UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT
Thurgood Marshall U.S. Courthouse 40 Foley Square, New York, NY 10007 Telephone: 212-857-8500

MOTION INFORMATION STATEMENT

Docket Number(s): 14-4624

Caption [use short title]
State of New York v. Actavis plc and Forest Laboratories, LLC v.

Motion for: Emergency Stay Pending Appeal of a Preliminary Injunction, and Motion for Expedited Review

Set forth below precise, complete statement of relief sought:
Appellant-Petitioners Actavis plc and Forest Laboratories, LLC respectfully request an emergency stay pending appeal of an opinion granting a preliminary injunction, dated December 11, 2014, and the Preliminary Injunction Order, dated December 15, 2014. An expedited schedule for briefing and oral argument of this appeal is also sought.

MOVING PARTY: Actavis plc and Forest Laboratories, LLC
☐ Plaintiff ☑ Defendant
☑ Appellant/Petitioner ☐ Appellee/Respondent

OPPOSING PARTY: State of New York

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Court-Judge/Agency appealed from: United States District Court for the Southern District of New York (Robert W. Sweet, J.)

Please check appropriate boxes:

Has movant notified opposing counsel (required by Local Rule 27.1):
☑ Yes ☐ No (explain):

Opposing counsel's position on motion:
☐ Unopposed ☑ Opposed ☐ Don't Know

Does opposing counsel intend to file a response:
☑ Yes ☐ No ☐ Don't Know

FOR EMERGENCY MOTIONS, MOTIONS FOR STAYS AND INJUNCTIONS PENDING APPEAL:
Has request for relief been made below? ☑ Yes ☐ No
Has this relief been previously sought in this Court? ☐ Yes ☑ No
Requested return date and explanation of emergency: Immediate.
The District Court erred in granting the Preliminary Injunction, which will delay/reduce availability of Alzheimer's drugs. The Injunction will also cause over $1 billion in unrecoverable damages to Appellants, along with many other forms of irreparable harm. On the other hand, Appellee will not suffer any injury by a temporary stay of the Preliminary Injunction pending appeal.

Is oral argument on motion requested? ☑ Yes ☐ No (requests for oral argument will not necessarily be granted)

Has argument date of appeal been set? ☐ Yes ☑ No If yes, enter date:

Signature of Moving Attorney: J. Mark Gidley **Date:** December 16, 2014 Service by: ☐ CM/ECF ☑ Other [Attach proof of service]

Form T-1080 (rev. 12-13)

14-4624

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

STATE OF NEW YORK, by and through ERIC T. SCHNEIDERMAN, Attorney General

Plaintiffs-Appellees,

v.

ACTAVIS plc AND FOREST LABORATORIES, LLC

Defendants-Appellants.

FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK
CASE NO. 14-CV-7473 (RWS)

EMERGENCY MOTION FOR A STAY PENDING APPEAL AND FOR AN EXPEDITED APPEAL

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INTRODUCTION AND SUMMARY

Actavis plc and Forest Laboratories, LLC (together, "Forest"), respectfully request an emergency stay pending appeal of a December 15, 2014, preliminary injunction from the Southern District of New York (Sweet, J.).[1] Forest further requests that this Court expedite this appeal for briefing and oral argument and render a decision by February 16, 2015.

This case raises a profoundly significant issue of first impression: whether, in order to maximize the opportunity for generic drugs, antitrust law bars a patent-holder's otherwise lawful exercise of its right to discontinue selling an older drug. Forest holds or licenses valid patents on three Alzheimer's drugs: twice-daily Namenda IR (tablets and oral solution), and an improved version, once-a-day Namenda XR capsules. In July 2015, Forest's patent and regulatory exclusivities on Namenda IR end based on agreements allowing early generic entry. Until then, Forest can sell Namenda IR free of competition, limit sales, or refuse to sell it at all. Forest has the same rights as to Namenda XR through 2029.

After July 2015, generic drug manufacturers will sell a generic version of IR at a lower price than Namenda IR or XR. For every Namenda IR prescription, New York's generic substitution law will require pharmacists to substitute generic IR, unless overridden by a doctor. But because Namenda XR has a different

[1] "Ex." Refers to exhibits attached to the Declaration of Jack E. Pace III, dated December 16, 2014. A copy of the December 15, 2014 Preliminary Injunction Order, Case No. 1:14-cv-07473 [Dkt. 84], is attached as Exhibit 4, and a copy of the December 11, 2014 opinion granting the injunction, Case No. 1:14-cv-07473 [Dkt. 80], is attached as Exhibit 5.

dosing, pharmacists may not unilaterally switch XR prescriptions to generic IR.

Forest announced Namenda XR on June 13, 2013. In February 2014, in anticipation of its loss of patent exclusivity for Namenda IR, Forest announced plans to cease distributing IR. In November 2014, Forest amended that plan, announcing that it would change the distribution of IR by making it available only to patients whose doctors deem IR medically necessary, *i.e.*, in the patient's best interest. Other patients would switch to XR. Forest did so to ensure that after July 2015, generic companies could not automatically capture the market by free-riding on New York's mandatory substitution law. Instead, generics and Forest would compete over whether the cheaper cost of the generic twice-a-day pill outweighs the benefits of Forest's new (but perhaps costlier) once-a-day pill.

After expedited briefing and a hearing, the district court entered an unprecedented injunction, an injunction based on a novel theory—that antitrust law requires Forest to sell its older drug until the exclusivity period for that drug expires. The injunction props up Forest's generic competitors by maximizing the number of IR prescriptions that will be automatically converted to generics in July 2015. Op. 81, 94-95. At that point, New York's generic substitution law will make pharmacists automatically switch Namenda IR patients to generic IR. The court extended its extraordinary injunction to the *entire* nation, even though 39 states do not force pharmacists to switch patients to generics. And the injunction

effectively requires Forest to start making a drug it no longer makes: Forest must "continue to make [IR] tablets available on the same terms and conditions applicable since July 21, 2013." Order ¶ 1.

No court has ever done anything like this before. No court has ever nullified a manufacturer's valid patent rights and commandeered its means of production and distribution to aid future competitors. Absent an immediate stay and expedited appeal, this injunction will effectively end the case, irreparably stymie Forest's exercise of its patent rights, and extinguish [redacted] in earnings. The injunction forces Forest to abruptly halt current production plans [redacted] manufacturing an immense amount of IR, and transfer away personnel and production from XR back to IR, compromising XR's competitiveness. This diversion would [redacted] another Alzheimer's drug, which the FDA is set to approve in ten days. The injunction sets a precedent that would chill innovation not just in pharmaceuticals, but across other industries as well. Any company will think twice before retiring an older product for an improved model, if the price of innovating is for courts to dictate business decisions. Consumers would lose the benefits of innovation, and patients would lose out on clinical improvements.

On the other hand, if the injunction is stayed and New York prevails, no party will be harmed in the interim. No evidence shows any harm to patients who

switch from Namenda IR to XR. The FDA has approved such switching as safe. Forest has an agreement with a specialty pharmacy that, after January 30, 2015, guarantees a Namenda IR supply to any patient whose doctor believes it necessary. Nor is there any harm to competition before July 2015; until then, generics cannot enter the market. And, under the Sherman Act, New York can recover three times any damages suffered by itself or New York consumers, if such damages exist. In any event, a decision before February 16, 2015 would protect New York's interest.

Forest's likelihood of success on the merits further justifies a stay. The district court applied the wrong standard in granting New York injunctive relief: its decision applied a more relaxed standard by holding that the injunction merely maintains the status quo. Op. at 99-101. But the injunction does not order Forest to restore the status quo; it compels Forest to change course. Order ¶ 1-2. The court's decision deploys antitrust law to punish the exercise of the very rights that patent law protects. The injunction rests on legally and factually unsupportable findings. And the injunction is so overly broad and vague that Forest cannot anticipate how to make Namenda IR available "on the same terms and conditions" since 17 months ago. *Id*. Given the urgency of this matter, Forest respectfully requests emergency consideration of this Motion.

BACKGROUND

1. Congress passed the 1984 Drug Price Competition and Patent Term

Restoration Act (the Hatch-Waxman Act) to balance two competing interests. On the one hand, Congress sought to encourage brand manufacturers to invest in inventing cutting-edge drugs by strengthening patent protections and by extending the period of exclusivity, during which only the brand drug may be sold. H.R. Rep. No. 98-857, pt. 1, at 14-17 (June 21, 1984). On the other hand, Congress sought to ensure that before these exclusivity periods ended, generic manufacturers could develop generics without replicating the extremely expensive and time-consuming research required to obtain FDA approval for a new drug. *Id.*

The Hatch-Waxman Act creates a streamlined approval process for generics. So long as the generic and brand drugs are "bioequivalent," the generic manufacturer can obtain FDA approval and sell the generic drug. 21 U.S.C. § 355(j). But a generic is "bioequivalent" or "AB-rated" to the brand only if the generic has identical amounts of the same active drug ingredient in the same dosage and method of administration. Op. 24.

Only eleven states, including New York, have mandatory generic substitution laws. Whenever a physician in these states prescribes a brand drug, pharmacists must substitute an AB-rated generic equivalent without contacting the doctor (unless the doctor wrote "Dispense as Written" on the prescription). *See, e.g.*, Ex. 1 at 155:9-13. These laws benefit pharmacies, which increase their margins by selling lower-priced generic drugs. Op. at 18. Likewise, healthcare

and managed care plans have strong financial incentives to encourage generics, and exercise tremendous influence over what prescriptions patients' plans will cover. Op. at 18-20, 24-25; Ex. 1 at 781:1-786:9. Brand manufacturers survive *only* by competing through innovation and coming up with new cures and improved drugs. The Hatch-Waxman Act gives brand manufacturers the right to use the benefits of patent exclusivity to recoup the cost of their innovation.

2. Forest manufactures and sells two memantine-based treatments for Alzheimer's disease: Namenda IR and Namenda XR. These are not the only FDA-approved Alzheimer's treatments, but they are the only memantine Alzheimer's treatments. Patients take Namenda IR, Forest's first-generation drug, either as a tablet or oral solution; either way, patients must take it twice daily.

After spending [redacted] on R&D and undertaking many years of clinical trials and regulatory approval, Forest unveiled Namenda XR in June 2013. Ex. 7 ¶ 8. Namenda XR requires only one capsule a day. The FDA determined that patients can safely switch from Namenda IR to XR and approved instructions in the XR label for transitioning patients from IR to XR. Ex. 8.

When Forest unveiled Namenda XR, Forest followed the common industry practice of negotiating [redacted] discounts for XR with health plans and wholesalers so that XR costs patients the same amount as IR. Ex. 9 at 120:6-18; Ex. 7 ¶ 12; Ex. 9 at 275:20-276:10. Forest also spent [redacted] promoting

Namenda XR's benefits to caregivers, health care providers, and pharmacists. Ex. 7 ¶ 10. Today, over 700,000 patients a month take either Namenda IR or Namenda XR; about 500,000 patients take Namenda IR, while some 240,000 patients take XR. Ex. 12 ¶ 53. Each month, over 18,000 patients voluntarily switch to XR based on the benefits of once-a-day administration. Ex. 12 ¶ 56; Ex. 25.

It is undisputed that Namenda is a significant breakthrough that has given Alzheimer's patients a chance to communicate with loved ones and function independently for longer. Nor does New York question Namenda XR's "clinical benefits." Quite the contrary: New York's witness Dr. Lah testified that now that Namenda XR is available, IR is not medically necessary, Ex. 1 at 71:25-72:16; 85:14-18, and *no market need for Namenda IR exists*. *Id.* at 85:19-23.

In late 2013, Forest decided to focus on its newer product, Namenda XR. Forest has an exclusive license to Merz's U.S. Patent No. 5,061,703, covering Namenda IR tablets. Ex. 10 ¶¶ 53, 55. Thus, Forest is the only company authorized to sell Namenda IR (memantine), and Forest can exercise (or refrain from exercising) that exclusive right as it chooses. Pursuant to various agreements, five generic manufacturers may start selling the generic version of Namenda IR after July 11, 2015. Ex. 11 ¶ 14. Another seven generic manufacturers may start selling IR on October 11, 2015. *Id.* ¶¶ 2-3, 14-15.

Thereafter, the competitive landscape changes. Under New York's generic

substitution law, pharmacists must switch patients from Namenda IR to generic IR without consulting patients or doctors, because the generic will be AB-rated. The only exception is if doctors in advance insist on the brand. Pharmacists will switch some 80-90% of patients to the generic within months. Op. at 26. But because Namenda XR is not AB-rated to Namenda or generic IR, most pharmacists cannot unilaterally switch patients from Namenda XR to generic IR. All pharmacists are free, however, to call the treating physician and recommend switching the Namenda XR patient to generic IR. Ex. 1 at 794:22-795:16. Forest's Namenda XR patent exclusivity expires in 2029.

Forest wants patients to switch from Namenda IR to XR before July 2015. Thereafter, patients and doctors will choose between the improved Namenda XR and generic IR, a cheaper but less convenient drug. At least eight other pharmaceutical manufacturers have used a similar strategy, and industries as varied as smartphones and packaged foods follow this practice of innovation and product replacement. Ex. 12 ¶ 30. As Actavis' CEO explained, "What we hoped for and what we'll have to see what plays out when generic competitors enter the market in 2015 is do patients and physicians and caregivers, you know, view the innovation of XR important enough to pay for it. . . . So people will have that chance to vote with their wallets." Ex. 1 at 202:22-203:7.

Forest had two options: discontinuing Namenda IR entirely or limiting its

distribution. Forest ultimately chose the latter. Before the injunction, Forest planned to sell Namenda IR tablets after January 31, 2015, through a specialty pharmacy, and took significant steps to implement that strategy. Ex. 1 at 265:3-266:1, 268:20-269:24.

After January 31, Foundation Care, a full-service specialty pharmacy, will handle all Namenda IR distribution. Foundation Care will provide Namenda IR to any patient whose physician deems IR medically necessary. Op. at 64-64. There is "no cap" on how many Namenda IR prescriptions Foundation Care can fill. Ex. 1 at 241:21-242:6, 551:14-552:4.

3. On December 15, 2014, the district court entered the injunction and denied Forest's motion for a stay until "thirty days after July 11, 2015 (the date when generic memantine will first be available)." Order ¶ 4.

ARGUMENT

I. THIS COURT SHOULD STAY THE INJUNCTION

Whether to grant a stay pending appeal depends on "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." *In re World Trade Ctr. Disaster Site Litig.*, 503 F.3d 167, 170 (2d Cir. 2007); *Nken v. Holder*, 556 U.S.

418, 434 (2009). This Court applies these criteria on a "sliding scale," where the "probability of success that must be demonstrated is inversely proportional to the amount of irreparable injury [movant] will suffer absent the stay." *Thapa v. Gonzales*, 460 F.3d 323, 334–35 (2d Cir. 2006) (quotations omitted). Given the gravity of the irreparable injury to Forest, even "some possibility of success" on the merits would warrant a stay. *Id*. But here, all four factors strongly favor a stay.

A. The Balance of Equities and Harms Strongly Favors A Stay

1. Forest Will Be Irreparably Harmed Absent a Stay

The injunction irreparably harms Forest in several distinct ways. Forest has unqualified patent rights, allowing it to produce or not produce Namenda IR. *See infra* p. 15. But the injunction obliterates that right for the benefit of Forest's future competitors: the injunction orders Forest not only to produce Namenda IR, but to do so "on the same terms and conditions applicable since July 21, 2013." Order ¶ 1. This infringement upon "the fundamental nature of patents as property rights granting the owner the right to exclude" is alone irreparable harm. *Robert Bosch LLC v. Pylon Mfg. Corp.*, 659 F.3d 1142, 1149 (Fed. Cir. 2011).

Absent a stay, the case will also effectively become moot. Forest's implementation of its plan to discontinue Namenda IR is at a critical stage, and must be completed by [redacted] 2015 if Forest is to effectively transition patients to XR. The injunction compels Forest to abandon a distribution and

marketing strategy worth over [redacted] to Forest. New York's economist testified that Forest stands to lose some [redacted] if Forest cannot transition patients to Namenda XR. Ex. 1 at 425:10-15. Forest presumably cannot recover that sum from the State should Forest prevail.

The injunction imposes massive and immediate irreparable costs on Forest to comply with its terms. [redacted] Ex. 16 ¶ 5. The injunction forces Forest to start selling IR at the same terms and conditions that existed as far back as July 21, 2013. Order ¶ 1. Forest would have to immediately [redacted] costly processes for manufacturing and distributing IR tablets [redacted]. Ex. 16 ¶¶ 4-6. [redacted]

Switching back to IR production would force Forest to change its current production and divert critical personnel and resources away from other Alzheimer's drugs. *Id.* ¶ 14. [redacted] *Id.* ¶ 3, 11-12. Switching would divert personnel and equipment from [redacted] Forest's new Alzheimer's treatment, the Fixed Dose Combination of Namenda XR and

donepezil. *Id*. ¶ 3, 8-10. [redacted]

[redacted] *Id*. ¶ 10.

These burdens unquestionably constitute irreparable harm. A significant financial loss that cannot be remedied later with financial compensation is irreparable harm. *E.g.*, *Tucker Anthony Realty Corp.*, 888 F.2d at 975. Likewise, irreparable harm exists if there is irreversible price erosion, loss of good will, personnel layoffs, and abandonment of research devoted to developing other uses for a drug. *Sanofi-Synthelabo v. Apotex, Inc.*, 488 F. Supp.2d 317, 342 (S.D.N.Y. 2006), *aff'd* 470 F.3d 1368, 1382-83 (Fed. Cir. 2006).

2. Other Parties Will Not Be Injured, and the Public Interest Supports a Stay

Other interested parties face no cognizable injury from a stay. The only harm antitrust law conceivably recognizes is the cost savings from forcing patients to substitute generic IR for Namenda IR starting in July 2015. If New York wins on the merits, the Donnelly Act provides for treble damages from any damage to competition, which would more than remedy any harm. And if New York is right and this case is decided quickly, there will be no harm to competition by July 2015.

Nor do Alzheimer's patients, caregivers, or healthcare professionals face any immediate harm. Although the FDA has approved procedures for safely switching from Namenda IR to XR, the district court expressed concern that patients would

be hurt by the switch. Op. at 91-92. But any patient whose doctor believes Namenda IR is medically appropriate for them will have full and continued access through Foundation Care. In other words, any patient who conceivably could be harmed from a switch will never need to switch. And other patients will receive the benefit of Namenda XR's improved once-a-day dosage.

Finally, a stay also serves the public interest by preserving innovators' socially beneficial incentives to invest in developing new products. Furthermore, the public has a strong interest in ensuring Forest's participation in the Alzheimer's therapeutic area, and protecting the lawful exercise of patents.

B. Forest's Appeal Is Substantially Likely to Succeed on the Merits

1. The district court applied the wrong legal standard, and its injunction cannot stand under the proper standard. If "an injunction will alter, rather than maintain, the status quo," the court can grant relief only if the movant shows a "clear" or "substantial" likelihood of success on the merits. *Tom Doherty*, 60 F.3d 27, 33-34 (2d Cir. 1995). By contrast, a movant can obtain an injunction that maintains the status quo by making a much weaker showing of "sufficiently serious questions going to the merits to make them fair ground for litigation." *Oneida Nation of New York v. Cuomo*, 645 F.3d 154, 164 (2d Cir. 2011). The court held New York to the lower standard because "[t]he requested interim relief would maintain the status quo, i.e., continue [Forest's] current Namenda IR sales

and distribution activities." Op. at 99.

But in no way does the district court's injunction maintain the status quo. By its express terms, the injunction requires Forest to start—*re*start—doing what it was doing a year and a half ago, before it started transitioning to XR. On pain of contempt, it orders Forest "to make [IR] tablets available on the same terms and conditions applicable since July 21, 2013 (the date Namenda XR entered the market.)." Order ¶ 1. Forest would have to [redacted] entirely revamp its current production and distribution operations. As a result, far from maintaining the status quo—which is Forest's current implementation of its strategy of scaling back Namenda IR distribution in favor of XR—the district court has mandatorily ordered a return to the status quo *ante*. The court thus granted injunctive relief under the wrong standard, relief that could not be justified under the higher standard the court should have applied.

2. Forest is likely to prevail on appeal because it did not engage in the type of anticompetitive, exclusionary conduct that antitrust law prohibits. New York must prove that Forest engaged in exclusionary conduct to thwart competition. *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). But Forest engaged in no conduct that the Supreme Court or this Court has ever deemed exclusionary, like tying arrangements, exclusive dealing, predatory pricing, monopoly leveraging, or sham patent that would block market entry.

The only conduct at issue is Forest's change in distribution or discontinuance of Namenda IR and the switch to XR during IR's patent exclusivity period. New York concedes that Forest has valid patent rights over Namenda IR. Ex. 10 ¶¶ 3, 63. "A patent . . . is an exception to the general rule against monopolies." *Walker Process Equipment, Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 177 (1965). "The patent laws which give a 17-year monopoly on 'making, using, or selling the invention' are *in pari materia* with the antitrust laws and modify them *pro tanto*." *Simpson v. Union Oil Co. of Cal.*, 377 U.S. 13, 24 (1964). Accordingly, a patentee's exercise of its right to "exclude others from the use of the invention . . . is not an [antitrust] offense." *United States v. United Shoe Mach. Co.*, 247 U.S. 32, 57 (1918). And Forest has the absolute right to sell or not sell Namenda IR during the patent exclusivity period, because a patentee is "'neither bound to use his discovery himself nor permit others to use it.'" *Cont'l Paper Bag Co. v. E. Paper Bag Co.*, 210 U.S. 405, 425, 429 (1908). Had Forest discontinued IR without XR on the market, its conduct unquestionably would be lawful. Likewise, Forest's launch of Namenda XR cannot violate antitrust law. "[A]ny firm, even a monopolist, may generally bring its products to market whenever and however it chooses." *Berkey Photo, Inc. v. Eastman Kodak Co.*,603 F.2d 263, 286 (1979).

The district court nonetheless found that Forest's exercise of both of these

rights together violates antitrust law and the "spirit of the Hatch-Waxman Act," Op. at 134, and "requires [Forest] to allow generic competitors a fair opportunity to compete using state substitution laws." *Id.* at 94-95. But two rights together do not make a wrong. Neither antitrust law nor the spirit of the Hatch-Waxman Act guarantees generic manufacturers the right to a fixed competitive landscape where most prescriptions automatically convert to generic prescriptions once a generic drug is on the market. No court has ever imposed a duty forcing a manufacturer to make and sell an older product to help competitors compete. "The antitrust laws . . . were enacted for 'the protection of competition, not competitors.'" *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977) (citation omitted); *see In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 135 (2d Cir. 2014). Competition means that when patent exclusivity ends, generic manufacturers can enter the market and compete against any brand drugs. Forcing brand manufacturers to guarantee that they will pit a brand drug against its exact generic equivalent is not competition; it is a stacked deck.

3. The district court's findings of irreparable harm rest on faulty legal assumptions and irreconcilable factual findings. The court determined that surveys showed that "many physicians, caregivers, and pharmacists are concerned about potential harm to patients from the forced switch." Op. at 92-93. But potential medical harm is not the concern of antitrust law. It is the concern of the FDA,

which has approved both Namenda XR and the switch from IR to XR. In any event, this finding is untenable. New York's witness, Dr. Lah, testified that Namenda IR is not medically necessary in light of Namenda XR, Ex. 1 at 72:11-16, and that he does "not see a market need" for Namenda IR beyond his personal preference, Ex. 1 at 85:14-23. Thousands of patients have seamlessly and safely switched from IR to XR, and also back from XR to IR (due to temporary shortages of XR), with no adverse effects. Ex. 1 at 656:7-24, 740:10-14; Ex. 17 at 4-7, 73-77 (DX513). Dr. Lah testified that he was not aware of any clinical studies indicating that patients would be injured by switching from IR to XR. Ex. 1 at 87:24-88:9.

The decisions also rest on wildly inconsistent factual assumptions. On the one hand, the court found that forcing any medication switch could harm vulnerable Alzheimer's patients. Op. at 89-92. But earlier in the opinion, the court dismissed IR's availability via Foundation Care as irrelevant, because Namenda IR is not *medically necessary* and thus doctors would not be "comfortable" prescribing it. In other words, there is no medical reason for patients *not* to switch to XR. *Id*. at 67-68. The court cannot have it both ways. If Namenda IR is medically necessary, doctors can prescribe it. If Namenda IR is not medically necessary, doctors should not be prescribing it.

The Court's finding that "only 2.4% of patients would be able" to obtain Namenda IR (Op. at 69) is also dead wrong; the unrefuted record was that there is

"no limit" or "cap" on the prescriptions that may be filled by Foundation Care. Ex. 1 at 241:24-242:6, 244:8-12, 590:25-591:2; Ex. 18. Rather, 2.4% is the estimated percentage of patients whose doctors are likely to find IR "medically necessary" for their patients. Ex. 15 ¶ 9; Ex. 1 at 241:21-242:2. That low number only highlights that IR is no longer medically necessary in light of XR.

The court's second basis for finding irreparable harm—that "[p]ermanent damage to competition in the memantine market can also result" from Forest's conduct—is equally flawed. Op. at 130. New York has pursued treble damages under the Donnelly Act. Ex. 12 at 40**.** Where, as here, money damages are available to remedy any harm to competition that actually materializes, there can be no irreparable harm. *Tucker Anthony Realty Corp. v. Schlesinger*, 888 F.2d 969, 975 (2d Cir. 1989). And finding that "permanent damage *can* also result from Defendants' planned hard switch strategy" is inherently speculative and thus also cannot constitute irreparable harm. Op. at 130 (emphasis added); *Tom Doherty Assocs., Inc.*, 60 F.3d at 37.

4. The district court committed reversible error in entering a nationwide injunction that is so sweeping and vague that Forest must guess at how to comply. It is "the essence of equity jurisdiction" that a court can "grant relief no broader than necessary to cure the effects of the harm caused by the violation." *Forschner Grp., Inc. v. Arrow Trading Co.*, 124 F.3d 402, 406 (2d Cir. 1997). The court had

no authority to grant a nationwide injunction when New York is using the Sherman Act to enhance the impact of New York's generic substitution law, which most other states do not follow.

The court also had no authority to force Forest to make Namenda IR available "on the same terms and conditions applicable since" July 2013. At the hearing on the injunction, the court refused to clarify what this meant, or how Forest can comply. The court stated that it was "not unaware of the difficulties that this creates." Ex. 1 at 47:24-25. But when Forest's counsel asked whether Forest would have to sell Namenda IR at its July 2013 price, the court responded, "you will have to make your own conclusions," and later added, "you are going to do whatever you think is consistent . . . and we will see." *Id.* at 48:12-14; 49:1-3. The injunction places "the entire conduct of [Forest's] business under the jeopardy of punishment for contempt for violating the injunction" unless Forest petitions every time uncertainty arises. *Sanders v. Air Line Pilots Assoc., Int'l*, 473 F.2d 244, 248 (2d Cir. 1972).

II. THIS COURT SHOULD EXPEDITE THE APPEAL AND DECIDE THIS CASE BY FEBRUARY 16, 2015

This Court, for good cause, may suspend generally applicable rules governing briefing deadlines and expedite the appeal. Fed. R. App. P. 2. An expedited appeal is imperative. New York concedes that this appeal must be

expedited in some form, and that unless this Court renders a decision "in advance of July 11, 2015," Forest will not "have the opportunity to accomplish the forced switch in advance of generic entry." Ex. 3 at 2. Forest's business plan for transitioning patients from IR to XR requires Foundation Care to assume exclusive distribution of Namenda IR by January 31, 2015. If the injunction is not stayed, February 16, 2015 is the latest date by which Forest realistically may implement its plan. Thereafter, if Forest prevails, a decision will have no practical effect. And if the injunction is stayed but New York prevails, delaying Forest's compelled ramp-up of Namenda IR until February 16 will not prejudice New York.

CONCLUSION

Forest respectfully requests that this Court stay the district court's December 15, 2014 preliminary injunction pending final resolution of this appeal, and that this Court expedite the appeal to allow for a decision by February 16, 2015.

Dated: December 16, 2014

Respectfully submitted,

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