UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Impax Laboratories, Inc.,

Plaintiff,

-against-

Turing Pharmaceuticals AG,

Defendant.

COMPLAINT

16 Civ. 3241

JURY TRIAL DEMANDED

Plaintiff Impax Laboratories, Inc. (together with its subsidiaries, "Impax") brings this action for declaratory judgment and breach of contract against Defendant Turing Pharmaceuticals AG ("Turing") and seeks declaratory relief, specific performance, damages, and other relief. In support of its complaint, Impax alleges as follows:

NATURE OF THE ACTION

1. This is an action seeking to hold Turing accountable for its breach of the terms of the contract by which Turing purchased from Impax the right to sell the drug Daraprim—a drug used to treat toxoplasmosis, a high risk disease for those affected by HIV, AIDS, and cancer (hereinafter, the "Purchase Agreement" or "PA"). Under the Purchase Agreement, Impax, among other things, transferred substantial Daraprim inventory (the "Inventory") to Turing and consented to Turing's sale of the already-packaged Inventory under Impax's labeler code and national drug code ("NDC"), a unique drug code identifier. Because Turing's sale of Daraprim under Impax's labeler code and NDC would require *Impax* to make certifications and pay rebates to the government, the Purchase Agreement included three clear conditions:

a. Turing promised to provide and certify as accurate pricing data for its Daraprim sales activities (the "Pricing Data") to Impax by the twenty-fifth day of each calendar month (to ensure that Impax could report the data to the federal government, as required by federal law). PA § 9.2 & Ex. E;

b. Turing promised to assume liability for *all* Medicaid rebate liability (the "Rebate Liability") directly arising out of, or in connection with, Turing's use, marketing, or sales of Daraprim, and to reimburse Impax for such Rebate Liability within 30 days of receiving an invoice from Impax. PA §§ 2.4(a), 8.3, 9.2(d) & Ex. E; and

c. Turing agreed both (i) to "use best efforts not to do any act [that] endangers, destroys or similarly affects the value of the goodwill pertaining to" Impax's trademarks or NDC (collectively, the "Corporate Names") and (ii) not to use the Corporate Names "in any manner that is inconsistent with" their usage by Impax "or that would otherwise violate applicable Law." PA § 8.5(c).

2. Turing has breached all three of these conditions.

3. Specifically, despite repeated requests, Turing has (i) failed to provide monthly Pricing Data to Impax at all for multiple months, provided quarterly Pricing Data to Impax late three quarters in a row, provided Pricing Data for the first quarter of 2016 ("Q1 2016") only belatedly and after receiving multiple demand letters and threats of legal action, and even recently suggested that the Pricing Data it certified to Impax for the third quarter of 2015 ("Q3 2015") may have been "incorrect" (without providing plausible explanations for why this may be); (ii) refused to pay $20 million in Rebate Liability due and owing to Impax; and (iii) caused (and may cause further) irreparable harm to Impax's relationship with the federal and state governments by hindering Impax's ability to comply with its Medicaid reporting obligations, potentially even subjecting Impax to legal action.

4. Turing's refusal to abide by the terms of the Purchase Agreement is all the more striking given its conduct following the close of the deal between Impax and Turing. In August 2015, shortly after it purchased the rights to Daraprim, Turing raised the wholesale

acquisition cost ("WAC") of Daraprim by *over 4,250%*—from $17.63 per unit (the WAC set by Impax prior to the close of the Purchase Agreement) to $750.00 per unit. As has been widely reported, Turing's price increase caused the cost of care for many HIV, AIDS, and cancer patients taking Daraprim to skyrocket, prompting significant negative press coverage and government scrutiny. While Impax had no forewarning of Turing's decision to raise the price of Daraprim (to be clear, Impax has received—and will receive—no financial remuneration linked to Turing's price increase), it nonetheless found itself subject to significant liability due to Turing's actions. Still, Turing retains the profits from its stunning price increase and at the same time refuses both to provide complete and timely information to Impax related to its Daraprim sales activities and to make Impax whole for the Rebate Liability.

5. Impax now has no choice but to file this lawsuit, premised on three causes of action: (i) a declaratory judgment that Impax may revoke Turing's right to sell Daraprim under Impax's NDCs, because Turing's failure to provide complete and timely certifications of Pricing Data has hindered Impax's ability to comply with its reporting obligations to the federal government, threatening its goodwill with the regulators that are most critical to its business; (ii) specific performance to require Turing to comply with its obligations under the Purchase Agreement for past due reports and for reports going forward (and to confirm the accuracy of its Pricing Data for Q3 2015 and Q4 2015); and (iii) money damages to remedy Turing's breach of the Purchase Agreement for failure to reimburse Impax for millions of dollars of Rebate Liability when due.

6. In brief, Impax seeks nothing more than what it is entitled to under the plain language of the Purchase Agreement.

PARTIES

7. Plaintiff Impax is a pharmaceutical company focused on researching, developing, manufacturing, and supplying a multitude of generic and specialty products. Impax is a Delaware corporation with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

8. Defendant Turing is a biopharmaceutical company founded in 2015 by its former CEO, Martin Shkreli. Turing is a Swiss stock corporation with its principal place of business in Baar, Zug, Switzerland.

JURISDICTION AND VENUE

9. The Court has subject matter jurisdiction over this action under 28 U.S.C. § 1332 because there is complete diversity between Plaintiff and Defendant and the amount in controversy exceeds $75,000.

10. The Court has personal jurisdiction over the defendants because under the Purchase Agreement, Turing "agree[d] and irrevocably submit[ted] to the exclusive jurisdiction of" this Court "for the purposes of any suit, action or other proceeding arising out of [the Purchase] Agreement or any transaction contemplated" therein and because Turing transacts business in the State of New York and in this judicial district. *See* PA § 13.9.

11. Venue in this Court is proper because the dispute arises from, and is related to, the Purchase Agreement, under which the parties agreed to "irrevocably and unconditionally waive[] any objection to the laying of venue" in this Court. *Id.*

FACTUAL ALLEGATIONS

A. Impax Acquires Daraprim and Sells It at a Reasonable Price.

12. In March 2015, Impax acquired the United States marketing rights for the drug pyrimethamine (trade name Daraprim) in connection with its acquisition of certain

companies, including Corepharma LLC, which had licensed the rights from GlaxoSmithKline LLC in 2010. Daraprim is an antiprotozoal medication mainly used to treat toxoplasmosis, a high risk and often times life-threatening disease for those affected by HIV, AIDS, cancer, and other diseases weakening the immune system.

13. In August 2015, when Impax sold the rights to Daraprim to Turing, Impax's WAC was $17.63 per unit for the drug.

B. The Applicable Regulatory Regime.

14. In order for prescriptions for Daraprim to be covered by Medicaid and paid under state Medicaid program drug benefits, the company associated with Daraprim's NDC must participate in the Medicaid Drug Rebate Program and execute a rebate agreement with the U.S. Department of Health & Human Services ("HHS"). *See* 42 U.S.C. § 1396r-8(a)(1). The Medicaid Rebate Agreement covering Daraprim sales under Impax's NDCs (the "Medicaid Rebate Agreement") was executed by the labeler, Amedra Pharmaceuticals LLC, which was acquired by Impax on March 10, 2015, along with its sister company Corepharma LLC. As Amedra's parent company, Impax assumed Amedra's obligations under that agreement.

15. The Centers for Medicare & Medicaid Services ("CMS") administer the Medicaid Drug Rebate Program at the federal level, and require Impax to calculate, submit, and certify Pricing Data[1] to CMS on a monthly and quarterly basis, as applicable, for all covered outpatient drugs under its labeler code(s), including the Daraprim NDCs under Impax's labeler

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[1] The Pricing Data consist of monthly average manufacturer price ("AMP") (as well as the number of units used to calculate monthly AMP), quarterly AMP, best price, customary prompt pay discounts provided to wholesalers, and prices that fall within the nominal price exclusion. *See* 42 U.S.C. § 1396r-8 (2012); 42 C.F.R. § 447.510(a); 42 C.F.R. § 447.510(d); CMS Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Rel. 81 (Nov. 1, 2010).

code.[2] CMS in turn calculates a "unit rebate amount" ("URA") at which the manufacturer is required to rebate the state Medicaid programs for utilization of the drug, by applying a statutory formula based on the manufacturer-submitted Pricing Data. *See* 42 U.S.C. § 1396r-8(c). Each state invoices manufacturers each quarter by multiplying the state Medicaid utilization (total units reimbursed to providers by the state Medicaid program during a quarter) for the NDC times the applicable URA for that quarter. *See* 42 C.F.R. § 447.511; *see also* Medicaid Rebate Agreement § I(n).

16. Because CMS administers the Medicaid Drug Rebate Program on a labeler code basis, *see* Medicaid Rebate Agreement § I(1), Impax remains obligated to calculate, submit, and certify Pricing Data, and to pay Rebate Liability based on Medicaid utilization of Daraprim under its NDC, even though Turing is now selling the drug and reaping all profits therefrom. Impax cannot selectively remove the Daraprim NDCs that are still marketed from its Medicaid Rebate Agreement, and it cannot terminate its Medicaid Rebate Agreement without affecting Medicaid coverage for other Impax drug products. *See id.* §§ VIII(b) and (d). Even if Impax were to terminate the Medicaid Rebate Agreement, Impax would remain liable to the states for already-accrued Medicaid Rebate Liability on Daraprim sold under its NDCs. *See id.* § VIII(e).

17. Impax thus has two key obligations under the Medicaid Drug Rebate Program with respect to the Daraprim sold under its NDCs that are pertinent here: (i) to timely

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[2] The CMS Medicaid Rebate Agreement was issued in 1991, *see* 56 Fed. Reg. 7,049 (Feb. 21, 1991), and has not been subsequently amended to reflect a number of statutory and regulatory updates (including, without limitation, monthly reporting, or reporting of metrics other than AMP and best price). Although the template agreement continues to form the basis for Medicaid Drug Rebate Program participation, more current program requirements are addressed via CMS regulations and sub-regulatory guidance. *See, e.g.*, 42 C.F.R. § 447.510; CMS Medicaid Drug Rebate Program Bulletin for Participating Drug Manufacturers, Rel. 81 (Nov. 1, 2010).

and accurately calculate, report, and certify Pricing Data to the federal government and (ii) to pay Rebate Liability to the states when due.

18. CMS requires Impax to make the following certification with each monthly and quarterly Pricing Data submission to CMS, via CMS's Drug Data Reporting system:

> I hereby certify, to the best of my knowledge, the data being sent to CMS with this submission is complete and accurate at the time of this submission, and was prepared in accordance with the manufacturer's good faith, reasonable efforts based on existing guidance from CMS and the manufacturer's reasonable assumptions regarding the provisions of section 1927 of the Social Security Act, the National Medicaid Drug Rebate Agreement, and applicable federal regulations. I understand that the information contained in this submission may be used for Medicaid rebate and payment purposes and that civil monetary penalties and/or termination from the Medicaid Rebate Program may be enforced if the information provided is found to be misrepresented. I further certify that I am authorized to submit this information in accordance with 42 CFR 447.510(e).

CMS, Drug Data Reporting System, https://ddr.cms.gov (2016) (access limited to authorized users). Turing also participates in the Medicaid Drug Rebate Program and is thus aware both that Impax must make this certification and that Impax is relying on Turing to provide complete, accurate, and timely Pricing Data.

19. If Impax fails to certify the relevant Pricing Data, it will be unable to submit the required data to CMS and thus can be subject to potential termination of the Medicaid Rebate Agreement (which would affect Medicaid coverage of Impax's other products and exclude Impax from the Medicaid program), civil monetary penalties, and/or other enforcement

action by the U.S. Office of Inspector General ("OIG")[3] or state enforcement agencies. *See* 42 U.S.C. § 1320a-7b(b)(3)(C)(i); *see also* Medicaid Rebate Agreement § IV(c). If Impax provides false data or false certifications to the government, it can also be subject to regulatory action, civil liability, and/or criminal prosecution. *See, e.g.*, 42 U.S.C. § 1320a-7b(b)(3)(C)(ii); *see also* Medicaid Rebate Agreement § IV(b). And if Impax fails to pay the Rebate Liability it owes, it is subject to interest, potential termination of the Medicaid Rebate Agreement (which again would affect Medicaid coverage of Impax's other products), and may be liable to regulators, including the OIG or state attorneys general.

C. Turing Acquires the Right to Sell Daraprim Subject to Certain Conditions and Only After Taking on Specific Obligations to Impax.

20. On August 7, 2015, Impax sold Turing the rights to sell Daraprim, together with the considerable Inventory. *See* PA §§ 1.1, 2.2(a). At the time of the sale, much of the Inventory had already been packaged into bottles bearing Impax labeling and Impax's NDCs.[4] Because Turing did not yet have its own NDC for Daraprim (and so Turing would not have to repackage the Inventory), and to ensure continued patient care, Impax authorized Turing to "sell to Third Parties any Inventory or Inventory packaging . . . containing any [of Impax's] Corporate Names," which include the Impax NDCs. *See id.* § 8.5(a).

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[3] The OIG issued a Special Advisory Bulletin, stating: "The failure by a manufacturer to submit and certify timely quarterly product and pricing data for a drug may impede CMS's ability to calculate a URA for that drug and may impede the States' ability to collect appropriate rebate amounts," and announcing an enforcement initiative "to promote increased compliance with the reporting requirements" and "timely submission". *See* OIG, Special Advisory Bulletin: Average Manufacturer Price and Average Sales Price Reporting Requirements (Sept. 2010).

[4] At various points, Impax sold Daraprim under two different NDCs: 52054-0330-10 (the "-10 Product"), and 52054-0330-95 (the "-95 Product").

21. However, the Purchase Agreement imposed three, critical conditions on Turing's sales of the Inventory:

a. *First*—because Impax would remain liable to government agencies for all Rebate Liability associated with Turing's use, marketing, or sales of Daraprim under Impax's NDCs, even though Impax would receive no additional consideration from Turing's use, marketing, or sales—Turing agreed to reimburse Impax for *all* Rebate Liability "directly arising out of or in connection with" Turing's use, marketing, or sales of Daraprim under Impax's NDCs. PA § 2.4(a). Under Section 2.4(a) of the Purchase Agreement:

> [Turing] will assume, be responsible for and pay, perform and/or otherwise discharge when due those Liabilities . . . directly arising out of or in connection with or primarily related to the Transferred Assets, the use thereof, or the marketing or sale of the Product [Daraprim], . . . including, . . . (iv) Rebates,[5] Chargebacks, discounts, allowances, incentives and similar payments in connection with the sale of Product[.]

See also id. §§ 8.3, 9.2(d) & Ex. E (same). Turing must reimburse Impax for any Rebate Liability it owes within 30 days of receiving an invoice from Impax. *See id.* Ex. E.

b. *Second*—because Impax would remain obligated to certify Pricing Data to CMS for any Daraprim sales activities that took place under its NDC (though Impax would not control, benefit from, or know the Pricing Data related to these activities to the extent they were derived from Turing's actions)—Turing (itself) agreed to provide and certify its Pricing Data each month to Impax. *See id.* § 9.2 & Ex. E. Specifically, Turing promised that, "[n]o later than the 25th of each month," it would both: (i) provide Impax with the relevant

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[5] Under the Purchase Agreement, Rebates are defined to include "rebates, price reductions, administrative fees and related adjustments charged by Medicaid, Medicare and other federal, state and local governmental programs and by health plans, insurance companies, mail service pharmacies and health care providers based upon the utilization of the Product." PA § 1.1.

Pricing Data for the preceding month and (ii) certify that the Pricing Data were accurate. *Id.* Ex. E.

c. *Third*—because Turing's sale of Daraprim under Impax's label and NDCs could potentially subject Impax to serious legal and reputational harm—Turing agreed both (i) to "use best efforts not to do any act which endangers, destroys, or similarly affects the value of the goodwill pertaining to [the Impax NDCs]" and (ii) not to use Impax's Corporate Names "in any manner that is inconsistent with [Impax's] use of the Corporate Names in its conduct of the Business or that otherwise violate applicable Law." *Id.* § 8.5(c). In acknowledgement of the seriousness of the harm that would befall Impax upon a breach of these provisions, the Purchase Agreement provided that, upon such a breach, Impax could revoke Turing's rights to sell Daraprim under Impax's Corporate Names or NDCs. *Id.* § 8.5(a).

22. The parties also agreed that "they shall each be entitled to seek specific performance of the terms [of the Purchase Agreement], in addition to any other remedy to which they may be entitled at law or in equity." *Id.* § 13.12.

D. Immediately After Buying the Drug, Turing Begins Selling Daraprim at Substantially Higher Prices, Generating Negative Press Attention and Government Scrutiny.

23. In August 2015, following Turing's acquisition of Daraprim and with no prior notice to Impax, Turing raised the price of the drug from $17.63 per unit to $750.00 per unit. The price increase caused medical costs to skyrocket for many patients using the drug, and generated substantial negative attention from the press and the government. For example, a February 2, 2016 memorandum by the House Committee on Oversight and Government Reform finds:

> Turing Pharmaceuticals . . . purchased Daraprim in 2015 and increased the price by 5,000%, from $13.50[6] to $750 per tablet, overnight. . . . [B]efore Mr. Shkreli [Turing's former CEO] purchased Daraprim for $55 million, the drug was affordable, readily available, and very effective at treating toxoplasmosis in people with HIV/AIDS, cancer, and other conditions that cause comprised immune systems. However, as a direct result of Mr. Shkreli's actions, Daraprim has now become prohibitively expensive, hospital budgets are straining under the huge cost increases, patients are being forced to pay thousands of dollars in co-pays and are experiencing major challenges obtaining access to the drug, and physicians are considering using alternative therapies.

House Comm. on Oversight and Gov't Reform, *Mem. Re Docs. Obtained by Comm. from Turing Pharmaceuticals* 1 (Feb. 2, 2016) (hereinafter "House Mem.").

24. Documents obtained in connection with the Congressional investigation revealed that Turing bought Daraprim "for the purpose of increasing the price dramatically and making hundreds of millions of dollars by exploiting its existing monopoly before any competitors could enter the market." House Mem. at 1. Turing knew that such a price increase would draw scrutiny not only from the press, but also from regulators such as CMS, including because of the expectedly significant Rebate Liability it would undoubtedly generate. According to the House Memorandum:

a. On May 27, 2015, months before the acquisition, in response to a report from Turing's Chairman that the company had "made significant progress towards acquiring Daraprim," Turing's then-CEO, Martin Shkreli, wrote: "Very good. Nice work as usual. $1bn [billion] here we come." *Id.* at 2.

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6 Although Daraprim had previously been sold for $13.50 per unit, when Turing acquired the rights to the drug in August 2015, Impax was selling it for $17.63 per unit.

b. On August 8, 2015, the day after the acquisition but shortly before the price increase, Mr. Shkreli estimated that sales for the product Turing had just bought for $55 million would "annualize" at "over $200 [million]." *Id.*

c. And later, after Turing raised the price of Daraprim and put its plan into action, Mr. Shkreli told an outside contact: "I think it will be huge. We raised the price from $1,700 per bottle to $75,000 . . . So 5,000 paying bottles at the new price is $375,000,000—almost all of it is profit and I think we will get 3 years of that or more. Should be a very handsome investment for all of us." *Id.*

d. On information and belief, Turing always knew that its profits from the August price increase would come at the expense of patients with HIV/AIDS, cancer, and other autoimmune diseases, and as a result, that all aspects of Daraprim sales would be subject to both public and governmental scrutiny alike. In fact, Turing's "company executives anticipated a potential backlash in response . . . but believed that physicians generally are not sensitive to price increases and that HIV/AIDS advocates—while organized and vocal—could be managed." *Id.* at 1.

E. Turing's 4,250% Price Increase for Daraprim Also Generates Significant Rebate Liability that Turing Refuses to Pay, in Violation of the Purchase Agreement.

1. Impax's Third Quarter 2015 Rebate Liability and the January Invoice.

25. On October 29, 2015 (four days after the deadline), Turing made its first certification to Impax of Pricing Data for Q3 2015, which included, among other things, a

quarterly AMP[7] for Q3 2015 of $750.000000 per unit and a best price of $17.628000. Impax subsequently reported these Pricing Data to CMS.

26. As a result of Turing's unilateral decision to increase the price of Daraprim from $17.63 per unit to $750.00 per unit, Impax's Q3 2015 Rebate Liability was enormous. State Medicaid agencies invoiced Impax for approximately 25,889 units of Daraprim in Q3 2015. Had these units been invoiced to Impax based on the pre-Purchase Agreement URA for Daraprim ($14.47 per unit), the total Medicaid Rebate Liability for this period would have been approximately $374,613.83. However, due to Turing's unprecedented price increase, the total Medicaid Rebate Liability invoiced to Impax for that quarter *was over $19 million*.[8]

27. Impax invoiced Turing for Turing's share of the Q3 2015 Rebate Liability caused by Turing's unprecedented price increase and use, marketing, and sales of the -10 Product and -95 Product on or after August 7, 2015 based on the Purchase Agreement. Specifically, pursuant to a January 15, 2016 invoice, Impax requested Turing pay it approximately $17.8 million for Rebate Liability (as corrected on January 21, 2016, the "January Invoice"). The January Invoice indicated that, based on invoices Impax had received from state Medicaid agencies through January 14, 2016, during Q3 2015: (i) state Medicaid programs had reimbursed 19,461 units of the -10 Product; (ii) Medicaid programs had reimbursed 4,424 units of the -95 Product; and (iii) the URA used to calculate Impax's Rebate Liability was equal to the $750.000000 AMP that Turing had certified to Impax, and Impax had submitted to CMS. The

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7 AMP is reported to six decimal places.

8 The URA calculation for single source drugs (such as Daraprim) includes an "additional rebate" component, which essentially increases rebate liability proportionally to the rate at which a drug's AMP increases greater than the rate of inflation over time (capped at 100% of AMP), as compared to AMP in the product's first full quarter of sales, or the base date AMP. *See* 42 U.S.C. § 1396r-8(c)(2); 42 C.F.R. § 447.509(a)(2).

January Invoice *excluded* the portion of Rebate Liability that, pursuant to Exhibit E of the Purchase Agreement and in the normal course, would have been attributable to Impax's sales of Daraprim at its prior pricing (approximately $155,000) during that time period.[9]

28. Turing was obligated to pay the January Invoice by February 16, 2016. *See* PA §§ 2.4(a), 8.3, 9.2(d) & Ex. E. It did not do so.

29. On February 16, 2016, Impax sent a letter to Turing demanding that Turing pay the January Invoice (the "February 16 Demand"). Turing neither responded to the February 16 Demand nor paid the January Invoice.

30. Instead, on March 22, 2016, Turing sent Impax a memorandum (the "Turing Memo"). The Turing Memo did not dispute that Impax had received invoices from state Medicaid agencies totaling Rebate Liability of at least $17.9 million. Rather, it suggested that the Rebate Liability invoiced to Turing by Impax was potentially overstated because the URA calculated by CMS based on Pricing Data Turing had calculated and certified to Impax "may be incorrect." Turing Mem. at 2. The Turing Memo did not provide sufficient detail to support a restatement of the URA, and instead contained a number of unsupported assumptions and inaccuracies. Nonetheless, it suggested that Impax and Turing might explore a "revised URA calculation" and a significantly lower calculation of Turing's liability. Notwithstanding that paying Impax at a lower amount would not have satisfied Turing's contract obligations, Turing also has not paid even this lower amount.

31. On April 26, 2016, Impax's CEO, G. Frederick Wilkinson sent a letter (the "April 26 Demand") to Turing's current CEO, Ron Tilles, explaining that if Turing did not pay

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[9] For Q3 2015, the total Rebate Liability was $19,811,940—*i.e.*, $19,641,594.64 (attributable to Turing's price increase and sales) *plus* $170,345.36 (attributable to Impax's sales at its pricing).

its outstanding Rebate Liability, and comply with its other obligations under the Purchase Agreement, by close of business that day, Impax would need to take action to protect its rights. That day, in telephone calls that followed, Mr. Tilles offered only to make a $1 million payment towards the Rebate Liability (an insufficient payment that Turing has also not provided).

32. To date, Turing has failed to pay the January Invoice.

2. Impax's Fourth Quarter 2015 Rebate Liability and the March Invoice.

33. On February 1, 2016, Turing provided Pricing Data for the fourth quarter of 2015 ("Q4 2015"), which included, among other things, a quarterly AMP of $719.392134 and a best price of $719.392134. Impax subsequently reported these Pricing Data to CMS.

34. Because Turing continued to calculate, report, and certify to Impax a quarterly AMP well above $700, Impax's fourth quarter Rebate Liability was also substantial. Medicaid Rebate Liability invoices from Q4 2015 continue to arrive, but Impax currently estimates that its total Rebate Liability for the quarter will exceed $14 million. Impax has already received invoices totaling over $11.1 million in Rebate Liability for Q4 2015, all of which is attributable to Turing's use, marketing, or sales of the -10 Product and the -95 Product.

35. On March 1, 2016, Impax sent a second invoice to Turing, requesting that it pay approximately $2.4 million in Rebate Liability from Q3 2015 and Q4 2015 (the "March Invoice"). The March Invoice indicated that, based on invoices Impax had received from state Medicaid agencies between January 15, 2016 and February 29, 2016, during Q3 2015 and Q4 2015: (i) state Medicaid programs had reimbursed 2,270 units of the -10 Product; (ii) state Medicaid programs had reimbursed 978 units of the -95 Product; and (iii) Impax's Rebate Liability had been calculated based on a URA of $750.00 for Q3 2015 and a URA of $719.39 for Q4 2015, respectively—each equal to the relevant quarterly AMPs that Turing had certified to Impax, and Impax had submitted to CMS. As with the January Invoice, the March Invoice

excluded the portion of Rebate Liability that in the normal course would have been attributable to Impax's sales of Daraprim at its prior pricing (approximately $10,600) during Q3 2015.

36. Turing was obligated to pay the March Invoice by March 31, 2016. *See* PA §§ 2.4(a), 8.3, 9.2(d) & Ex. E. It did not do so.

37. At present, Turing owes and is past due on approximately $20 million in Rebate Liability that Impax has invoiced to it for Q3 2015 and Q4 2015. Further, Impax has invoiced Turing for an additional approximately $10 million which will be due and owing on May 19, 2016.[10] Impax has paid over $5 million in Rebate liability to CMS on behalf of Turing, and in May 2016, Impax will make additional payments of approximately $25 million to state Medicaid agencies, also on behalf of Turing.

F. Turing Fails to Provide Daraprim Pricing Data to Impax.

38. Wholly apart from Turing's reimbursement obligations under the Purchase Agreement, on October 25, 2015, Turing was obligated to calculate, provide, and certify as accurate Pricing Data for September 2015 and Q3 2015. *See* PA Ex. E. As discussed above, timely receipt of the data is critical so that Impax can comply with its own governmentally required reporting obligations. Turing provided these data late to Impax, on October 29, 2015. Turing's certification of Pricing Data for Q3 2015 included the quarterly AMP of $750.000000 per unit and best price of $17.628000, discussed above. Impax subsequently reported these Pricing Data to CMS.

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[10] On April 19, 2016, Impax sent a third invoice to Turing, requesting that it pay approximately $10.2 million in Rebate Liability from Q4 2015 (the "April Invoice"). Payment will be due on the April Invoice on May 19, 2016.

39. On November 25, 2015, Turing was obligated to calculate, provide, and certify as accurate monthly Pricing Data for October 2015. *See id.* It did not do so.

40. On December 25, 2015, Turing was obligated to calculate, provide, and certify as accurate monthly Pricing Data for November 2015. *See id.* It did not do so.

41. On January 25, 2016, Turing was obligated to calculate, provide, and certify as accurate monthly Pricing Data for December 2015 and quarterly Pricing Data for Q4 2015. *See id.* It provided these data—which included the AMP of $719.392134 discussed above—late, on February 1, 2016. Impax subsequently reported these Pricing Data to CMS.

42. On February 25, 2016, Turing was obligated to calculate, provide, and certify as accurate monthly Pricing Data for January 2016. *See id.* It did not do so.

43. On March 25, 2016, Turing was obligated to calculate, provide, and certify as accurate monthly Pricing Data for February 2016. *See id.* It did not do so.

44. On April 25, 2016, Turing was obligated to calculate, provide, and certify as accurate monthly Pricing Data for March and quarterly Pricing Data for Q1 2016. *See id.* It did not do so.

45. On April 26, 2016, Impax sent the April 26 Demand to Turing, demanding that it comply with its reporting obligations and certify Pricing Data for Q1 2016 immediately. Later that day, Turing provided *some* of these data. However, it did not provide sufficient information to satisfy Turing's reporting obligations, or any certification whatsoever.[11] That same day, Impax wrote to Turing again, explaining that the Pricing Data which Turing provided

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[11] The information supplied by Turing did not include, among other things, (i) monthly AMP for January, February, or March 2016, (ii) monthly AMP units for January, February, or March 2016, (iii) quarterly AMP for Q1 2016, or (iv) prompt pay discounts for Q1 2016.

were insufficient and taking the position that it would need to evaluate all options for fulfilling its reporting obligations if Turing did not provide the Pricing Data by noon Pacific Time the following day.

46. The following evening, April 27, 2016, in a message from its CEO, Turing provided additional Pricing Data for sales activities for *Turing*-labeled Daraprim, and indicated that Impax should report the Q1 2016 AMP for Turing-labeled Daraprim in place of the Impax-labeled product for the Pricing Data due to CMS for Q1 2016. While Turing "recommended" Impax use the Turing NDC Pricing Data for filing with CMS on Impax NDC for the Q1 2016 period, Turing's submission still failed to provide the requested monthly AMP and unit figures for January, February, and March 2016.

47. Thus, in clear violation of its obligations under Section 9.2 and Exhibit E of the Purchase Agreement, although Turing has provided quarterly Pricing Data late for each of Q3 2015, Q4 2015, and Q1 2016 (uncertified), it has still not certified Pricing Data for October 2015, November 2015, January 2016, February 2016, or March 2016, except insofar as such monthly Pricing Data were included in the subsequent quarterly Pricing Data that Turing provided late and only after repeated demands from Impax.

48. Impax does assume that Turing's recommendation to Impax on April 27, 2016 finally provides a basis for it to meet its Q1 2016 reporting obligations to CMS. Regardless, Turing has not complied technically with its obligations under the Purchase Agreement, and more importantly, Impax cannot operate in its highly regulated environment under a regime where it must regularly demand contract compliance and then live with belated quasi-performance that does not meet key and specific contract requirements.

49. Turing's unwillingness to provide and certify these basic data, consistent with the Purchase Agreement, has forced Impax to file data with CMS based on its best knowledge and without the certainty that compliance with the Purchase Agreement was designed to provide. For example, when Turing failed to provide any Pricing Data for January 2016, Impax was left with no other recourse for fulfilling its reporting obligations to CMS than to certify an AMP consistent with the AMP Turing previously certified as accurate for Q4 2015 (*i.e.*, $719.392134). However, when Turing failed to provide any Pricing Data for the second month in a row, February 2016, and simultaneously told Impax that the Pricing Data it had certified as accurate for Q3 2015 "may be incorrect", Impax was unable to timely submit to CMS any Pricing Data regarding sales activities for Daraprim for February 2016. Of the 211 drugs for which Impax was required to certify Pricing Data to CMS, Daraprim was the only drug for which Impax failed to perform this regulatory obligation. Likewise, it was only after repeated demands and threats of legal action that Turing provided the Q1 2016 Pricing Data to Impax.

G. Pursuant to Section 8.5 of the Agreement, Turing's Refusal to Provide Timely and Accurate Pricing Data Gives Impax a Basis to Preclude it From Selling Inventory under the Impax NDCs.

50. Further, Turing agreed that it would "use best efforts not to do any act which endangers, destroys or similarly affects the value of the goodwill pertaining to [Impax's] Corporate Names" and that it would not use Impax's Corporate Names or NDCs in any manner "inconsistent with [Impax's] use" or that violates applicable law. *See* PA § 8.5(c). Turing has breached these obligations, hindering Impax's ability to comply with federal law and risking harm to Impax's relationship with CMS and the federal government, as well as other reputational harm.

51. As is plain from the above, Impax has no independent means of discerning Turing's Daraprim Pricing Data, and thus is wholly reliant on Turing for the information it needs to make accurate reports to CMS.

52. Turing's failure to provide and certify Pricing Data has therefore been the but-for cause of Impax's inability to comply fully with its reporting obligations, and thus has exposed Impax to both reputational harm and the type of legal action envisioned by Section 8.5 of the Purchase Agreement.[12]

53. Turing's suggestion that Pricing Data it had previously supplied "may be incorrect" has caused Impax further harm by exposing it to potential regulatory action for certifying incorrect information to the federal government.[13] Moreover, Turing's statement that the Pricing Data it certifies to Impax cannot be relied upon has a paralyzing effect on Impax, which must decide whether it can confidently certify the accuracy of future prices to the government, where misrepresentation of these data risks termination of Impax's entire participation in the Medicaid Drug Rebate Program. Notwithstanding Turing's stated doubt about the veracity of the Pricing Data it has certified to Impax, Turing has not provided any plausible alternate data, nor the means or methodology by which Impax might appropriately calculate such alternate data on its own.

54. Because Impax is engaged in the manufacture and sale of pharmaceuticals, Impax's relationship with CMS, as well as other governmental regulators, is critical to its

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12 *See, e.g.*, 42 U.S.C. § 1320a-7b(b)(3)(C)(i) (2012) (failure to report Pricing Data on a timely basis subjects manufacturer to penalties—which may be "increased by $10,000 for each day in which such information has not been provided"—and potential suspension of participation in the Medicaid Drug Rebate Program).

13 *See, e.g.*, 42 U.S.C. § 1320a-7b(b)(3)(C)(ii) (2012) (manufacturer may be penalized for knowingly providing false information under the Medicaid Drug Rebate Program).

business. Impax manufactures 211 products covered by Medicaid and/or Medicare. Harm to its reputation with its regulators would therefore be irreparable (and implicate far more than just Daraprim sales activities under Impax's NDCs). Nevertheless, without the requisite pricing information, Impax has no way to confidently comply with its obligations. Accordingly, by withholding the Daraprim Pricing Data for sales activities relating to Daraprim under Impax's NDCs, Turing has (and may yet) affirmatively endangered the goodwill pertaining to those NDCs and Impax's other Corporate Names.

55. By conducting sales activities for Daraprim under Impax's NDCs without providing accurate and timely Daraprim Pricing Data to Impax, Turing has also effectively used (and may be using) Impax's Corporate Names in a manner totally inconsistent with Impax's use and that hinders Impax's compliance with applicable law.

56. Accordingly, Turing has breached Section 8.5 of the Purchase Agreement, and Impax is entitled to revoke Turing's right to use Impax's Corporate Names and NDCs at any time. *See* PA § 8.5(a).

H. Turing Obtains Its Own NDC but Refuses To Confirm That It Will No Longer Use Impax's NDC.

57. Turing has the ability and obligation to take on the Rebate Liability and reporting obligations associated with its own sales activities for Daraprim under its own NDC. Indeed, as early as Q4 2015, Turing obtained its own NDC, under which it can now sell Daraprim.

58. Thus, in addition to paying its outstanding Rebate Liability, Turing could mitigate further injury to Impax by selling Daraprim only under Turing's own NDC. If it did, utilization of Impax-labeled Daraprim would decline over time and limit the potential to accrue additional Rebate Liability.

59. Yet, Turing continues to conduct sales activities for Daraprim under Impax's NDCs. For example, on March 18, 2016, Turing advised Impax that Medicare Part D was refusing to cover sales of Daraprim under Turing's NDC. *See* Email from Ron Tilles, Chairman and Chief Exec. Officer, Turing Pharm., to G. Frederick Wilkinson, President and Chief Exec. Officer of Impax Lab. (Mar. 18, 2016, 16:31 EST). On information and belief, Turing has responded by instructing pharmacists dispensing Daraprim to use only *Impax's* NDC in sales to Medicare Part D patients, and to reserve Turing's NDC for sales to patients with private insurance. Stated differently, it appears that Turing is reserving Turing-labeled Daraprim for sales that generate zero or low Rebate Liabilty, and providing Impax-labeled product for sales that generate high Rebate Liability.

60. In the April 26 Demand, Impax demanded—based upon Turing's actions in violation of Section 8.5 of the Purchase Agreement and otherwise—that Turing immediately cease all sales activities for Daraprim Inventory under Impax's labeler code and NDCs and take efforts to prevent any third parties from doing the same. Absent confirmation from Turing that it has ceased such sales activities, Impax reserves the right to seek a preliminary injunction or other appropriate relief.

COUNT ONE
(Declaratory Judgment)

61. Impax repeats and realleges paragraphs 1 through 60 above as though set forth here in full.

62. There is an actual and substantial controversy between Impax and Turing regarding Turing's rights to continue selling Daraprim Inventory under the Impax NDCs pursuant to Section 8.5 of the Purchase Agreement. Impax seeks a declaratory judgment that

Turing breached Section 8.5 and that, as a result, Impax may revoke any rights Turing was granted to use the Impax NDCs or other Corporate Names.

63. Impax and Turing have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment, because Turing continues to conduct sales activities for Daraprim under the Impax NDCs, threatening ongoing legal, financial, and reputational harm to Impax and increasing Impax's Rebate Liability to the government.

64. A declaratory judgment that Turing breached Section 8.5 and that Impax may revoke the rights granted therein would serve a useful purpose by clarifying and settling the parties' rights under that provision of the Purchase Agreement, and Turing's right to continue using Impax's Corporate Names, including its NDCs.

COUNT TWO
(Breach of Contract – Specific Performance)

65. Impax repeats and realleges paragraphs 1 through 64 above as though set forth here in full.

66. In violation of Section 9.2 and Exhibit E of the Purchase Agreement, Turing provided no monthly certified Pricing Data for October 2015, November 2015, January, February, or March 2016. Likewise, it provided some Pricing Data for Q3 2015, Q4 2015, and Q1 2016 late and (with respect to Q1 2016) only after repeated demands. Accordingly, Impax is entitled to specific performance requiring Turing to perform its obligations under those provisions of the Purchase Agreement that mandate Turing to provide accurate and timely Daraprim Pricing Data on an ongoing basis.

67. The Purchase Agreement is a valid agreement, entered into by both Turing and Impax, which includes a clear and unambiguous description of Turing's responsibilities in providing accurate and timely Daraprim Pricing Data to Impax. Further, under Section 13.12 of

that agreement, Impax and Turing agreed that they would "each be entitled to seek specific performance of [its] terms."

68. Impax has performed its obligations under the Purchase Agreement, is ready, willing, and able to perform its ongoing obligations under the Purchase Agreement, and has done so by, among other things, transferring to Turing the rights to sell Daraprim and the Inventory, allowing Turing to sell the Inventory consistent with the terms of the Purchase Agreement, and otherwise complying with Section 9.2 and Exhibit E of that agreement.

69. It is within Turing's power—and only Turing's power—to perform its obligations to provide Daraprim Pricing Data to Impax. Turing alone has access to the Pricing Data related to its own sales activities for Daraprim, and Turing only needs to share and certify those Pricing Data with Impax to perform its obligations under Section 9.2 and Exhibit E.

70. Because Impax must provide (and certify as accurate) Daraprim Pricing Data to CMS on a monthly and quarterly basis, there is no other adequate remedy at law.

COUNT THREE
(Breach of Contract – Money Damages)

71. Impax repeats and realleges paragraphs 1 through 70 above as though set forth here in full.

72. The Purchase Agreement is a valid agreement entered into by both Impax and Turing.

73. Impax has performed and continues to perform its obligations under the Purchase Agreement, including by transferring to Turing the rights to sell Daraprim and the Inventory, allowing Turing to sell the Inventory consistent with the terms of the Purchase Agreement, and otherwise complying with Section 9.2 and Exhibit E of that agreement.

74. In violation of Sections 2.4(a), 8.3, and 9.2(d) and Exhibit E of the Purchase Agreement, Turing has refused to reimburse Impax for the January Invoice and the March Invoice.

75. In violation of Section 8.5 and Exhibit E of the Purchase Agreement, by selling Daraprim under Impax's NDCs while simultaneously failing to provide Daraprim Pricing Data to Impax, thereby hindering Impax's ability to comply fully with its reporting obligations and to confidently certify Pricing Data to CMS (as required by law), Turing is using Impax's Corporate Names in a manner that endangers, destroys, or similarly affects the value of the goodwill pertaining to those Corporate Names and that violates applicable law.

76. As a result of these breaches of the Purchase Agreement, Impax has suffered serious financial, legal, and reputational harm, including over $20 million in Rebate Liability that is owed and past due to Impax by Turing, plus additional Rebate Liability that continues to accrue by virtue of Turing's sales activities for Daraprim Inventory under Impax's NDCs.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully demands judgment in its favor against the Defendant:

a) for a declaratory judgment that Defendant breached Section 8.5 of the Purchase Agreement, allowing Plaintiff to revoke Defendant's rights to use the Impax Corporate Names granted therein;

b) for specific performance of Defendant's ongoing and previous obligations to report accurate and timely Daraprim Pricing Data;

c) for all actual damages incurred and accruing in an amount in excess of $20 million, including prejudgment and postjudgment interest and future amount that will soon be owing;

d) for a preliminary injunction ordering Defendant to stop selling Daraprim using the Impax Corporate Names and to take steps to ensure all third parties likewise stop such sales, if Defendant will not confirm that it has already done so;

e) awarding the Plaintiff attorney's fees, costs, and disbursements in prosecuting this action to the extent permitted by law; and

f) awarding the Plaintiff such further relief as this Court deems just and appropriate.

Dated: New York, New York

May 2, 2016

Respectfully Submitted,

LATHAM & WATKINS LLP

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