Settlement Structures in the Pharmaceutical Industry

A reverse payment agreement ("RP"), also known as a reverse payment settlement, is a unique type of settlement between a brand-name drug manufacturer and a competing generic manufacturer to resolve patent litigation disputes under the Hatch-Waxman Act.[238] As a result of the expedited "30-month stay," litigants often settle in lieu of pursuing a final court determination.[239] While settlement is normally a preferred form of dispute resolution due to its cost savings and outcome certainty, RPs have drawn significant antitrust scrutiny.[240] Under an RP, the brand-name manufacturer agrees to pay the generic manufacturer to avoid seeking patent invalidation of its patented brand-name drug and to delay manufacturing a generic version until the patent expires.[241] In this way, a brand-name manufacturer is able to maintain its drug monopoly in the market until the expiration of its patent, thereby maintaining a longer monopoly than if the generic manufacturer would have successfully entered the market.[242]

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[229] *See* Kristen O'Shaughnessy et al., *A Decade of FTC v. Actavis: The Reverse Payment Framework Is Older, But Are Courts Wiser In Applying It?*, 86 ANTITRUST L.J. 473, 476 (2024).
[230] *See* CONG. RSCH. SERV., *supra* note 221, at 6–7.
[231] *Id.*
[232] *Id.*
[233] *Id.*
[234] *See* 35 U.S.C. § 271(e)(2)(A); *see also Eli Lily & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) (describing the function of 35 U.S.C. § 271(e)(2) as "defin[ing] a new (and somewhat artificial) act of infringement.").
[235] *See* 21 U.S.C. § 355(j)(5)(B)(iii).
[236] *See* 35 U.S.C. § 271(e)(4); *see also* CONG. RSCH. SERV., *supra* note 221 at 7.
[237] *Id.*
[238] *See* Zarema Jaramillo et al., *Status of reverse payment cases against pharmaceutical companies*, GLOB. COMPETITION REV. (July 28, 2023), https://globalcompetitionreview.com/review/the-antitrust-review-of-the-americas/2024/article/status-of-reverse-payment-cases-against-pharmaceutical-companies; *see also F.T.C. v. Actavis*, 570 U.S. 136, 140 (2013).
[239] *Id.*
[240] *See id.*
[241] *See Actavis*, 570 U.S. at 140.
[242] *See id.*

Reverse payment cases have evolved over time to include not only simple cash payments, but also No Authorized Generic Agreements, or "No-AG Agreements."[243] Under a No-AG Agreement, there is no monetary compensation for the generic manufacturer.[244] Instead, the brand-name manufacturer agrees to not produce its own generic version of a patent drug, and the generic manufacturer agrees not to advertise its generic.[245] Therefore, the brand-name manufacturer is able to preserve a greater percentage of its market share due to the generic manufacturer's lack of marketing, and the generic manufacturer's drug is not forced to compete with an authorized generic produced by the brand-name manufacturer. Plaintiffs have argued that this form of agreement constitutes a reverse payment, allowing a generic manufacturer to obtain greater revenues from its generic sales than it would if the brand-name manufacturer was marketing its own authorized generic ("AG").[246]

B. F.T.C. v. Actavis, Inc.

In the early 2000s, circuit courts were divided on the legality of reverse payment settlements.[247] The Supreme Court resolved the question in *F.T.C. v. Actavis*, where the Supreme Court held that, under the right conditions, RPs can violate antitrust laws and were subject to the "rule of reason" standard, as in any other antitrust challenge.[248]

Actavis involved a Federal Trade Commission ("FTC") challenge to an RP alleging that the agreement violated antitrust laws.[249] Actavis sought to manufacture a generic version of AndroGel, a patented drug produced by Solvay Pharmaceuticals.[250] Solvay then sued Actavis for patent infringement.[251] Actavis countersued and alleged that the patents covering AndroGel were invalid.[252] The parties settled and agreed to an RP. The RP specified that Actavis would not bring its generic to market until 65 months after the expiration of Solvay's patent.[253] Furthermore, Actavis agreed to promote AndroGel to urologists. In consideration, Solvay agreed to pay Actavis an estimated $19–30 million annually, for nine years.[254] The companies justified these payments as compensation for other services the generics promised to perform.[255]

The FTC filed a lawsuit against all settling parties alleging violations of antitrust law because the parties unlawfully agreed to share Solvay's monopoly profits, abandon their patent challenges, and

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[243] *See King Drug Co Florence, Inc. v. Smithkline Beecham Corp.*, 791 F.3d 388, 393 (3d Cir. 2015); *see also* O'Shaughnessy et al., *supra* note 229, at 484.
[244] *See Smithkline*, 791 F.3d at 393.
[245] *See id.*
[246] *See Impax Laboratories, Inc. v. F.T.C.*, 994 F.3d 484, 487 (5th Cir. 2021).
[247] *See* O'Shaughnessy et al., *supra* note 229, at 477.
[248] *Actavis*, 570 U.S. at 145.
[249] *Id*. at 141.
[250] *Id.* at 144–145.
[251] *Id.* at 145.
[252] *Id.*
[253] *Id*. The agreement permitted Actavis to enter the market earlier only if another generic manufacturer sought to enter the market; if that were the case, Actavis was permitted to enter the market at the same time as the other generic manufacturer.
[254] *Id.*
[255] *Id.*

refrain from launching low-cost generic products that would compete with AndroGel.[256] The Eleventh Circuit affirmed the district court's ruling that the FTC's allegations did not set forth an antitrust law violation.[257] The court stated that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the exclusionary potential of the patent."[258]

However, the Supreme Court rejected this position, holding that RPs may potentially violate antitrust law, particularly if the payments are "large and unjustified."[259] The Court also rejected the FTC's position that reverse payment settlement agreements are presumptively unlawful and that courts reviewing such agreements should be subject to a "quick look" analysis rather than "rule of reason."[260] The Court held that the "rule of reason" analysis should apply due to the complexities of the potential anticompetitive effects of RPs. Specifically, the Court stated that the anticompetitive effects of an RP depend "upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification" and "the existence and degree of any anticompetitive consequence may also vary as among industries."[261]

Under the rule of reason framework, the plaintiff bears the initial burden of showing that the alleged restraint "has a substantial anticompetitive effect that harms consumers in the relevant market."[262] If the burden is met, the burden shifts to the defendant to show a "procompetitive rationale for the restraint."[263] If the defendant makes this showing, the plaintiff must then demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means.[264] While the Court stated that reverse payments may have significant anticompetitive effects if they are "large and unjustified," it specifically left "to the lower courts the structuring of the present rule-of-reason antitrust litigation."[265]

C. Post-Actavis

Prior to *Actavis*, application of antitrust law to Hatch-Waxman settlements was an open question.[266] Thus, the decision was viewed as a "victory for the FTC in its efforts to stop anticompetitive pay-for-delay agreements of the Hatch-Waxman Act."[267] The 2013 *Actavis*

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[256] *Id.* There were several other generic manufacturers besides Actavis itself that sought to introduce generics of AndroGel and agreed to similar deals with Solvay. The FTC sued all of them, so all of them were involved in *Actavis* as it reached the Supreme Court. For simplicity's sake, we focus our attention here exclusively on Actavis the manufacturer.
[257] *Id.*
[258] *Id.*
[259] *See id.* at 158.
[260] *Id.* at 158–59.
[261] *Id*.
[262] *O'Shaughnessy et al.*, *supra* note 229, at 491 (citing *Ohio v. Am. Express Co.*, 585 U.S. 529, 541 (2018)).
[263] *Id.*
[264] *Id.*
[265] *Actavis*, 570 U.S. at 158, 160.
[266] *See* David Shotlander et al., *10 Years after Actavis, the Cases that Follow Tell a Story*, JDSUPRA (Oct. 11, 2023), https://www.jdsupra.com/legalnews/10-years-after-actavis-the-cases-that-7008277/.
[267] Press release, Fed. Trade Comm'n, FTC: Recent Supreme Court Decision Puts Agency in Stronger Position to Protect Consumers From Anticompetitive Pay-for-Delay Drug Settlements (July 23, 2013),

decision, and the large potential damages associated with delayed generic versions of widely used brand-name drugs, gave plaintiffs increased incentive and opportunity to bring antitrust challenges to pharmaceutical patent litigation, though the number of RPs have decreased over the years.[268]

Following *Actavis*, more than 30 separate antitrust cases were filed or revived under that decision.[269] By 2016, three years after *Actavis*, there was both a decrease in the overall number of district court *Actavis* cases filed and a decline in the instances of potential RPs.[270] The FTC stated in its 2015 annual report that "the vast majority (at least approx. 86% and up to approx. 92%) of patent disputes filed in FY 2015 were resolved without compensation to the generic manufacturer and/or without restrictions on generic competition."[271] According to the FTC's 2021 annual report, 33 out of 199 reported final settlements (17%) in the 2021 fiscal year contained both explicit compensation from a brand-name manufacturer to a generic manufacturer and a restriction on the generic manufacturer's ability to market its product in competition with the branded product.[272] Litigation fees are the sole form of explicit compensation in all these agreements.[273] The payments range from $100,000 to $7 million, with an average payment of $3.082 million. One hundred fifty-two of the 199 final settlements (76%) restrict the generic manufacturer's ability to market its product but contain no explicit or possible compensation.[274]

i. What Constitutes a Large and Unjustified Payment?

The *Actavis* Court implied that a settlement value beneath a lower threshold—such as a sum lower than avoided litigation costs or fair value for services—would not be subject to antitrust scrutiny.[275] However, the Court provided no other bright-line guidance on when a payment becomes large and unjustified.[276] Instead, the *Actavis* Court listed several factors that should be considered when determining if a payment creates an antitrust violation, including: (1) the size of the payments, (2) the scale of the payments in relation to litigation costs, (3) the independence of

https://www.ftc.gov/news-events/news/press-releases/2013/07/ftc-recent-supreme-court-decision-puts-agency-stronger-position-protect-consumers-anticompetitive.

[268] *See O'Shaughnessy et al.*, *supra* note 229, at 478.

[269] *See O'Shaughnessy et al.*, *supra* note 229, at 479; *see also* Adam Acosta et al., *FTC v Actavis and pricing practices spearhead rise in US pharmaceutical antitrust cases*, GLOB. COMPETITION REV. (Aug. 12, 2024), https://globalcompetitionreview.com/review/the-antitrust-review-of-the-americas/2025/article/ftc-v-actavis-and-pricing-practices-spearhead-rise-in-us-pharmaceutical-antitrust-cases.

[270] *See O'Shaughnessy et al.*, *supra* note 229, at 478.

[271] FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF THE AGREEMENTS FILED IN FY 2015 at 3 (2015) [hereinafter FTC 2015 Report].

[272] FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: OVERVIEW OF THE AGREEMENTS FILED IN FY 2021 at 1 (2021) [hereinafter FTC 2021 Report].

[273] *Id.*

[274] *Id.* at 2.

[275] *See Actavis*, 570 U.S. at 156 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement.").

[276] *See id.*

the payment from other services for which they might be fair considerations, and (4) any other convincing justification for the payment, or lack thereof.[277]

Since *Actavis*, most of the reverse payment case law has developed in the First, Second, Third, and Ninth Circuits.[278] Citing *Actavis*, these circuits have provided different interpretations of "large and unjustified" payments. Courts have inferred anticompetitive effect—that payments were "large" under *Actavis*—in cases with a range of monetary settlements.[279] For example, *Actavis* itself contemplated payments to three generic manufacturers of $12 million, $60 million and an estimated $171–$270 million over a nine-year period.[280] The Third Circuit held that a no-AG agreement, valued by plaintiff's antitrust expert to be $233 million, was "large," comparing the payment value to those in *Actavis*.[281] The court engaged in minimal analysis, stating simply that $233 million is "an amount that would qualify as large in most any context."[282] The Third Circuit further held that under *Actavis*, plaintiffs must sufficiently allege that a reverse payment was "large" enough to permit a plausible inference that the brand-name manufacturer possessed enough power to bring about an unjustified anticompetitive harm through its patents and had serious doubts about the ability of those patents to lawfully prevent competition.[283] In doing so, the court rejected the district court's determination that plaintiffs must plead a "reliable" monetary estimate of the dropped claims so that they may be analyzed against the *Actavis* factors to determine whether the value of those claims is large once the subtraction of legal fees and other services provided by generics occurs.[284] The Fifth Circuit similarly acknowledged a jury finding that a $300–$690 million payment was large.[285]

Courts have also been divided on how to determine whether a payment is "unjustified" under *Actavis*. For example, the Second Circuit, in *Watson Laboratories, Inc.*, emphasized that to find a payment unjustified, plaintiffs "must plausibly allege that the payment is a pretext for nefarious anticompetitive motives rather than made pursuant to traditional settlement considerations."[286] The Second Circuit found that plaintiffs failed to plausibly allege that defendant's reverse payments were "unjustified" reverse payments, stating that there was no allegation that the payments reflected anything other than "'fair value' for goods and services obtained as a result of good faith business dealings."[287] In contrast, the Third Circuit held that "[to] plausibly allege an unjustified reverse payment, an antitrust plaintiff need only allege the absence of a 'convincing justification' for the payment."[288] The Third Circuit has found that a payment was unjustified when "it was not

[277] *See id.* at 158–159.
[278] *See O'Shaughnessy et al.*, *supra* note 229, at 449.
[279] *See, e.g.*, *In re Wellbutrin XL Antitrust Litigation Indirect Purchaser Class*, 868 F.3d 132, 162 (3d Cir. 2017).
[280] *Actavis*, 570 U.S. at 145.
[281] *Wellbutrin*, 868 F.3d at 162.
[282] *Id.*
[283] *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 255 (3d Cir. 2017).
[284] *Id.* at 254.
[285] *See Impax*, 994 F.3d at 487.
[286] *Watson Laboratories, Inc.*, 101 F.4th 223, 239 (2d Cir. 2024).
[287] *See id.* at 239–40.
[288] *Id.*

tied to the merits of the litigation," and the payment was not tied to the merits of the litigation because "its value did not depend on the outcome of the appeal."[289]

In 2021, the FTC brought its first post-*Actavis* suit alleging that a large and unjustified payment under an RP justified an antitrust violation.[290] The FTC charged Impax Laboratories, an opioid manufacturer, with antitrust violations for accepting payments worth more than $100 million to delay the entry of its generic drug for two years.[291] The FTC administrative hearing concluded that Impax had violated antitrust law under the principles illustrated in *Actavis*.[292] On petition by the Fifth Circuit, the court affirmed the FTC's decision and denied review.[293]

Impax involved an opioid drug sold by the brand-name manufacturer, Endo, in an extended release formulation named Opana.[294] Opana was the only known extended-release formulation of this opioid in the market at the time of its release.[295] In 2007, one year after Opana entered the market, Impax filed an application to market a generic extended-release drug of the same type of opioid.[296] The brand-name drug manufacturer then sued Impax, delaying FDA approval of the generic for 30 months, unless the litigation concluded earlier.[297]

When Impax's generic was unable to enter the market, the brand-named manufacturer prepared a new formulation of the drug that was crush-resistant and planned to remove the original formulation from the market.[298] As a result, pharmacists would be unable to automatically substitute Impax's generic under state law for the brand-name Opana, as they no longer were therapeutically equivalent.[299] The success of this product strategy depended on the new formulation of Opana reaching the market before Impax's generic.[300]

In furtherance of this strategy, the brand-name manufacturer entered settlement negotiations with Impax following the FDA's tentative approval of Impax's generic.[301] The settlement was for an RP with a No-AG agreement.[302] Impax agreed to delay its generic product until expiration of the brand-name patent, and the brand-name manufacturer agreed to not launch its own generic, and to pay Impax a credit if sales of the original formulation of Opana fell more than 50 percent before Impax's generic launch.[303] The credit provision resulted in the brand-name manufacturer paying Impax $102 million.[304] The FTC found that the settlement only saved the brand-name

[289] *Wellbutrin*, 868 F.3d at 162.
[290] *Impax*, 994 F.3d at 488.
[291] *Id*.
[292] *Id.*
[293] *Id.*
[294] *Id.* at 489.
[295] *Id.*
[296] *Id.*
[297] *Id.*
[298] *Id.* at 489–490.
[299] *Id.*
[300] *Id.* at 490.
[301] *Id.*
[302] *Id.*
[303] *Id.*
[304] *Id.* at 492.

manufacturer approximately $3 million in litigation expenses.[305] The FTC administrative hearing concluded that Impax had violated antitrust law under the principles illustrated in *Actavis*.[306]

The Fifth Circuit agreed with the Commission that the $102 million credit was large and unjustified in light of only $3 million in saved litigation expenses, and that a payment of this size was comparable to other cases in which courts had inferred anticompetitive effect.[307] Because generic competition was possible, and because the brand-name manufacturer was willing to pay a large amount relative to the saved litigation expenses, the court found an anticompetitive effect and thus an antitrust violation.[308]

ii. Plausibility Requirements of 12(b)(6) Motions to Dismiss and Payment Size/Justifiability

The ambiguity regarding what constitutes a sufficiently "large and unjustified" payment under *Actavis* extends to the pleading requirements. Calculating with precision whether a reverse payment is sufficiently large and unjustified to trigger antitrust scrutiny may require information solely in the possession of the defendant that is not discoverable until after surviving a motion to dismiss.[309] Additionally, precisely calculating the value of nonmonetary settlements such as No-AG agreements may be even more difficult. Accordingly, requiring plaintiffs to plausibly allege factual details regarding the exact terms and value of an RP would impose a substantial barrier to *Actavis* claims.

The Third Circuit addressed this question in *In re Lipitor*, overruling a district court decision that said plaintiffs must plead an estimate of the total monetary value of a No-AG agreement and a reliable foundation for that value to survive plausibility pleading.[310] The court held that such a heightened pleading standard would be contrary to the *Twombly* and *Iqbal* plausibility standard, as well as the *Actavis* decision, which "did not require [] advanced valuations."[311] Thus, it was sufficient for a plaintiff to allege that a No-AG agreement "provided the alleged infringer with 'many millions of dollars of additional revenue,'" "that the patentee otherwise had 'an incentive to launch its own authorized generic[,]'" and that the No-AG agreement "resultantly induced the alleged infringer to agree to delay the launch of its generic drug that would compete with the patentee's drug, which purportedly relied on an invalid patent."[312] The court also relied upon a First Circuit decision finding that allegations that "a patentee entered into a no-AG agreement with a generic manufacturer, providing the generic manufacturer with favorable promotion deals in exchange for the generic manufacturer's delaying entry into the patentee's market" were sufficient under *Actavis*.[313] Similarly, district courts have held that because a motion to dismiss requires the court to accept the allegations of the non-movant as true, pleadings which make specific allegations

[305] *Id.* at 494.
[306] *Id.* at 488.
[307] *Id.* at 494–95.
[308] *Id.* at 495.
[309] *See Aggrenox*, 94 F. Supp. 3d at 243–45.
[310] *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 254–57 (3d Cir. 2017).
[311] *Id.* at 254.
[312] *Id.* at 255 (citing *King Drug Co. of Florence*, 791 F.3d at 409–10).
[313] *Id.* at 257 (citing *In re Loestrin 24 Fe Antitrust Litigation*, 814 F.3d 538, 541, 552 (1st Cir. 2016)).

about the terms of a settlement and their relative value satisfy the plausibility requirement even if they do not assign dollar values with significant precision or methodological justification.[314]

iii. Can Noncash Settlements, such as No-AG Agreements, be Subject to an Antitrust Analysis under Actavis?

Noncash settlements, such as No-AG agreements, do not require a payment.[315] Therefore, the natural question is whether these settlements can be subject to antitrust liability under *Actavis* even though they arguably lack a large and unjustified payment. Several circuit courts have affirmatively held that antitrust scrutiny elucidated in *Actavis* applies to noncash settlements such as No-AG agreements.

The First Circuit addressed this in *In re Loestrin*, where the parties' settlement agreement included a No-AG agreement from the brand-name manufacturer and a nonexclusive, fully paid license to the generic manufacturer.[316] Furthermore, the brand-name manufacturer agreed to not grant any licenses to other generic manufacturers for at least 180 days after the generic manufacturer had entered the market.[317] The First Circuit found that nonmonetary RPs trigger liability under *Actavis* because if *Actavis* were construed narrowly, then drug manufacturers would have "carte blanch" to negotiate anticompetitive settlements so long as they do not involve cash payments.[318] The Third Circuit ruled similarly in *King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp*.[319] The court held that "because [the No-AG agreement] may represent an unusual, unexplained transfer of value from the patent holder to the alleged infringer that cannot be adequately justified—whether as compensation for litigation expenses or services, or otherwise—[the agreement] is subject to antitrust scrutiny under the rule of reason."[320] The Fifth Circuit similarly found antitrust liability for an RP and No-AG agreement in *Impax*.[321]

Furthermore, a district court in Massachusetts has also found *Actavis* antitrust liability in a nonmonetary settlement agreement that did not on its face prevent the brand-name manufacturer from launching an authorized generic but did allow the generic manufacturer to enter the market early while preserving the brand-name manufacturer's patent.[322] Theoretically, this is not a No-AG agreement, but the district court disagreed.[323] The district court reasoned "[this] Court has previously explained that . . . 'explicit reservation . . . does not on its own preclude the existence of an *implicit* No-AG agreement' . . . . A contract that purports to prohibit an unlawful agreement is insufficient to establish the lack of such an agreement[.]"[324] While the Supreme Court and other

[314] *See, e.g.*, *Aggrenox*, 94 F. Supp. 3d. at 244–45.
[315] *See King Drug Co. of Florence*, 791 F.3d at 393.
[316] *In re Loestrin*, 814 F.3d at 546.
[317] *Id.*
[318] *Id.* at 550; *accord King Drug Co. of Florence*, 791 F.3d at 394 ("We believe this no-AG agreement falls under *Activis*'s rule because it may represent an unusual, unexplained reverse transfer of considerable value from the patentee to the alleged infringer and may therefore give rise to the inference that it is a payment to eliminate the risk of competition.").
[319] 791 F.3d at 409.
[320] *Id.*
[321] *See Impax*, 994 F.3d at 494, 500.
[322] *In re Intuiniv Antitrust Litigation*, 496 F. Supp. 3d 639, 668–69 (D. Mass. 2020).
[323] *Id.* at 668.
[324] *Id.*

circuits have not addressed this issue, it appears that No-AG and other nonmonetary settlement agreements in the pharmaceutical space always trigger scrutiny under *Actavis*. Accordingly, parties in the pharmaceutical space are cautioned to carefully present pro-competitive benefits even when constructing nonmonetary agreements that do not forbid authorized generics, lest they face antitrust scrutiny.

As another example: the consumer class plaintiffs in the *In re EpiPen* multi-district litigation alleged the manufacturer of EpiPen entered a delay-for-delay scheme with a potential generic manufacturer in which no money changed hands.[325] Specifically, the plaintiffs alleged that Mylan, which marketed the EpiPen, agreed to a deal whereby Teva agreed to delay the entry of its generic EpiPen in exchange for Mylan agreeing to delay entry of its generic competitor to one of Teva's branded drugs, Nuvigil.[326] Mylan argued on summary judgment that there could not be a "large and unjustified payment" where there was no payment at all, but the district court rejected that argument.[327] Instead, it allowed plaintiffs' claims to proceed and concluded that an agreement by Mylan to delay the entry of its competitor to Nuvigil was effectively a payment to Teva, as it allowed Teva to continue earning monopoly profits on Nuvigil for a longer period than it would have if Mylan had entered that market.[328]

iv. Questions of Causation and the But-For World

Reverse payment allegations are in some sense unique among antitrust issues in that they arise from a situation where consumers have already benefitted. That is because a reverse payment agreement is a settlement of actual, or at least threatened, patent litigation by the brand against the generic.[329] If the brand were to win that patent litigation—that is, if the brand's patent were valid and the generic's product infringed the patent—then the generic would not be able to enter the market until patent expiry.[330] The RP takes that possibility off the table; instead of the generic potentially having to wait until patent expiry to enter, it can enter at some agreed-upon date prior to patent expiry.[331] And consumers benefit by having the generic enter earlier than it would have if the brand won the patent litigation.[332] This reasoning formed the basis for Chief Justice Roberts's dissent in *Actavis*.[333]

To avoid that straightforward reasoning, plaintiffs in RP cases try to construct what is usually called a "but-for" world—a world without the RP—where the central contention is that, in a world

[325] *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices, & Antitrust Litig.*, 545 F. Supp. 3d 922 (D. Kan. 2021).
[326] *Id.* at 952–54, 980–81.
[327] *Id.* at 994, 999.
[328] *Id.*
[329] *Actavis*, 570 U.S. at 140.
[330] *See id.* at 169 (Roberts. J., dissenting).
[331] *Id.* at 140–41.
[332] *Id.* at 161, 168-9 ("The point of antitrust law is to encourage competitive markets to promote consumer welfare. . . . the patent holder plaintiff is a defendant against an invalidity counterclaim[]. . . . While the alleged infringer may not be suing for the patent holder's money, it is suing for the right to use and market the (intellectual) property, which is worth money.") (Roberts, J., dissenting).
[333] *See id.* at 161 (Roberts, J., dissenting) ("The point of antitrust law is to encourage competitive markets to promote consumer welfare."); *id*. at 174-75 (discussing "consumer interests" promoted by patent and antitrust law).

without the RP, the generic would have entered earlier and benefitted consumers earlier.[334] Defendants then try to attack the various hypotheses that underlie the but-for world, with the basic thrust of the arguments being that there was no causation: If the generic product could not enter the market before the agreed entry date in the RP under any circumstance, then the RP cannot have caused a consumer any injury.[335]

How do defendants attack the plaintiffs' construction of the but-for world? Generally, there are competing expert reports on these issues. The plaintiffs' experts will generally try to show the following:[336]

- The branded manufacturer's patents or the infringement case were relatively weak, so that if the generic had continued the patent litigation that was settled through the reverse payment agreement, it would have won, or that the resolution of the litigation without a reverse payment agreement would have otherwise resulted in a sooner entry of the generic drug into the market.[337]

- The generic manufacturer would have been able to enter the market before the agreed entry date in the reverse payment agreement—i.e., it would have been able to manufacture the drug, secured the necessary FDA approvals, gotten the necessary access to channels of distribution, etc.[338]

- The benefit to consumers of that earlier access would not have been offset by higher prices on the generic (which could have been necessary to fund continued patent litigation, accelerate the timetable for getting the generic approved, etc.).[339]

Defense experts, unsurprisingly, will try to show the opposite: the patents were strong such that continued litigation would have resulted in a win for the branded manufacturer; the generic would not have been ready to enter prior to the agreed entry date; and consumers would have ended up paying more for the generic if it had come onto the market earlier.[340]

The above defenses are usually available only after-the-fact; it is difficult, as an example, for a branded manufacturer to know ahead of making a RP whether the generic will actually be able to enter on the agreed-upon date. But they can be potent tools in a defendant's toolbox if it finds itself facing an antitrust lawsuit over a reverse payment agreement.

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[334] *In re EpiPen*, 545 F. Supp. 3d at 983 ("An antitrust plaintiff must show that a defendant's anticompetitive act was a 'material' and 'but-for' cause of plaintiff's injury, although not necessarily the sole cause.") (quoting *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 97 (2d Cir. 2017)).
[335] As an illustrative example, this line of argument was made by the defendants in *In re EpiPen*, where the defendants argued that the RP in question did not delay the generic drug's entry into the market. *See id.* at 981 ("Defendants say that the undisputed summary judgment facts establish that: (1) the EpiPen settlement never caused any delay in Teva's generic entry . . . .").
[336] Regarding these common expert-arguments, the arguments advanced by the parties' experts in *In re EpiPen* provide useful examples.
[337] *Id.* at 984–5, 992–3.
[338] *Id.* at 992–3.
[339] *Id.* at 1000–2.
[340] *Id.* at 983–4, 991–2.

II. Product Hopping and Antitrust Liability

A. Background

"Product hopping" is the practice of transitioning from a brand-name drug with a soon-to-expire patent to a new reformulation of that same drug that was recently patented and therefore has longer patent protection.[341] Product hopping can be conducted as a "hard switch" wherein the original, soon-to-be unprotected formulation is pulled from the market simultaneously with the entry of the new formulation into the market.[342] Conversely, a "soft switch" keeps the original product in the market when a brand simultaneously enters a new product into the market.[343] Because the removal of the original formulation from the market can prevent the FDA from certifying a generic version of the original formulation, a properly timed product hop can delay or entirely prevent the entry of generic versions of the original formulation into the market.[344] Courts have taken different opinions on whether product hopping is anticompetitive in nature, resulting in different considerations for pharmaceutical companies in different jurisdictions.

B. Circuit Split on Product Hopping as an Antitrust Issue

The Second Circuit was the first circuit court to consider the question of when product hopping triggers antitrust liability. In *New York ex. rel. Schneiderman v. Actavis* ("*Namenda*"), the defendant, Actavis, manufactured a twice-daily drug named Namenda designed to treat Alzheimer's disease.[345] In 2015, as the patent covering the twice-daily drug was set to expire, the defendant introduced a new once-daily formulation with patent protection until 2029.[346] The defendant then withdrew nearly all of the original twice-daily formulation from the market, effectively preventing the entry of a generic twice-daily drug.[347] The State of New York then brought an antitrust action under the Sherman Act against the defendant.[348] Because the parties agreed that Actavis had a monopoly in the relevant market due to its patent, the Second Circuit held that the key consideration of the case was whether Actavis had sought to maintain its monopoly in violation of Section 2 of the Sherman Act.[349]

As the Second Circuit noted, courts generally are skeptical of classifying product redesigns as anticompetitive and in violation of antitrust law.[350] Product redesign becomes anticompetitive, however, when it coerces consumers and impedes competition.[351] Product withdrawal itself is "certainly" not anticompetitive, but when a product is withdrawn in addition to some other conduct, such as product redesign, the overall effect is seen by courts as anticompetitive and

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[341] Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, MICH. STATE L. REV. 631, 636 (2007).
[342] Michael A Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, NOTRE DAME L. REV. 167, 170 (2016).
[343] *Id.*
[344] *See* Devlin, *supra* note 341, at 636.
[345] 787 F.3d 638, 642 (2d Cir. 2015).
[346] *Id.*
[347] *Id.*
[348] *Id.* at 643.
[349] *Id.* at 652.
[350] *Id.* (citing *U.S. v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001); *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 544–45 (9th Cir. 1983)).
[351] *Id.*

coercive to consumers.[352] The Second Circuit noted that the *combination* of withdrawing a successful drug from the market *and* simultaneously introducing a reformulated version of that drug was a "hard switch" with the dual effect of impeding competition and coercing adoption of the new product, and so was in violation Section 2 of the Sherman Act.[353] Therefore, in the Second Circuit, "hard shift" product hopping that both coerces consumers and forecloses competition will be subject to antitrust liability at the preliminary injunction stage.[354] Pharmaceutical companies should consider other approaches to extend patent coverage on their products.

In 2021, the Fifth Circuit briefly addressed the question of whether a product hop alone can be anticompetitive. In *Impax Laboratories, Inc. v. FTC*, the primary issue was whether the RPA/No-Ag settlement violated antitrust law under *Actavis*, but a key consideration in the settlement was the brand-name manufacturer's product hop.[355] While the Fifth Circuit did not directly address the issue, it agreed in a footnote with the Second Circuit that a product hop alone can be anticompetitive and thus potentially trigger antitrust liability.[356]

The Supreme Court has not weighed in on the question of whether product hops are subject to antitrust liability,[357] so a circuit split persists. Following *Namenda*, the Third Circuit also considered the issue of product hopping with respect to antitrust liability.[358] In *Mylan Pharmaceuticals*, a generic drug manufacturer brought suit under the Sherman Act against a brand-name manufacturer that manufactured "Doryx," a branded oral antibiotic.[359] Notably, Doryx is an unpatented product.[360] After selling Doryx for several years, the brand-name manufacturer entered into an agreement with a competitor, planning to bring a new version of Doryx to market.[361] The brand-name manufacturer sought and received FDA approval for a reformulation of Doryx, Doryx tablets.[362] They also removed the original formulation from their website, destroyed some of their original formulation inventory, bought back original formulation stocks from customers, and informed "wholesalers, retailers, and doctors" that the original formulation had been replaced by Doryx tablets.[363] The plaintiff argued that these tactics constituted a "hard switch" and were anticompetitive in nature, thus violating the Sherman Act.[364]

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[352] *Id.* at 653–54.
[353] *Id.* at 648, 659.
[354] *But see In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litig.*, 325 F.R.D. 551, 557–58 (E.D. Pa. 2016) ("*Namenda* [] did not hold, as a matter of law, that in every pharmaceutical antitrust case, the automatic generic substitution system is the only cost-efficient means of generic competition . . . . In order to establish antitrust liability, the plaintiffs must prove antitrust injury . . . [which] must include consideration of whether Defendant's conduct severely restricted the market.") (internal citations omitted).
[355] *Impax*, 994 F.3d at 489–93.
[356] *Id.* at 490 n.1 (citing *Namenda*, 787 F.3d at 643, n.2, 652–59) ("Product hopping can itself be anticompetitive.").
[357] *Impax Lab'ys, Inc. v. Fed. Trade Comm'n*, 142 S. Ct. 712 (2021) (denying certiorari).
[358] *See generally Mylan Pharmas. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421 (3d Cir. 2016).
[359] *Id.* at 426.
[360] *Id.* at 429.
[361] *Id.*
[362] *Id.*
[363] *Id.*
[364] *See id.* ("Mylan refers to these steps as a 'hard switch' from capsules to tablets and claims that this was done in an effort to stifle generic competition.").

The Third Circuit ruled there was no antitrust violation.[365] The Court found that because there was no approaching "patent cliff," i.e., the end of patent protection, and because many other competitors had already entered the generic market for this type of drug, there was insufficient evidence that the defendants' conduct was anticompetitive.[366] However, the Court did not rule that just because a pharmaceutical product is unpatented it is *per se* protected from Sherman Act claims.[367] Certain insignificant design changes or reformulations, when combined with other coercive acts, could create antitrust liability even for unpatented drugs.[368] In such a case, courts may consider additional non-exhaustive factors, such as public interest in encouraging innovation in the industry, the obligation to protect consumers, and the obligation to ensure fair competition under antitrust law.[369] Accordingly, any Third Circuit determination of antitrust liability in the pharmaceutical space will turn on the unique facts and circumstances of the alleged anticompetitive conduct.[370]

III. "Patent Thickets" and Antitrust Liability

A. Background

A "patent thicket" occurs when a company blocks competitors from a market by holding a large number of overlapping patents, which generally cover a single lucrative product.[371] While patent laws "do not set a cap on the number of patents any one person can hold . . . pertaining to a single subject,"[372] some litigants and commentators argue patent thickets violate antitrust laws.[373] Because the company can assert the group of patents against any potential competitor and due to the cost of litigating and invalidating a single patent, let alone many, the competitor is unable to enter the market and the original company may maintain a monopoly despite the questionable validity of its patents.[374]

B. Skepticism by the Circuit Courts

The Seventh Circuit was the first circuit court to consider the issue of whether patent thickets violate antitrust law. AbbVie manufactured a highly profitable drug, Humira.[375] While the primary patent covering Humira expired in 2016, AbbVie obtained 132 additional patents related to Humira's manufacture and administration.[376] These additional patents did not expire until 2034.[377] A group of welfare-benefit plans that pay for Humira on behalf of their beneficiaries sued AbbVie,

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[365] *Id.* at 441.
[366] *Id.* at 440–41.
[367] *See id.* at 440.
[368] *Id.*
[369] *Id.*
[370] *Id.* at 441.
[371] *See generally Mayor and City Council of Baltimore v. AbbVie Inc.*, 42 F.4th 709, 711–12 (7th Cir. 2022).
[372] *Id.* at 712 (citation omitted).
[373] *See*, *e.g.*, *id.* at 711; Daniel L. Rubinfeld & Robert Maness, *The Strategic Use of Patents: Implications for Antitrust*, *in* ANTITRUST, PATENTS & COPYRIGHT (2005).
[374] *See generally Abbvie*, 42 F.4th at 712–13.
[375] *Id.* at 711.
[376] *Id.*
[377] *Id.*

alleging that these additional patents violated Section 2 of the Sherman Act because the patent thicket "scared off" any potential competitors from market entry.[378]

The district court dismissed the suit.[379] To bring a Sherman Act § 2 claim, plaintiffs needed to show that AbbVie's patent petitions were "objectively baseless" and thus not immunized by the *Noerr–Pennington* doctrine.[380] The district court held that AbbVie's 53.4% patent application success rate "compel[led] the conclusion, as a matter of law, that more than half of AbbVie's patent applications were not objectively baseless."[381] Even if the complaint "describes a kernel of objectively baseless petitioning," the district court found that such conduct was inseparable from the immunized conduct, as well as insufficient standing alone to show that AbbVie "intimidated [others] into delaying the launch of their biosimilars (or otherwise caused any antitrust injury.)"[382]

The Seventh Circuit affirmed and largely adopted the district court's reasoning.[383] It noted that AbbVie's 53.4% success rate was "stellar," "mak[ing] it hard to see how AbbVie can be penalized for successful [i.e., not objectively baseless] petitions to the Patent Office."[384] The payors also failed to show how unsuccessful applications imposed costs on rivals and subsequently stifled competition: "Patent applications, successful or not, do not impose costs on rivals; only issued patents do so."[385] Finally, the payors failed to show that any of the properly issued patents were used in an improper way, such as in entirely frivolous litigation against would-be entrants.[386] While the Seventh Circuit did not find AbbVie's patent thicket anticompetitive, it left open the possibility that a patent thicket could be anticompetitive if the patent applications were baseless.[387]

The Ninth Circuit addressed much the same question in *Intel Corp. v. Fortress Investment Group LLC*.[388] In *Intel Corp.*, Intel alleged that Fortress aggregated weak patents of questionable validity and enforceability and then sought to extract large settlements through meritless but difficult-to-defend infringement suits.[389] The Ninth Circuit declined to decide whether such aggregation of weak patents into a patent thicket violates antitrust law and instead dismissed Intel's suit for failure to plead sufficient facts to state its claims.[390] Specifically, to state a claim under Section 1 of the Sherman Act, Intel needed to plausibly allege that Fortress had placed a restraint on trade that will lead to "substantial anticompetitive effect[s]."[391] To bring a Clayton Act § 7 claim, Intel needed

[378] *Id.* at 711–12.
[379] *Id.* at 711.
[380] *In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811, 827 (N.D. Ill. 2020) (citing *Pro. Real Est. Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 51 (1993)).
[381] *Id.* at 830.
[382] *Id.* at 832, 835.
[383] *Abbvie*, 42 F.4th at 716.
[384] *Id.* at 713.
[385] *Id.* at 713–14.
[386] *See id.* at 714.
[387] *Id*. at 713.
[388] *See generally* No. 21–16817, 2022 WL 16756365 (9th Cir. Nov. 8, 2022).
[389] *Id.* at *1.
[390] *Id.*
[391] *Id.* at *2.

to plausibly allege an appreciable danger or a reasonable probability of anticompetitive effects in the relevant markets.[392]

Intel's allegations focused on how the alleged patent aggregation led to increased prices.[393] But Intel did not point to any instance where it paid higher royalties after Fortress's patent aggregation and failed to plead that any price increases were the result of said aggregation.[394] Additionally, Fortress provided obvious alternative explanations for the alleged price increases.[395] Finally, Intel failed to plead that Fortress's conduct restricted output in any relevant patent market.[396] Because Intel failed to plead sufficient facts to support its claim, the Ninth Circuit dismissed the case.[397]

In sum, while some parties have continued to bring claims under a patent thicket theory, no court has found antitrust liability under this theory. Following the rulings in *Abbvie* and *Intel Corp.*, it seems unlikely that the patent thicket theory will be a viable vehicle for antitrust claims.

[392] *Id.*
[393] *Id.*
[394] *Id.*
[395] *Id.*
[396] *Id.* at *3.
[397] *Id.*

Standard Essential Patents

Standard Essential Patents ("SEPs") are patents that claim technology that is necessary to implement a technical standard.[398] This requires any standard-compliant manufacturer to either negotiate a license from the patent holder or infringe the patent.[399] Because of this significant market power, SEP holders could potentially extract a larger royalty than the licensee would have otherwise been willing to pay.[400] SEPs are common in industries where technical compatibility is critical, like wireless voice and data communications, personal computers, or personal or local area networks.[401]

Voluntary, private organizations known as standards-setting organizations ("SSOs") are typically responsible for developing, maintaining, and promoting industry standards.[402] For example, an SSO may promulgate a standard protocol for wireless communication so that wireless signals transmitted by one standard-compliant device can be received and understood by other standard-compliant devices regardless of manufacturer.[403] There is no obligation aside from market pressure for a patent holder to join an SSO; however, this pressure can be substantial as interoperability between producers is critical for market success.[404]

To avoid the potential "hold-up" of an SEP holder extracting a larger royalty than they would have otherwise received, SSOs often require members to agree to license SEPs to prospective or current standard implementers on fair, reasonable, and non-discriminatory ("FRAND") terms.[405] Most SSOs similarly require each participant to timely disclose their patents or patent applications that are reasonably expected to read on the standard.[406] These agreements serve as a contractual limitation on the SSO participants.[407] It is important to note that FRAND terms are often open-ended and leave many details open to judicial interpretation, which causes disagreement as to when conduct violates FRAND terms.[408] The potential "hold-up" problem of SEPs and the resulting FRAND commitments have raised questions under antitrust law.[409] In particular, there is significant discussion regarding the role that antitrust law can and should play in enforcing FRAND commitments.[410]

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[398] *See* Erik Hovenkamp, *Tying, Exclusivity, and Standard-Essential Patents*, 19 COLUM. SCI. & TECH. L. REV. 79, 81 (2017).
[399] *Id*.
[400] *See* Thomas F. Cotter, Erik Hovenkamp, & Norman Siebrasse*, Demystifying Patent Holdup*, 76 WASH. & LEE L. REV. 1501, 1505 (2020).
[401] *See* Stanley Besen, *Looking for FRAND: Patent Owners, Standard-Setting Organizations, and the Courts*, 25 TUL. J. TECH. & INTELL. PROP. 213, 215 (2023).
[402] *Id*.
[403] The Sedona Conference, *Framework for Analysis of Standard-Essential Patent (SEP) and Fair, Reasonable, and Non-Discriminatory (FRAND) Licensing and Royalty Issues* (U.S. Edition), 24 SEDONA CONF. J. 605 (2023).
[404] Herbert J. Hovenkamp, *FRAND and Antitrust*, 105 CORNELL L. REV. 1683, 1688–89 (2020).
[405] E. Hovenkamp*, supra* note 398, at 81–82.
[406] H. Hovenkamp, *supra* note 404, at 1687.
[407] *Id.* at 1686.
[408] E. Hovenkamp, *supra* note 398, at 83.
[409] Joshua D. Wright, *SSOs, FRAND, and Antitrust: Lessons from the Economics of Incomplete Contracts*, 21 GEO. MASON L. REV. 791, 795 (2014).
[410] *Id*.

I. Policy Background

Administrations have differed in their stance as to whether public policy supports the use of injunctions to enforce SEP rights.[411] Because every new administration typically results in a policy shift, it is important for SEP holders to stay apprised of the current landscape.

In 2013, under the Obama Administration, the Department of Justice ("DOJ") and U.S. Patent and Trademark Office ("USPTO") issued a joint policy statement regarding the use of exclusion orders and injunctions in SEP cases.[412] The statement ultimately concluded that injunctive relief was generally inappropriate for FRAND-encumbered SEP infringement.[413] The agencies explained that the remedy of an injunction or exclusion order may be inconsistent with the public interest, particularly where FRAND-encumbered SEP holders could attempt "to use an exclusion order to pressure an implementer of a standard to accept more onerous licensing terms than the patent holder would be entitled to receive consistent with the F/RAND commitment."[414] However, the agencies also noted that "[a]n exclusion order may still be an appropriate remedy in some circumstances, such as where the putative licensee is unable or refuses to take a F/RAND license and is acting outside the scope of the patent holder's commitment to license on F/RAND terms."[415]

However, in 2019, under the Trump Administration, the DOJ, USPTO, and National Institute of Standards and Technology ("NIST") issued a statement withdrawing the 2013 Statement.[416] In the 2019 Statement, the agencies stated that "a patent owner's F/RAND commitment is a relevant factor in determining appropriate remedies, but need not act as a bar to any particular remedy."[417] Accordingly, "all remedies available under national law, including injunctive relief and adequate damages, should be available for infringement of standards-essential patents subject to a F/RAND commitment, if the facts of a given case warrant them."[418] The agencies clarified that "there are no special rules limiting the remedies available for the infringement of any standards-essential patents, whether subject to a F/RAND commitment or not."[419]

This statement was withdrawn in 2022 under the Biden Administration.[420] In doing so, the agencies were clear that they were not reinstating the 2013 statement.[421] The new statement did not contain much formal guidance, but stated that "[i]n exercising its law enforcement role, DOJ will review

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[411] Benjamin C. Elacqua et al., *The Outlook for SEPs in 2025: Anti-Suit Injunctions, DOJ Policy and GenAI*, IPWATCHDOG (March 25, 2025, 9:15 AM), https://ipwatchdog.com/2025/03/21/the-outlook-for-seps-in-2025-anti-suit-injunctions-doj-policy-and-genai/id=187157/.
[412] *See* U.S. Dep't of Justice & U.S. Patent & Trademark Office, *Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments* (Jan. 8, 2013).
[413] *Id*. at 6.
[414] *Id*.
[415] *Id*. at 7.
[416] See U.S. Dep't of Justice, *U.S. Patent & Trademark Office & Nat'l Inst. of Standards & Tech., Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments* (Dec. 19, 2019).
[417] *Id*. at 4.
[418] *Id*. at 4–5.
[419] *Id*. at 4 n.10.
[420] *See* U.S. Dep't of Justice, U.S. Patent & Trademark Office & Nat'l Inst. of Standards & Tech., *Withdrawal of 2019 Policy Statement on Remedies for Standards-Essential Patents Subject to Voluntary F/RAND Commitments* (June 8, 2022).
[421] *Id*. at 1 n.1.

conduct by SEP holders or standards implementers on a case-by-case basis to determine if either party is engaging in practices that result in anticompetitive use of market power or other abusive processes that harm competition."[422]

II. FRAND and Antitrust

Litigation surrounding SEPs and FRAND commitments often focuses on the size of the royalty and how it should be measured; however, there are also issues surrounding SEP holders attempting to evade FRAND requirements, SEP holders refusing to license a particular patent to competitors or to anyone, SEP holders imposing exclusive dealing or loyalty requirements on licensees, and SEP holders tying a FRAND-encumbered patent to an unregulated device (allowing the patent licensee to overcharge for the product which is not subject to FRAND obligations).[423]

While some of these practices are subject to the SEP holder's contractual obligations and could be dealt with under contract law,[424] a subset is also subject to scrutiny under antitrust law.[425]

A. Refusals to Deal

A refusal to deal occurs when a business declines to engage in commercial transactions with another party, like competitors, customers, or suppliers. This conduct can have significant implications under antitrust law. The Sherman Act "does not restrict the long recognized right of a trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal."[426] However, the general rule that there is no antitrust duty to deal does not apply where a company (1) unilaterally terminates a voluntary and profitable course of dealing, (2) the only conceivable rationale or purpose is to sacrifice short-term benefits in order to obtain higher profits in the long run from the exclusion of competition, and (3) the refusal to deal involves products that the defendant already sells in the existing market to other similarly situated customers.[427]

In the SEP context, a breach of a FRAND commitment (e.g., refusing to license rivals or conditioning access to SEPs on purchasing patentee's hardware) may support antitrust liability where market power and anticompetitive effects are shown.[428] This is analyzed under general antitrust principles, and there are no special requirements when a FRAND-encumbered patent, or even a patent, is involved.[429] While the fact that a FRAND-encumbered patent is involved does not determine antitrust liability, it is highly relevant to questions of market power.[430]

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[422] *Id*. at 2.
[423] H. Hovenkamp, *supra* note 404, at 1693–94.
[424] The application of contract principles to FRAND commitment violations are outside the scope of this Handbook, *but see Microsoft Corp. v. Motorola, Inc.*, 795 F.3d 1024, (9th Cir. 2015) (analyzing claims for contractual breach for failing to offer RAND licenses in good faith).
[425] H. Hovenkamp, *supra* note 404, at 1694.
[426] *F.T.C. v. Qualcomm Inc.*, 969 F.3d 974, 993 (9th Cir. 2020) (*quoting Verizon Commc'ns Inc. v. L. Offs. of Curtis v. Trinko, LLP*, 540 U.S. 398, 408 (2004)) (cleaned up).
[427] *Id*. at 993–94 (citing *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1987)).
[428] H. Hovenkamp, *supra* note 404, at 1697.
[429] *Id*. at 1700–01.
[430] *Id*. at 1705.

i. Federal Trade Commission v. Qualcomm, Inc. ("Qualcomm")

In 2020, the Ninth Circuit analyzed whether Qualcomm's SEP licensing policies constituted anticompetitive conduct under the Sherman Act.[431] The court ultimately held that the policies did not, reversing the district court's decision and vacating the injunction it had ordered.[432]

Qualcomm, a manufacturer of cellular modem chips, held several SEPs involving the technology underlying modern cellular systems practiced by most modern cellphones as well as other, non-cellular SEPs and non-SEPs.[433] But "[r]ather than license its patents individually, Qualcomm generally offer[ed] its customers various 'patent portfolio' options, whereby the customer/licensee pays for and receives the right to practice all three types of Qualcomm patents[.]"[434] In addition to its patent portfolio, from 2006 to 2016, Qualcomm constituted over 90% of the CDMA modem chip market. From 2011 to 2016, it had a market share over 70% in the premium LTE market. By the time of litigation, however, its share had decreased to 79% and 64%, respectively.[435] Nonetheless, Qualcomm occupied a unique market position: companies like Nokia, Ericsson, and Interdigital have comparable SEP portfolios but do not compete with Qualcomm in the modem chip market, while its main competitors in the chip markets "do not hold or have not held comparable SEP portfolios."[436]

The Federal Trade Commission ("FTC") alleged Qualcomm was excluding competitors and harming competition in violation of the Sherman Act. Specifically, the FTC identified three practices it alleged were unfair: 1) Qualcomm's practice of licensing patents only to original equipment manufacturers ("OEMs") and not to rival chipmakers, 2) its "no license, no chips" policy, which required OEMs to obtain a patent license before buying Qualcomm's chips, and 3) Qualcomm's agreements with Apple which included incentive payments for Apple to buy chips exclusively from Qualcomm.

ii. Qualcomm's Practices

1. OEM-Only Licensing

Qualcomm licensed its portfolios exclusively at the OEM level, setting royalty rates on its code division multiple access ("CDMA") and premium long-term evolution ("LTE") patent portfolios as a percentage of the end product's sale price.[437] As a result of that policy, it refused to license its cellular SEPs to rival modem chip suppliers.[438] Without a license to Qualcomm's SEPs, a rival could not sell modem chips without creating a risk that Qualcomm would pursue patent infringement claims against the rival and its customers. Qualcomm instead offered rival chip manufacturers "what it terms 'CDMA ASIC Agreements,' wherein Qualcomm promises not to

[431] *Qualcomm Inc.*, 969 F.3d at 974.
[432] *Id*. at 1005.
[433] *Id*. at 982.
[434] *Id.* at 983.
[435] *Id.* at 984.
[436] *Id.* at 983.
[437] *Id.* at 984.
[438] *Fed. Trade Comm'n v. Qualcomm Inc.*, 411 F. Supp. 3d 658, 744 (N.D. Cal. 2019), *rev'd and vacated*, 969 F.3d 974 (9th Cir. 2020).

assert its patents in exchange for the [rival] company promising not to sell its chips" to OEMs that had not already purchased licenses from Qualcomm.[439] Those agreements required rival chip manufacturers to inform Qualcomm about their supply agreements with various OEMs, but allowed Qualcomm's competitors to practice Qualcomm's SEPs "royalty-free."[440]

The FTC alleged that the policy had two primary effects. First, by subjecting rival chip makers to CDMA ASIC Agreements rather than allowing those rivals to take a license to the patents themselves, Qualcomm was allegedly able to "hamstr[i]ng" its rivals by restricting their customer bases to Qualcomm-approved OEMs and gather sensitive market information.[441] Second, the FTC alleged that Qualcomm's OEM-only licensing policy effectively worked around two elements of patent law doctrine—patent "exhaustion" and "SSPPU" apportionment—that would otherwise have led to lower royalty rates.[442]

The first of these two patent-specific benefits was that, by selling to OEMs, Qualcomm allegedly avoided the risk of patent exhaustion, thereby reinforcing its "no license, no chips" policy. The patent exhaustion doctrine reflects a general concern that "patent holders [may] us[e] . . . licenses to limit the use of their products and thereby us[e] the patents to secure market control of related, unpatented items." In *Morton Salt*, for example, the Supreme Court effectively barred patent owners from pursuing an infringement claim against certain licensees, holding that "a patentee who has granted a license on condition that the patented invention be used by the licensee only with unpatented materials furnished by the licensor, may not restrain as a contributory infringer one who sells to the licensee like materials for like use."[443] In 2008, the Supreme Court further developed the doctrine of patent exhaustion when it held that "the initial authorized [or licensed] sale of a patented item terminates all patent rights to that item."[444] Accordingly, the Court held that "[t]he authorized sale of an article that substantially embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking patent law to control postsale use of the article."[445]

Prior to the Supreme Court's 2008 ruling in *Quanta Computer*, Qualcomm had entered "into non-exhaustive, royalty bearing agreements" with rival chip manufacturers.[446] Following the Supreme Court's ruling, Qualcomm ceased licensing to rival chip manufacturers "in response to [such] developments" and began selling exclusively to OEMs.[447] In place of licenses, Qualcomm and its rivals entered CDMA ASIC agreements, which "functionally act[ed] as de facto licenses."[448] However, unlike a true license, the CDMA ASIC agreements would likely not have raised concerns of patent exhaustion when Qualcomm's rivals sold infringing, unlicensed chips to

[439] *Qualcomm*, 969 F.3d at 984.
[440] *Id.*
[441] Brief of Plaintiff-Appellee at 15, Federal Trade Commission v. Qualcomm, No. 19-16122 (9th Cir. Nov. 22, 2019).
[442] *Id*.
[443] *Morton Salt Co. v. G. S. Suppiger Co.*, 314 U.S. 488, 491 (1942), *abrogated in part on other grounds by Illinois Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006).
[444] *Quanta Comput., Inc. v. LG Elecs., Inc.*, 553 U.S. 617, 625 (2008).
[445] *Id.* at 638.
[446] *Qualcomm*, 969 F.3d at 994.
[447] *Id*.
[448] *Id.* at 996.

OEMs.[449] Thus, when paired with its "no license, no chips" policy, Qualcomm's policy of licensing exclusively to OEMs effectively ensured that *every* OEM would need to purchase licenses from Qualcomm, even if they bought chips from other manufacturers.[450]

The second patent-specific benefit was that Qualcomm allegedly captured greater than the smallest saleable patent-practicing unit ("SSPPU") value for its patents. In patent law, reasonable royalty damages for infringement are the "minimum amount of infringement damages 'adequate to compensate for the infringement.'"[451] In calculating this amount, "[t]he essential requirement is that the ultimate reasonable royalty award must be based on the incremental value that the patented invention adds to the end product."[452] This leads to a two-step analysis. First, if the end product is a multi-component system, "it is generally required that royalties be based not on the entire product, but instead on the 'smallest salable patent-practicing unit.'"[453] This requires apportioning the royalty "base" to include only the price of the SSPPU.[454] In the second step, the fact finder must proceed to "estimate what portion of the value of that [SSPPU] product is attributable to the patented technology" in order to reach a reasonable royalty rate.[455] Requiring the first step (limiting the royalty base to the value of the SSPPU) is an essentially *evidentiary* rule; mathematically, a fact finder could reach an adequate damages award by starting with the market value of the entire multi-component system and then using a "royalty rate that is low enough" to capture only the incremental value of the patented invention.[456] However, as a practical matter, "the disclosure that a company has made [substantial] revenue from an infringing product cannot help but skew the damages horizon for the jury, regardless of the contribution of the patent component to this revenue."[457]

By licensing to OEMs, Qualcomm anchored the negotiations against the price of an entire handset, rather than the (much lower) price of the patent-practicing modem chips. In the district court's view, this allowed Qualcomm to command higher royalties despite changes in the industry that meant "a handset's value is now attributable primarily to the 'user experience' and not 'modem leadership.'"[458]

2. *"No License, No Chips" Policy*

Qualcomm used a "unique in the industry" "no license, no chips" policy to "reinforce" its CDMA ASIC agreements and OEM-only licensing practices.[459] Under the policy, Qualcomm "refuse[d]

[449] *See id.* at 994.
[450] *Id.* at 985.
[451] *LaserDynamics, Inc. v. Quanta Computer, Inc.*, 694 F.3d 51, 66 (Fed. Cir. 2012) (quoting 35 U.S.C. § 284).
[452] E.g., *Ericsson, Inc. v. D-Link systems, Inc.*, 773 F.3d 1201, 1227 (Fed. Cir. 2014).
[453] *Laser Dynamics*, 694 F.3d at 67 (quoting *Cornell Univ. v. Hewlett–Packard Co.*, 609 F. Supp. 2d 279, 283, 287–88 (N.D.N.Y. 2009)).
[454] *Id*. at 66–70.
[455] *Sci. Applications Int'l Corp. v. United States*, 169 Fed. Cl. 346, 361 (2024) (quoting *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1327–28 (Fed. Cir. 2014)).
[456] *See Uniloc USA, Inc. v. Microsoft Corp.*, 632 F.3d 1292, 1319 (Fed. Cir. 2012) (summarizing appellant's argument).
[457] *Id*. at 1320 (Once jury learned of Microsoft's un-apportioned Office and Windows revenue, "[t]he $19 billion cat was never put back into the bag").
[458] *Qualcomm*, 411 F. Supp. 3d at 783.
[459] *Qualcomm*, 969 F.3d at 985, 1003.

to sell modem chips to OEMs that d[id] not take licenses to practice Qualcomm's SEPs."[460] Thus, in effect, "OEMs [were] required to pay a per-unit licensing royalty to Qualcomm for its patent portfolios regardless of which company they choose to source their chips from."[461] Without the policy, Qualcomm would not "obtain[] the maximum value for its patents," as, due to patent exhaustion, OEMs could argue that purchasing chips from Qualcomm extinguished its patent rights as to any SEPs those chips embodied.[462]

3. Apple Contracts

In 2011 and 2013, Qualcomm agreed to multiple contracts with Apple. Under those contracts, Qualcomm offered large incentives contingent upon Apple purchasing certain annual quantities of chips and upon Apple sourcing its iPhone modem chips solely from Qualcomm. Apple ultimately terminated these agreements in 2014, however, and began sourcing modem chips from a rival manufacturer.[463]

iii. The Ninth Circuit's Opinion

The district court found that 1) Qualcomm's refusal to license rival chipmakers violated both its FRAND commitments and an antitrust duty to deal under § 2 of the Sherman Act; 2) Qualcomm's "no license, no chips" policy was anticompetitive as to OEMs, but not independently illegal; 3) Qualcomm's deals with Apple violated both provisions of the Sherman Act; 4) Qualcomm's royalty rates were "unreasonably high" and untethered to the value of its patents; and 5) Qualcomm's royalties, in conjunction with its "no license, no chips" policy, imposed "an artificial surcharge" on rivals that increased the effective price of rival chips, "resulting in anticompetitive exclusivity."[464]

The Ninth Circuit reversed.[465] The court applied *Aspen Skiing Co.*, which established a limited exception to the general rule that there is no duty to deal under antitrust law, and found that "none of the required elements for the *Aspen Skiing* exception are present."[466]

Analyzing the first *Aspen Skiing* element, the court found Qualcomm did not terminate a voluntary and profitable course of dealing.[467] Qualcomm asserted that it had never granted exhaustive licenses to rival chip suppliers.[468] While it previously entered into non-exhaustive agreements with chipmakers, Qualcomm ceased this practice in response to developments in patent law's exhaustion doctrine.[469] The court stated that "no evidence" showed Qualcomm had ever provided exhaustive licenses to other chip manufacturers since "the time [it] first gained monopoly power

[460] *Id.* at 985.
[461] *Id.*
[462] *Id.*
[463] *Id.* at 986.
[464] *Id.* at 987 (citing *Qualcomm*, 411 F. Supp. 3d at 658, 697–98, 751–62, 766, 771–97).
[465] *Id.* at 988.
[466] *Id*. at 995.
[467] *Id*. at 994.
[468] *Id*.
[469] *Id*.

in the modem chip market in 2006[.]"[470] Under the second *Aspen Skiing* element, the court found that Qualcomm's rationale for only licensing to OEMs was not to sacrifice short-term benefits to obtain higher profits because OEM-level licensing was more profitable in both the short and long-term, despite the district court's concern about exclusion and rent-seeking behavior.[471] Finally, the court concluded that the third factor was not met because there was no evidence that Qualcomm singled out any specific chip supplier for anticompetitive treatment.[472] "Because Qualcomm applie[d] the latter policy neutrally with respect to *all* competing modem chip manufacturers, the third *Aspen Skiing* requirement does not apply."[473]

The FTC also argued that, notwithstanding the inapplicability of *Aspen Skiing*, Qualcomm had a duty to deal with its rival chipmakers because Qualcomm was contractually obligated via its SSO commitments to grant FRAND licenses to those competitors.[474] However, the Ninth Circuit declined to create an SEP-specific "additional exception[] beyond the *Aspen Skiing* exception."[475]

The FTC had argued that Qualcomm's OEM-only licensing policy impaired the opportunities of its rivals and did not further competition on the merits.[476] The Ninth Circuit determined that the facts did not support such a conclusion: Qualcomm's CDMA ASIC agreements functioned as a "de facto" and "royalty free" license available to *all* rivals.[477] Indeed, several of Qualcomm's competitors had actually entered the market during this timeframe.[478] Additionally, the Ninth Circuit credited the several "academics and practitioners with significant experience in SSOs, FRAND, and antitrust enforcement," who had "expressed caution about using the antitrust laws to remedy what are essentially contractual disputes between private parties engaged in the pursuit of technological innovation," declining to find breaches of SSO commitments constituted anticompetitive conduct in violation of § 2 of the Sherman Act.[479] The Ninth Circuit noted that an antitrust violation might arise where a SEP-holder "intentionally deceived" an SSO into standardizing its patented technology by agreeing to a FRAND obligation it knowingly intended to breach.[480] Those facts, however, were not present in the *Qualcomm* dispute.[481] In summary, the court determined that businesses, even those that own SEPs, "are free to choose the parties with whom they will deal," even if that choice resulted in a contractual breach.[482]

Separate from its duty-to-deal arguments, the FTC argued that the "anticompetitive surcharge" Qualcomm realized through its licensing policies was its own antitrust harm.[483] While the Ninth Circuit acknowledged that Qualcomm's conduct may have "raise[d] the all-in price that an OEM

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[470] *Id.*
[471] *Id*.
[472] *Id*.
[473] *Id*. at 995.
[474] *Id*. at 995–97.
[475] *Id*.
[476] *Id*. at 995.
[477] *Id*. at 996.
[478] *Id*. at 996.
[479] *Id.* at 997.
[480] *Id*. at 996 (discussing *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007)).
[481] *Id*. at 996-97.
[482] *Id*. at 997.
[483] *Id*. at 998-1001 (addressing effects of OEM-only licensing policy); *id.* at 1001-03 (addressing effects of "no license, no chips" policy).

must pay for modem chips (chipset + licensing royalties)," it determined that effect was "chip neutral" and occurred "regardless of which chip supplier the OEM chooses to source its chips from."[484] As such, any harm was borne by Qualcomm customers, not competitors.[485] Accordingly, it found antitrust offered no remedy, as "whether that all-in price is reasonable or unreasonable is an issue that sounds in patent law, not antitrust law."[486] The Ninth Circuit also specifically engaged with the FTC's argument that licensing to OEMs, rather than to chipmakers, necessarily distorted the market by including the entire end product in the negotiations, rather than just the SSPPU.[487] The Ninth Circuit reasoned that while apportionment to an SSPPU royalty base might be necessary in a jury trial, the rationale for requiring apportionment would be "absent" in a bench trial, let alone during the negotiations that occur when "[s]ophisticated parties . . . enter into license agreements."[488] The court refused to adopt what it considered a per se rule that "patent royalties *cannot* be based on total handset price and that doing so exposes a firm to potential antitrust liability."[489]

As to the Apple contracts, the court found that, over the relevant period, Qualcomm only faced "serious competition" for Apple's business from Intel.[490] However, the record did not show that Intel was a "viable" competitor prior to 2014—after Qualcomm and Apple had signed the agreements. Thus, the agreements could not have foreclosed competition in the CDMA modem chip market.[491]

iv. Competing Authorities

At bottom, the *Qualcomm* decision rejected the creation of any special antitrust liability for SEP holders. The *Qualcomm* decision is binding on courts in the Ninth Circuit. The Fifth Circuit has also affirmed the dismissal of similar refusal-to-deal antitrust claims brought against SEP holders.[492] However, no other circuit court has cited *Qualcomm* in an antitrust case against SEP holders.

And even if courts find no duty to deal under antitrust law, SSOs may approach the matter differently. The Telecommunications Industry Association, the Alliance for Telecommunications Industry Solutions, and the International Telecommunications Union each require FRAND licensing to all comers.[493] The European Telecommunications Standards Institute in contrast, does not explicitly require such conduct—though its policies are subject to debate.[494] As the *Qualcomm*

[484] *Id*. at 1002.
[485] *Id*.
[486] *Id.*
[487] *Id.* at 998-99.
[488] *Id*. at 999.
[489] *Id*.
[490] *Id.* at 1005.
[491] *Id.* at 1006.
[492] *Continental Automotive Sys., Inc. v. Avanci, L.L.C.*, 2022 WL 2205469, *1 (5th Cir., June 21, 2022). Notably, the Fifth Circuit issued, and then withdrew, a more fulsome opinion that explicitly cited to *Qualcomm* in a footnote. *Continently Automotive Sys., Inc. v. Avanci, L.L.C.*, 27 F.4th 326 (5th Cir., 2022) (rehearing granted, withdrawn by 36 F.4th 1185 (5th Cir. 2022)).
[493] *Qualcomm*, 969 F.3d at 986; *Microsoft Corp. v. Motorola, Inc.*, 696 F.3d 872, 884 (9th Cir. 2012).
[494] Bertram Huber, *Why the ETSI IPR Policy Does Not and Has Never Required Compulsory 'License to All': A Rebuttal to Karl Heinz Rosenbrock* at 2, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3038447 (Sep. 20,

court pointed out, if a company breaches its FRAND commitments, "the remedy for such a breach lies in contract and patent law."[495]

B. Failure to Disclose SEPs

In 2008, the D.C. Circuit Court addressed whether deceptively failing to disclose patent interests in technology being standardized to an SSO could constitute an antitrust violation.[496] In *Rambus*, the FTC found that Rambus, a developer in computer memory technologies, violated § 5(a) of the FTC Act by engaging in monopolistic conduct in violation of § 2 of the Sherman Act.[497] The FTC specifically pointed to Rambus' failure to disclose patent interests in developing technology standards, ranging from issued patents, pending patent applications, and plans to amend patent applications to add new claims.[498] The FTC asserted that Rambus' conduct was exclusionary because it either 1) enabled Rambus to acquire a monopoly through the standardization of its patented technologies rather than possible alternatives; or 2) allowed Rambus to avoid limits on its patent licensing fees that the SSO would have imposed as part of its normal process.[499]

The D.C. Circuit reversed, finding that the FTC failed to demonstrate that Rambus inflicted any harm on competition.[500] The court explained that because the FTC left open the likelihood that the SSO would have standardized Rambus' technologies even if the SEPs and pending SEPs were disclosed, the only harm suffered was the lost opportunity for the SSO to secure a FRAND commitment.[501] "[L]oss of such a commitment is not harm to competition from alternative technologies in the relevant markets."[502] Because the SSO's loss of an opportunity to seek favorable licensing terms was not an antitrust harm, the FTC failed to demonstrate Rambus unlawfully monopolized relevant markets.[503]

Rambus demonstrates that while a firm's failure to disclose technology may be a violation of its SSO agreement, it will not be a Sherman Act violation absent traditional exclusionary conduct under antitrust law.[504]

III. Jurisdiction and Anti-Suit Issues

SEP holders and product manufacturers incorporating those SEP standards are often geographically dispersed. This adds additional legal complexity as courts in multiple countries often have concurrent jurisdiction over the same FRAND disputes, leading to potential

2017); *but see* Karl Heinz Rosenbrock, Licensing *At All Levels Is The Rule Under The ETSI IPR Policy: A Response to Dr. Bertram Huber* at 6, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3064894 (Nov. 3, 2017).
[495] *Qualcomm*, 969 F.3d at 1005.
[496] *Rambus Inc. v. F.T.C.*, 522 F.3d 456, 459 (D.C. Cir. 2008).
[497] *Id*.
[498] *Id*.
[499] *Id*.
[500] *Id*. at 467.
[501] *Id*. at 466.
[502] *Id*.
[503] *Id*. at 467.
[504] H. Hovenkamp, *supra* note 404 at 1736.

jurisdictional conflicts and parallel FRAND litigation in multiple jurisdictions.[505] This has led to a rise in antisuit injunctions ("ASIs"), which are injunctions forbidding a party from initiating, continuing, or participating in judicial proceedings in foreign fora.[506]

U.S. courts have a relatively liberal standard for granting ASIs compared to other common law jurisdictions, and the first FRAND ASI was issued by a U.S. court.[507] Other jurisdictions followed U.S. courts' lead, including China which issued its own ASI for the first time in history.[508] This has eventually resulted in other jurisdictions, including England, India, France, and Germany all responding to ASIs by issuing anti-antisuit injunctions ("AASIs") which prevent the obtaining or enforcement of foreign ASIs.[509] This has culminated in a Chinese court issuing an anti-anti-antisuit injunction ("AAASI") in anticipation of an AASI and a German Court issuing an anti-anti-anti-antisuit injunction ("AAAASI").[510]

Choosing the appropriate jurisdiction is an important foundation in litigation strategy. For example, European courts tend to grant exclusive jurisdiction to the court where an action is first filed.[511] This encourages "a race to the courthouse," even if the ultimate forum is suboptimal or has a weaker connection to the dispute.[512] A party can use this to their advantage by either stalling the dispute by pinning the case to a slower jurisdiction or expediting resolution of the dispute by choosing a faster jurisdiction.[513] The practice of choosing a slower jurisdiction effectively "torpedoes" the potential case in the faster court—leading slower courts to become known as "torpedo" jurisdictions.[514]

[505] King Fung Tsang et al., *The Ping-Pong Olympics of Antisuit Injunctions in FRAND Litigation*, 28 MICH. TECH. L. REV. 305, 307 (2022).
[506] *Id*. at 306–07.
[507] *Id*. at 307 (citing *Microsoft Corp. v. Motorola, Inc.*, 871 F. Supp. 2d 1089 (W.D. Wash. 2012), aff'd, 696 F.3d 872 (9th Cir. 2012)).
[508] *Id*. (citing *Huawei Tech. Co. v. Conversant Wireless Licensing S.A.R.L.*, 2019 Zui Gao Fa Zhi Min Zhong No. 732, 733, 734 (Sup. People's Ct. Aug. 28, 2020) (China)).
[509] *Id*. at 308.
[510] *Id*. (citing *Samsung Elecs. Co., v. Telefonaktiebolaget LM Ericsson*, E 01 Zhi Min Chu No. 743 (Wuhan Interm. People's Ct. Dec. 25, 2020) (China); Landgericht München I [LG] [regional court Munich I] Feb. 25, 2021, 7 O 14276/20 (Ger.)).
[511] Raghavendra R. Murthy, *Why Can't We Be Frands?: Anti-Suit Injunctions, International Comity, and International Commercial Arbitration in Standard-Essential Patent Litigation*, 75 VAND. L. REV. 1609, 1619–20 (2022).
[512] David Kenny & Rosemary Hennigan, *Choice-of-Court Agreements, the Italian Torpedo, and the Recast of the Brussels I Regulation*, 64 INT'L & COMP. L. QUARTERLY 197, 197 (2015).
[513] *Id*.
[514] *Id.*