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The Regulatory Compliance Defense for "Improper" Orange Book Listings

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The U.S. Food and Drug Administration (FDA) publication known as the "Orange Book" lies at the center of the complex statutory and regulatory scheme that governs approval of generic drugs in the United States.[1] The Hatch-Waxman Act[2] requires that every sponsor of a new, "branded" drug submit for listing in the Orange Book certain patents that either "claim[] the drug" or "a method of using [the] drug."[3] The listing is intended to provide notice of those patent rights to would-be generic applicants, but the Hatch-Waxman Act also allows branded drug companies to seek to enforce those Orange Book–listed patents before the generic drug hits the market. In fact, when Orange Book–listed patents are asserted against generic challengers under the procedures created by the Hatch-Waxman Act, FDA approval of the generic drug is automatically stayed for up to 30 months as the patent infringement case is litigated.

For years, patent holders and generic applicants have litigated which types of patents must, and must not, be submitted for listing in the Orange Book, leading courts on several occasions to recognize the ambiguity in the language of the listing statute and associated regulations.[4] Generic challengers regularly seek to have patents "delisted," arguing that their FDA approvals are improperly delayed by 30-month stays caused by the assertion of patents that do not belong in the Orange Book. In December 2024, the U.S. Court of Appeals for the Federal Circuit

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handed down its decision in *Teva Branded Pharmaceutical Products R&D, Inc. v. Amneal Pharmaceuticals of New York, Inc.*,[5] one of the most closely followed Orange Book listing disputes to date. That case involved five listed patents that claimed the dose counter and canister parts of an FDA-approved albuterol inhaler product, but not the active ingredient. The Federal Circuit ultimately ruled that those patents should be "delisted," holding that "to qualify for listing, a patent must claim at least what made the product approvable as a drug in the first place—its active ingredient."[6]

A delisting order is not the only consequence of an improper Orange Book submission. The Federal Trade Commission (FTC) has argued for decades that branded drug companies intentionally file improper Orange Book submissions to obtain the benefit of an undeserved 30-month stay, thereby delaying the introduction of lower-priced generic alternatives.[7] Pharmaceutical companies that file those allegedly improper Orange Book listings thus face antitrust scrutiny. Yet while antitrust claims arising from improper Orange Book listings stretch back a quarter century,[8] the relevant legal standard for evaluating whether such listings violate the antitrust laws long remained unclear. Over the last several years, however, a new standard has emerged from a pair of cases within the U.S. Court of Appeals for the First and Second Circuits, including from decisions of each of those appellate courts. Those cases hold that antitrust plaintiffs may establish a prima facie case for monopolization without having to prove that the erroneous listing was unreasonable or in bad faith.[9] Instead, the antitrust defendant would bear the burden, as part of an affirmative defense, of proving that the listing was *both* objectively reasonable and filed with a good faith belief that the listing was required.[10]

The first cases applying this "regulatory compliance" defense framework to Orange Book antitrust cases have now reached the summary judgment phase. In this article, we discuss what those cases—and especially the first summary judgment decision—teach us about how litigants and courts will adjudicate the defense in the context of a fully developed record. Among other things, these cases illustrate the practical consequences of shifting the burden to the patent holder to affirmatively prove good faith. Most significantly, because of the fundamentally legal nature of the listing decision—which involves interpretation of statutes and regulations and potentially construction of patent claims—proving good faith, or at least doing so effectively, may as a practical matter require assertion of the advice-of-counsel defense and thus waiving the attorney-client privilege relating to the listing decision. Indeed, on remand in the cases decided by the First and Second Circuits, the defendants did just that. And, in another antitrust case, the antitrust plaintiff has argued on summary judgment that the refusal to waive the privilege was fatal to meeting the defendant's burden of proving good faith.[11]

Orange Book Listings and Alleged Exclusionary Effects

The Orange Book ostensibly provides notice of patent rights covering branded drugs, informing prospective generic applicants of patents that might stand in the way of their products. For that reason, Orange Book listings are mandatory; the statute requires that branded drug sponsors submit for listing *all* patents eligible to be listed.[12] At the same time, listing a patent in the Orange Book confers benefits on the patentee, including most significantly (and as detailed below) the potential for an automatic stay of FDA approval of the generic drug.

The Hatch-Waxman Act and its implementing regulations define the scope of patents that may be (and must be) submitted for listing in the Orange Book. With the Orange Book Transparency Act of 2020, Congress sought to resolve some of the ambiguity of the statute as originally enacted.[13] The statute requires sponsors of new drugs (i.e., holders of new drug applications, or NDAs) to submit for listing any patent that "claims the drug" or "claims a method of using such drug."[14] The amended statute specifies that to "claim[] a method of using" the drug, the patent must claim a use "for which approval is sought or has been granted in the application," excluding from the scope of the listing statute those method-of-use patents that claim only off-label uses of the drug.[15] Further, the amendments clarify that to "claim[] the drug," the patent must be "a drug substance (active ingredient) patent or a drug product (formulation or composition) patent."[16] Despite these amendments, and revisions to implementing regulations, many NDA holders argue that ambiguities remain.[17]

The procedures relating to Orange Book–listed patents explain why these listings are often the subject of antitrust scrutiny. For any unexpired patent listed in the Orange Book, a generic drug applicant must certify either that it does not seek final approval until the patent has expired (a "paragraph III" certification) or that the patent is invalid or will not be infringed by the proposed product (a "paragraph IV" certification).[18] For a listed method-of-use patent that covers one or more approved uses, and where the branded drug has other approved uses not covered by that patent, the generic drug applicant may also, or alternatively, submit a "section viii" statement that certifies that the generic company will market its generic only for the approved uses not claimed by the listed patent.[19] Section viii statements, however, are unavailable for a patent purporting to claim the drug substance or drug product or patents covering all approved uses. In those cases, the generic applicant must file either a paragraph III or a paragraph IV notice.

One central feature of the Hatch-Waxman Act is that it makes the paragraph IV notice an "artificial" act of infringement—meaning the patent holder may bring a claim for patent infringement and adjudicate its patent rights long before the generic drug is on the market.[20] If the patent holder brings a patent infringement action within 45 days of receiving a paragraph IV notice from the generic applicant, that action will automatically stay FDA approval of the generic product for up to 30 months while the parties litigate the infringement claim in district court.[21] These provisions enable pharmaceutical patent holders to enjoy what is effectively a preliminary injunction (of up to 30 months) for Orange Book–listed patents.[22] It is this automatic stay of generic approval that makes an improper Orange Book listing, in the FTC's eyes, exclusionary. In the FTC's view, an improper listing can lead to an undeserved stay of generic entry, thus delaying the launch of cheaper alternatives many consumers would purchase instead of the brand drug.[23]

Development of the *Lantus* and *Actos* Framework for the Two-Pronged Regulatory Compliance Defense

Antitrust suits alleging improper Orange Book listings are brought as monopolization claims—framed as efforts by branded drug companies that allegedly possess monopoly power to delay entry of generic competition that would put an end to monopoly pricing. This type of monopoly maintenance case requires the plaintiff to prove (1) that the defendant branded drug company possessed monopoly power in some relevant market, (2) that the improper Orange Book listing constituted "exclusionary conduct" to maintain that monopoly power, and (3) that the plaintiff suffered some antitrust injury caused by the listing (e.g., overpayment by purchasers or lost profits by allegedly delayed generic competitors).[24]

Early antitrust claims arising from Orange Book listings resulted in a series of district court decisions holding that such listings were not entitled to *Noerr-Pennington* immunity, which otherwise bars antitrust claims arising from First Amendment–protected petitioning activity unless the petitioning is shown to be a "sham."[25] Those courts held that Orange Book listings did not constitute "petitioning" activity because the FDA's role with respect to Orange Book listings was merely "ministerial"—i.e., it does not independently decide whether the patent should be listed in the Orange Book or that the listing was otherwise accurate.[26] Nevertheless, it remained unclear what standard should apply, with some courts dismissing Orange Book antitrust claims after determining as a matter of law that the allegedly improper listing was nonetheless "reasonable" given ambiguities in the listing requirements.[27] But those courts did not explain why that conclusion was dispositive.[28]

Beginning in 2019, the now-prevailing standard for evaluating the exclusionary conduct element in a monopolization case arising from an allegedly improper Orange Book listing began to emerge. Initially, the U.S. District Court for the Southern District of New York in *In re Actos End-Payor Antitrust Litigation* held that an antitrust plaintiff could satisfy its prima facie burden in a monopolization case arising from an allegedly improper Orange Book listing without pleading or proving that the defendant drug company's listing was in bad faith or that the listing was objectively unreasonable.[29] A few months later, in February 2020, the First Circuit in *In re Lantus Direct Purchaser Antitrust Litigation* adopted the same framework, holding that the element of exclusionary conduct could be established in a monopolization case based solely on a post hoc legal determination that the patent should not have

been listed, irrespective of whether the listing was "reasonable" given regulatory ambiguities.[30] In 2021, the Second Circuit affirmed the district court's decision in *Actos*, aligning itself with the First Circuit.[31]

Central to each of these holdings was the fact that "bad faith" or anticompetitive intent is not an element of a monopoly maintenance claim.[32] Rather, plaintiffs must generally show only that the conduct "has or is likely to have the *effect* of controlling prices or excluding competition."[33] As the Second Circuit observed in *Actos*, the only "intent" required in a typical monopoly maintenance claim is the mere "intent to do the act" that caused the exclusionary effect.[34] In fact, the court went on to observe, "benign intent does not shield anticompetitive conduct from liability."[35] As a result of these principles, the courts in *Lantus* and *Actos* held that the plaintiff merely needed to prove as part of its prima facie case that the patent listing was improper (and caused generic delay); the plaintiff did not need to plead or prove that "the listing decision was unreasonable."[36]

The courts, however, recognized that strict antitrust liability for erroneous listings may have negative policy ramifications.[37] The First Circuit, for example, recognized that the mandatory nature of potentially ambiguous listing requirements could put NDA holders in an untenable position. Both the First Circuit in *Lantus* and the district court in *Actos* determined that the "regulatory compliance" affirmative defense, developed in the context of telecommunications regulations, supplied the solution. That defense required a showing that "the defendant's action was taken as part of a good faith, reasonable attempt to comply with a regulatory scheme."[38] Accordingly, under this framework adopted by *Lantus* and *Actos*, if the court determined that the Orange Book listing was improper in some way, and the plaintiff otherwise satisfied the monopoly power and causation elements of its monopoly maintenance claim, the antitrust defendant could avoid liability if it could prove that the listing was both objectively reasonable and subjectively made in good faith.[39]

Regulatory Compliance Defense in Practice: The *Actos* Summary Judgment Decision

Until recently, no court has had the opportunity to apply the regulatory compliance defense to the facts of an Orange Book antitrust case. However, in March 2025, a summary judgment decision in the *Actos* litigation offered the first case study on how the regulatory compliance affirmative defense is litigated in practice.

The *Actos* litigation involves the brand-name diabetes medication ACTOS, and specifically the listing of two "combination" patents that claimed the original active ingredient approved in the initial NDA (pioglitazone) combined with other drugs, as well as methods of using those combinations.[40] Unlike many Orange Book antitrust cases, the matter did not focus on patents that allegedly should not have been listed at all, but rather on how the applicant classified these patents in its listing and in subsequent submissions to the FDA. The NDA holder had classified the patents as both "drug product" and "method-of-use" patents in its initial submission.[41] The plaintiffs—classes of direct and indirect purchasers—alleged that the NDA holder had incorrectly identified the patents as "drug product" patents—requiring generic applicants to submit a paragraph IV certification and enabling the NDA holder to file a patent infringement action that triggered an automatic 30-month litigation stay.[42] The plaintiffs contended that if the patent had been characterized as a "method-of-use" patent only, generics would have been able to get to market more quickly by making a section viii certification.

Due to the particularities of this case, the court held that the original listing was not actionable because it could not, in and of itself, have caused any delay.[43] As the court explained, despite the NDA holder's characterization of the patents as "drug product" patents as well, the Orange Book listing showed the method-of-use characterization only.[44] As a result, generic applicants were able—initially—to file a section viii statement (i.e., that the generic would seek approval for noninfringing uses only), and a "handful of generics" did just that.[45] Other applicants, however, also filed paragraph IV certifications as to drug product claims they saw within the patents.[46]

One of the paragraph IV filers then filed a citizen's petition to the FDA, seeking to have the FDA require all generics to make paragraph IV certifications.[47] The antitrust case centered on two statements the NDA holder made to the FDA that (the court concluded) led the FDA to grant that petition and to require paragraph IV certifications. First,

in late 2009, the NDA holder submitted a letter to the FDA confirming its view that it had correctly characterized the patents as including both method-of-use and drug product claims. That letter was then filed on the public docket associated with the citizen petition in January 2010.[48] The FDA then granted the citizen petition, citing the NDA holder's response, and confirming the agency's "ministerial" approach to defer entirely to the NDA holder's characterization of its patents.[49] A generic applicant sought reconsideration, asserting that the non-method-of-use claims in the relevant patents were not "drug product" claims within the meaning of FDA regulations because they did not claim ACTOS, and instead claimed only combinations in which ACTOS was an ingredient.[50] The FDA then forwarded that petition to the NDA holder, seeking confirmation that the drug product claims "claim the approved ACTOS drug product."[51] The NDA holder responded in May 2010, this time explicitly stating that the patents did "claim[] the approved ACTOS® drug product."[52] Again, the FDA deferred. As a result of these submissions, generic applicants seeking approval before the expiration of the combination patents needed to file a paragraph IV certification. Those certifications led to patent suits that triggered the automatic stay of approval.

The question on summary judgment was whether the January 2010 statement and May 2010 statement satisfied the "willful maintenance" (or exclusionary conduct) element of the monopoly maintenance claim.[53] The court found that there was no genuine dispute that the defendant's statements were improper because the patents should not have been identified as "drug product" patents.[54] Citing an earlier decision of the court, affirmed by the Second Circuit, the court explained that an NDA holder could identify a patent as a "drug product" patent only if it "claim[ed] the drug under submission in the NDA."[55] Because the drug at issue comprised just one of the active ingredients in the claimed combination, the court held that the patents at issue did not qualify as "drug product" patents.[56] The court, however, explained that the regulatory compliance defense could negate this finding of willful maintenance.[57]

Objective Reasonableness

As to the objective reasonableness prong, the court explained that the relevant considerations were:

> (1) whether the text of the regulatory provisions are ambiguous and can plausibly be read in the way the defendant (mis)construed it; (2) whether the defendant's misreading is consistent with the "regulatory policy" underlying those provisions; (3) whether others in the industry had adopted the same misinterpretation, as evidenced by "custom and practice"; and (4) whether "any legal opinions" supported the defendant's misinterpretation.[58]

The court held that the objective reasonableness prong is "ultimately a question of law that must be decided by a court," because "juries are not qualified to answer the ultimate question of whether an antitrust defendant made a reasonable mistake of law in attempting to comply with the applicable regulations."[59] The court explained, however, that juries may have a limited role in deciding subsidiary factual questions, such as what the "custom and practice" was in the industry at the relevant time or "other matters of 'historical fact.'"[60]

The NDA holder argued that the January 2010 statement was reasonable because it was supported by a reasonable interpretation of the listing regulations, the "identify-all-claim-types"—that if the patent included claims that qualified for listing (e.g., method-of-use claims), the NDA holder must then describe the patent based on all of the types of claims within the patent (including drug product claims that might otherwise not have qualified for listing on their own).[61] The court itself concluded that the theory was "at odds with the plain text" of the statute and regulations and "at best an unnatural reading" of them.[62] The court declined to credit as evidence the NDA holder's argument that another branded drug company had relied on an "identify-all-claim-types" theory in a prior citizen's petition to the FDA.[63] The court reasoned that although the FDA ultimately sided with the NDA holder on that petition, the FDA did so merely because it deferred to the NDA holder "consistent with its ministerial role" and not necessarily because the FDA agreed with the theory advanced.[64]

But while the court found these factors relevant to the ultimate question of objective reasonableness, they were not dispositive. The court explained that while the theory was not supported by the statute, regulations, or regulatory

policy, it was not "entirely foreclosed" by them either.[65] The court then considered additional evidence that the NDA holder presented relating to industry custom and practice as well as advice of counsel the NDA had received, and ultimately concluded that the jury must first make factual findings regarding that evidence.[66] The court explained that it "will then factor the jury's determinations on these fact issues into its ultimate legal ruling on objective reasonableness."[67] Because that genuine issue of material fact existed, the court denied both the plaintiffs' and the defendant's cross motions for summary judgment as to the objective reasonableness prong with regard to the January 2010 statement.

The court, however, went on to hold that the May 2010 statement was objectively reasonable as a matter of law. The NDA holder argued that, in responding to the FDA's second inquiry in May, it represented that the patents included "drug product" claims based on an "induced-infringement" interpretation of the listing requirements—that if the sale of the generic version of ACTOS could arguably constitute induced infringement of the drug product claims within the patent, those claims qualified as "drug product" claims within the meaning of the statute.[68] Although the court and the Second Circuit had previously rejected the "induced-infringement" theory as well, the court held that the theory itself was a "reasonable interpretation" that found some "textual support" in the listing statute and regulations.[69] The court recalled, for example, its earlier acknowledgement that there was "a substantial ground for difference of opinion" as to the correctness of the "induced-infringement" theory.[70] As to the May 2010 statement, though, the court noted that the defendant would still need to satisfy the good faith prong of the defense.[71]

Subjective Good Faith

The court determined that the second prong of the regulatory compliance defense, subjective good faith, "is a question of fact for a jury."[72] It explained that the inquiry "requires examining whether a defendant acted out of a subjective belief that its conduct was required by regulatory law, as opposed to for 'competitive' reasons."[73] The court observed that "[q]uestions of intent . . . are usually inappropriate for disposition on summary judgment."[74] The only question, then, was whether genuine issues of material fact existed as to the NDA holder's subjective good faith with respect to both the January 2010 and May 2010 statements. The court decided that question in the affirmative, thus sending the matter to the jury.

As evidence of subjective good faith, the NDA holder produced privileged legal advice, seeking to show that it acted in good faith reliance on advice of counsel when it made each of the January 2010 and May 2010 statements.[75] The court ruled, however, that the fact of legal advice was not dispositive. The court explained that a jury would have to evaluate the substance of that advice, along with other evidence, to determine whether it proved that the NDA holder believed it was required to describe the patents as including "drug product" claims.[76] The court identified several factors relevant to the jury's determination, such as whether the evidence suggested that the defendant sought advice to find out what the listing statute and regulations required, or alternatively, to find some justification to support a listing it was intent on making. The substance of the request for advice and the advice itself would also be critical, according to the court. For example, the court suggested that a jury may not find it sufficient if a lawyer opined that an interpretation of the listing statute was merely "colorable" or "defensible," as that may not be enough to establish a genuine belief that the conduct was required by law.[77] The court also highlighted the potential relevance of dissenting legal opinions given to the NDA holders (i.e., lawyers who did not believe the statute and regulations supported the description) and of the fact that the NDA holder apparently shifted to the different, "induced-infringement" theory of statutory interpretation to justify the "drug product" claim classification in response to the more pointed inquiry from the FDA in May 2010.[78]

Key Takeaways and Looking Ahead

Several key takeaways about the operation of the regulatory compliance defense in the context of Orange Book antitrust cases emerge from *Actos* and other recent litigation:

First, even if a court finds against the NDA holder as to the interpretation of the listing requirements, it may nevertheless acknowledge ambiguity in those requirements that supports the regulatory compliance defense. And even if the court finds that the listing was at odds with the statutory and regulatory language, the applicant may still be able to establish "objective reasonableness" with compelling evidence of "industry practice" or supportive legal advice.

Second, even if a court finds that the listing was objectively reasonable, the NDA holder will still need to prove subjective good faith. Unlike the *Noerr-Pennington* framework, in which a determination that the petitioner's case was not "objectively baseless" would be case dispositive, under the regulatory compliance defense, the defendant must still prove that it subjectively believed its listing was required. Evidence suggesting that the NDA sought out advice for the purpose of justifying a decision to list may cut against the defendant.

Third, proving subjective good faith may require—at least as a practical matter to do so persuasively—asserting an advice-of-counsel defense and waiving privilege at least as to that subject matter. The defendant in *Actos* did so. And, in a recently filed summary judgment motion in another matter, one antitrust plaintiff argued that the defendant could not establish good faith under the regulatory compliance defense without waiving privilege.[79] And even if the defendant relies on advice of counsel, that advice will be scrutinized. Courts and jurors, for example, may distinguish between, on the one hand, advice that concludes a legal theory supporting the listing is "colorable" and, on the other hand, advice that concludes it is the appropriate way to interpret the statute and regulations. Waiving the privilege to assert an advice-of-counsel defense also likely subjects the defendant to discovery into any dissenting views provided in other privileged communications.

Of course, beyond the regulatory compliance defense, antitrust claims based on allegedly improper Orange Book listings will still require proof of monopoly power and causation. As discussed above, the court in *Actos* rejected any claim that antitrust liability would arise from the initial listing in that case after finding as a matter of law that the listing did not have the effect of delaying competition. In another matter pending at the time of this writing, the defense leans heavily on an argument that separate regulatory requirements—and not the allegedly improper Orange Book listing—dictated the timing of generic entry.[80] An allegedly improper listing that does not actually result in any delay of generic entry will not support a monopoly maintenance claim.

And, finally, litigants in future cases—at least outside the First and Second Circuits—may push back on the standard adopted by the courts in *Actos* and *Lantus* and press instead that the burden should be on the antitrust plaintiff to prove that the listing was made in bad faith. Such an argument may find support in a long line of cases that require proof of bad faith before subjecting the use of patent rights to antitrust liability as a means to achieve a "suitable accommodation" between competing policies of patent and antitrust law.[81] It remains to be seen whether arguments such as this will reverse the current momentum behind the prevailing standard adopted by the *Actos* and *Lantus* courts. If it does, that shift in law could have significant practical consequences—if the defendant does not bear the burden of affirmatively proving subjective good faith, it may not feel it needs to waive privilege to mount its defense.

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Endnotes

1. *See* U.S. Food & Drug Admin., Approved Drug Products with Therapeutic Equivalence Evaluations (45th ed. 2025) [hereinafter Orange Book].
2. 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).
3. 21 U.S.C. § 355(b)(1)(A)(viii).

4. *E.g.*, Organon Inc. v. Mylan Pharms., Inc., 293 F. Supp. 2d 453, 460 n.8 (D.N.J. 2003); *In re* Lantus Direct Purchaser Antitrust Litig., 284 F. Supp. 3d 91, 106 (D. Mass. 2018), *rev'd on other grounds*, 950 F.3d 1 (1st Cir. 2020).

5. 124 F.4th 898 (Fed. Cir. 2024).

6. *Id.* at 911.

7. Fed. Trade Comm'n, Federal Trade Commission Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sep. 14, 2023) [hereinafter FTC Policy Statement], https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

8. *See, e.g.*, *In re* Buspirone Pat. Litig., 185 F. Supp. 2d 363 (S.D.N.Y. 2002).

9. United Food & Com. Workers Loc. 1776 & Participating Emps. Health & Welfare Fund v. Takeda Pharm. Co. Ltd. (*Actos III*), 11 F.4th 118, 124 (2d Cir. 2021); *Lantus*, 950 F.3d at 3–4; *In re* Actos End-Payor Antitrust Litig. (*Actos II*), 417 F. Supp. 3d 352, 372 (S.D.N.Y. 2019), *aff'd*, 11 F.4th 118 (2d Cir. 2021).

10. In 2024, the U.S. District Court for the District of Delaware similarly held that the antitrust plaintiff need not prove bad faith and instead the burden would be on the defendant to prove reasonableness and good faith. Jazz Pharms., Inc. v. Avadel CNS Pharms., LLC, No. 1:22-CV-00941-GBW, 2024 WL 2700031 (D. Del. May 24, 2024).

11. *See* Defendant & Counter-Plaintiff Avadel CNS Pharmaceuticals, LLC's Opening Brief in Support of Its Motions for Partial Summary Judgment & Daubert Motions, *Jazz Pharms.*, No. 1:22-CV-00941-GBW (D. Del. May 9, 2025), Dkt. No. 272 [hereinafter *Jazz Pharms.* Motion].

12. *Lantus*, 950 F.3d at 11.

13. Orange Book Transparency Act of 2020, Pub. L. No. 116-290, 134 Stat. 4889 (2001) (codified at 21 U.S.C. § 355).

14. 21 U.S.C. § 355(b)(1)(A)(viii).

15. *Id.* § 355(b)(1)(A)(viii)(II).

16. *Id.* § 355(b)(1)(A)(viii)(I).

17. *See, e.g.*, Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., Inc., 124 F.4th 898, 916–17 (Fed. Cir. 2024).

18. 21 U.S.C. § 355(j)(2)(A)(vii)(III), (IV).

19. *Id.* § 355(j)(2)(A)(viii).

20. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990).

21. 21 U.S.C. § 355(j)(5)(B)(iii).

22. While the automatic stay is beneficial to the patentee, the ability to litigate patent claims before market entry can be significantly beneficial to the generic applicant as well. The ability to challenge even the strongest Orange Book–listed patents without risking potentially massive damages exposure lowers a barrier to entry for generics. *In re* Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188 (E.D.N.Y. 2003).

23. FTC Policy Statement, *supra* note 7, at 4.

24. *Actos III*, 11 F.4th 118, 137 (2d Cir. 2021).

25. *See In re* Buspirone Pat. Litig., 185 F. Supp. 2d 363, 372–73 (S.D.N.Y. 2002); Organon Inc. v. Mylan Pharms., Inc., 293 F. Supp. 2d 453, 458 (D.N.J. 2003); Rochester Drug Co-op., Inc. v. Braintree Lab'ys, 712 F. Supp. 2d 308, 321 n.14 (D. Del. 2010).

26. *Buspirone*, 185 F. Supp. 2d at 369–71.

27. *Organon*, 293 F. Supp. 2d at 458; *In re* Lantus Direct Purchaser Antitrust Litig., 284 F. Supp. 3d 91, 107 (D. Mass. 2018).

28. *Organon*, 293 F. Supp. 2d at 458; *Lantus*, 284 F. Supp. 3d at 107.

29. *Actos II*, 417 F. Supp. 3d 352, 372 (S.D.N.Y. 2019).

30. 950 F.3d 1, 3–4 (1st Cir. 2020).

31. *Actos III*, 11 F.4th 118, 124 (2d Cir. 2021).

32. *Lantus*, 950 F.3d at 3.

33. *In re* Actos Antitrust Litig. (*Actos IV*), 783 F. Supp. 3d 749, 775 (S.D.N.Y. 2025) (emphasis added).

34. *See Actos III*, 11 F.4th at 137.

35. *Id.*

36. *Id.* at 137–38.

37. *Lantus*, 950 F.3d at 12; *Actos II*, 417 F. Supp. 3d 352, 372 (S.D.N.Y. 2019). While the Second Circuit has agreed that "bad faith" is not an element of a plaintiff's prima facie case, that court has not yet had an opportunity to address the regulatory compliance defense. *See Actos IV*, 783 F. Supp. 3d at 782.

38. *Lantus*, 950 F.3d at 12 (citing MCI Commc'ns Corp. v. Am. Tel. & Tel. Co., 708 F.2d 1081, 1109–10 (7th Cir. 1983)).

39. *Id.* at 13–14.

40. *Actos IV*, 783 F. Supp. 3d at 762–63.
41. *Id.* at 763. NDA holders are required to specify whether the listed patent was a drug substance, drug product, or method-of-use patent. *Id.* at 760.
42. *Id.* at 767.
43. *Id.* at 775.
44. *In re* Actos End-Payor Antitrust Litig. (*Actos I*), 848 F.3d 89, 98–99 (2d Cir. 2017).
45. *Actos IV*, 783 F. Supp. 3d at 764.
46. *Id.*
47. *Id.* The court explained that the first paragraph IV filer is entitled to 180 days of generic exclusivity. If subsequent generics were able to file section viii certifications alone, they would be able to avoid the "bottleneck" that would otherwise delay subsequent paragraph IV filers to the benefit of the initial one. *Id.* at 762.
48. *Id.* at 766.
49. *Id.*
50. *Id.*
51. *Id.*
52. *Id.* at 767.
53. *Id.* at 775. The court also held that the plaintiffs were not entitled to summary judgment of monopoly power. *Id.* at 774–75.
54. *Id.* at 775–82.
55. *Id.* at 763 (citing *Actos II*, 417 F. Supp. 3d 352, 369 (S.D.N.Y. 2019)).
56. *Id.*
57. *Id.* at 782.
58. *Id.* at 782–83 (citations omitted).
59. *Id.* at 784–85.
60. *Id.* at 786.
61. *Id.*
62. *Id.* at 787.
63. *Id.* at 787–88.
64. *Id.* at 788.
65. *Id.*
66. *Id.* at 791.
67. *Id.*
68. *Id.* at 793–94.
69. *Id.*
70. *Id.* at 794.
71. *Id.*
72. *Id.* at 783.
73. *Id.*
74. *Id.* at 792 (alteration in original).
75. *Id.* at 790–91, 794–95.
76. *Id.* at 792–95.
77. *Id.* at 794.
78. *Id.*
79. *See Jazz Pharms.* Motion, *supra* note 11.
80. *Id.*
81. *See, e.g.*, Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965); Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986 (9th Cir. 1979); Zenith Elecs. Corp. v. Exzec, Inc., 182 F.3d 1340 (Fed. Cir. 1999); *see also In re* Buspirone Pat. Litig., 185 F. Supp. 2d 363, 376–77 (S.D.N.Y. 2002) (addressing the defendant's argument that patentees enjoy a "qualified immunity" that requires proof of bad faith before antitrust liability may attach based on Orange Book listing).