No. 16A74

IN THE SUPREME COURT OF THE UNITED STATES

MERCK & CIE, ET AL.,

Applicants,

v.

WATSON LABORATORIES, INC.,

Respondent.

On Application for Stay

RESPONDENT'S OPPOSITION TO APPLICATION TO STAY MANDATE

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RULE 29.6 STATEMENT

Watson Laboratories, Inc. is a wholly owned subsidiary of Actavis, Inc. Allergan plc is a publically held company that owns more than 10% of Actavis, Inc. No corporation owns more than 10% of Allergan plc.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

OPPOSITION TO APPLICATION TO RECALL AND STAY MANDATE

To the Honorable John G. Roberts, Jr., Chief Justice of the United States and Circuit Justice for the Federal Circuit:

The application for a stay of mandate should be denied. First and foremost, this is a case in which the ordinary remedies for patent infringement would completely remedy any injury that applicants might suffer, *if* they succeeded in winning reversal of the Federal Circuit's judgment. Applicants complain that once respondent Watson launches a generic drug, the market will stay generic forever. But if that is true, it has nothing to do with Watson: the generic that will supposedly remain on the market is *applicants' own product*. Applicants have (purportedly) signed an irrevocable commitment to let another company sell their product *as an authorized generic*, even if Watson exits the market. But applicants cannot turn a reparable injury into an irreparable one by signing away their ability to restore the *status quo ante*. Watson did not put applicants in that position, and it is not for this Court to save applicants from their own Doomsday Machine.

Second, applicants have not shown any likelihood that certiorari will be granted or that the decision below will be reversed. Applicants want to present a question about the scope of the "on sale" bar—does a *private* sale count?—that they *never litigated* in the district court, in their appellate brief, or at oral argument. Moreover, this newly raised question is not properly presented by this case, for case-specific reasons: the limited record developed indicates that the sale at issue was a public commercial sale. And even if the question were presented, applicants are

simply wrong in arguing that this Court has held that "on sale" actually means "on sale *publicly*." The plain language of the statute does not support grafting on a "public" sale limitation to the "on sale" bar, and this Court has never read the statute to impose such an additional requirement.

If there were any doubt about the application, the equities and the public interest both support granting consumers access to lower-cost generic medicine, *now.* Applicants' invalid patent should no longer be allowed to block that access pending a certiorari decision.

STATEMENT

When an invention is ready for patenting, the inventor must promptly submit a patent application. As relevant here, the inventor has no more than one year after it first offers the ready-to-patent invention for sale. *See* 35 U.S.C. § 102(b). This "on-sale bar" prevents patent applicants from effectively extending its monopoly by starting to commercially exploit an invention for a significant period before applying for the full term of a patent monopoly.

The Federal Circuit held the patent in this case invalid because the patent owner made an offer to sell the patented invention more than one year before applying for a patent. Throughout this litigation, the dispute has been over whether the offer was really an offer, under the particular terms of the parties' contractual relationship. Only after the Federal Circuit ruled that it *was* an offer did applicants attempt to reframe the case as one about whether the offer must be not only a commercial offer, but a *public* offer.

1. Claim 4 of U.S. Patent No. 6,441,168 ("the '168 patent") is directed to a specific crystal form of a particular salt known as MTHF. The Federal Circuit held that MTHF was "on sale" in this country more than one year before the patent application that became the '168 patent. That patent application was filed on April 17, 2000.

In 1997, Merck KGaA ("Merck"), parent of one of the applicants, and Weider Nutrition International, Inc. ("Weider") began "exploring a strategic partnership to introduce dietary supplements with Merck ingredients into the United States." 125 F. Supp. 3d at 508. The first potential partnership was with respect to U.S. marketing of dietary supplement products containing Merck's raw ingredient, MTHF. C.A. App. 1287–90, 1434. From the outset, Weider made clear that it was "interested in putting together a product containing MTHF." C.A. App. 1367.

In connection with those discussions, Merck and Weider executed a Confidentiality and Noncompetition Agreement (the "Merck-Weider Agreement") in February 1998. C.A. App. 1368–73. The Merck-Weider Agreement restricted the parties' disclosure of shared "Confidential Information."[1]

[1] Section 1.3 of the Confidentiality Agreement defines "Confidential Information" as: "[A]ny and all information disclosed by the Disclosing Party to the Receiving Party, orally visually or in writing, in drawings, by observation or otherwise during laboratory or plant visits or in any other way, including but not limited to all scientific, medical, clinical, engineering, statistical, commercial, technical or process data; all information and knowhow regarding products, samples, manufacturing capabilities, techniques and processes, business or marketing strategies, existing and potential customers; evaluation material, nutritional supplements, beverages, food bars, powdered food supplements, inventions, intellectual property, trade secrets, drawings, models, mock-ups, prototypes samples, formulas, products, processes, materials, marketing information, pricing information, business plans, patent applications, competitiveness information, and the like." C.A. App. 1477–78.

The litigation below would focus on a particular provision of the Merck-Weider Agreement, Section 5.2, which actually does not pertain to confidentiality at all. Section 5.2 set out the circumstances under which the parties would be bound by what it refers to as "such definitive agreement"–though there is no "definitive agreement" antecedent anywhere in the document. Specifically, Section 5.2 provided: "Unless and until such definitive agreement regarding a transaction between Weider and Merck has been signed by both parties, neither party will be under any legal obligation of any kind with respect to such a transaction." Appl. App. B, at 13.

Throughout the summer of 1998, the companies planned for Weider to develop a platform and plan to introduce Weider products containing MTHF to the U.S. consumer market. C.A. App. 1444–45. However, in August 1998, Weider notified Merck that it was no longer interested in forming a joint venture to market MTHF in the United States. C.A. App. 1419. Weider told Merck that it instead wished to purchase two kilograms of MTHF on a stand-alone basis. C.A. App.1419, 1446–48. In a fax to Merck, Weider confirmed that the purpose of the purchase was to sell MTHF in Weider products to the consuming public. "Confirming: We will be using this product to develop need and or improved vitamin products." C.A. App. 1446. Weider testified at trial its internal estimate that the 2 kilograms of MTHF would provide 62.5 million doses, and that Weider was planning on "putting [MTHF] into products that [Weider] would sell." C.A. App. 1075 at 199:19-200:10.

Weider explained that "[i]n order to complete the transaction," it needed information on the price for the product. C.A. App. 1446. Weider also informed Merck that it would like to handle the purchase of MTHF in a way that was "simplest . . . for both companies." *Id.*

In response, on September 9, 1998, Dr. Roland Martin, a manager in Merck's Health, Cosmetic and Nutrition Business Unit, sent Weider a signed fax stating:

> [W]e would like to handle your purchase of [MTHF] very simpl[y].
>
> Therefore please send the order to my attention and I will arrange everything. In addition we need the exact delivery address/person.
>
> The price is 25,000 US$ per kg [of MTHF] free delivered to your R & D center in the U.S. Payment terms are 60 days net. With Rick Blair and Richard Bizzaro we discussed a purchase of 2 kg [of MTHF]. If you need more, we have no problem for an immediate[ ] delivery. After receiving your order you will get the official confirmation of the order.

C.A. App. 1386. In the meantime, Dr. Martin began coordinating the work within Merck to provide the requested information and arrange shipment of the 2 kg order. C.A. App. 1419 & 1421.

On September 16, 1998, Weider responded to Martin, confirming that Weider would order two kilograms of MTHF for delivery to its Salt Lake City facility. C.A. App. 1352. Weider advised that it "will order 2 kg of the material against PO [purchase order] #29337," and asked Merck for certain information needed to complete the purchase order, including addresses and phone numbers. Weider also asked for a "[s]pecification sheet for the raw material outlining physical, analytical, and microbial characteristics; certificate of analysis, material

safety data sheets, [and] certificate of insurance naming Weider as an additional insured." C.A. App. 1352.

On September 25, 1998, Merck sent Weider the requested materials. Merck again confirmed that the purchase price would be $25,000 per kilogram with free delivery to Weider's Utah facility. C.A. App. 1354.

On October 8, 1998, Merck sent Weider a letter confirming that "a first order for 2 kg was placed." C.A. App. 1453–56. Merck minutes of a meeting with Weider on December 14, 1998 confirm that the two parties "discussed routes to market L-5MTHD into the dietary supplement market," and that "Weider will initially try and launch L-5MTHF as a stand-alone product." C.A. App. 1387.

In the meantime, however, Merck also pursued selling MTHF to a Weider competitor, Whitehall Robins ("Whitehall"). C.A. App. 1398, 1461–62. Whitehall told Merck that it was interested in obtaining *exclusive rights* to market MTHF in the United States and Canada. C.A. App. 1461–62. Shortly thereafter, Merck told Weider for the first time that Merck no longer could find the order it had confirmed, but would "try and locate the order for 2 kg L-5MTHF." C.A. App. 1388. Weider noted in an internal document that it needed to "track" its MTHF order and "determine [a] delivery date." C.A. App. 1438.

In January 1999, Merck asked Weider "whether the PO [purchase order] for 5-MTHF is active." C.A. App. 1428. Weider eventually wrote Merck that it had decided to cancel Weider's "existing order for [MTHF]." C.A. App. 1463.

2. Applicants sued Watson for infringing claim 4 of the '168 patent. Watson defended on the ground that claim 4 is invalid under the on-sale bar because Merck offered MTHF for sale in 1998. The dispute in the district court centered on whether Merck's communication to Weider was an offer.

Applicants did not invoke any confidentiality-related provision of the Merck-Weider Agreement; rather, they argued "that, in light of § 5.2 of the [Merck-Weider Agreement], there was no commercial sale or offer for sale." 125 F. Supp. 3d at 509. The district court agreed with applicants: it held that there was no commercial offer, because under Section 5.2 there could be no "legally binding sale until reduced to writing and signed by both parties," and so Merck's correspondence to Weider "was also not an offer that could be made binding upon acceptance." *Id.* at 510. The district court also thought that "industry-standard terms were missing from the communications": the court acknowledged that "an offer can sometimes be sufficiently definite with only the terms present in the September communications," but it thought that this case involved "a potentially dangerous new drug" and so a "liability apportionment" term was necessary. *Id.* The district court therefore rejected Watson's reliance on the on-sale bar.

Watson appealed the holding that there was no "commercial offer or sale of MTHF." *Id.* Applicants did not argue in their brief that the MTHF was offered for a commercial *but secret* sale; indeed, the parties' appellate briefs did not discuss confidentiality at all. Rather, they focused entirely on the same grounds on which

the district court decided the case: whether Merck's offer to sell was an offer at all, under industry practice or under the Merck-Weider Agreement.

3. The court of appeals reversed. Appl. App. B.

The court first concluded that Merck's fax to Weider "contained all the required elements to qualify as a commercial offer for sale." Appl. App. B, at 8. And "in the weeks following Martin's fax both Merck and Weider proceeded on the understanding that Merck had made an unequivocal offer to sell MTHF." *Id.* at 9.

Second, the court rejected applicants' reliance on Section 5.2 of the Agreement. The Court noted at the outset that "[applicants] point[ed] to nothing in that agreement indicating that it was intended to have any applicability to a stand-alone product purchase." *Id.* at 13. But "[e]ven assuming *arguendo* . . . that the [Merck-Weider] Agreement can be stretched to cover a standalone purchase of MTHF," the court of appeals wrote, "it does not help [applicants]," because Section 5.2 does not require that "an offer for sale and a completed sales agreement . . . be contained in the same document." *Id.* Thus, even if the offer could not become a sales agreement upon Weider's signature, it was still "a commercial offer to sell MHTF." *Id.* at 13-14.

The court of appeals noted two issues *not* raised by this case. First, the court acknowledged that the *en banc* court was then considering, in *Medicines Co. v. Hospira, Inc.*, No. 2014-1469, whether an agreement between an inventor and a manufacturer could "trigger the on-sale bar," but explained that this case was different because here "there is no dispute that the bar arises when a product is

marketed to the public prior to the critical date." Appl. App. B, at 14 n.4. Second, the court noted that Merck's offer to sell MHTF was not "for experimental purposes," but for commercial exploitation. *Id.* at 14.

4. Applicants then filed a petition for rehearing changing their theory. They contended that the on-sale bar did not apply because the offer was not a public one. The court of appeals denied rehearing and the requested stay of mandate. Appl. App. A, C.

REASONS FOR DENYING THE APPLICATION

An applicant seeking a stay of a court of appeals' mandate must demonstrate "(1) 'a reasonable probability' that this Court will grant certiorari, (2) 'a fair prospect' that the Court will then reverse the decision below, and (3) 'a likelihood that irreparable harm [will] result from the denial of a stay.'" *Maryland v. King*, 133 S. Ct. 1, 2 (2012) (Roberts, C.J., in chambers) (citation omitted; brackets in original). Each of these showings is required; thus, for instance, even when the first two conditions are met, the Court will deny a stay if the applicant fails to show that irreparable harm would result during this Court's consideration of the case. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 134 S. Ct. 1621, 1621 (2014) (Roberts, C.J., in chambers). "In close cases the Circuit Justice or the Court will balance the equities and weigh the relative harms to the applicant and to the respondent." *Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010) (*per curiam*).

This is not a close case. Applicants have completely failed to show why "damages . . . for past patent infringement" will not remedy their claim of injury, just as the Circuit Justice concluded in *Teva*. 134 S. Ct. at 1621. There is no

reasonable likelihood that the Court will grant certiorari. And respondents' arguments fail on the merits, largely for case-specific reasons. As a result, a stay is not warranted.

I. Applicants have failed to show irreparable injury.

Relying on Federal Circuit preliminary-injunction cases, the application essentially assumes that a brand-name pharmaceutical company necessarily faces irreparable injury whenever it faces the prospect of generic competition. As the Circuit Justice's denial of an identical stay request in *Teva* demonstrates, that simply is not the case. The few differences between this case and *Teva* only underscore why a stay should be denied here as well: here, (1) applicants rely on self-inflicted harms, having voluntarily signed a contractual commitment to let another generic company sell applicants' product at a generic price; and (2) the pharmaceutical products in this case command a far smaller market than the multibillion-dollar product at issue in *Teva*, making any damages award easier to determine and quieting any possible doubts about either the patentee's viability or the defendant's ability to pay. In short, this is a considerably weaker stay application than the one denied in *Teva*. It should be denied as well.

A. As the Circuit Justice has previously recognized, the ability to pursue damages refutes a claim of irreparable harm.

Teva arose in the same procedural posture as this case. The brand-name pharmaceutical company had prevailed at trial, but the patent was held invalid on appeal. The brand-name company therefore asked for a stay of the Federal Circuit's mandate—both after it issued, No. 13A458, and after this Court had granted

certiorari, No. 13A1003. Both times the brand-name company contended that a generic launch would cause it irreparable injury. Both times the application was denied. The Circuit Justice explained that even though the brand-name company had shown the requisite likelihood of success, he was "not convinced, however, that it ha[d] shown likelihood of irreparable harm from denial of a stay." *Teva*, 134 S. Ct. at 1621. If the brand-name company "prevail[ed] in this Court," it could "recover damages from [the generic defendants] for past patent infringement." *Id.* "Given the availability of that remedy, the extraordinary relief that [the brand-name company sought was] unwarranted." *Id.*

Applicants cite a number of Federal Circuit cases for the proposition that the launch of a generic product categorically "results" in irreparable harm, Appl. 14-15. But even the Federal Circuit applies no such absolute rule (nor would that rule govern in this Court, as the *Teva* stay denials show). Several of the cited cases predate this Court's rejection of automatic injunctive relief in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006). And the others simply affirm injunctive relief, on abuse-of-discretion review, based on lower-court findings about the particular market. *See, e.g.*, *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1011 (Fed. Cir. 2009) (decisions affirming the grant of injunctive relief merely "highlight[] [the Federal Circuit's] deference to a district court's determination whether a movant has sufficiently shown irreparable harm"). Here, of course, there is no lower-court finding of irreparable injury; to the contrary, the Federal Circuit quickly rejected applicants' request for a stay. Appl. App. C. That

disposition is consistent with numerous other cases in which the Federal Circuit has declined to enjoin the launch of a generic product pending appeal, or to disturb the district court's denial of a preliminary injunction, despite claims by the brand company asserting the same kinds of harms that appellants advance here. *See, e.g.*, *id.*; *accord Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568, 1578-79 (Fed. Cir. 1996).

That is because the harm from a generic launch, particularly a temporary one, often is not "difficult to quantify" (Appl. 15) at all. Indeed, even applicants' declarant estimates the loss of sales attributable to generic entry. Appl. App. E, at 4, 14. And in fact, as Dr. Blackburn explains in the attached declaration, applicants' potential lost sales would be "readily quantifiable" if applicants prevailed on the merits; by the time a damages calculation would have to be made, "there would no longer be any uncertainty about the breadth of such damages," including from Watson products already in distribution at the time applicants prevailed in getting Watson ordered off the market. Blackburn Decl, *infra*, ¶¶ 10-11.

In fact, in two cases applicants' declarant cites, Appl. App. E, at 15, the parties litigated damages after a launch at risk, and reached substantial settlements. Blackburn Decl., *infra*, ¶ 19 n.23. In this case the market is much smaller and thus much easier to quantify. *See* Appl. App. E, at 9 (claiming combined annual sales of about $90 million). And applicants have raised no question about Watson's ability to satisfy any damages judgment; any such

argument would be meritless. *See* Blackburn Decl., *infra*, ¶¶ 6, 24. By contrast, in the *Teva* litigation, the brand-name drug product generated "nearly $3 *billion* in annual sales." 13A1003 Stay Appl. 16 (emphasis added). Despite the greater difficulties with reducing damages to a money judgment and with getting such a judgment paid, the Circuit Justice denied relief.

The applicants' suggestion that Congress has endorsed injunctive relief as a "mandatory remedy" in this context (Appl. 17)—and that irreparable injury should be presumed as a result—is similarly mistaken, and it is flatly inconsistent with the Circuit Justice's decision in *Teva*. Contrary to the applicants' assertion (*id.*), Watson was *not* enjoined under 35 U.S.C. § 271(e)(4)(D)—a new provision adopted as part of the Patient Protection and Affordable Care Act that applies specifically to patents for biologics. *See* Pub. L. No. 111-48, 124 Stat. 119, 816 (2010). Rather, the district court enjoined Watson pursuant to section 271(e)(4)(*B*). *See Merck & Cie v. Watson Labs., Inc.*, Nos. 13-cv-978, 13-cv-1272, ECF No. 117, ¶ 4 (D. Del.). That provision uses permissive rather than mandatory language, providing that "injunctive relief *may* be granted" against an infringer, 35 U.S.C. § 271(e)(4)(B) (emphasis added). Courts applying section 271(e)(4)(B) have recognized that the standard *eBay* framework applies, under which irreparable injury is not presumed and the ability to recover damages will defeat a claim for injunctive relief. *See, e.g.*, *Janssen Prods. L.P. v. Lupin Ltd.*, 109 F. Supp. 3d 650, 695-96 (D. N.J. 2014); *see also* Appl. 17 n.4 (conceding that *eBay*'s framework applies "when the lower courts are given discretion by the Patent Act" over whether to issue an injunction). That is

precisely the conclusion that the Circuit Justice reached in *Teva*, and the same reasoning should control here. *See also* p. 27, *infra* (discussing, for purposes of public interest analysis, statutory provision confirming that a patent held invalid on appeal is no longer a block to approval and launch of a generic drug).

B. Applicants claim other harms if a generic enters, but those harms would dissipate once the generic exits.

Applicants and their declarant spend considerable space arguing that, once a generic enters, it will quickly gain market share. That does not establish an *irreparable* injury. If applicants prevailed on the merits, they could seek a permanent injunction that would remove Watson's generic product from the market until the patent expires years from now. Applicants do not give any reason why they could not regain their current market share and favorable treatment by insurance companies if all generics exited the market. And applicants could seek money damages for the interim period.

As Dr. Blackburn explains, experience shows that when generics enter but later exit, brand-name pharmaceuticals are able to return to their pre-generic sales and growth figures. Blackburn Decl., *infra*, ¶¶ 18-20. Similarly, any change in how insurance formularies treat applicants' drugs would be reversible if there were no longer any generics on the market.

Notably, applicants do not claim any injury that could not be reversed if generics left the market. Applicants do not even try to argue that generic entry would cause it to permanently cut employees or take some other irrevocable step, because applicants have *already* voluntarily taken steps to prepare for generic

entry. For example, beginning "in 2015," applicants "material[ly]" "curtailed . . . marketing and promotional efforts as a result of this ongoing action." Appl. Ex. E, at 9.

C. Applicants' claim of lasting harm is entirely self-inflicted: the only reason generics would remain on the market is that applicants have voluntarily signed a contract to sell their own product as a generic, permanently.

The real basis of applicants' claim of irreversible injury is a decision *applicants themselves have made*: to have their own product sold at generic prices, without any ability to withdraw that "authorized generic" from the market. Applicants represent that they have signed a contract allowing another generic company, not a party here, to launch an "authorized generic" product.[2] Applicants will supply their product to that company, which will then sell it at generic prices. Applicants and "AG Pharma" will split the profits. And the contract supposedly is irreversible: applicants say that even if Watson leaves the market, applicants' generic partner would stay on the market indefinitely. If the market would remain genericized, it would be genericized *by applicants*.

That self-inflicted wound does not justify relief from this Court. *Cf. Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1152 (2013). Nothing compelled applicants to enter into an authorized-generic arrangement, much less to do so without the ability to withdraw. Other pharmaceutical companies have entered into authorized-generic arrangements without allowing a business partner to salt the

[2] Despite Watson's request, applicants failed to produce this agreement. Even applicants' declarant apparently has not seen it. Applicants insist that Watson, and this Court, simply must accept applicants' own characterizations of a document crucial to their irreparable-harm theory. There is no reason why the document could not have been produced pursuant to a suitable protective order.

earth permanently, by leaving open (and exercising) the ability to withdraw the authorized generic at a later date. Blackburn Decl., *infra*, ¶¶ 22-23. If applicants are right that the market will irreversibly settle at generic prices, even if applicants ultimately win the ordinary patent-law remedies against Watson, it is *only* because applicants have irrevocably committed to having their own product sold by a partner at those generic prices rather than enter a more traditional authorized-generic arrangement. Applicants made a business decision to try and make money in the generic market using an unnecessary and atypical approach to selling an authorized generic; they should not expect this Court to relieve them of the consequences of their decision or bless a strategy that would allow Hatch-Waxman plaintiffs to bootstrap their way to irreparable injury through their own contractual choices.

II. There is no reasonable likelihood that the Court will grant certiorari and no fair prospect of reversal on the merits.

Applicants attempt to conflate the chances of certiorari and the chances of reversal. But those are distinct inquiries for good reason. Even if the Federal Circuit had erred here—and as discussed below, it did not—the proper question on certiorari is whether this Court should exercise its discretion to decide that question *in this case*. For a variety of reasons, it should not. And even if it did grant certiorari, applicants' case for reversal misreads this Court's decisions.

A. This Court is unlikely to grant applicants' petition to decide a question that the court of appeals did not answer and that applicants failed to preserve below.

This Court "do[es] not decide in the first instance issues not decided below,"

especially when those issues were not even *argued* below. *NCAA v. Smith*, 525 U.S. 459, 470 (1999); *see, e.g.*, *United States v. United Foods, Inc.*, 533 U.S. 405, 417 (2001); *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 237 (1990); *Lebron v. Nat'l Railroad Passenger Corp.*, 513 U.S. 374, 379 (1995). Yet that is precisely what applicants will ask the Court to do here. Neither the district court nor the Federal Circuit passed upon, or even alluded to, the sole question on which applicants' contemplated petition for writ of certiorari centers—whether only sales or offers for sale *to the public* can invalidate a patent under the pre-Leahy-Smith America Invents Act on-sale bar of 35 U.S.C. § 102(b), such that an inventor can defeat the on-sale bar by the mere expedient of using a confidentiality agreement. Applicants did not even advance this argument until their petition for rehearing to the Federal Circuit, long after it was permissible to do so.

The Federal Circuit and the district court's opinions here show that neither court addressed the issue applicants now plan to raise on certiorari. The Federal Circuit's opinion spoke to whether Merck's fax was in fact an offer for sale, and whether that offer was required to (and alternatively did) comply with a signed writing provision within the parties' CDA. Appl. App. B, at 7–14. The district court likewise addressed only whether the fax qualified as an offer for sale, as well as other invalidity defenses that are indisputably irrelevant here. *Merck & Cie v. Watson Labs., Inc.*, 125 F. Supp. 3d 503, 508-10 (D. Del. 2015). Neither court asked or decided whether the fax was an offer for *public* sale.

The reason the lower courts never addressed that issue, of course, is that

applicants did not raise it. Applicants did not argue at the district court that any offer or sale between Merck and Weider was not available to the public and therefore not invalidating. *See Merck & Cie v. Watson Labs., Inc.*, Nos. 13-cv-978, 13-cv-1272, ECF No. 100 (D. Del.). The same goes for applicants' briefing and oral argument on appeal at the Federal Circuit.

Merck first mentioned (but did not adopt) in a post-oral argument letter to the Federal Circuit the argument that a sale must be available to the public under Section 102(b), by referencing the *amicus* brief of the United States in a different pending case, *Medicines Company*. *Merck & Cie v. Watson Labs., Inc.*, Nos. 2015-2063, -2064, Dkt. No. 50 (Fed. Cir.). But it is well-established that Merck could not have raised its new argument through that letter, even if it had tried. "Rule 28(j) . . . permits a party to bring supplemental authorities to the court's attention, not supplemental argument." *Desper Prods., Inc. v. Qsound Labs., Inc.*, 157 F.3d 1325, 1335 (Fed. Cir. 1998); *Hall v. Shinseki*, 717 F.3d 1369, 1373 n.4 (Fed. Cir. 2013) ("Of course, if the letter presented new argument, it would be improper.").

Nor could Merck's petition for rehearing, which for the first time purported to adopt the United States *amicus* brief's argument in the *Medicines Company* case, properly inject such a new issue into this litigation. A rehearing petition is too late to preserve an argument not previously pressed or passed upon. *See Adams v. Robertson*, 520 U.S. 83, 89 n.3 (1997).

B. Applicants have failed to show that the question presented warrants review.

Although applicants now seek to frame this case as one about confidential relationships between inventors and their suppliers, in order to make the question appear more certworthy, *see, e.g.*, Appl. 2, the facts of this case do not fit that theory. Nor do applicants show that the supposed "supplier question" calls for this Court's immediate review in any event.

1. The Federal Circuit was correct to be skeptical of the claim of confidentiality. Appl. App. B, at 13. This was not a secret sale. By the time of the sale, Merck and Weider had already terminated their plans to market as a joint venture. And the Merck-Weider Agreement did not restrain Weider from doing what it plainly planned to do: sell the product commercially. The 2 kg that Weider agreed to buy would make 62.5 million doses. Merck was fully aware and in agreement that Weider intended to use some of the 62.5 million doses in dietary supplement products that Weider would sell to the public. As Merck confirmed in a December 16, 1998 memorandum, "Weider will initially try and launch L-5MTHF as a standalone product." C.A. App. 1387.

Other evidence of the public nature of the offered sale is not part of the record in the district court or on appeal to the Federal Circuit. This is because applicants never raised the "secret sale" argument below, when Watson could make a full record on the issue. That heightens the unfairness of raising that argument for the first time at this Court.[3]

[3] Applicants contend that Watson has conceded the point, but that is not correct; Watson agreed that

2. Nor should this Court take this case to resolve the more general question of how the on-sale bar applies to relationships with suppliers and contract manufacturers. *See* Appl. 2 (attempting to invoke the plight of small inventors who need "the assistance of other firms" without triggering the on-sale bar). The Federal Circuit considered the supplier question *en banc* in a different, subsequent case, *Medicines Company.* In that decision, the Federal Circuit unanimously narrowed the scope of the on-sale bar so that the supplier relationship in that case did not fall within it. "[T]he confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature," the court held. *Medicines Co.*, slip op. 24. Applicants have now come, belatedly, to the view that confidentiality must be dispositive, because that broad rule is necessary to rescue *their* particular patent. But applicants fail to show why the *en banc* decision in *Medicines Company* does not adequately deal with the policy considerations they invoke.

This case involves an entirely different scenario in any event. In *Medicines Company*, the patentee contracted with a supplier to make the patented invention for it, on a confidential basis; the patentee retained title at all times. Here, by contrast, *Merck* made the invention itself, and then sold it to Weider so that Weider could commercialize it—*i.e.*, sell it to the public. Merck did not agree to *buy*

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the Merck-Weider Agreement was *in force* at the relevant time, but that says nothing about whether it *covers* the transaction at issue. C.A. App. 1318 at 794:10-16. Nor is there any merit to applicants' argument that the district court found as a matter of fact that the agreement covered the sale of MTHF; the trial court made eleven enumerated findings of fact, 125 F. Supp. 3d at 508, and applicants' desired finding was not among them. The scope of the contract is a question of law in any event. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015).

manufacturing services, as in *Medicines Company*; it agreed to *sell* the patented invention itself.

At a minimum, applicants' forecast of "severe" "consequences" from the Federal Circuit's decision in *Medicines Company* (Appl. 2) is premature. The issue should be allowed to percolate for more than two weeks—the *Medicines Company* decision issued only July 11—before this Court deems it certworthy.

3. In addition, this case involves the *pre-2011* version of the statute. Congress has since amended the statute in various material ways; indeed, applicants rely heavily on the statutory amendment, Appl. 12-13, apparently on the belief that the amendment is probative of what a prior Congress meant. But when the meaning of a statute is not clear, an amendment can settle the meaning *going forward*, but it does not ordinarily show what the statute *has always meant*. *See, e.g.*, *Graham County Soil, Water & Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280 (2010) (Congress amended statute to settle circuit split; this Court nonetheless construed the pre-amendment statute to mean the opposite of what the amended statute means). And here, Congress did not just clarify Section 102(b); it materially changed the provision's scope, *e.g.*, by allowing foreign sales to invalidate a patent. All the amendment definitively shows is that the question of how to interpret the *pre*-amendment statute is of declining significance.

4. At bottom, applicants' argument for certiorari rests on the view that the Federal Circuit—in *Medicines Company*, not actually in this case—has misinterpreted the on-sale bar. But even if that were right, not every decision by

the Federal Circuit warrants certiorari review. And as discussed below, applicants are simply wrong in their argument that the rule in the Federal Circuit now conflicts with decisions of this Court.

C. Applicants have failed to show a fair probability of reversal.

Applicants do not dispute that an invention is "on sale" if it is offered for sale; a completed sale is not required. Appl. App. B, at 9. Nor do applicants dispute that a *single* offer to sell can be enough. Rather, applicants' central argument on the merits is that even though the pre-2011 version of Section 102(b) makes no mention of the patented invention being on *public* sale, this Court has construed the statute that way and the Federal Circuit has been ignoring this Court's holdings. That argument lacks merit.

1. The plain language of pre-2011 Section 102(b) uses the word "public" in describing *another* way a patent may be invalid, but *not* in the on-sale bar. A person cannot obtain a patent if:

> the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. §102(b) (2006). Thus, the statute requires an invalidating "use" to be "public," but does not require invalidating "on sale" activity to be "public." The Fifth Circuit long ago characterized as "unrealistic" an attempt "to construe the statute so that 'public' in the phrase 'in public use or on sale' modifies not only 'use' but also 'sale.'" *Hobbs v. United States*, 451 F.2d 849, 860 (5th Cir. 1971).

2. This Court has never rejected that plain reading of the statute, and it certainly has never affirmatively held that invalidating sales or offers must be

public. None of the snippets applicants cite establishes that invalidating sales or offers must be "public," or that confidential sales are not really sales.

This Court unanimously held in *Pfaff v. Wells Electronics*, 525 U.S. 55 (1998), that the on-sale bar requires that "the product must be the subject of a *commercial* offer for sale." *Id.* at 67 (emphasis added). The Court did not hold that commercial equals public, nor could it have on the facts of the case.

Pfaff came to the Court as a case about whether an invention could be "on sale" if the inventor was taking orders for it, but had not yet physically produced the invention. *See id.* at 57 ("We granted certiorari to determine whether the commercial marketing of a newly invented product may mark the beginning of the 1-year period even though the invention has not yet been reduced to practice."). There was no dispute in *Pfaff* about whether commercial marketing had *occurred*; the inventor had accepted a purchase order, "and there [wa]s no question that the sale was commercial rather than experimental in character." *Id.* at 67.

The Court identified two conditions to satisfy the on-sale bar. The first, not controverted, was that "the product must be the subject of a commercial offer for sale." *Id.* The second condition, responsive to the question presented in *Pfaff*, was that the product must also be "ready for patenting," even if not yet reduced to practice. *Id.* Nowhere in these two conditions, or anywhere in its unanimous decision, did the Court even imply that an offer for sale must be "public" to be invalidating. Thus, under *Pfaff*, the touchstone is whether an offer or sale was commercial, not whether it was "public" or "confidential."

Indeed, it is far from clear that *Pfaff* involved a "public" sale in any meaningful sense. Texas Instruments asked Pfaff to develop a new type of socket, and he did so; the relevant sale occurred when he showed a sketch of his idea to Texas Instruments and they agreed to order the sockets once they were made. *Id.* at 58. There is no indication whatsoever that Pfaff made his invention available to the general public at that time.

The two 19th-century cases that applicants cite likewise do not conflict with the decision below, or with the Federal Circuit's interpretation of the on-sale bar. The first, *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829), did not interpret the on-sale bar, which did not yet exist. Rather, the statute in *Pennock* prohibited patenting if an invention was "known or used before the application." *Id.* at 17. Applicants contend (at 11) that the on-sale bar enacted several years later codifies *Pennock*'s reference to "public use, or [being] publicly sold for use," but Congress, unlike *Pennock*, did not repeat the word "public." And in *Pennock*, the Court used "public" use to mean lawful use by people other than the inventor or his assistants. *See id.* at 18-19. Use outside the inventor's immediate circle (other than by a thief) would be invalidating. The Court did not suggest that a private, confidential sale of the invention to someone else would not result in "use[]."

The second 19th-century case, *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1878), is also of no help to applicants. In *Elizabeth*, this Court broadly articulated the on-sale bar, without limiting it to "public" sales or offers: "Any attempt to use [the invention] for a profit, and not by way of

experiment, for a longer period than two years before the application, would deprive the inventor of his right to a patent." *Id.* at 137; *accord Pfaff*, 525 U.S. at 65 (same). *Elizabeth* went on to establish the "experimental use" exception: the invention in that case plainly was not on sale, but it was being tested in a public roadway, so the defendant asserted that it was in "public use." The Court disagreed, because the inventor had kept control of it during the experiment. 97 U.S. at 135-36. The Court repeatedly used the inventor's control as the touchstone: the inventor "did not sell it, nor allow others to use it or sell it. He did not let it go beyond his control." *Id.* at 136. Of course, a private sale would have put the invention beyond the inventor's control, and the Court did not suggest otherwise. To the contrary, it stated that "[a]ny attempt to use [the invention] *for a profit*, and not by way of experiment, for a longer period than two years [now one year] before the application, would deprive the inventor of his right to a patent." *Id.* at 137; *accord Pfaff*, 525 U.S. at 66 (same).

Thus, applicants' case for certiorari *and* their case for reversal both founder on the fact that this Court has never laid down the type of "public sale" interpretation that applicants need to prevail.

3. Even if this Court were to grant certiorari in the absence of any conflict with its own decisions, applicants' rule would run contrary to the purpose of the on-sale bar, and there is no fair prospect that the Court would adopt it. Applicants contend that inventors should be able not just to *offer* their invention, but to *sell* their invention, for as long as they like before patenting, so long as all the sales are secret. Applicants suggest that shielding confidential offers and sales is

appropriate because Section 102(b) is solely aimed at preventing inventors from removing existing knowledge from public use. Appl. 14.

But that is not the only policy objective of the on-sale bar: rather, the statute prevents inventors from preserving a monopoly "for a longer period than allowed by the policy of the law." *Elizabeth*, 97 U.S. at 136-37. An inventor can fine-tune as long as he likes, but once the invention is ready for patenting, he cannot start using his invention "for a profit" outside the one-year grace period. *Id.* at 137. Allowing inventors to circumvent the on-sale bar with non-disclosure agreements would remove the statutory incentive to seek a patent; many inventors could easily have their cake and eat it too, first selling their invention for private use for as long as possible and later obtaining a full period of patent monopoly.

4. The amicus brief for the United States in *Medicines Company* does not suggest otherwise. The government brief does not contend "that [an] offer must be broadcast to the public at large." U.S. Br. at 13, *Medicines Co.*, No. 14-1469 (Fed. Cir. filed Mar. 2, 2016). The government acknowledges that the single sale in *Pfaff* rules out any such reading. Rather, the government's approach asks whether a particular sale makes (or offer would make) the invention "available to interested members of the public." And on that question, the government endorses a multi-factor test drawn from this Court's decisions, *see id.* at 14-15 ("The Supreme Court has identified several factors as relevant to determining whether a use makes the invention publicly available . . . .")—far from the bright line that applicants say this Court has demanded, *see* Appl. 2, 14. As explained above, Merck's sale to Weider so

that Weider could commercialize the product was far from the type of confidential outsourcing of manufacturing at issue in *Medicines Company*. Even if the government's amicus brief were the law, applicants cannot even claim they would win under it.

III. Allowing applicants' invalid patent to continue blocking access to affordable generic medicine would not serve the public interest.

A patent that has been finally held invalid by the Federal Circuit can no longer block the FDA from approving a generic version of a brand-name drug. *See* 21 U.S.C. § 355(j)(5)(B)(iii)(II)(aa)(AA) (FDA approval shall be made effective on "the date on which the court of appeals decides that the patent [protecting the brand-name drug] is invalid or not infringed"). That statute reflects Congress's judgment that, once the court of appeals has ruled, the public interest lies with allowing generic drugs access to the marketplace.[4] And it is consistent with the overall purpose of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetics Act: "to speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). In the unlikely event that this Court grants certiorari and reverses, the brand-name company can still obtain its patent-law remedies. But consumers need not wait many months to see whether that will happen; delay is no longer in the public interest.

[4] Confirming that statutory inference, Congress has provided that when a generic manufacturer has been awarded a period of marketing exclusivity for successfully challenging a pharmaceutical patent, it *must* begin marketing the generic equivalent within 75 days after a final Federal Circuit decision, or else forfeit its exclusivity. The statute specifies that the 75-day period begins running when no more appeals can be taken in the patent case, "other than a petition to the Supreme Court for a writ of certiorari." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

Against those important considerations, applicants offer only the view that the public interest lies, *per se*, with protecting patent rights and encouraging investment in patented pharmaceutical inventions. But the Hatch-Waxman Act more than adequately protects those considerations by keeping generic drugs off the market while a patent case is litigated—*but only until the patent is found invalid*, as the statutory provisions cited above demonstrate. The cases applicants cite, by contrast, pertain to "valid pharmaceutical patents," Appl. 20 (citation omitted), and nothing in any of those cases suggests that an invalid patent should continue to block generic approval while the brand-name company seeks discretionary review in this Court. The assertion that stays of a mandate invalidating a pharmaceutical patent are necessarily in the public interest ignores that such a stay is an "extraordinary" remedy, not a routine one.

Furthermore, applicants ignore the harm to Watson from continued delay—harm that truly would be irreparable. If a stay is denied but applicants eventually prevail in this Court, they can seek their patent-law remedies for infringement. But if a stay is granted but *Watson* then prevails (on certiorari or on the merits), Watson will *never* be able to recoup the money it would have made while its entry into the market was wrongly delayed.

Even if this were one of those "close cases" in which this Court weighs the competing equities, *Hollingsworth*, 558 U.S. at 190, Watson's interests and the public interest plainly outweigh applicants'.

* * * * *

The question presented is not properly presented. The alleged irreparable injury is not irreparable. The supposed conflict with the decisions of this Court is illusory. And the continued use of an invalidated patent to block access to generic drugs is inequitable and contrary to the public interest. In short, applicants have met *none* of the requirements for a stay.

CONCLUSION

The application for a stay should be denied, and the temporary stay entered July 21, 2016, should be dissolved forthwith.

Respectfully submitted.

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July 26, 2016

No. 16A74

IN THE SUPREME COURT OF THE UNITED STATES

MERCK & CIE, ET AL.,

Applicants,

v.

WATSON LABORATORIES, INC.,

Respondent.

On Application for Stay

CERTIFICATE OF SERVICE

I am a member of the Bar of this Court, and I hereby certify pursuant to Supreme Court Rules 22.2, 29.3, and 29.5 that I have, this 26th day of July, 2016, served one copy of Respondent's Opposition to Application to Stay Mandate with first-class postage prepaid addressed to counsel of record for applicants at the address listed below:

Jonathan F. Cohn, Esq.
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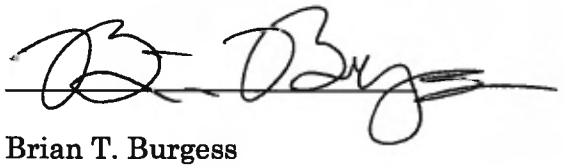
In addition, pursuant to Supreme Court Rule 29.3, I have caused an electronic version of the application to be served on counsel of record at the email addresses listed above.

I further certify that all persons required to be served have been served.



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July 26, 2016

APPENDIX 1

DECLARATION OF DAVID BLACKBURN

I, David Blackburn, declare as follows:

I. Qualifications

1. I am an applied microeconomist and Vice President for NERA Economic Consulting ("NERA"), an economic consulting firm based in White Plains, New York. I am based in NERA's Washington, D.C. office. I earned a B.Sc. in Applied Mathematics and Economics from Brown University and a M.A. and Ph.D. in Economics from Harvard University. I have taught economics courses at the graduate and undergraduate level at several institutions. I have written and spoken publicly on a number of economic issues, including intellectual property issues. At NERA, my practice has focused on the economics of intellectual property, antitrust economics, and calculating economic damages in commercial disputes; a substantial portion of my economic research has involved the pharmaceutical industry – and, in particular, oral contraceptives – including issues related to the entry or potential entry of generic competition. I have used economic models to calculate lost profits and reasonable royalty damages in patent infringement cases in many industries, including the pharmaceutical industry, and have analyzed and evaluated damages claims by other economic experts in patent infringement cases on numerous occasions. My CV, including my past testimony, is attached as **Attachment 1**.

II. Overview

2. I was asked by counsel for Watson Laboratories, Inc. ("Watson") to determine if the types of economic injury that Plaintiffs Merck & Cie, Bayer Pharma AG, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") might suffer would be irreparable: (a) if Watson were to launch generic versions of Bayer's formulations of drospirenone, ethinyl estradiol, and levomefolate calcium, sold as Beyaz® ("Beyaz") and Safyral® ("Safyral"), in tablets of various dosage

strengths;[1] and (b) if, subsequent to that launch, U.S. Patent No. 6,441,168 ("the '168 patent" or "the patent-at-issue") was found to be valid and infringed by Watson's generic versions.[2] I was also asked to evaluate and comment on the opinions expressed by Christopher Vellturo, Bayer's expert, and determine if, as an economic matter, the economic injury to Bayer arising from this assumed infringement would be irreparable.[3] Finally, I was asked to evaluate whether or not the granting of a stay would, as an economic matter, be in the public interest.

3. This declaration is based on my experience and professional training as an economist and on my review and analysis (or that of NERA staff working under my direction and supervision) of information from a variety of sources ordinarily considered by economists undertaking this type of analysis. These include documents produced by the parties in this matter as well as information from publicly available sources. [See **Attachment 2**.]

4. My research and analyses are continuing and, while I do not expect to change my methodology or general approach, I reserve the right to revise my conclusions to the extent I receive and consider additional information, or if additional research or reflection leads me to change my opinions. I also expect to respond, if asked, to any further opinions that may be provided by Bayer or its experts.

5. Dr. Vellturo alleges that Bayer will be irreparably harmed following entry of generic drospirenone, ethinyl estradiol, and levomefolate calcium products as a result of loss of revenue and market share, price erosion, and loss of formulary

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[1] I understand that Beyaz and Safyral are registered trademarks. For simplicity, I refer to Beyaz and Safyral, and any other branded drug, without using the trademark symbol.

[2] NERA was retained by counsel according to our ordinary retention terms. That is, NERA bills on an hourly basis, with out-of-pocket expenses billed separately at cost. Charges are based on time actually spent. My hourly billing rate is $550.

[3] Declaration of Christopher Vellturo, Ph.D. In Support of the Motion of Plaintiffs-Appellees To Stay the Mandate, July 18, 2016 ("Vellturo Declaration").

position. However, as I describe in more detail below, these potential harms are all measurable, and can be quantified to a reasonable degree of certainty at the time of trial in this matter.

6. More specifically, based on my research to date, it is my opinion that:

- An at-risk launch of generic drospirenone, ethinyl estradiol, and levomefolate calcium products by Watson may cause a decline in sales and profits for Bayer's Beyaz and Safyral products, as is generally the case when a market experiences generic entrants.

- However, Bayer will not suffer irreparable harm if the court ultimately finds that any claims of the '168 patent are valid and infringed by Watson's generic drospirenone, ethinyl estradiol, and levomefolate calcium products. Bayer will be able to be fully compensated for its potential economic injury, if any, with monetary damages at the time a verdict is reached at trial. Such economic harm is quantifiable – indeed, economists such as Dr. Vellturo and myself often calculate economic damages in patent infringement matters – and can be calculated to a reasonable degree of certainty using data that will be readily available at the time of trial.

- There is no reason to believe that Bayer would continue to be harmed following the removal of generics from the marketplace and before the expiration of the '168 patent.[4] History has proven that pharmaceutical products are able to regain their past prescriptions and sales revenues after at-risk launches that later were withdrawn.

[4] I understand that the '168 patent will expire in 2022. [FDA Orange Book: Approved Drugs with Therapeutic Equivalence Evaluations, available at http://www.accessdata.fda.gov/scripts/cder/ob/docs/newobpat.cfm, accessed July 20, 2016.]

- Any further harm Bayer may suffer resulting from contracting with another pharmaceutical company to produce and distribute authorized generic versions of Beyaz and Safyral following generic entry will be self-inflicted. While it may turn out that authorized generics will continue to compete with Beyaz and Safyral even if Watson's generic formulations are removed from the marketplace, this is a result of Bayer's agreement with this manufacturer. While I have not seen the agreement – nor, apparently, has Dr. Vellturo – the potential entry of Watson's generic products does not itself cause future competition from an authorized generic and many branded drug manufacturers do not enter into such agreements that would "poison" the well following an at-risk launch.

- Beyaz and Safyral generate annual sales (and therefore, presumably, profits) that are minor relative to the size and scope of both Bayer and Allergan plc. Thus, there is no reason to worry either that Bayer would be unable to function normally up until a resolution of this matter or that Allergan plc would not be able to pay any damages that might ultimately result from the at-risk launch.

- Finally, granting a stay and preventing Watson's release of generic drospirenone, ethinyl estradiol, and levomefolate calcium products would not serve the public interest. Any harm possibly suffered by Bayer by not granting a stay would be fully compensable at a later date, but the harm suffered by consumers who would be denied access to cheaper generic drospirenone, ethinyl estradiol, and levomefolate calcium products would never be remedied, if a stay were granted.

7. I understand that, as a legal matter, if Watson's generic drospirenone, ethinyl estradiol, and levomefolate calcium products were allowed to enter the market and were subsequently found to infringe the '168 patent, Bayer may be

entitled to receive lost profits[5] and would, at a minimum, be entitled to no less than a reasonable royalty.[6]

8. In my opinion, there are well-known and generally-accepted approaches that could be used to determine, to a reasonable degree of certainty, Bayer's injury, if any, assuming Watson is permitted to sell generic drospirenone, ethinyl estradiol, and levomefolate calcium products and a court were to later determine that the '168 patent was valid and infringed by Watson's products. Indeed, in my experience with pharmaceutical-related patent disputes, there is readily-available information to conduct such analyses, including data and documents produced by the parties in the course of litigation (*e.g.*, IMS data,[7] company financials, planning documents, and the like) – several of which are the same types of documents referenced and relied upon in the Vellturo Declaration.

9. As I discuss in more detail below, Dr. Vellturo describes a number of forms of economic injury that he believes that Bayer may suffer from the launch of generic versions of Beyaz and Safyral. Dr. Vellturo's two primary arguments for why his identified forms of economic injury would be *irreparable* appear to be: (a) Bayer will suffer substantial losses as soon as Watson launches generic versions of

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5 See, *e.g.*, *Panduit Corp. v. Stahlin Bros. Fiber Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978).

6 See, *e.g.*, 35 U.S.C. §284.

7 IMS Health is a well-regarded information and technology provider to the healthcare and related industries. In my experience, the data collected by IMS Health is considered the industry standard of national prescription activity for pharmaceutical products in the U.S. [See, *e.g.*, IMS Health: Our Company, available at http://www.imshealth.com/en/about-us/our-company, accessed July 20, 2016; HSRN DataBrief: National Prescription Audit, IMS Institute for Healthcare Informatics, available at https://www.imshealth.com/files/web/IMSH%20Institute/NPA_Data_Brief-.pdf, accessed July 20, 2016.]

Indeed, in my experience, the majority of pharmaceutical companies rely on IMS data for planning purposes with regards to their pharmaceutical offerings in order to determine, *e.g.*, their products' positions in their respective markets relative to their competitors' products, their gains and losses in market share, and for planning purposes related to entry and other changes in market conditions. Moreover, economists such as myself and Dr. Vellturo have relied on IMS data in our own analyses of, *e.g.*, monetary damages in pharmaceutical-related patent disputes. Indeed, Dr. Vellturo has relied on IMS data in his declaration. [See, *e.g.*, Vellturo Declaration, ¶ 22.]

Beyaz and Safyral; and (b) once the market responds to Watson's launch, Bayer will incur future damages because the market will be permanently changed and Bayer will be unable to return to its previous competitive behavior.[8]

10. However, at the time that damages would likely be determined in this case, determining the extent of these losses would be well within the realm of damages experts for both parties, and Dr. Vellturo admits as much:

> While a portion of the harm generated by Watson's generics may be reasonably quantified and assessed as compensation to Bayer should circumstances warrant, the breadth and longevity of this harm (harm that will extend long after Watson's product may be withdrawn) leaves substantial portions that cannot be reasonably quantified (in particular those that extend well into the future).[9]

Indeed, at the time that damages would need to be determined, there would no longer be any uncertainty about the breadth of such damages. Sufficient information would be available from the parties and third-parties such as financial and IMS data to address these questions.

11. As for possible future, post-verdict harm, in my opinion (and as I describe in further detail below) damages resulting from Watson's launch of generic versions of Beyaz and Safyral are unlikely to continue should Watson be required to exit the market. I disagree with Dr. Vellturo's opinion to the contrary. The research I have done indicates that – if the court ultimately rules in its favor – the impact of Watson's launch of its generic versions (including sales of Watson products remaining in distribution channels) would be readily identifiable and, therefore, not irreparable.

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[8] See, *e.g.*, Vellturo Declaration, ¶ 7.

[9] Vellturo Declaration, ¶ 7

III. Summary of the Vellturo Declaration

12. Dr. Vellturo opines that Watson's sales and promotion of generic drospirenone, ethinyl estradiol, and levomefolate calcium products will result in the following economic outcomes:

- Watson's launch "would cause Bayer to lose 80% and quite possibly more than 90%" of sales of Beyaz and Safyral "that it would otherwise have made," and that Bayer would lose 60 percent of sales within 90 days, and 80 percent of sales within six months of Watson's launch;[10]

- Watson's extended shelf-life for its generic products would result in generic products "shipped by Watson before an ultimate resolution of this matter's decision [that] could take significant sales" from Beyaz and Safyral "for a considerable period of time";[11]

- The presence of authorized generic versions of Beyaz and Safyral triggered by the launch of Watson's generic products will prohibit "Bayer's ability to earn any meaningful profit" from its sales of Beyaz and Safyral, and that "these profits cannot be restored at any time in the future";[12]

In the next section, I analyze these claims and explain why, in my opinion, the types of potential economic injury Bayer may suffer due to the introduction of generic versions of Beyaz and Safyral will not be irreparable.

[10] Vellturo Declaration, ¶ 21.

[11] Vellturo Declaration, ¶ 23.

[12] Vellturo Declaration, ¶ 26.

IV. Analysis of Potential Economic Harm

A. The Types and Amounts of Economic Injury Bayer May Suffer are Quantifiable

13. Dr. Vellturo states that "the damages sustained by Bayer would be substantial" while Watson's generic products are sold, and that Watson's launch will "cause Bayer to rapidly lose 80% or mode of the sales" of Beyaz and Safyral.[13] He also states that Watson's generic launch will alter the formulary positions of Beyaz and Safyral.[14]

14. I do not disagree with the proposition that generic entry typically results in a significant loss of sales revenue by the corresponding branded drug. Indeed, Dr. Vellturo cites to specific examples of such losses to sales and, as well, to academic literature that has quantified the size of such losses.[15] The extent to which such loss of revenue and corresponding profits would be attributable to Watson would be calculable within a reasonable degree of certainty, however, as Dr. Vellturo himself seems to understand.[16]

15. While I agree that Bayer is likely to lose sales of Beyaz and Safyral were Watson to launch generic drospirenone, ethinyl estradiol, and levomefolate calcium, those sales will be readily quantifiable to a reasonable degree of certainty through the use of readily-available information (*e.g.*, IMS data, company financials, planning documents, and the like) at the time of trial. Additionally, I note that in many of these aforementioned academic studies Dr. Vellturo cites, the authors are able to determine the amount of loss to generic entrants in order to complete their

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[13] Vellturo Declaration, ¶ 7.

[14] Vellturo Declaration, ¶ 7.

[15] See, *e.g.*, Vellturo Declaration, ¶¶ 16-9, 22.

[16] Vellturo Declaration, ¶ 7.

studies, often using IMS data.[17] As a result, by using IMS data and financials from Bayer, these potential financial losses would be quantifiable.

16. Dr. Vellturo also states that Watson's generic drospirenone, ethinyl estradiol, and levomefolate calcium products will "flood the market" and that the extended shelf-life of Watson's products "could take significant sales from" Beyaz and Safyral "for a considerable period of time."[18] As I stated above, I understand the '168 patent will expire in 2022. Accordingly, should Watson's products be removed from the marketplace, it is unlikely that their already-shipped inventories will continue to be sold through the life of the patent-at-issue. Furthermore, to the extent that Bayer would continue to suffer harm due to the sales of already-shipped generic products following Watson's exit from the market, as stated above, this harm would be readily-quantifiable to a reasonable degree of certainty at the date of a trial for Watson's alleged infringement of the '168 patent. Any product sold by Watson but not yet dispensed (and therefore not counted in IMS tallies of sales and prescriptions) would still be identifiable in Watson's own sales data. Thus, there is no reason to worry that lost sales to Watson's product still in distribution channels would not be readily compensable.

17. Similarly, Dr. Vellturo argues that Beyaz and Safyral would "likely be taken off formulary in many instances," or be demoted to lower tiers on many formularies, should Watson's generic enter the market, resulting in further harm to Bayer.[19] However, as Dr. Vellturo notes, Beyaz and Safyral are already on Tier 3 for most formularies, and thus would likely not be affected by the entry of generic competitors (which are moved to Tier 1 upon entry).[20] Furthermore, in my

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[17] See, *e.g.*, Vellturo Declaration, ¶ 16 and footnotes 8 and 9.

[18] Vellturo Declaration, ¶¶ 22-3.

[19] Vellturo Declaration, ¶ 7.

[20] See Vellturo Declaration, ¶ 7. See also, *e.g.*, Empire BlueCross BlueShield Prescription Program, available at https://www.empireblue.com/shared/noapplication/f3/s4/t3/pw_b128129.pdf?refer=ehpmember, accessed July 23, 2016; Excellus BlueCross BlueShield 3-Tier Formulary Guide, available at

experience and as I describe in more detail below, branded drugs typically recover to their sales levels prior to generic entry in instances where the generic competitors are removed from the market, in part due to the fact that they are restored to their formulary status pre-generic entry. These facts notwithstanding, as I have described above, to the extent Bayer may be harmed by formulary tier demotion due to Watson's generic entry, this harm will be able to be calculated with a reasonable degree of certainty in the form of economic damages at the time of trial.[21]

18. Dr. Vellturo also claims that "the marketplace will not revert to its pre-genericized state" even after generic competitors have exited the market.[22] However, a review of past at-risk launches that later were withdrawn demonstrates that Dr. Vellturo's doubt is unfounded.

19. I have identified six branded pharmaceutical products with corresponding generic versions that: (1) were launched at-risk; (2) were subsequently pulled from the market leading to a period of time in which generics were no longer available; and (3) had data available for a sufficient period of time to identify whether or not there was a lasting impact from that temporary generic

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https://www.excellusbcbs.com/wps/wcm/connect/1786b4d6-ab4e-4844-8b96-96b5a929952a/B_1354_Excellus_3tier_Formulary_%28WEB%29_5.1.16.pdf?MOD=AJPERES&CACHEID=1786b4d6-ab4e-4844-8b96-96b5a929952a, accessed July 23, 2016; COVA Care Prescription Drug List by Tier, available at https://www.anthem.com/provider/noapplication/f0/s0/t0/pw_e194654.pdf, accessed July 23, 2016.

In general, the following types of drugs may be found on the different tiers of most formularies: generic drugs reside on Tier 1, preferred brand-name drugs typically reside on Tier 2, and non-preferred brand name drugs typically reside on Tier 3. [See Glossary, Medicare.gov, available at https://www.medicare.gov/find-a-plan/staticpages/glossary/planfinder-glossary.aspx?TermID=0086&AspxAutoDetectCookieSupport=1, accessed July 25, 2016.] In addition, I understand that brand-name drugs are typically moved from Tier 2 to Tier 3 on most formularies once a generic version of the drug has entered the market.

[21] Dr. Vellturo also argues that Beyaz's and Safyral's formulary demotions would likely be irreversible even if Watson subsequently left the market due to the continued presence of an authorized generic on the marketplace. However, as I will describe in greater detail below, even if this were so, this is of Watson's own doing (*i.e.*, due to its own licensing program) and not due to Watson's at-risk launch.

[22] Vellturo Declaration, ¶ 27.

entry. As shown in **Attachment 3**, a review of the experiences of these six branded products demonstrates that, despite Dr. Vellturo's arguments about the potential for harm after the removal of generics from the marketplace, the prescription volume, and total dollar sales of the branded products were typically able to return to the pre-generic levels once the generic products left the market.[23] That is, in these situations, there appears to be little reason for concern that the temporary entry of a generic product would have a lasting impact on the market that would prevent the branded product from re-establishing the pre-generic market equilibrium.

20. Indeed, as is shown in in **Attachment 3**, each of the six branded pharmaceutical products returned to their pre-generic growth (or loss) trends in

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[23] These six branded drugs are: Amrix, Eloxatin, Ortho Tri-Cyclen Lo, Plavix, Pulmicort Respules, and Tarka.

Additionally, I note that Dr. Vellturo cites Plavix as an illustrative example of generics' ability to quickly capture sales and market share from their branded counterparts. [Vellturo Declaration, ¶ 22.] He does not note that – as with the other drugs – Plavix's sales and prescriptions rebound after the generic competitor withdrew from the market, even though the document he cited ("Plavix Weekly Prescription Data – IMS.pdf") shows this clearly. [Vellturo Declaration, ¶ 22 and footnote 17.]

Dr. Vellturo also cites Protonix and Lotrel as examples of short-lived at-risk generic launches. A review of data related to Protonix demonstrates that while the at-risk products were pulled from the market, they continued to be available to patients until the expiry of the patent in early 2011. Thus, in this case, the patent expired before branded Protonix had a chance to recover. However, I note that damages were able to be calculated to a degree sufficient to lead to a $2.15 billion settlement between the at-risk generics and the patent holder, thus providing further evidence that the harm was quantifiable to a degree that satisfied the parties. ["Pfizer Obtains $2.15 Billion Settlement from Teva and Sun for Infringement of Protonix® Patent," *Pfizer Press Release*, June 12, 2013, available at http://press.pfizer.com/press-release/pfizer-obtains-215-billion-settlement-teva-and-sun-infringement-protonix-patent, accessed July 21, 2016.] In addition, I note that because a trial in this matter commenced late in the life of the patent covering Protonix, it is not applicable to the current matter.

In addition, while Dr. Vellturo notes strong sales of generic versions of Lotrel following at-risk launch by Teva Pharmaceutical Industries Limited ("Teva"), he provides no evidence that the branded drug manufacturer was irreparably harmed by the at-risk launch. While in this available time frame, I was not able to obtain sales and prescription data for Lotrel in order to analyze the effect of this at-risk launch as I did with the six drugs discussed above, Novartis AG and Teva were able to determine the harm suffered to a sufficient degree that a settlement was reached by the parties. [Chris Dolmetsch, "Teva Settles Litigation With Novartis Over Generic Lotrel," *Bloomberg*, available at http://www.bloomberg.com/news/articles/2011-07-21/teva-reports-settlement-of-novartis-suit-based-on-generic-lotrel, accessed July 22, 2016.]

total prescriptions and average weekly dollar sales following the removal of generics from the market. Moreover, two such branded drugs, Eloxatin and Plavix, achieved higher levels of total prescriptions following the removal of generics from the marketplace than they had prior to the at-risk launches of these generics. Furthermore, three of these branded pharmaceutical products, Eloxatin, Plavix, and Ortho Tri-Cyclen Lo, reached higher levels of weekly average dollar sales following the removal of their generic competitors, than they had attained prior to the at-risk launches of their generics. Further, Ortho Tri-Cyclen Lo is an oral contraceptive sold in competition with Beyaz and Safyral, and thus there is no reason to worry about oral contraceptives in particular, despite Dr. Vellturo's concerns about the shelf life of generic oral contraceptives.

B. The Potential Harm Due to the Presence of an Authorized Generic is Self-Inflicted

21. Dr. Vellturo asserts that the launch of the authorized generics of Beyaz and Safyral triggered by Watson's launch will lead to "full genericization" of the marketplace and that "this full and irrevocable genericization that will result from Watson's entry generates ongoing harm beyond Watson's product availability."[24] As I will describe in more detail below, the harm incurred by Bayer as a result of the presence of authorized generics in the marketplace is *not* caused by Watson's entry. Rather, it is a direct result of the terms that Bayer negotiated with the unnamed third-party pharmaceutical company for the distribution of these products.

22. I first note that Dr. Vellturo's analysis of this agreement is based on "communications" with Michael Lynch, a Bayer employee.[25] Neither I nor Dr. Vellturo have seen the agreement and thus it is not possible to know what the agreement says and the extent to which Bayer may be able to reduce (or to stop) the availability of authorized generics if Watson is ultimately required to withdraw its

[24] Vellturo Declaration, ¶ 27.

[25] See, *e.g.*, Vellturo Declaration, ¶¶ 24-7 and footnotes 5 and 21-2.

generic versions. Indeed, in my experience, it is not common for branded drug manufacturers to enter into non-revocable authorized generic agreements such as those discussed by Dr. Vellturo regarding Bayer and its authorized generic. In fact, of the six drugs identified in **Attachment 3**, only Pulmicort Respules and Amrix competed with authorized generic formulations for a time during the period immediately following the at-risk generics were forced to exit the market and when it was reintroduced (although in both cases, the authorized generics were also eventually removed from the market).[26]

23. As noted above, despite the continued presence of an authorized generic, Pulmicort Respules was able to return to the sale and prescription levels it had established prior to the at-risk launch. Similarly, while total molecule sale and prescription levels for cyclobenzaprine HCl extended release tablets (branded and generic Amrix) continued their downward trajectory following the generic at-risk

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[26] CVS/Caremark TrendsRx® Generic Launch Alert, available at https://www.caremark.com/portal/asset/TrendsRxGenericLaunch_Pulmicort_Resp.pdf, accessed July 21, 2015; "Watson Launches Generic Amrix," *PR Newswire*, May 16, 2011, available at http://www.prnewswire.com/news-releases/watson-launches-generic-amrix-121885593.html, accessed July 21, 2016; IMS Data.

I note that, with respect to Pulmicort Respules, AstraZeneca licensed Par Pharmaceutical Companies ("Par") to distribute an authorized generic version of Pulmicort Respules in November 2008, at the time of Teva's at-risk generic launch. [See "AstraZeneca Enters Agreement for Authorized Generic Pulmicort Respules," *Evaluate Press Release*, November 19, 2008, available at http://www.evaluategroup.com/Universal/View.aspx?type=Story&id=170413, accessed July 25, 2016.] However, once AstraZeneca reached a settlement in its lawsuit with Teva, a settlement which also included Teva's exit from the marketplace until December 2009, AstraZeneca and Par discontinued the distribution of the authorized generic version of Pulmicort Respules. [See "UPDATE 1-AstraZeneca, Teva Settle Generic Pulmicort Dispute," *Reuters*, November 25, 2008, available at http://www.reuters.com/article/astrazeneca-teva-asthma-idUSN2529857120081125, accessed July 25, 2016.]

In addition, with respect to Amrix, I note that the court agreed to grant a temporary injunction against Mylan Pharmaceuticals, Inc.'s generic extended-release cyclobenzaprine products if plaintiffs Eurand, Inc. and Anesta AG agreed to remove their generic version of Amrix from the marketplace as well. [See Memorandum Order, *In re: Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litigation*, United States District Court, District of Delaware, Civ. No. 09-MD-2118-SLR, May 20, 2011, ¶ 14.] The plaintiffs agreed to this memorandum order in writing. [See Letter from William J. Marsden, Jr. of Fish & Richardson P.C. to the Honorable Sue L. Robinson Re: *In re Cyclobenzaprine Hydrochloride Extended Release Capsule Patent Litigation*, C.A. No. 09-md-2118, May 20, 2011.]

launch, sales and prescriptions of Amrix rebounded and began to grow after the grant of an injunction against the at-risk generics, even while an authorized generic formulation continued to be available. Eventually, however, sales and prescriptions of the authorized generic for Amrix also went to zero, indicating that the agreement for an authorized generic for Amrix was not like the supposed agreement discussed by Dr. Vellturo.

24. I am aware of no evidence, and Dr. Vellturo provides none, that Bayer contracted with this third-party pharmaceutical company to produce authorized generics of Beyaz and Safyral as a direct response to Watson's potential generic entry. Indeed, Bayer has the financial resources to withstand the losses that could occur with the entry of Watson's generic products (and, as I have described above, would be fully-compensated for the losses incurred at the time of a trial). Indeed, as is shown in **Attachment 4**, the Bayer Group's Pharmaceuticals segment generated over $73 billion in revenues, and over $13 billion in operating profits from 2011 through 2015. Furthermore, the Bayer Group's HealthCare subgroup, and the Bayer Group itself, generated approximately $124 billion and $262 billion in revenues, respectively, and approximately $21 billion and $31 billion in operating profits, respectively, over this same time period. That is, Bayer was not forced into a situation in which the potential losses of profits from Beyaz and Safyral forced it to make such a decision. Dr. Vellturo was told that the net sales of Beyaz and Safyral were about $90 million total in 2015 and about $46 million in the first half of 2016 – thus the sales of these drugs are minor relative to the size and scope of Bayer.[27] Moreover, as is shown in **Attachment 5**, Allergan plc, the parent of Watson,[28] generated over $27 billion in net sales and about $9.3 billion in contribution profits from its generics business over the period from 2011 through 2015. Similarly, the sales of Beyaz and Safyral are small relative to the size and scope of Allergan plc's generic business. Thus, there is no reason to worry either

[27] Vellturo Declaration, ¶ 13 and footnotes 5 and 6.

[28] Allergan plc Form 10-K for the fiscal year ended December 31, 2015.

that Bayer would be unable to function normally up through a resolution of the matter or that Allergan plc would not be able to pay any damages that might ultimately result from the at-risk launch.

25. Bayer's supposed decision to enter into an authorized generic agreement that would (according to Dr. Vellturo) permanently poison the ability of Beyaz and Safyral to compete if Watson's products are ultimately found to infringe the '168 patent makes no economic sense, unless either Bayer does not believe that there is irreparable harm from Watson's launch or Bayer does not believe it will ultimately prevail. As noted above, in similar situations, many branded drug manufacturers did not enter into such agreements and following the withdrawal of the at-risk generic products, sales and prescriptions fully rebounded. Accordingly, if Bayer reasonably believed that the court would rule in its favor and that the launch of generic competition would cause irreparable harm in the meantime, it would not make financial sense for Bayer to license an authorized generic that could not later be withdrawn if Watson's generic versions were subsequently withdrawn as well. Thus, it is clear that as an economic matter, if such an agreement exists and it does not allow Bayer to stop the sale of an authorized generic, then any continued harm from the existence of an authorized generic would not be the result of Watson's at-risk launch of generic versions of Beyaz and Safyral, but rather is the result of Bayer's own decisions. If such an agreement exists, then Bayer can address any future harm it has caused itself by dealing with the third-party generic manufacturer with which it has supposedly contracted.

V. It Is Not in the Public Interest to Grant a Stay

26. Should a stay be granted that would prevent Watson from selling its generic formulations of drospirenone, ethinyl estradiol, and levomefolate calcium, the public would lose out on less expensive, generic versions of Beyaz and Safyral. Specifically in the pharmaceutical industry, one of the benefits of not enjoining entry is that "at-risk" launch of generic formulations creates benefits to patients.

Indeed, one of the goals of the Hatch-Waxman Act of 1984 was to reduce the barriers to entry for generic manufacturers of branded pharmaceuticals, and therefore allow these drug manufacturers to provide patients with bioequivalent and less expensive alternatives to branded drug products.[29] As such, the public is allowed greater access to competing versions of branded pharmaceutical drugs.

27. Additionally, and as I have described above, should Watson's generic products be wrongfully allowed to enter the marketplace, Bayer will likely be made whole in the form of quantifiable monetary damages at the completion of trial.[30] Thus, from the perspective of the public interest, there is little reason to worry about Bayer, as it can be made whole in the form of economic damages awarded at trial.

28. However, if a stay is granted and Watson's generics are prevented from entering the market, but, the court ultimately finds that the '168 patent is invalid or not infringed, then the public will have been denied access to less expensive versions of drospirenone, ethinyl estradiol, and levomefolate calcium for a period in which it would have had access to these alternatives had Watson's product been allowed to enter the market. This harm to consumers and patients (*i.e.*, higher prices for drospirenone, ethinyl estradiol, and levomefolate calcium products) will not be compensated after trial. Consideration of the public interest in whether or not to grant a stay should account for this non-remunerable harm to the public

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[29] See, *e.g.*, Henry Grabowski, Genia Long, and Richard Mortimer, "Recent Trends in Brand-Name and Generic Drug Competition," *Journal of Medical Economics*, 2013: 1-8, available at: http://fds.duke.edu/db/attachment/2575, accessed July 23, 2016; Henry G. Grabowski and John M. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act," *Journal of Law and Economics*, Vol. 35, 1992: 331-50; Henry Grabowski and John Vernon, "Longer Patents for Increased Generic Competition in the US: The Waxman-Hatch Act After One Decade," *Pharmacoeconomics*, Vol. 10(2), 1996: 110-23.

[30] In addition, as stated above and as shown in **Attachment 3**, in many cases, branded drugs fully recover to their pre-generic sales levels following the removal of generics launched at-risk in the marketplace, and, to the extent they were harmed during the period in which they competed with the at-risk generics, this harm can be quantified to a reasonable degree of certainty at the time of trial.

interest that would flow from granting a stay. In other words, the public would be harmed because some patients may not currently be able to afford access to Beyaz and Safyral, but would otherwise be able to afford access to a generic product. Others who can currently afford it might be able to recognize a savings. Both of these indicate that entry would serve the public interest, especially expanded patient access. To the contrary, if entry is allowed and Bayer ultimately prevails, the public will have benefited from the at-risk launch, at no cost to Bayer, which would be fully compensated via monetary damages. As an economic matter, therefore, the public interest favors not granting a stay.

I declare under penalty of perjury that the foregoing is true and correct.

David Blackburn
July 26, 2016

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Attachment 1

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Education

Harvard University
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Brown University
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Professional Experience

NERA Economic Consulting

2012-	Vice President
2008-2012	Senior Consultant
2005-2008	Consultant

Framingham State College

2003	Instructor - Intermediate Microeconomics

Universidad Nacional de Tucumán, Argentina

Summer 2002	Visiting Professor
	Instructor - Regulation in Network Industries

Written Testimony

Rebuttal Expert Report of David Blackburn, Ph.D., *PPC Broadband, Inc., d/b/a PPC v. Corning Optical Communications RF, LLC,* U.S. District Court, Northern District of New York, Case No. 5:13-cv-00538-GLS-DEP, March 2016. Assess PPC's damages from Corning's alleged patent infringement.

Expert Report of David Blackburn, Ph.D., *PPC Broadband, Inc., d/b/a PPC v. Corning Optical Communications RF, LLC*, U.S. District Court, Northern District of New York, Case No. 5:13-cv-00538-GLS-DEP, November 2015. Assess PPC's damages from Corning's alleged patent infringement.

Expert Report of David Blackburn, Ph.D., *Cubist Pharmaceuticals LLC v. Agila Specialties Inc. and Mylan Laboratories Limited*, U.S. District Court, District of Delaware, Case No.: C.A. No. 13-1679 (GMS), October 2015. Assess the commercial success of Cubicin, a pharmaceutical product sold by Cubist.

Rebuttal Declaration of David Blackburn, Ph.D., *Torrent Pharmaceuticals Limited and Apotex, Inc. and Mylan Pharmaceuticals, Inc., Petitioners v. Novartis AG and Mitsubishi Pharma Corp., Patent Owners,* Before the Patent Trial and Appeal Board, Case IPR2014-00784, Case IPR2015-00518, Patent 8,324,283 B2, June 2015. Assess the commercial success of Gilenya, a pharmaceutical product sold by Novartis.

Supplemental Rebuttal Expert Report of David Blackburn, *International Business Machines Corporation v. BGC Partners, Inc., BGC Brokers US, L.P., BGC Financial L.P., and BGC USA, L.P.*, U.S. District Court, Southern District of New York, Civil Action No. 1:10-cv-00128, May 2015. Assess IBM's supplemental claim for damages resulting from BGC's alleged breach of contract and copyright infringement.

Expert Report of David Blackburn, Ph.D., *Supernus Pharmaceuticals, Inc. v. Actavis Inc., and Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Watson Laboratories, Inc., and ANDA, Inc.*, United States District Court, District of New Jersey, Civil Action No. 13-4740 (RMB) (JS) and Civil Action No. 14-1981 (RMS)(JS), May 2015. Assess the commercial success of Oxtellar XR, a pharmaceutical product sold by Supernus.

Declaration of David Blackburn, Ph.D. in Support of SoundExchange's Motion in Limine to Exclude the Written Rebuttal Testimony of Todd Kendall, *14-CRB-0001-WR (2016-2020) Determination of Royalty Rates for Digital Performance in Sound Recordings and Ephemeral Recordings (Web IV),* Before the United States Copyright Royalty Judges, Library of Congress, Washington, D.C., April 2015.

Declaration of David Blackburn, Ph.D., *Torrent Pharmaceuticals Limited and Apotex, Inc. and Mylan Pharmaceuticals, Inc., Petitioners v. Novartis AG and Mitsubishi Pharma Corp., Patent Owners,* Before the Patent Trial and Appeal Board, Case IPR2014-00784, Case IPR2015-00518, Patent 8,324,283 B2, April 2015. Assess the commercial success of Gilenya, a pharmaceutical product sold by Novartis.

Updated: July 25, 2016

Declaration of David Blackburn, Ph.D., *Otsuka Pharmaceutical Co., Ltd. v. Actavis Elizabeth LLC, Jubilant Life Sciences Limited, Jubilant Generics Limited and Jubilant Life Sciences (USA) Inc.*, United States District Court, District of New Jersey, Civil Action No. 14-cv-07106-JBS-KMW, March 2015. Assess potential impact of at-risk entry by Actavis and others of a generic formulation of aripiprazole.

Written Rebuttal Testimony of David Blackburn, Ph.D., On Behalf of SoundExchange, Inc., *14-CRB-0001-WR (2016-2020) Determination of Royalty Rates for Digital Performance in Sound Recordings and Ephemeral Recordings (Web IV)*, Before the United States Copyright Royalty Judges, Library of Congress, Washington, D.C., February 2015. Assess webcasting and relationship to other music distribution channels.

Expert Report of David Blackburn, Ph.D., *Endo Pharmaceuticals Inc. and Grünenthal GmbH v. Actavis Inc., Actavis South Atlantic LLC, and Watson Pharmaceuticals, Inc.*, United States District Court for the Southern District of New York, C.A. No. 13-cv-436-TPG, January 2015. Assess the commercial success of Opana ER, a long-acting opiod sold by Endo.

Expert Report of David Blackburn, Ph.D., *Takeda Pharmaceuticals Co., Ltd., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. v. TWI Pharmaceuticals, Inc.*, United States District Court for the Northern District of California, Case No. 5:13-cv-02420 LHK (PSG), December 2014. Assess the commercial success of Takeda's Dexilant pharmaceutical product.

Report of David Blackburn, Ph.D., On Behalf of SoundExchange, *14-CRB-0001-WR (2016-2020) Determination of Royalty Rates for Digital Performance in Sound Recordings and Ephemeral Recordings (Web IV)*, Before the United States Copyright Royalty Judges, Library of Congress, Washington, D.C., October 2014. Assess webcasting and relationship to other music distribution channels.

Expert Report of David Blackburn, Ph.D., *Carrier Corporation v. Goodman Global, Inc., Goodman Manufacturing Company, L.P., Goodman Global Holdings, Inc., Goodman Distribution, Inc., and Goodman Sales Company*, United States District Court, District of Delaware, C.A. No. 12-930 (SLR), February 2014. Assess commercial success of Carrier's Infinity HVAC system and related patents.

Declaration of David Blackburn, Ph.D., *Ferring B.V. v. Watson Laboratories, Inc. - Florida*, United States District Court, District of Nevada, Case Nos.: 3:11-cv-00481-RCJ-VPC, 2:12-cv-01935-RCJ-VPC, and 3:11-cv-00853-RCJ-VPC, February 2014. Asses potential impact of continued sale of Watson's generic tranexamic acid tables.

Updated: July 25, 2016

Expert Report of David Blackburn, Ph.D. and Supplemental Expert Report of David Blackburn, Ph.D., *In re: Cengage Learning, Inc. et al.*, U.S. Bankruptcy Court, Easter District of New York, Case No.: 13-44106 (ESS), Case No.: 13-44105 (ESS), Case No.: 13-44107 (ESS), and Case No.: 13-44108 (ESS), December 2013 and January 2014. Assess the appropriate royalty rates to use in determining the value of certain copyrights held by Cengage.

Expert Report of David Blackburn, Ph.D., *Energy Intelligence Group, Inc. and Energy Intelligence Group (UK) Limited v. Canal Barge Company, Inc.*, United States District Court, Eastern District of Louisiana, Civil Action No.: 12-cv-02107-JCZ-DEK, June 2013. Supplemental Expert Report of David Blackburn, Ph.D., December 2013. Assess EIG's claim for damages resulting from Canal Barge's alleged copyright infringement.

Expert Report of David Blackburn, Ph.D., *Machine Maintenance Inc., d/b/a Luby Equipment Services, Inc. v. Generac Power Systems, Inc.*, United States District Court, Eastern District of Missouri, Eastern Division, Case No: 4:12-cv-793-JCH, September 2013. Assess the reasonableness of Generac's determination of the market opportunities available to Luby.

Declaration of David Blackburn, Ph.D., *Endo Pharmaceuticals, Inc. v. Actavis, Inc. and Actavis South Atlantic LLC*, United States District Court, Southern District of New York, Civil Action No. 12-cv-8985-TPG-GWG, August 2013. Assess potential impact of at-risk entry by Actavis and Roxane of a generic extended-release oxymorphone.

Rebuttal Expert Report of David Blackburn, Ph.D., *Ferring B.V. v. Watson Laboratories, Inc. - Florida*, United States District Court, District of Nevada, Case Nos.: 3:11-cv-00481-RCJ-VPC, 2:12-cv-01935-RCJ-VPC, and 3:11-cv-00853-RCJ-VPC, June 2013. Assess commercial success of Lysteda and related patents.

Expert Report of David Blackburn, Ph.D., *Warner Chilcott Company, LLC v. Watson Laboratories, Inc.* and *Warner Chilcott Company, LLC v. Lupin Ltd. and Lupin Pharmaceuticals, Inc.*, United States District Court, District of New Jersey, 12-cv-2928-JAP-TJB, June 2013. Assess commercial success of Lo Loestrin Fe and related patents.

Expert Report of David Blackburn, Ph.D. and Declaration of David Blackburn, *Edward L. White, P.C., v. West Publishing Corporation d/b/a "West"; and Reed Elsevier Inc., d/b/a LexisNexis*, United States District Court, Southern District of New York, Case No. 12-cv-1340, September 2012 and October 2012. Assess economic factors related to fair use considerations in Lexis's and West's alleged copyright infringement.

Updated: July 25, 2016

Expert Report of David Blackburn, Ph.D., *William F. Shea, LLC, et al. v. Bonutti Research, Inc., et al.*, United States District Court, Southern District of Ohio, Case No. 2:10-cv-615, January 2012. Assess issues relating to alleged competition related to Shea's alleged breach of contract and other claims.

Rule 26(b)(4) Expert Witness Disclosure of Plaintiffs Wildheart Entertainment, L.P., Maxim Langstaff, and Michele Langstaff, *Wildheart Entertainment, L.P., Maxim Langstaff, and Michele Langstaff v. Higher Ground, LLC et al.*, Superior Court for the District of Columbia (Civil Division), Civil Action No. 2010 CA 005253 B, June 2011. Assess Wildheart's claims for damages resulting from Higher Ground's alleged breach of contract, interference, and other claims.

Expert Report of David Blackburn and Christine S. Meyer, *Waddington North America, Inc. v. Sabert Corporation*, United States District Court for the District of New Jersey, Civil Action No. 2:09-cv-04883-GEB-MCA, January 2011. Assess Waddington's claim for damages resulting from Sabert's alleged infringement of patented metalized cutlery technology.

Rebuttal Expert Report of David Blackburn, *International Business Machines Corporation v. BGC Partners, Inc., BGC Brokers US, L.P., BGC Financial L.P., and BGC USA, L.P.*, U.S. District Court, Southern District of New York, Civil Action No. 1:10-cv-00128, November 2010. Assess IBM's claim for damages resulting from BGC's alleged breach of contract and copyright infringement.

Expert Report of David Blackburn, *Danforth S. DeSena, DPM and Solstice Corporation v. Beekley Corporation*, United States District Court, District of Maine, Civil Action No. 2:09-cv-00352-DBH, December 2009. Assess DeSena's claim for damages from Beekley's alleged infringement of patented radiographic scanner technology.

Report of David Blackburn on Claimed Monopolistic Impact of Proposed New York State Legislation (Senate Bill Number 3708-D), Letter to Governor David Paterson, December 2009.

Expert Report of David Blackburn, Ph.D., *Carolina Power & Light Co., et al. v. Aspect Software, Inc. and BellSouth Communications Systems, L.L.C.*, United States District Court, Eastern District of North Carolina, Western Division, Case No. 5:08-cv-00449, October 2009. Assess Aspect's indemnification obligation relating to a patent settlement entered into by Carolina Power.

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Updated: July 25, 2016

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Updated: July 25, 2016

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Charles H. Smith Fellowship in Economics, Harvard University

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Updated: July 25, 2016

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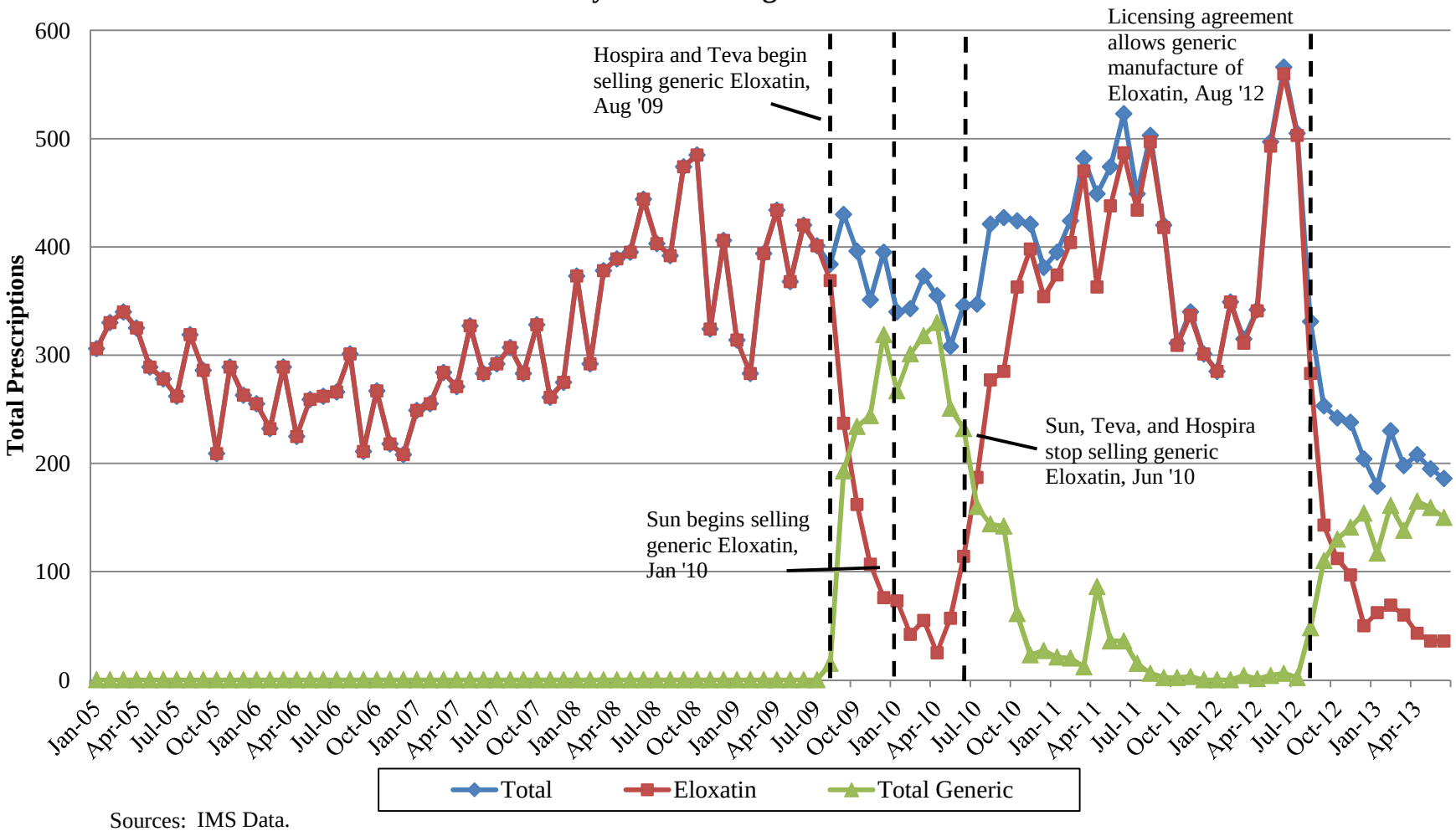

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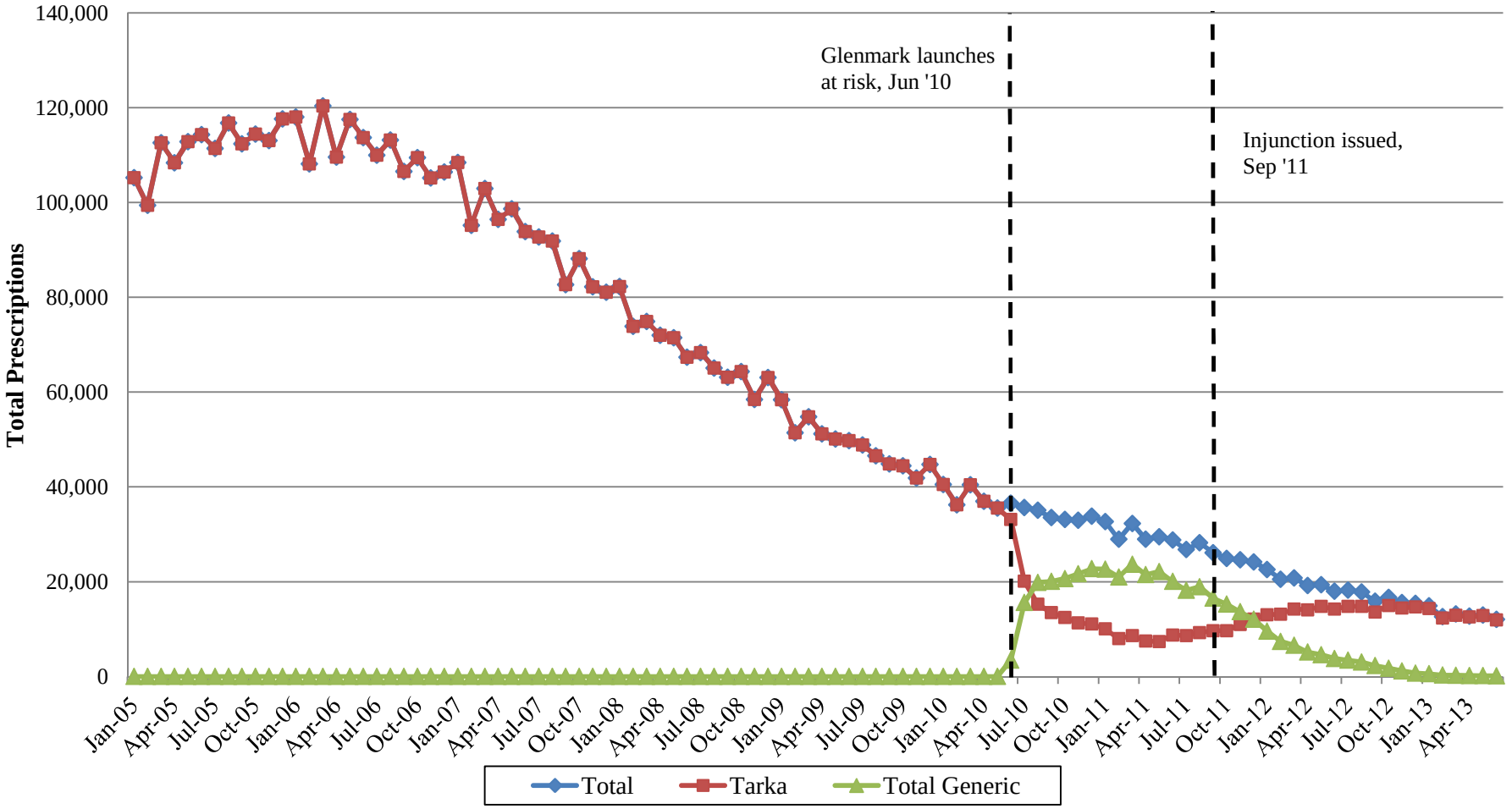

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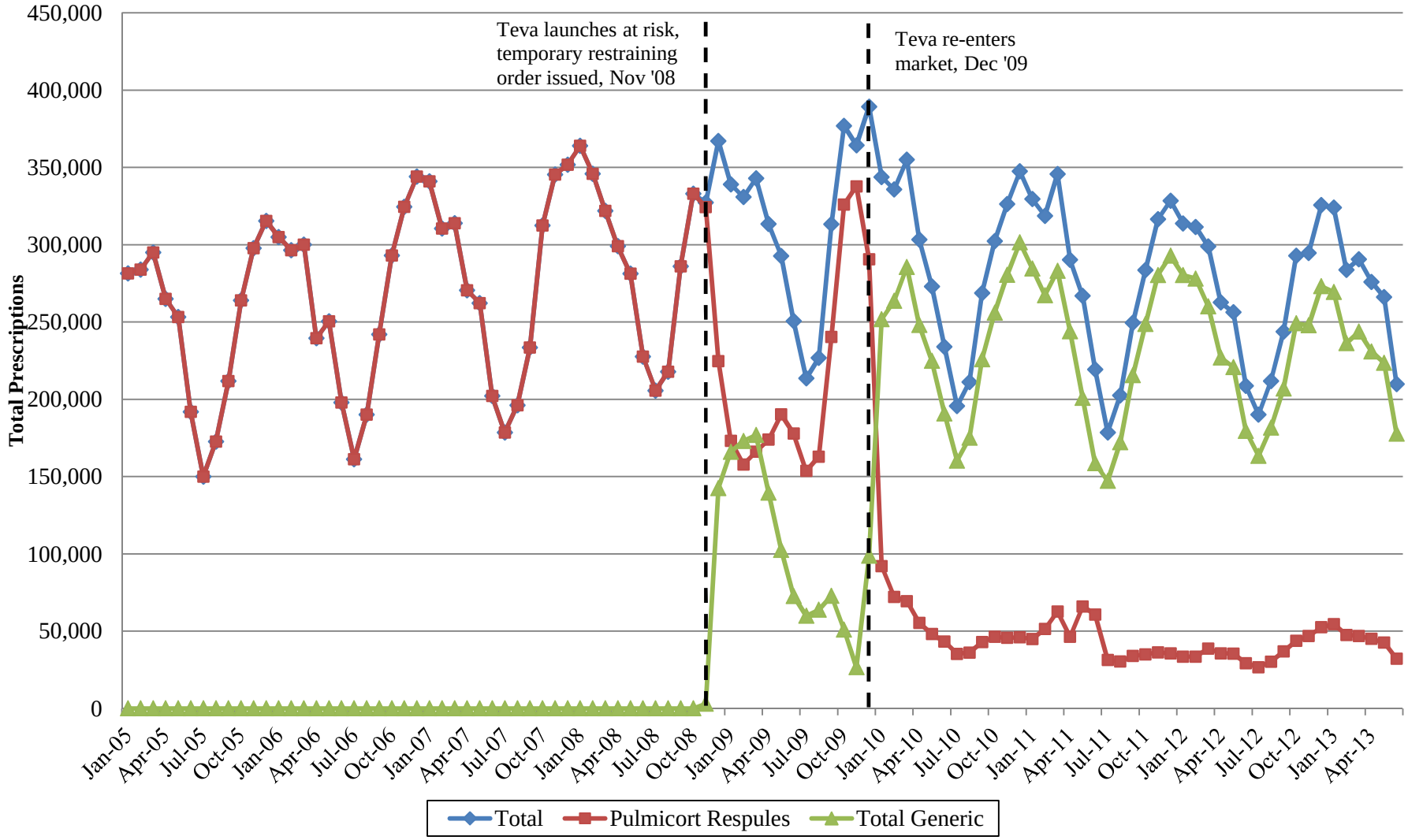

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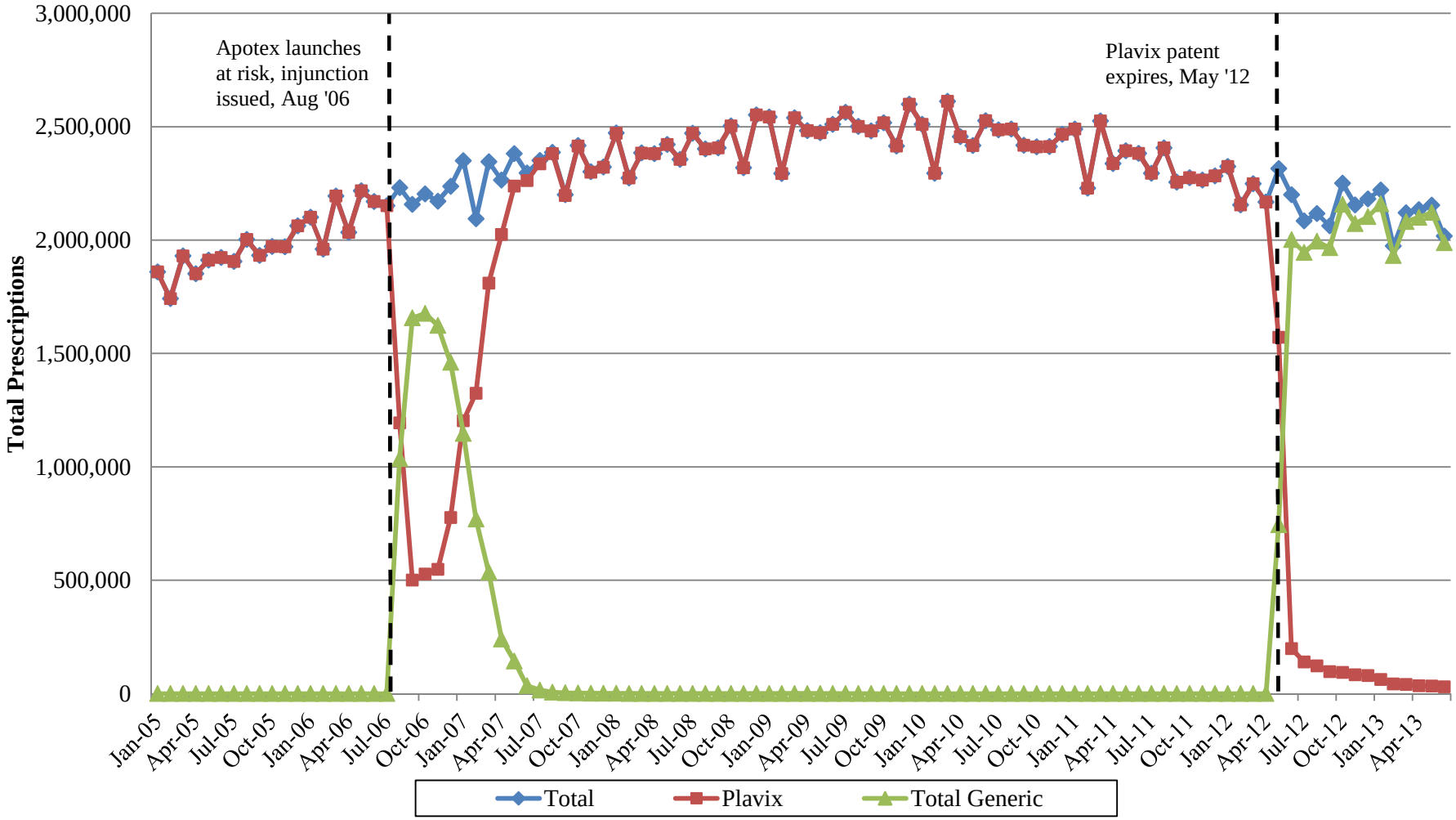

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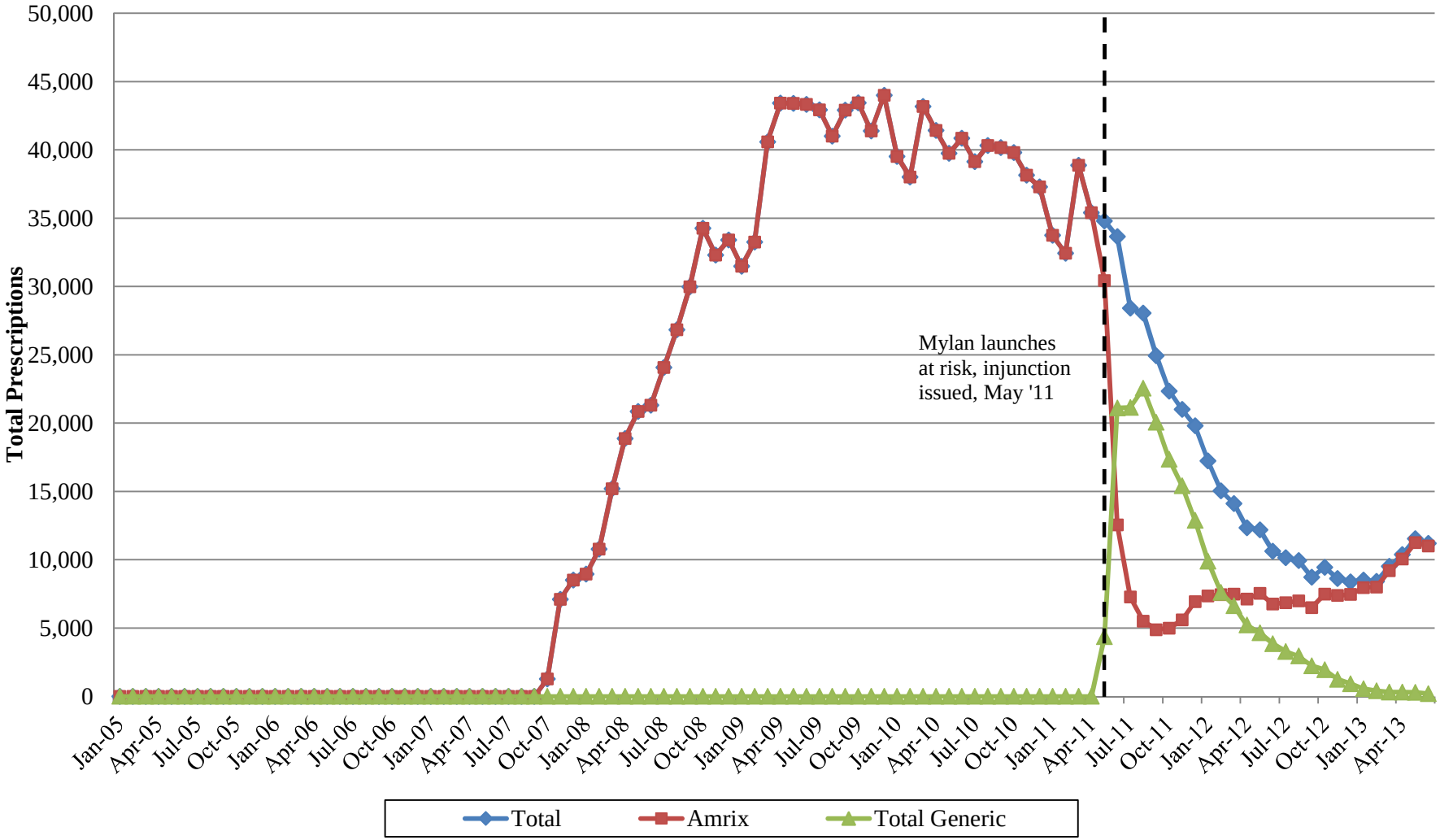

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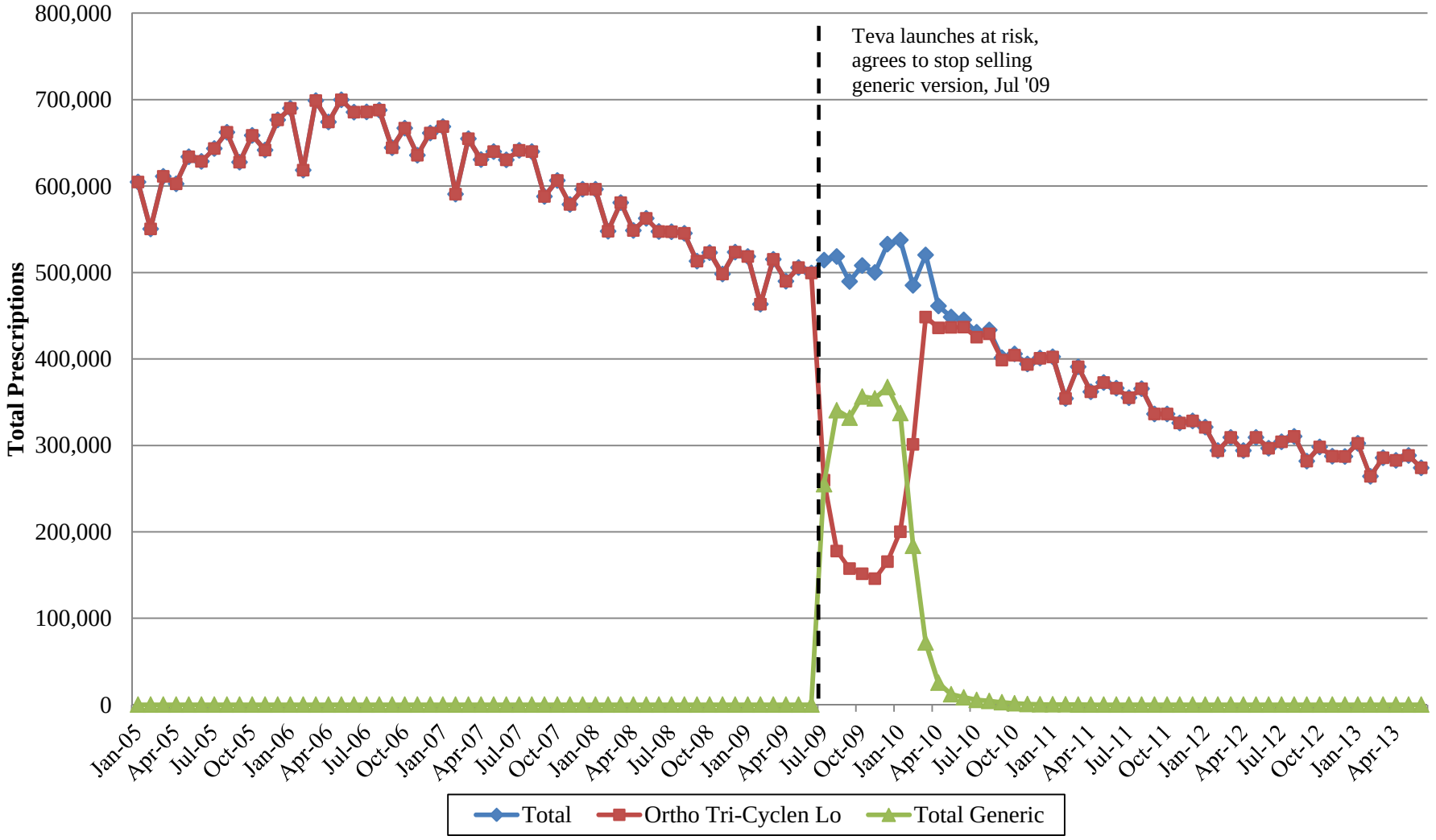

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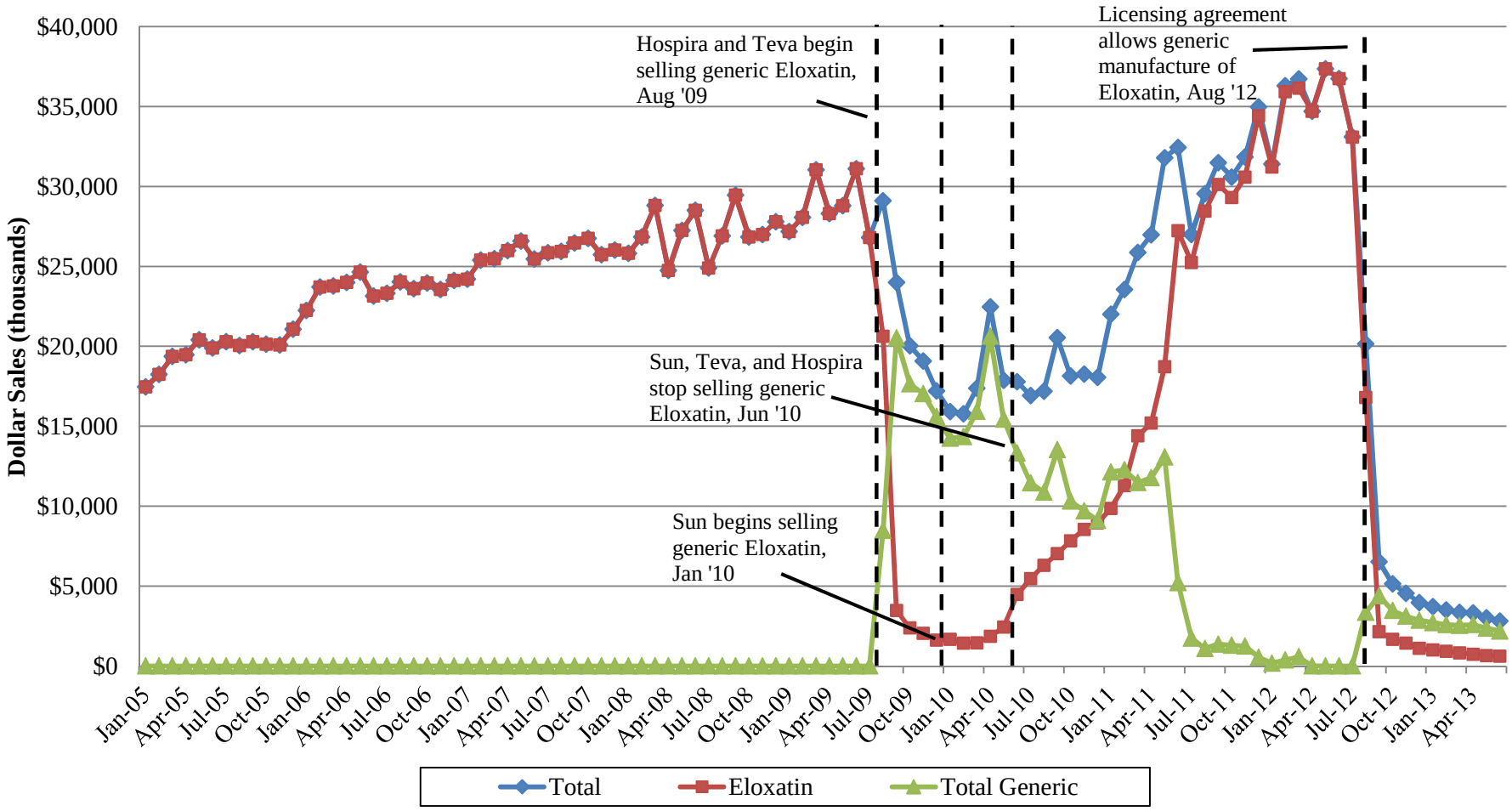
Weekly Average Dollar Sales of Eloxatin and Its Generics
January 2005 through June 2013



Sources: IMS Data.
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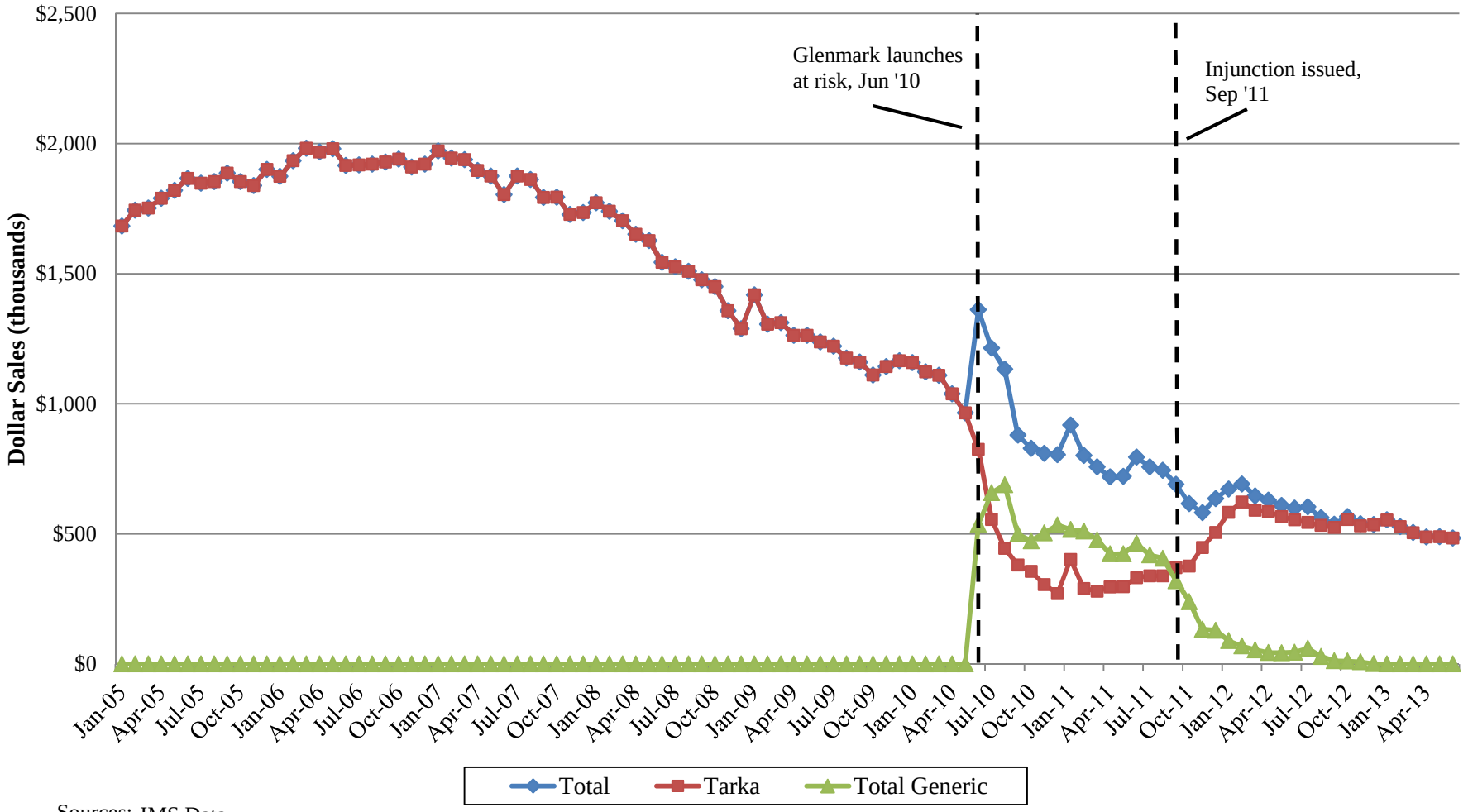
Weekly Average Dollar Sales of Tarka and Its Generic
January 2005 through June 2013



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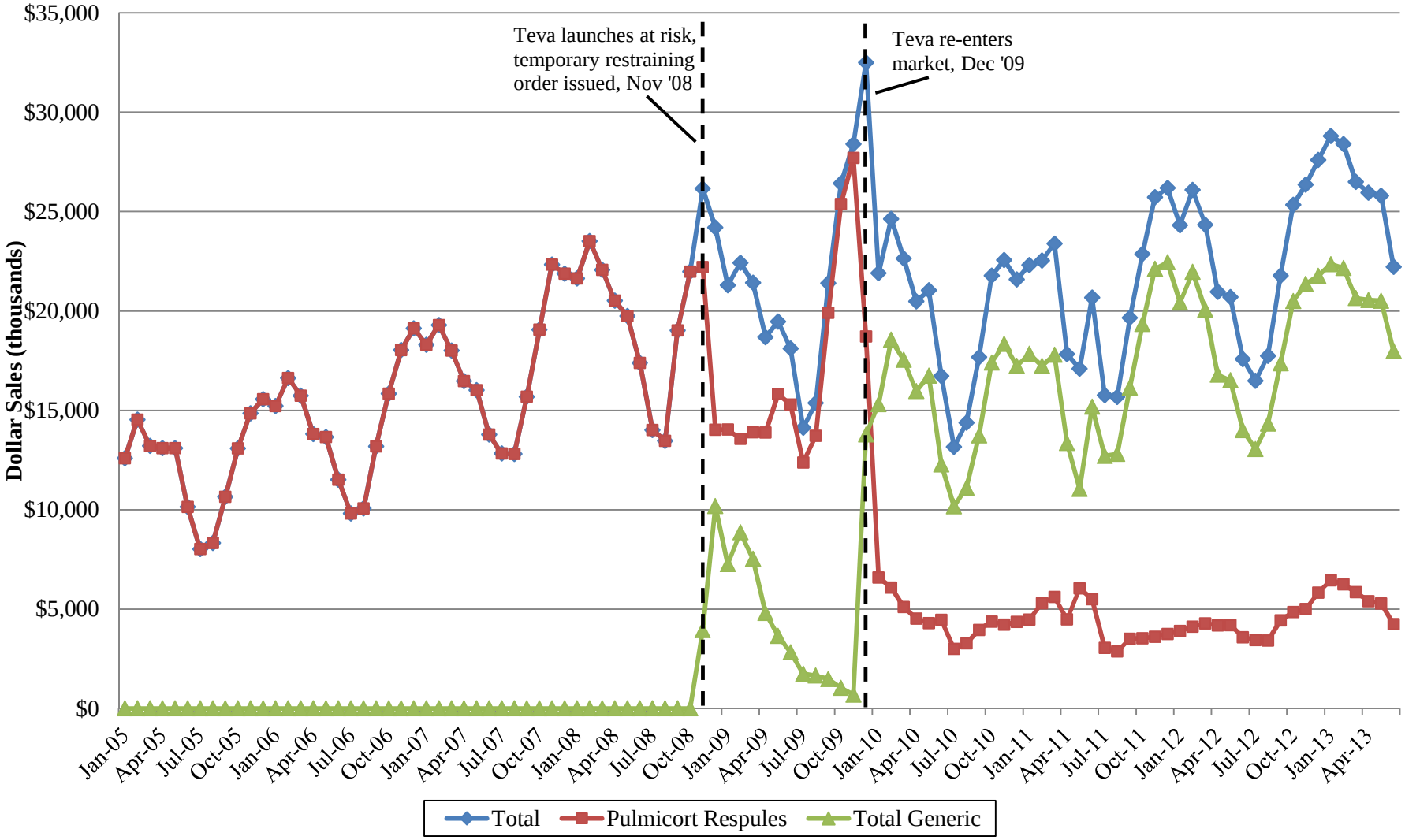
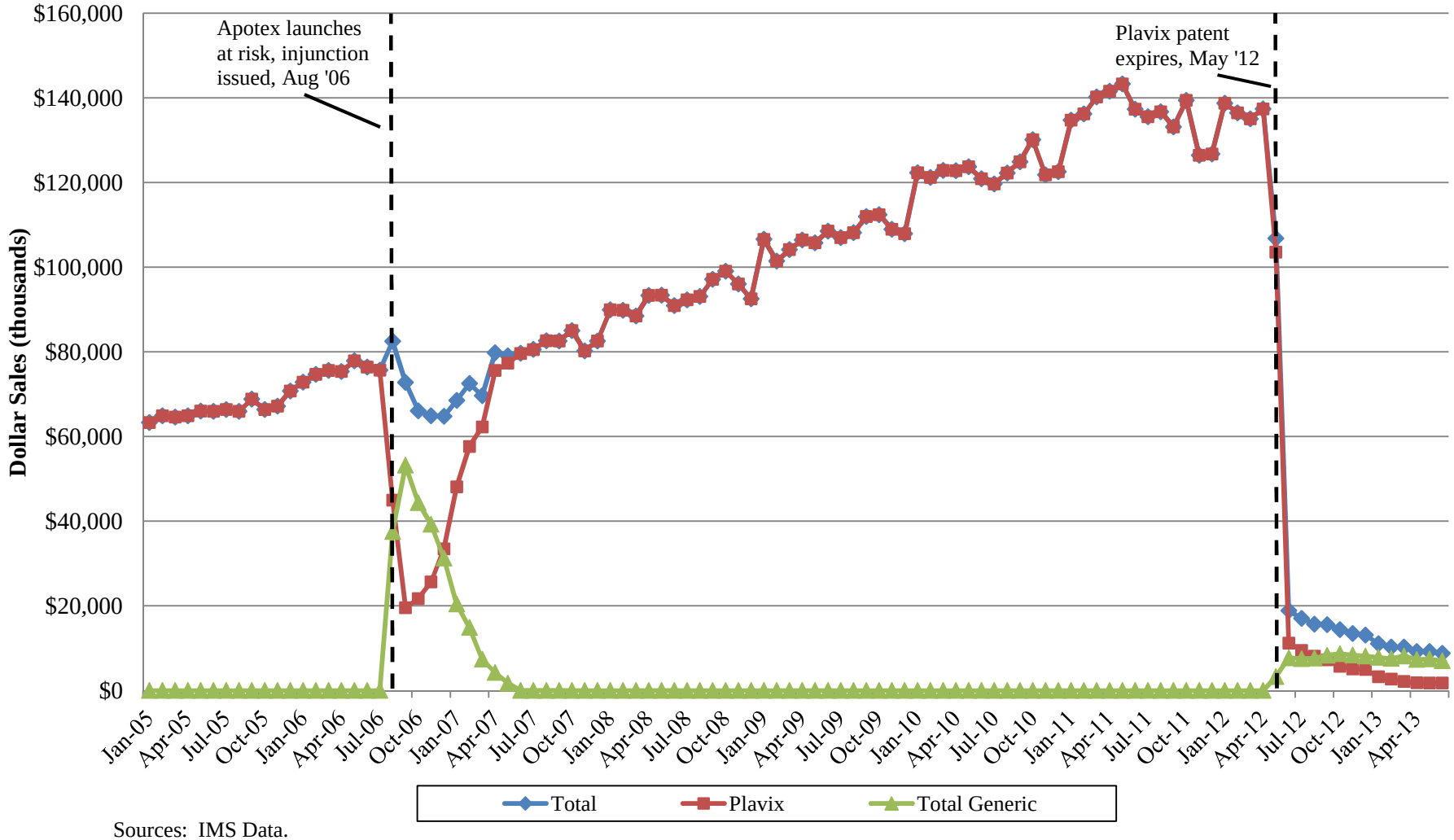
Opinion of Hon. Dennis M. Cavanaugh, *Sanofi-Aventis Deutschland GMBH, Aventis Pharma S.A., Abbott GMBH & Co. KG and Abbott Laboratories v. Glenmark Pharmaceuticals Inc., USA and Glenmark Pharmaceuticals LTD*, United States District Court District of New Jersey, Civil Action No. 07-CV-5855 (DMC-JAD), September 30, 2011, available at http://docs.justia.com/cases/federal/district-courts/new-jersey/njdce/2:2007cv05855/209132/ accessed July 21, 2016.

Weekly Average Dollar Sales of Pulmicort Respules and Its Generics
January 2005 through June 2013



Sources: IMS Data.
Jeffrey Bouley, "AstraZeneca and Teva settle generic Pulmicort squabble," available at http://www.ddn-news.com/index.php?newsarticle=2601, accessed July 21, 2016.

Weekly Average Dollar Sales of Plavix and Its Generics
January 2005 through June 2013



Sources: IMS Data.
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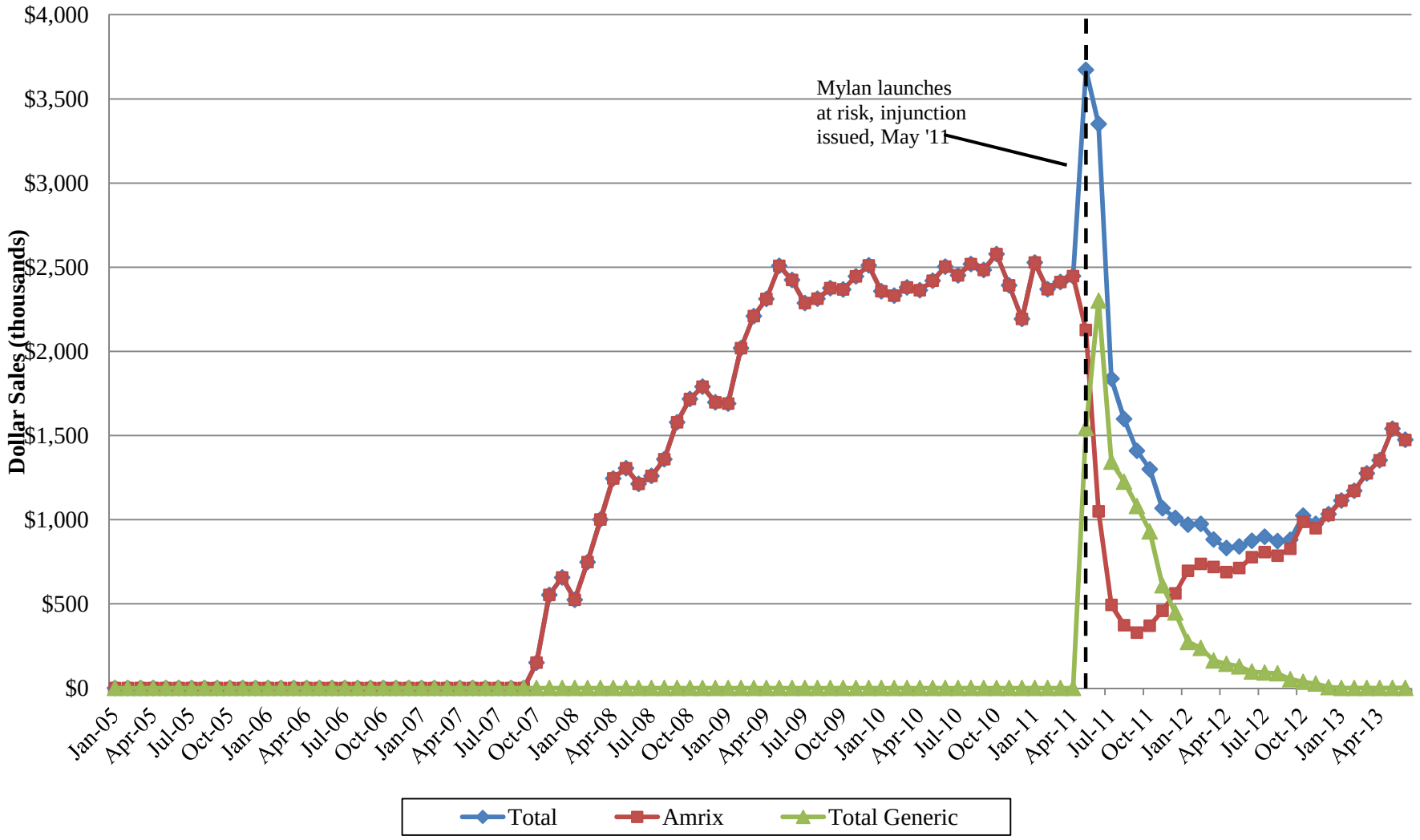
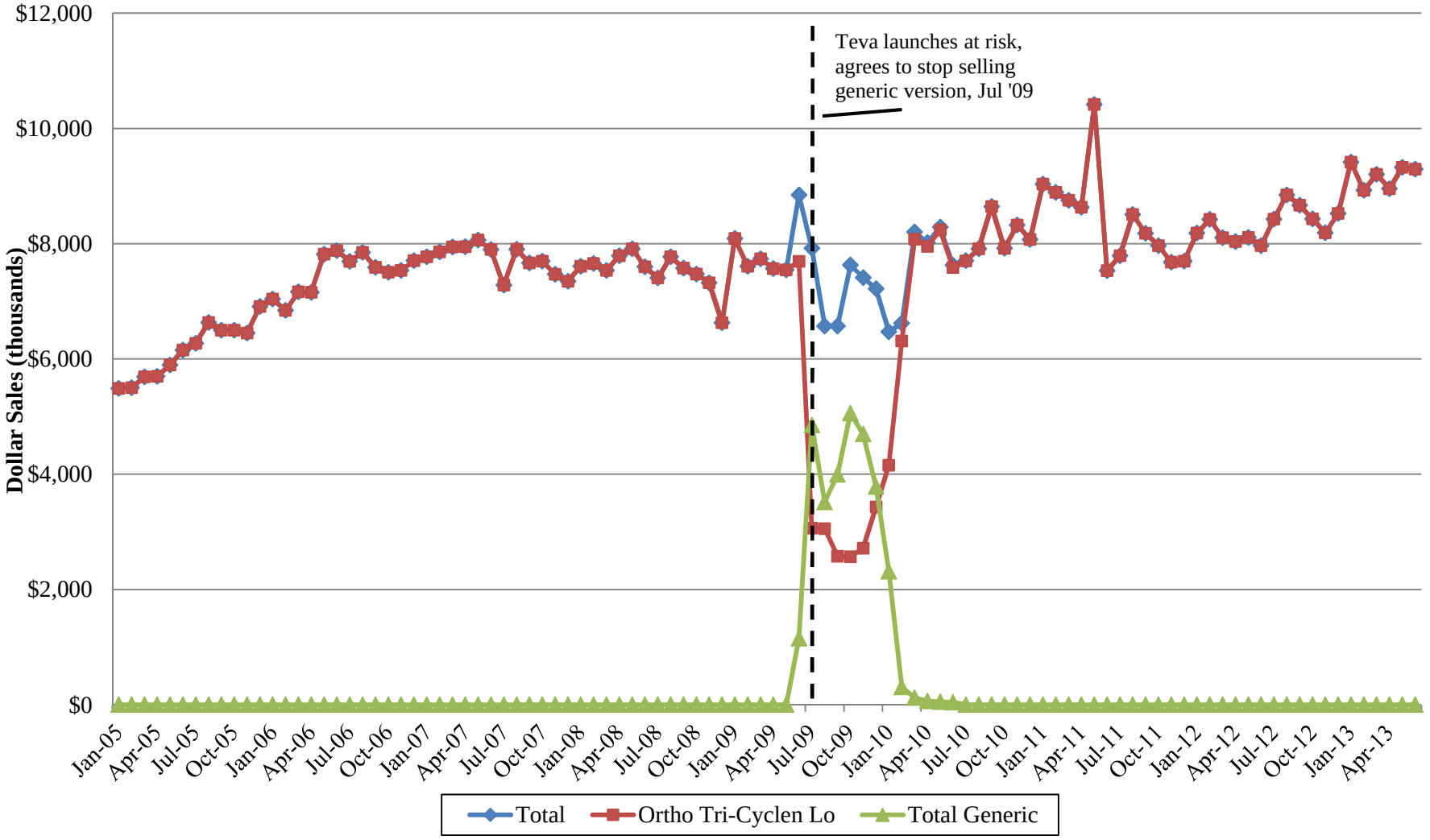
Weekly Average Dollar Sales of Amrix and its Generics
January 2005 through June 2013



Sources: IMS Data.
Aaron Barkoff, "Mylan Launches Generic Amrix; Cephalon Files Motion for TRO," available at http://www.orangebookblog.com/2011/05/mylan-launches-generic-amrix-cephalon-files-motion-for-tro.html, accessed July 21, 2016.

Weekly Average Dollar Sales of Ortho Tri-Cyclen Lo and Its Generic
January 2005 through June 2013



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Bayer AG Financial Results[1]
2011 through 2015

	Millions USD					
	2011	**2012**	**2013**	**2014**	**2015**	**Total**
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f) = (a) + … + (e)**
Bayer Group						
Revenue	$ 50,888	$ 51,102	$ 53,334	$ 54,967	$ 51,402	**$ 261,693**
Operating Profit	5,780	5,051	6,553	7,174	6,935	**31,493**
Operating Margin	*11.4 %*	*9.9 %*	*12.3 %*	*13.1 %*	*13.5 %*	***12.0 %***
Bayer HealthCare Subgroup						
Revenue	$ 23,919	$ 23,922	$ 25,134	$ 25,363	$ 25,381	**$ 123,720**
Operating Profit	4,445	2,835	4,330	4,614	4,494	**20,718**
Operating Margin	*18.6 %*	*11.9 %*	*17.2 %*	*18.2 %*	*17.7 %*	***16.7 %***
Bayer Pharmaceuticals Segment						
Revenue	$ 13,860	$ 13,885	$ 14,859	$ 16,025	$ 15,252	**$ 73,881**
Operating Profit	2,643	1,420	2,697	3,153	3,115	**13,027**
Operating Margin	*19.1 %*	*10.2 %*	*18.2 %*	*19.7 %*	*20.4 %*	***17.6 %***

Note:

[1] Revenues and operating profits have been converted from Euros to USD using the annual average of the daily USD-Euro exchange rate.

Sources:
- Bayer Annual Report 2012.
- Bayer Annual Report 2013.
- Bayer Annual Report 2014.
- Bayer Annual Report 2015.
- Historical Rates of the EU Euro, Board of Governors of the Federal Reserve System, available at http://www.federalreserve.gov/releases/H10/hist/dat00_eu.htm, accessed July 20, 2016.

Allergan plc Financial Results
Global Generics[1] Segment
2011 through 2015

	Millions USD					
	2011	**2012**	**2013**	**2014**	**2015**	**Total**
	(a)	**(b)**	**(c)**	**(d)**	**(e)**	**(f)**
						= (a) + … + (e)
Net Sales	$ 3,367	$ 4,446	$ 6,348	$ 6,579	$ 6,375	**$ 27,116**
Contribution Profit[2]	1,166	1,478	1,958	2,344	2,347	**9,293**
Contribution Margin	*34.6 %*	*33.2 %*	*30.8 %*	*35.6 %*	*36.8 %*	***34.3 %***

Notes: Watson Pharmaceuticals, Inc. acquired Actavis Group in October 2012, and became Actavis. Actavis plc acquired Allergan, Inc. in March 2015 and became Allergan in June 2015.

[1] Allergan's Global Generics segment is reported as "Income from discontinued operations" in 2013 through 2015, and as "Actavis Pharma" in 2011.

[2] Contribution Profit is calculated as "Net revenues" less "Cost of sales (exludes amortization and impairment of acquired intangibles including product rights)," "Research and development," and "Selling and marketing," in 2013 through 2015 in order to maintain consistency with prior reporting periods.

Sources:
- Actavis, Inc. Form 10-K for the fiscal year ended December 31, 2012.
- "Actavis Completes Allergan Acquisition," *Allergan Press Release* , March 17, 2015, available at http://www.actavis.com/news/news/thomson-reuters/actavis-completes-allergan-acquisition, accessed July 21, 2016.
- "Actavis Name Change to Allergan Becomes Official," *FirstWord Pharma* , June 15, 2015, available at http://www.firstwordpharma.com/node/1291417#axzz4F5kmeGrt, accessed July 21, 2016.
- Actavis plc Form 10-K for the fiscal year ended December 31, 2013.
- Allergan plc Form 10-K for the fiscal year ended December 31, 2015.
- "Watson Announces New Name - Actavis - for Global Operations," *Actavis Press Release* , available at http://phx.corporate-ir.net/phoenix.zhtml?c=65778&p=irol-newsArticle&ID=1752588, accessed July 21, 2016.
- "Watson Completes Actavis Acquisition," *Actavis Press Release* , available at http://phx.corporate-ir.net/phoenix.zhtml?c=65778&p=irol-newsArticle&ID=1752587, accessed July 21, 2016.