

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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FERRING B.V., FERRING  
INTERNATIONAL CENTER S.A., and  
FERRING PHARMACEUTICALS INC.,

17 Civ. 9922

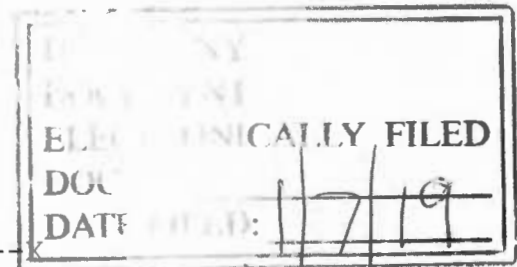
OPINION and ORDER

Plaintiffs and Counter-  
Defendants,

-against-

SERENITY PHARMACEUTICALS, LLC,  
REPRISE BIOPHARMACEUTICS, LLC,  
AVADEL SPECIALTY PHARMACEUTICALS, LLC

Defendants and  
Counterclaimants.



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**Sweet, D.J.**

Plaintiffs Ferring B.V., Ferring International Center S.A., and Ferring Pharmaceuticals Inc. ("Ferring," the "Plaintiffs," or the "Counter-Defendants") have moved for leave to amend their first amended complaint of June 30, 2017 ("First Amended Complaint" or "FAC") and to reply to counterclaims, affirmative defenses, and amended counterclaims of Defendants Serenity Pharmaceuticals, LLC, Reprise Biopharmaceutics LLC, and Avadel Specialty Pharmaceuticals LLC ("Serenity" or "Defendants"). ECF No. 221.

Based on the conclusions set forth below, Plaintiff's motion is denied.

**I. Prior Proceedings**

Familiarity with the facts of this case and the related 2012 case, Ferring B.V. v. Allergan, Inc., No. 12 Civ. 2650 (RWS), (the "2012 Action") is assumed. The following summary is provided only as necessary to resolve the pending motions.

On April 28, 2017 Ferring commenced this action in the District of Delaware against Allergan, Inc. ("Allergan"), Serenity, and Reprise, seeking a declaratory judgment of patent invalidity, unenforceability, and non-infringement with respect to United States Patent No. 7,405,203 (the "203 Patent"), United States Patent No. 7,579,321 (the "321 Patent"), and United States Patent No. 7,799,761 ("the 761 Patent") (together, the "Patents in Suit"). See generally Pl. Compl., ECF No. 1.

Ferring amended its complaint on June 30, 2017. ECF No. 18.

After briefing from parties on the issue of jurisdiction in Delaware and transferability, the case was transferred to this District where it was designated related to the 2012 Action. See ECF Nos. 25-27, 58. Around the same time, Allergan was voluntarily dismissed from the case. ECF No. 35.

Following much dispute over whether Ferring's NOCDURNA drug would be approved, and with Serenity's motion to dismiss for lack of jurisdiction pending, Ferring received FDA approval of its New Drug Application ("NDA") on June 21, 2018. See ECF No. 99.

On June 28, 2018 Serenity and Reprise, together with newly-joined patent licensee Avadel Specialty Pharmaceuticals, LLC ("Avadel") answered Ferring's Amended Complaint and asserted various counterclaims, including patent infringement and willful patent infringement by NOCDURNA over the 203 Patent and the 321 Patent. ECF No. 101.

On July 19, 2018, Ferring moved to strike certain of Serenity's defenses and to dismiss certain of its counterclaims, including those alleging patent infringement under 35 U.S.C. § 271(a). ECF No. 114 at 13-14.

On July 23, 2018, Serenity moved for a preliminary injunction to block the commercial release of NOCDURNA. ECF No. 117.

On August 2, 2018, Serenity filed a cross-motion to strike certain of Ferring's affirmative defenses asserted in its July 19 motion to strike and dismiss. ECF No. 136.

On August 14, 2018, Serenity filed a motion for judgment on the pleadings. ECF No. 148.

On August 20, 2018, Ferring withdrew its July 19, 2018 motion to strike and dismiss certain of Serenity's affirmative defenses. ECF No. 160.

On September 10, 2018, Ferring moved for summary judgment on the issue of invalidity under 35 U.S.C. § 112 for lack of enablement (ECF No. 178) and for non-infringement or, alternatively, invalidity due to lack of written description (ECF No. 182).

On September 21, 2018, Serenity moved for judgment on the pleadings on the issue of collateral estoppel. ECF No. 206.

On October 10, 2018, Plaintiffs filed the instant motion for leave to amend/ correct the First Amended Complaint and to reply to counterclaims and affirmative defenses. ECF No. 221. The motion was heard and marked fully submitted on November 13, 2018.

## II. The Applicable Standard

While leave to amend should be "freely given . . . when justice so requires," district courts "ha[ve] broad discretion to decide whether to grant leave to amend." Gurary v. Winehouse, 235 F.3d 792, 801 (2d Cir. 2000). Leave to amend is properly denied in cases of "undue delay, bad faith or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of the allowance of the amendment, [or] futility of the amendment." Ruotolo v. City of New York, 514 F.3d 184, 191 (2d Cir. 2008) (quoting Foman v. Davis, 371 U.S. 178, 182 (1962)). However, courts have emphasized the inquiry into prejudice and bad faith over "mere delay." Ruotolo, 514 F.3d at 191 (citing to 6 CHARLES ALLEN WRIGHT, ARTHUR R. MILLER & MARY KAY KANE, FEDERAL PRACTICE AND PROCEDURE: CIVIL 2D, § 1487, at 613 (1990 & 2007 Supp.) (discussing prejudice as "the most important factor" and "the most frequent reason for denying leave to amend")); see also State Teachers Ret. Bd. v. Fluor Corp., 654 F.2d 843, 856 (2d Cir. 1981).

In determining what constitutes "prejudice," courts in this circuit consider whether the assertion of the new claim

would: "(i) require the opponent to expend significant additional resources to conduct discovery and prepare for trial; (ii) significantly delay the resolution of the dispute; or (iii) prevent the plaintiff from bringing a timely action in another jurisdiction." Block v. First Blood Associates, 988 F.2d 344, 350 (2d Cir. 1993). When the non-moving party asserts that the movant is acting in bad faith, "there must be something more than mere delay or inadvertence for the court to refuse to allow amendment," such as seeking to derive some unique tactical advantage through their amendment. Primetime 24 Joint Venture v. DirecTV, Inc., No. 99-3307, 2000 WL 426396, \*5-\*6 (S.D.N.Y. Apr. 20, 2000). Unless the non-moving party demonstrates prejudice or bad faith, courts generally allow a party to amend its complaint. City of New York v. Grp. Health Inc., 649 F.3d 151, 157 (2d Cir. 2011) (citing AEP Energy Servs. Gas Holding Co. v. Bank of Am., N.A., 626 F.3d 699, 725 (2d Cir. 2010)).

The burden of establishing prejudice or bad faith falls to the party opposing a motion to amend, as does the burden of establishing futility. See Block, 988 F.2d at 350; see also Blaskiewicz v. County of Suffolk, 29 F. Supp. 2d 134, 137-38 (E.D.N.Y. 1998) (citing Harrison v. NBD Inc., 990 F. Supp. 179, 185 (E.D.N.Y. 1998)). A proposed amendment is futile



if it cannot "withstand a motion to dismiss pursuant to Rule 12(b)(6)." Oneida Indian Nation of New York v. City of Sherrill, 337 F.3d 139, 168 (2d Cir. 2003), rev'd on other grounds, 544 U.S. 197 (2005) (citing Ricciuti v. N.Y.C. Transit Auth., 941 F.2d 119, 123 (2d Cir. 1991)). Therefore, "[f]or the purposes of evaluating futility, the 12(b)(6) standard is applied: all well pleaded allegations are accepted as true, and all inferences are drawn in favor of the pleader." E\*Trade Fin. Corp. v. Deutsche Bank AG, 420 F. Supp. 2d 273, 282 (S.D.N.Y. 2006) (citing Mills v. Polar Molecular Corp., 12 F.3d 1170, 1174 (2d Cir. 1993)).

However, "a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (internal quotation marks omitted). A complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 663 (2009) (quoting Twombly, 550 U.S. at 570).

### III. Ferring's Motion for Leave is Denied

"[T]he district court plainly has discretion to deny leave to amend where the motion is made after an inordinate delay, no satisfactory explanation is made for the delay, and the amendment would prejudice the defendant." See, e.g., MacDraw, Inc. v. CIT Group Equipment Financing, Inc., 157 F.3d 956, 962 (2d Cir. 1998), Foman, 371 U.S. at 182. The party seeking leave to amend has the burden to explain the delay See id.

Ferring's late-stage amendment—with trial looming and motions for summary judgment, among others, pending—relies on facts that have been known for years. After initially alleging inequitable conduct against Seymour Fein ("Fein") in the April 2017 Complaint (ECF No. 1), and again in the FAC (ECF No. 18), Ferring now seeks to "add additional allegations and grounds supporting its unenforceability claims" over the Patents in Suit. See Memo. in Supp. at 4, ECF No. 4.

Ferring's conduct in seeking to amend its complaint constitutes undue delay. Through the lengthy and ongoing related litigation, Ferring v. Allergan, No. 12-cv-2650 (RWS) (S.D.N.Y.),

which concerns the same underlying conduct, Ferring has been aware for years of Dr. Fein's patents and their prosecution history. See Ferring v. Allergan, 4 F.Supp.3d 612, 633 (RWS) (S.D.N.Y. 2014). Ferring alleged in that case that "Fein's patent application did in fact disclose information confidential and proprietary to Ferring" and "acknowledge[d] that it had reviewed [and was aware of] Fein's patent application." Id. Ferring further demonstrated knowledge of the patents-in-suit, arguing that they "contained data that emanated from Ferring," including "information that was not in Ferring's UK application." See id. at 632.

To explain the significant delay in asserting the additional inequitable conduct claim, Ferring claims to have "waited to plead the additional grounds for its inequitable conduct claims until after it had *more fully developed the underlying facts.*" Pl.'s Memo in Supp. at 1, ECF No. 222. But the facts underlying the inequitable conduct claim have been known for 15 years.<sup>1</sup> In this litigation, which commenced in April

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<sup>1</sup> The patents-in-suit and their specifications, clinical trial data, and inventorship origins are old news. See Ferring v. Allergan, 4 Supp.3d 612, (S.D.N.Y. 2014) ("in a letter dated December 9, 2004, Ferring's counsel raised concerns that Fein's patent application might include confidential Ferring data"). The facts required to assert an inequitable conduct claim with respect to the patent prosecution in this case were available

2017, Ferring had the facts necessary to assert the additional claim of inequitable conduct from the start, having deposed Dr. Fein over 3.5 years ago in connection with Ferring v. Allergan. Its explanation is thus unsatisfactory. Cresswell v. Sullivan & Cromwell, 922 F.2d 60, 72 (2d Cir. 1990) (denial of motion for leave to amend appropriate "where the motion is made after an inordinate delay, [and] no satisfactory explanation is made for the delay . . .").

That Ferring's motion for leave was filed before the October 1, 2018 deadline to amend does not preclude a finding of undue delay. Ferring had the facts necessary to bring this additional claim at an earlier junction and chose not to. Ferring's decision to file an eleventh-hour amendment just weeks before trial—with a panoply of motions pending—constitutes undue delay. See Zahra v. Town of Southhold, 48 F.3d 674, 685 (2d Cir. 1995) ("It was entirely reasonable for the district court to deny a request to amend a complaint that was filed two and one-half years after the commencement of the action, and three months prior to trial."); see also Ansam Assoc., Inc. v. Cola Petroleum, Ltd., 760 F.2d 442 (2d Cir. 1985) (affirming denial

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after Fein's deposition, which concluded over 3.5 years ago. See Defs.' Memo in Opp. at 2, ECF No. 265.

of motion to amend filed after close of discovery and with summary judgment motion pending).

District Courts must also "take into account any prejudice that might result to the party opposing the amendment." Ansam Assoc. v. Cola, 760 F.2d at 446 (quoting Zenith Radio Corp. v. Hazeltine Research, Inc., 401 U.S. 321, 330-3 (1971)). Were Ferring permitted to amend its complaint for the second time, the Defendants would be unfairly prejudiced. First, the motions pending in this case—and those yet to be heard—are numerous and include summary judgment, claim construction, sanctions, motions to strike, and a motion for judgment on the pleadings. An amended complaint at this stage could render moot certain of these motions, requiring renewal by Defendants at great cost to both parties and the Court. The amendment could likewise require supplemental discovery of Dr. Fein, which would be prejudicial to Defendants.

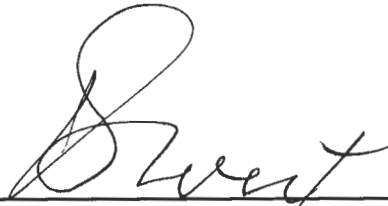
In view of the undue delay by Ferring in seeking to amend its complaint at this late stage—just weeks before trial after knowing for years the facts underlying the additional cause of action—and the potential prejudice to Defendants, Ferring's motion is denied.

Conclusion

For the reasons set forth above, Plaintiff's motion for leave to amend its complaint and its counterclaims in reply is denied.

It is so ordered.

New York, NY  
January 4<sup>th</sup>, 2019

A handwritten signature in cursive script, appearing to read "Sweet", written over a horizontal line.

ROBERT W. SWEET  
U.S.D.J.