SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

ELOBIX AB, *Plaintiff*, v. FERRING INTERNATIONAL CENTER SA, *Defendant*.	Index No.

COMPLAINT

Plaintiff Elobix AB, as affiliate Albireo AB's assignee under the Asset Transfer Agreement between Elobix AB and Albireo AB dated December 18, 2013,[1] by its undersigned attorneys, as and for its Complaint against defendant Ferring International Center SA, alleges as follows:

INTRODUCTION

1. Albireo AB ("Albireo") is a pharmaceutical research and development company that was spun off from AstraZeneca in 2008. Albireo owns the rights in a valuable pharmaceutical compound called Elobixibat. Albireo recognized early on that with appropriate development, Elobixibat could generate significant sales for a variety of lucrative therapeutic uses that had few competitors. Recognizing that the successful commercialization of Elobixibat in the United States and Europe required expertise,

[1] The Complaint quotes from the License Agreement, wherein Albireo is referred to directly by name. Any reference to Albireo, unless the context indicates otherwise, should be construed as a reference to Elobix.

capital, and efficient and high-quality development efforts, in 2012 Albireo turned to Ferring International Center SA ("Ferring"), a pharmaceutical company that touts its ability to usher compounds through the various developmental stages, including: (a) successful and efficient clinical trials, (b) efficient regulatory approval (including FDA approval in the United States and the Marketing Authorization Applications ("MAA") process in member countries of the European Union), and ultimately (c) achieving significant and rapid global sales through successful marketing and sales techniques. In Ferring, Albireo thought that it had found a sufficiently qualified multinational partner.

2. Defendant Ferring holds itself out as a global leader in research, development, and commercialization of compounds in general and pediatric endocrinology, gastroenterology, infertility, obstetrics/gynecology, orthopaedics, and urology. On this basis, Albireo—the original contracting party who assigned its interest under the contract to Plaintiff Elobix AB ("Elobix")—entered into a License Agreement with Ferring to commercialize Albireo's promising new compound, the first-in-class drug "Elobixibat," for chronic idiopathic constipation (CIC), a growing, multi-billion-dollar indication. The License Agreement covered commercialization of Elobixibat for CIC in the United States and Europe, as well as many other countries. Albireo signed a separate licensing agreement with a different company for commercialization of Elobixibat in Japan. This other company successfully obtained approval of Elobixibat in Japan for CIC, and the product has been commercialized in that country. But Ferring failed to honor its contractual obligations under the License Agreement, and as a direct result of these failures, Elobixibat has not been approved for

CIC in the United States or Europe, and for that reason it has not been commercialized in these large markets. This has deprived Elobix of significant milestone payments and royalties contemplated in the License Agreement and has greatly delayed and diminished the value of Elobix's key compound for this indication and in these key markets.

3. Ferring breached the License Agreement by failing to follow the contractually required rules and regulations to properly conduct Phase III clinical trials that were necessary for FDA approval. Ferring then compounded its material breach by failing to use commercially reasonable methods to remedy its own failures. Ferring then refused to pay Elobix a €5 million[2] milestone payment that had become due and payable, and instead tried to use the delays caused by its own failures to force Elobix into accepting lower milestone and royalty payments. Ferring then terminated the License Agreement, which deprived Elobix of contractual milestone payments specified in the License Agreement.

4. Separate and distinct from its breaches of contract, Ferring used its superior size to strongarm Elobix into accepting inferior new terms under threat of terminating the License Agreement. Ferring then terminated the License Agreement to defeat any further milestone payments anyway. After terminating the License Agreement, Ferring quickly proceeded in its attempts to induce Elobix to waive its

[2] Because the License Agreement specifies all monetary amounts in euros, this Complaint uses euros to refer to amounts contemplated by the License Agreement. As of February 18, 2019, one euro is worth approximately 1.1312 US dollars. *See* Bloomberg, *EURUSD:CUR*, https://www.bloomberg.com/quote/EURUSD:CUR (last visited Feb. 18, 2019).

rights to obtain milestone payments that were due and payable and release Ferring from any claims for breach of contract. Ferring's actions constitute a breach of the implied covenant of good faith and fair dealing.

5. The economic harm to Plaintiff has been significant, and through this action, Plaintiff seeks full recovery under the law.

EXECUTIVE SUMMARY

6. This is primarily an action for breach of contract arising from the License Agreement, dated July 2, 2012 (the "License Agreement") and amended by Amendment No. 1 to License Agreement, dated October 2013 ("Amendment"), both between Ferring International Center SA ("Ferring") and Albireo AB ("Albireo"), whereby Ferring was to take certain actions to commercialize the pharmaceutical compound "Elobixibat."

7. In less than a year, Ferring breached the License Agreement by, among other things, failing to comply with Good Clinical Practice, Good Laboratory Practice, and Good Manufacturing Practice in its Phase III trials—the trials that were expected to provide the necessary support for Elobixibat's FDA approval to treat chronic idiopathic constipation ("CIC"). Specifically, Ferring used sloppy and commercially unreasonable means to expose patients enrolled in a clinical trial to a drug "mix-up." Ferring's mix-up caused patients enrolled in a clinical trial to be supplied with incorrect dosage strengths.

8. Confronted with its errors and breach of contract, Ferring compounded its breach through a series of ill-advised, willful, and commercially unreasonable decisions designed to conceal or minimize its liability and to shift the costs of its mistakes onto

Elobix. Specifically, Ferring unilaterally terminated the Phase III trials and decided it would try to pool the data as part of an FDA submission for approval without first seeking feedback from the FDA on whether the FDA would consider such a strategy. Had Ferring consulted with the FDA in advance, it would have learned that its strategy would not be acceptable to the agency, but that it had sufficient time and opportunity to develop a different approach.

9. Ferring then tried to capitalize on its own breach and unreasonable decisions by using the stalled development program as leverage to re-write the License Agreement and extract financial concessions from the much smaller Elobix. While the proposed changes in the terms were unfair and insulting to Elobix, Elobix nonetheless sought a compromise in good faith. But as the negotiations proceeded, Ferring realized that the first milestone payment had come due—a significant milestone worth €5 million. Rather than pay the milestone, Ferring abruptly terminated the executed License Agreement without further explanation. Despite repeated requests, Ferring has consistently refused to make the milestone payment.

10. Ferring's breaches of the contract also deprived Elobix of additional milestone payments that, while not due and payable, represented the value of the performance promised that the parties clearly contemplated in the License Agreement. These payments, totalling no less than €37 million, were the natural, probable, and foreseeable consequence of the breach and are profits lost by reason of Ferring's failure to honor its contractual commitments.

11. Furthermore, there is no dispute that Albireo and Elobix have fully complied with their obligations under the License Agreement.

THE PARTIES

12. Plaintiff Elobix AB ("Elobix") is a corporation formed under the laws of Sweden and with its principal place of business in Gothenburg, Sweden. Albireo Pharma, Inc., a publicly traded corporation formed under the laws of Delaware and with its principal place of business in Boston, Massachusetts, indirectly owns 100% of Albireo AB ("Albireo"), which in turn directly owns 100% of Elobix. Elobix has standing to pursue these claims as the assignee of the rights under the License Agreement. Under Section 12.8 of the License Agreement, Albireo assigned its interests under the License Agreement to Elobix in and around December 18, 2013.

13. Defendant Ferring International Center S.A. ("Ferring") is a corporation organized under the laws of Switzerland, and with its principal place of business in Saint-Prex, Switzerland.

JURISDICTION AND VENUE

14. This Court has jurisdiction over this matter because the parties agreed in writing that any legal action or proceeding arising out of or relating to the License Agreement may be brought in "the state and federal courts sitting in New York County, New York." License Agreement § 12.1.2.

15. Venue is proper in this county pursuant to N.Y. C.P.L.R. § 327(b) and General Obligations Law § 5-1402 because this action arises out of the License Agreement pursuant to which the parties have agreed to submit to the laws and

jurisdiction of the State of New York and which involves obligations arising out of transactions covering in the aggregate not less than one million dollars. Venue is also based on N.Y. C.P.L.R. § 501 because this action arises out of the License Agreement pursuant to which the parties have agreed that New York County is an appropriate venue. Venue is also based on N.Y. C.P.L.R. § 503(a) because, upon information and belief, none of the parties are deemed to be a resident of a particular county in New York, and Plaintiff Elobix AB designates New York County as the venue.

16. This Court has personal jurisdiction over Ferring pursuant to N.Y. Gen. Oblig. § 5-1402 because Ferring has agreed in Section 12.1.2 of the License Agreement to submit to the "exclusive jurisdiction of the state and federal courts sitting in New York County, New York."

17. As specified under Section 12.1.3 of the License Agreement, Elobix gave written notice to Ferring by overnight courier and e-mail, giving notice that Ferring had breached the License Agreement and requesting Ferring to remedy the breaches identified therein (the "Notice of Breach"). Ferring received the notices of breach on or around August 18, 2015, and again on or around October 31, 2018. More than 30 days have passed since Ferring received the notices of breach, and the breaches identified therein have not been remedied.

FACTUAL BACKGROUND

18. The License Agreement covered the primary indication of chronic idiopathic constipation (CIC). Patients with CIC experience symptoms of constipation of unknown cause lasting several months. The prevalence of CIC is estimated at 14% of

the global population. The worldwide market for treatment of CIC is worth billions of dollars annually.

19. For the Japanese market, Albireo licensed Elobixibat to Ajinomoto Pharmaceuticals Co., Ltd (now known as EA Pharma Co. Ltd ("EA Pharma")). Through EA Pharma's efforts, on January 19, 2018, Japan's Ministry of Health, Labor and Welfare (MHLW) approved the new drug application for Elobixibat 5-mg tablets to treat CIC in Japan. Elobixibat has been successfully commercialized in Japan for CIC.

20. For the markets in the United States, Europe, and several other countries, Albireo licensed Elobixibat to Ferring. Under this License Agreement, Ferring was to develop and commercialize Elobixibat for CIC in these markets. For Elobixibat to come to market in these places, Ferring was to perform the Phase III Clinical Trials. Ferring chose to have two simultaneous Phase III Clinical Trials, Echo 1 and Echo 2.

21. The Echo trials studied Elobixibat in both 5-mg and 10-mg tablet formulations. The trials were double-blind, placebo controlled trials, so patients and investigators would not know if a patient was receiving a placebo, a 5-mg pill, or a 10-mg pill.

22. The License Agreement obligated Ferring to comply with Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Good Manufacturing Practice (GMP), all of which required standards to ensure the drugs were properly labeled and that the blind was maintained.

23. Ferring failed to comply with GCP, GLP, and GMP, resulting in patients being exposed to doses of study medication that were incorrectly labeled, with no

practical means to inspect, reconcile, or track which shipments of which pill-strengths went to which centers and no means to correct any errors before patients were randomized and exposed to study medication. This was a colossal blunder and a breach of the License Agreement.

24. After discovering its errors, Ferring unilaterally decided to terminate both Echo trials before receiving any feedback from the FDA on the viability of Ferring's strategy to pool data from the Echo trials to support advancing the approval process, compounding Ferring's failures.

25. Ferring subsequently learned that the FDA would reject Ferring's plan to pool data from the two terminated Phase 3 studies, stating that the pooled data could at best only be considered "supportive."

26. Under the License Agreement, Ferring owed Albireo, and later Elobix, various cascading development and regulatory milestone payments in connection with the efforts to commercialize Elobixibat for CIC in the US, European, and other markets.

27. These milestone payments were as follows:

a. €5 million for completion of a Phase III Clinical Trial, as defined in the License Agreement;

b. €5 million for the filing of a New Drug Application ("NDA");

c. €2 million for the filing of a Marketing Authorization Application ("MAA") in a European market;

d. €25 million for NDA approval; and

e. €10 million for MAA approval in the first five major European countries.

28. After realizing that its errors had effectively stalled the commercialization program for Elobixibat for CIC in the United States and Europe, Ferring attempted to force the much-smaller Elobix to accept milestone payments that were a fraction of the original terms to which the two sides had agreed. After significant negotiation, Ferring eventually agreed to slightly less Draconian reductions in milestone payments that still reduced them by as much as 60–80%.

29. During the renegotiations brought about by Ferring's breaches of the contract, Ferring realized that the first milestone payment for completion of a Phase III Clinical Trial as described in the preceding paragraphs had come due and payable. At that point, Ferring had three choices: (a) pay the milestone payment at the agreed upon sum (€5 million); (b) consummate the re-negotiation of the License Agreement that forced inferior terms upon Elobix and pay the milestone payment at the reduced amount (€2 million); or (c) refuse to pay altogether. Ferring chose option (c).

30. Recognizing that Elobix would soon demand the milestone, Ferring's board rejected the renegotiated terms that Ferring's executives had agreed to and abruptly terminated the License Agreement without any explanation. Ferring did so in the hopes that Elobix would either mistakenly believe that its rights to the milestone payment would be similarly terminated, or that Elobix would be deterred by the prospect of challenging the more economically powerful Ferring.

31. Yet Elobix knew that the milestone payment was due and payable, and Elobix promptly demanded payment. Ferring refused to make the payment, however,

and it still refuses to make this contractually required payment despite repeated demands. This alone is a clear breach of the License Agreement.

32. Ferring's other breaches that led to the drug mix-up caused a failure to commercialize Elobixibat for CIC in the US, Europe, and other markets within the scope of the License Agreement, even though the same drug in the hands of a different licensee is now approved in other jurisdictions for the same indication at the same dose studied in the Echo trials. Conservatively, Elobix's lost contractual profits as contemplated in the License Agreement is no less than €37 million, which is broken down as follows:

a. €5 million in direct contract damages for the Phase III milestone payment (recoverable by Elobix even assuming in the alternative that this milestone had not become due and payable at the time of termination);
b. €5 million in direct contract damages based on the lost NDA filing milestone payment;
c. €2 million in direct contract damages based on the lost MAA filing milestone payment; and
d. €25 million in direct contract damages based on the lost NDA approval.

33. Alternatively, the cost of replacing the Phase III Clinical Trials that Ferring mishandled are reasonably estimated to be no less than US$30 million. Even if Elobix were to conduct replacement studies in CIC, however, it has suffered significant damages in the form of several years of lost sales for the CIC indication.

The License Agreement

34. On July 2, 2012, Albireo and Ferring signed the License Agreement under which Ferring received a license for the development rights for Elobixibat in exchange for an upfront payment of €35 million to Albireo.

35. The License Agreement covered the commercialization of Elobixibat in the United States, Europe, and a large number of other countries. Albireo entered into a separate licensing agreement with EA Pharma Co., Ltd., for commercialization of Elobixibat in Japan and five other countries in Asia.

36. Section 4.1.2 of the License Agreement required Ferring to undertake its development activities of Elobixibat in accordance with Good Clinical Practice ("GCP"), Good Laboratory Practice ("GLP"), and Good Manufacturing Practice ("GMP"). Under the License Agreement, complying with GCP, GLP, and GMP includes complying with "the then current standards … as set forth in the [Food, Drug, and Cosmetic Act] and applicable regulations promulgated thereunder, as amended from time to time, and such standards … as are required by other Governmental Authorities in countries in which Products are intended to be sold." License Agreement §§ 1.68–1.70.

37. Under Section 4.1.4, Ferring was obligated to use "Commercially Reasonable Efforts to Develop Products for CIC … in the Territory." Ferring was also required to use "Commercially Reasonable Efforts to implement and conduct the Development activities assigned to such Party under the Global Development Plan, and to cooperate with and provide reasonable support to the other Party in such other Party's conduct of Development activities under the Global Development Plan."

38. Under Section 4.4.3, Ferring was obligated to use "Commercially Reasonable Efforts to Commercialize Products in the Field in the Territory."

39. Under Section 1.28 of the License Agreement, "Commercially Reasonable Efforts" means:

> those efforts and resources that ***a similarly situated pharmaceutical company would reasonably devote*** to a product or compound owned by it or to which it has rights of the type it has hereunder, which is of similar market potential at a similar stage in its development or product life, taking into account the competitiveness of the global and local marketplace, the pricing and launching strategy for the respective product, the proprietary position of the product, the profitability and the relative potential safety and efficacy of the product and other relevant factors, including technical, legal, scientific, regulatory or medical factors.

(Emphasis added).

40. Under Section 4.1.1 and 4.1.2, Ferring's responsibility for development activities included Phase III Clinical Trials.

41. Under section 1.24 of the License Agreement, "Clinical Trial" means:

> a human clinical study conducted on sufficient numbers of human subjects that is designed to (a) establish that a pharmaceutical product is reasonably safe for continued testing; (b) investigate the safety and efficacy of the pharmaceutical product for its intended use, and to define warnings, precautions and adverse reactions that may be associated with the pharmaceutical product in the dosage range to be prescribed; or (c) support Regulatory Approval of such pharmaceutical product or label expansion of such pharmaceutical product.

42. Under section 1.115 of the License Agreement, "Phase III Clinical Trial" means:

> a Clinical Trial as defined in 21 C.F.R. 312.21(c), as may be amended from time to time, or any equivalent thereto in any jurisdiction in the Territory.

43. Under 21 C.F.R. 312.21, the "clinical investigation of a previously untested drug is generally divided into three phases." That regulatory section notes that "in

general the phases are conducted sequentially." Unlike Phase I studies, which are conducted on "normal volunteer subjects," and Phase II studies, which are conducted on a "relatively small number of patients," 21 C.F.R. 312.21(c) defines Phase III studies as:

> expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and ***are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling***. Phase 3 studies usually include from several hundred to several thousand subjects.

21 C.F.R. 312.21(c) (emphasis added).

Milestone Payments

44. Pharmaceutical licensing is a specific type of transaction where the parties agree to commercialize a pharmaceutical compound through the clinical trial, regulatory approval, and sales stages. These agreements are carefully negotiated and are a transactional alternative to a partnership, joint venture, or co-promotion agreement. The licensor—usually a company that is smaller, less tolerant of risk, or less experienced in the therapeutic area, the conduct of clinical trials, or the obtaining of regulatory approval or successful sales in the specific geographic region—grants permission to the licensee—usually a larger, more diversified, or more experienced company—to use and commercialize the intellectual property rights of the drug compound. In exchange for the granting of such a license, the licensor bargains for a mix of staggered payments rather than a single lump-sum. A typical deal involves an upfront fee, milestone payments based on clinical and regulator achievements that are

equal to or sometimes many multiples of the up front payment, and royalties based on post-approval sales.

45. Under the License Agreement, Ferring owed Albireo monetary payments based on the achievement of a cascading series of milestones.

46. The first significant milestone was a €5 million payment for achieving a Phase III CIC milestone, defined as:

> the earlier of (a) ***the completion of a Phase III Clinical Trial*** for a Product conducted by a Party or its Affiliates or Sublicensees (excluding Ajinomoto) (but, in the case of Albireo or its Affiliates or Sublicensees, only at the request of Ferring), or Third Parties acting on any of their behalf, ***for the treatment of CIC that demonstrates a statistically significant difference versus placebo for the primary endpoint*** which, as advised by the FDA, ***means a responder analysis of complete spontaneous bowel movements and no Adverse Events that preclude registration***; or (b) filing by Ferring or its Affiliates or Sublicensees of an NDA [New Drug Application] for Regulatory Approval of a Product for the treatment of CIC in any Major Market Country in the Territory. For purposes of this definition, "completion of a Phase III Clinical Trial" means ***the earlier of (i) completion of the final study report for such Phase III Clinical Trial or (ii) completion of the final statistical analysis report (SAR) for such Phase III Clinical Trial***.

License Agreement, § 5.2.1 (emphasis added).

47. The Parties tied the next significant milestones to regulatory submissions: a €5 million payment for submission of an NDA for CIC in the United States; and a €2 million payment for submission of an MAA for CIC in Europe.

48. Under Section 5.2.1, these payments would be due regardless of the outcome of the regulatory filings.

49. If the regulatory submissions were approved, Ferring would then owe additional milestone payments.

50. For example, Ferring would owe Albireo a €25 million payment just for FDA approval.

51. Additionally, once on the market, if Ferring achieved aggregate annual net sales in the United States of at least €100 million in a calendar year, Ferring would have owed a sales milestone worth €8 million.

52. Each time Ferring surpassed further sales thresholds, Ferring would have owed additional payments for reaching those sales milestones.

53. Additionally, all milestone payments were subject to interest, calculated using the annual percentage rate of the then-current base rate of three (3) month Euro LIBOR plus three and one-half percent (3.5%) if Ferring fails to pay within forty-five (45) days of its receipt of notice that such amount is past due. License Agreement § 5.5.8.

54. Collectively, the milestone payments were an essential part of the License Agreement and represented the direct and immediate fruits of the contract that Albireo bargained for extensively.

Ferring Breached the License Agreement by Failing to Prevent a Drug Mix-Up and Exposing Patients to Improperly Labeled Drug Supply

55. On May 2, 2013, Ferring issued a press release announcing that it had begun Phase III Clinical Trials of Elobixibat for Chronic Idiopathic Constipation.

56. According to the press release, the two studies, Echo 1 and Echo 2, would be conducted at close to 200 sites worldwide and would enroll nearly 1,700 patients.

57. The studies aimed to demonstrate the efficacy and safety of repeated daily doses of Elobixibat against placebo over a period of up to 26 weeks.

58. Both Echo 1 and Echo 2 studies were registered as Phase III studies at clinicaltrials.gov.

59. Patients did not begin receiving study medication until—at the earliest—May or June 2013.

60. In breach of the contract, Ferring utilized methods that did not comply with GCP, GLP, or GMP, and that were not commercially reasonable. Specifically, Ferring failed to implement proper procedures to prevent a drug mix-up, failed to use study medication that had been properly inspected and reconciled to prevent the use of mislabeled medication, and exposed patients to incorrect dosages of study medication.

61. Beginning in May 2013, Ferring unknowingly caused patients to be supplied with incorrect drug dosages, a mix-up that initially went undetected.

62. During a later annual inventory review, Ferring discovered that there was a discrepancy in the number of bottles for each of the 5-mg and 10-mg formulations. The 10-mg formulation was short 128 bottles; the 5-mg formulation had a surplus of 128 bottles. In a later analysis, Ferring determined that the most likely scenario was that a drum with 128 bottles of 10-mg tablets was wrongly labeled with the 5-mg labels. Ferring caused these mislabeled tablets to then be placed with the 5-mg stock without physical separation, such that they were commingled. Ferring failed to identify or correct these errors by the start of clinical trials, when there was an opportunity to correct the errors through inspection or reconciliation without contaminating study results.

63. Ferring discovered the mix-up as early as December 2013.

64. By the time Ferring discovered the mix-up, 99 bottles of 10-mg tablets had been sent to the 5-mg arms of the studies. This failure did not conform with GCP, GLP, or GMP, widely-accepted standards in the industry, and Ferring's contractual duties.

65. Ferring's failure to inspect or reconcile the mislabeled study medication before their use in the Phase III trials resulted in a need for a product recall. On January 7, 2014, Ferring initiated a recall of all unopened bottles of the study drug and a temporary halt to recruitment in the Echo 1 and 2 trials.

66. Upon information and belief, Ferring halted recruitment to minimize the chances that Ferring's error would expose patients to the wrong treatment.

67. However, on January 29, 2014, Ferring reported to clinicaltrials.gov that "[r]ecruitment of new participants [was] temporarily suspended due to limited availability of trial medication." This statement was intended to conceal the nature of the suspension and the existence of Ferring's many errors.

Ferring Undermines the CIC Development Program by Unilaterally Terminating the Phase III Trials Without Consulting the FDA

68. The License Agreement required the parties to form a joint development committee (the "JDC") that was responsible for overseeing the development project and exchanging information. The JDC had broad responsibilities for coordinating, reviewing, evaluating, approving, and modifying drug-development activities. JDC members were required to use reasonable efforts to reach unanimous consensus on all decisions. If members of the JDC were not able to reach consensus on a particular issue, Ferring's Executive Officer was permitted to make a decision that was final and

determinative, so long as Ferring's Executive Officer reasonably considered Albireo's views and interests and made only commercially-reasonable decisions.

69. On February 4, 2014, Ferring discussed the Echo Phase III recall due to the drug labeling mix-up with Albireo at a JDC meeting.

70. Ferring explained that although recall activities are underway, "two scenarios have been thoroughly evaluated by the project team":

> (a) CONTINUE, whereby recruitment of subjects would resume once root cause investigations are completed; and (b) STOP/NEW whereby Echo trials would be discontinued (all enrolled subjects to complete 12 week primary endpoint period and then roll over into Echo 3 long-term extension trial). Pooled data from ECHO 1 and 2 would be proposed to support a Single 'pivotal' dataset that would be supplemented by results of a NEW confirmatory trial (12 weeks, identical design to current studies' first 12 weeks) to support NDA [New Drug Application] filing.
>
> ***Ferring's key objective is to minimize impact of IMP mix-up and recall on the trials' integrity and the STOP/NEW scenario is clearly favored from that point of view.*** Another advantage of this scenario is the 'early' availability of phase III data (target June '14) that could support further investments into the program. Drawback for STOP/NEW scenario is a potentially a longer time to regulatory approval compared with CONTINUE scenario, but that assumes that authorities would not require conduct of a confirmatory trial in the CONTINUE scenario which is seen as doubtful by the project team.

Under either scenario, the exact same dosages—*i.e.* 5mg versus 10mg—were contemplated. Ferring made no statements contemplating any studies at dosages at or above 15mg.

71. Despite expressing its "commit[ment] to keep Albireo informed about all significant developments," just two weeks later—on February 20, 2014—Ferring abruptly announced that it had unilaterally decided to "STOP Echo 1 and Echo 2 trials."

72. Ferring conveyed this decision to Albireo in a post-meeting note at the end of the minutes of the earlier meeting.

73. In letter and spirit, Ferring's decision did not comply with the terms of the License Agreement concerning JDC decision making. Ferring was required to use "reasonable efforts to reach unanimous consensus on all decision." At a minimum, Ferring was also required to "reasonably consider Albireo's views and interests in reaching any decision." In terminating the studies, Ferring neither considered Plaintiff's views nor sought a consensus.

74. Ferring made this decision without consulting with or seeking any feedback from the FDA, feedback which would have critically impacted the feasibility of the STOP/NEW scenario for the purpose of obtaining FDA approval.

75. Because Ferring had not sought feedback from the FDA, it did not know that the FDA would likely reject its proposal to obtain regulatory approval based on "Pooled data from ECHO 1 and 2 ... to support a Single 'pivotal' dataset that would be supplemented by results of a NEW confirmatory trial."

76. On May 1, 2014, Ferring met with the FDA's Center for Drug Evaluation and Research in Silver Springs, Maryland.

77. Ferring admitted that it halted the Phase III trials due to a study drug mix-up and that it had ordered a product recall in January 2014 before terminating the studies one month later.

78. The FDA indicated that it would reject Ferring's plan to pool data from the two terminated studies, stating that the combined data under Ferring's plan could at best be considered "supportive" for the CIC indication rather than pivotal.

79. As a result, the FDA stated that it would view Ferring's plan to conduct an additional Phase III trial as seeking to gain approval with only one clinical trial, not two trials as is "[u]sually…needed for a new indication."

80. For this reason, Ferring would need to conduct "a single large trial that would require highly persuasive evidence of efficacy and internally homogenous results across subgroups to support approval."

81. The FDA referred Ferring to FDA internal guidance UCM078749, which discusses the "FDA's position that Congress generally intended to require at least two adequate and well-controlled studies, each convincing on its own, to establish effectiveness."

82. The minutes make clear that the FDA considered the Echo studies to be Phase III studies. The minutes also make clear that there was no discussion of the need to study Elobixibat at dosages at or above 15mg.

Ferring Admits Blame for the Drug-Supply Mixup

83. In June 2014, Ferring completed its root cause analysis, which determined that Ferring was responsible for the mix-up.

84. The initial error was the application of the 5-mg label to a drum containing bottles of 10-mg tablets.

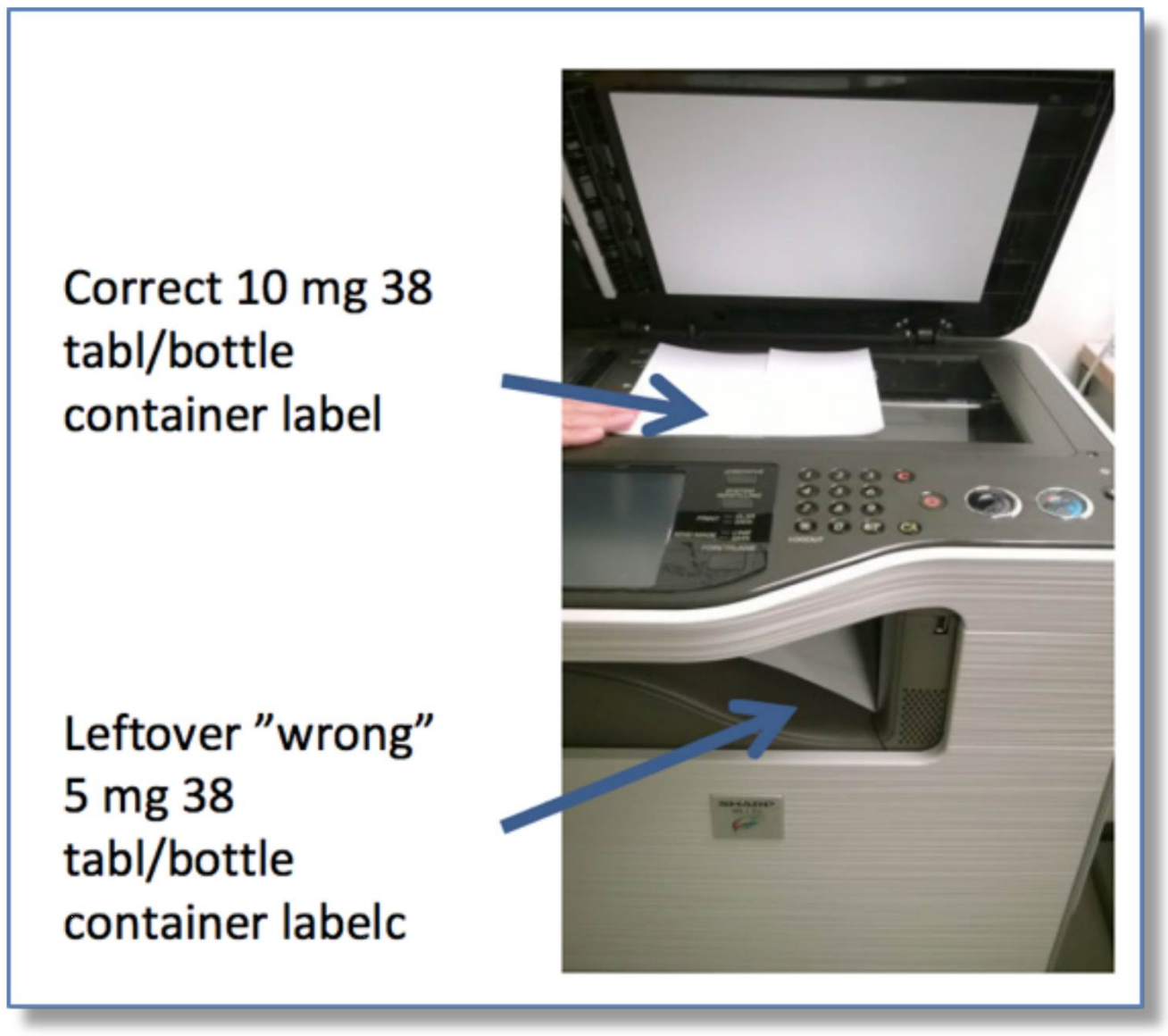
85. A lack of line clearance in the photocopy machine caused this error.

86. Drums typically received a label with information photocopied from the label of a source container.

87. The investigation revealed that an employee had photocopied a source container's label but left the photocopy in the photocopier's output tray.

88. The next day, an employee mistook the photocopy in the output tray for a photocopy that he or she had just made of a different source container label.

89. Ferring prepared the following color illustration of the error:



90. Because Ferring used the leftover label for 5-mg tablets but what Ferring was packing was 10-mg tablets, a drug mix-up occurred that went undetected until a discrepancy was later uncovered.

91. The same photocopier was used to generate the different strength labels, and there were no differences in the size, shape, or color of the labels that would have alerted the employee to the mistake.

92. Ferring recognized that its procedures with no form of timely verification, inspection, reconciliation, or tracking were prone to human error and failed to comply with GCP, CLP, and GMP.

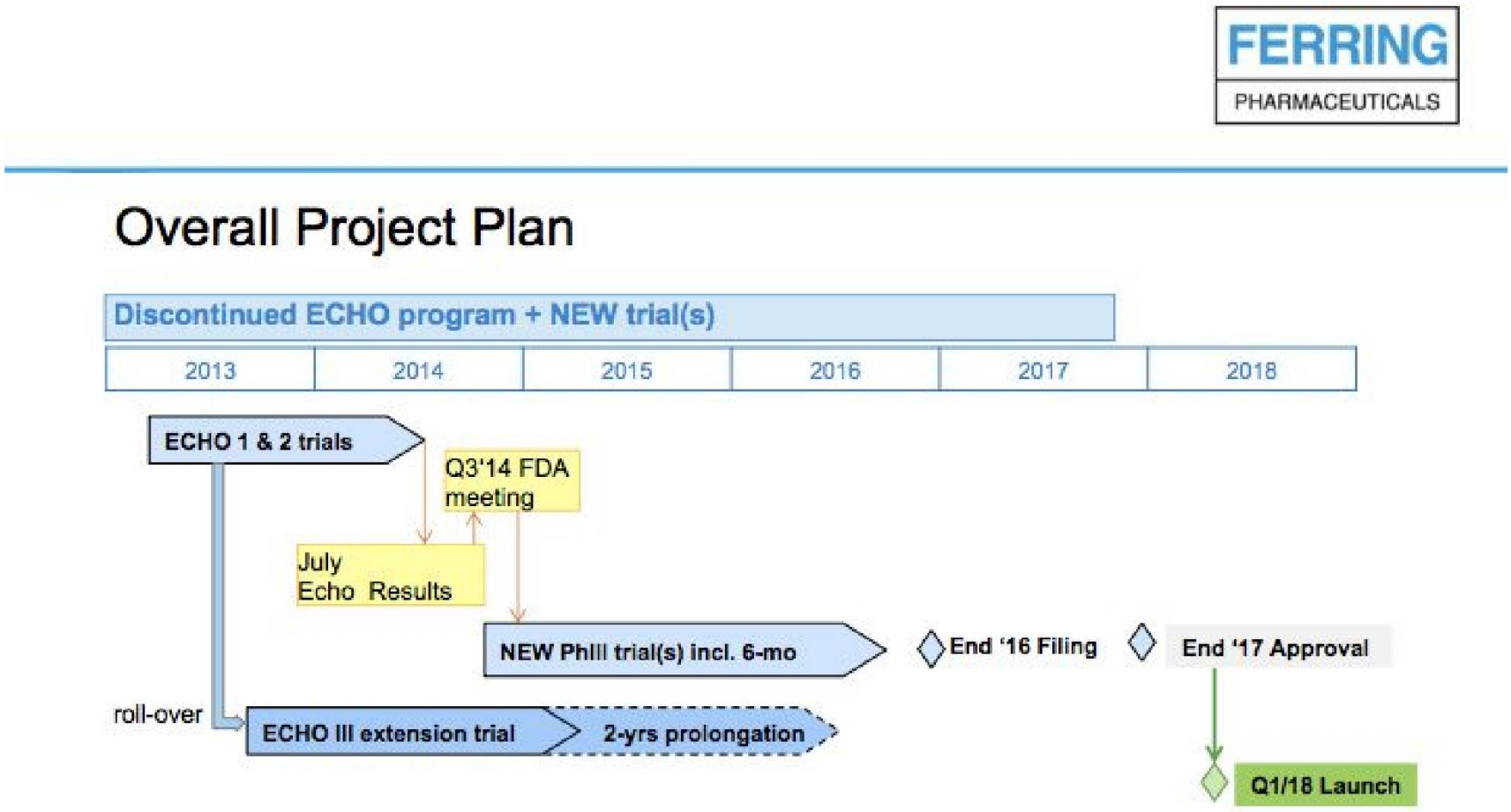
93. Ferring mandated the implementation of certain corrective measures. These included that bulk containers containing different strengths be maintained in separate stock rooms, that all bulk containers receive an individual container number to enable tracking, and that reconciliation be done each time bottles are moved from a bulk container.

94. Had Ferring properly implemented the corrective measures by the time it began exposing patients in the Echo studies to the drug products, the mix-up would not have occurred. Ferring's failure to implement these corrective measures breached the contract and caused injury to Elobix.

95. Ferring exposed patients to mislabeled drugs, without properly inspecting them, performing a reconciliation, or removing the mislabeled drugs from the study, in breach of the License Agreement.

Ferring Attempts to Use Its Breach as Leverage to Extract Additional Contract Benefits from Elobix

96. In June 2014, Ferring proposed a new clinical trial program that would have allowed for registration in early 2018:



In this proposal, no mention was made of any Phase IIb study for CIC study at doses at above 15mg.

97. In November 2014, Ferring proposed conducting a new Phase III study with a "higher dose (at or above 15mg) … that can deliver target efficacy/safety profile." No mention was made of any Phase IIb study for CIC study at doses at above 15mg.

98. In those same discussions, Ferring also proposed an "alternative" program for an "IBS-c [Irritable Bowel Syndrome with Constipation] phase IIb as first step to de-risk the project prior to phase III investment, aiming at reaching market with

both CIC and IBS indications (2020)." No mention was made of a Phase IIb study for CIC study at doses at above 15mg.

99. At this point, Ferring told Elobix that it would not move forward with Elobixibat ***unless Elobix agreed to renegotiate the License Agreement to provide Ferring with more favorable terms***.

100. Using the collapse of the Elobixibat clinical trial program caused by its own breach and unreasonable decisions as financial leverage, Ferring began extracting concessions out of Elobix.

101. A December 2014 term sheet reflects these concessions, wherein Ferring insisted on massive, across-the-board reductions of royalty payments due under the contract.

102. For example, Ferring insisted that Albireo agree to reduce the Phase III CIC milestone payment by 60%, from €5 million to €2 million.

103. Ferring similarly insisted that the milestone for filing a New Drug Application ("NDA") for CIC be reduced from €5 million to €2 million.

104. Ferring also insisted that the milestone payment for approval of the CIC NDA be reduced 80%, from €25 million to €5 million.

105. Ferring also insisted that sales milestones be slashed, with reductions ranging from 23% to 80% depending on the level of sales achieved.

106. With little choice, Elobix grudgingly indicated that it would agree to the reduced milestone payout structure.

107. Ferring informed Elobix that its board would need to approve the new terms, and the board could still decide to terminate the license despite the renegotiated terms.

Satisfaction of the Phase III CIC Milestone, Ferring's Termination of the License Agreement and Coverup of the Phase III CIC Milestone, and Elobix's Demand

108. On December 19, 2014, Ferring's Lionel Pidoux sent Kristina Torfgård an email with the Tables, Listings, and Figures ("TLF") for Echo 1.

109. In a later email sent on June 22, 2015, Mr. Pidoux confirmed to Ms. Torfgård that the TLF constituted the statistical report for the Phase III study.

110. The statistical tables generated by Ferring showed that there was statistically significant difference versus placebo for the 5-mg group on the primary endpoint (p=0.0286).

111. Accordingly, Ferring owed Elobix the €5 million Phase III CIC milestone payment by no later than January 19, 2015.

112. Ferring did not pay the €5 million Phase III CIC milestone by January 19, 2015 or at any time thereafter.

113. On March 27, 2015, Ferring notified Elobix of its decision to terminate the contract.

114. Ferring's termination triggered a round of further discussions between the two sides.

115. On May 26, 2015, Ferring discussed the problem of the "Camilleri trial," a short term Phase 2 trial of 36 patients with chronic idiopathic constipation to study the effects of Elobixibat on colonic motor effects. Ferring had registered the trial on or about

March 13, 2015, just two weeks before giving notice of termination. Now Ferring needed to inform clinicaltrials.gov of the reasons for withdrawing the study. According to an email dated May 26, 2015 written by Lionel Pidoux: "we searched for potential reasons to justify withdrawal, I would suggest we stick to the simplest possible text i.e. 'business reasons.'"

116. On August 18, 2015, Elobix demanded the Phase III CIC Milestone payment for the completion of Phase III clinical trial.

117. Elobix noted in its letter that Ferring completed the trial before Ferring's termination notice and that the results demonstrated statistically significant difference versus placebo for the 5-mg group on the primary endpoint.

118. On August 26, 2015, Ferring sent a written response falsely claiming that Echo 1 and Echo 2 were not Phase III trials and making an erroneous claim that the FDA had made it clear that neither study qualified as a Phase III study.

119. Ferring's claims were contradicted by Ferring's own press releases, Ferring's internal communications and documents, the official FDA minutes, and the trial registrations at clinicaltrials.gov, all of which clearly demonstrate that Echo 1 and Echo 2 studies were Phase III studies.

120. Moreover, Ferring's claims ran afoul of the plain terms of the License Agreement, which defines the Phase III CIC Milestone based solely on the internal availability of study results, not on the FDA's interpretation of those results. Indeed, no submission or presentation of the study results to the FDA is even required. Nor is there any requirement that the study itself reach completion.

121. The License Agreement did not refer to or imply any separate requirement that the trial "qualify" as a Phase III study beyond the requirements set forth in the Code of Federal Regulations, which defines Phase III studies as "expanded controlled and uncontrolled trials … performed after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling. Phase III studies usually include from several hundred to several thousand subjects." 21 C.F.R. § 312.21.

122. On September 10, 2015, Elobix sent a reply letter, which refuted Ferring's contentions but nevertheless made a conciliatory offer to make some adjustments to the unpaid milestone to attempt to resolve the matter. Ferring refused to engage in any conciliation.

123. On January 19, 2018, Japan's Ministry of Health, Labor and Welfare approved the new drug application for Elobixibat 5-mg tablets for the treatment of CIC in Japan, for which Elobix had licensed EA Pharma Co., Ltd., to develop.

Ferring Breached the License Agreement by Failing to Pay the Phase III Milestone Payment

124. Ferring breached the License Agreement by failing to make the €5 million development milestone payment due upon the prior completion of a Phase III Clinical Trial for the treatment of CIC that demonstrates a statistically significant difference versus placebo for the primary endpoint, which, as advised by the FDA, means a

responder analysis of complete spontaneous bowel movements and no Adverse Events that preclude registration.

125. The License Agreement defines "completion of a Phase III Clinical Trial" as the earlier of "(i) completion of the final study for such Phase III Clinical Trial or (ii) completion of the final statistical analysis report (SAR) for such Phase III Clinical Trial."

126. All elements required by the License Agreement for the completion of a Phase III Clinical Trial were met, as has already been fully described in the letters that Elobix sent to Ferring on August 18, 2015 and September 10, 2015, respectively.

127. Ferring identified the TLF as the final statistical analysis report for the Echo 1 and Echo 2 trials, and that report showed a statistically significant difference on the primary endpoint of complete spontaneous bowel movements, with no adverse events that precluded registration.

128. The registration of the Echo 1 and Echo 2 studies at clinicaltrials.gov, Ferring's press releases and internal communications, and the CFR definition of Phase III studies all show that Echo 1 and Echo 2 studies were Phase III studies.

129. The official titles of both trials contain the phrase "Phase 3 Trial."

130. And for each study, Ferring listed the study phase as "Phase 3."

131. Ferring has attempted to evade the plain meaning of a Phase III trial by suggesting that the FDA found that "neither the Echo 1 nor the Echo 2 studies were sufficient to qualify as Phase III studies."

132. The FDA made no finding that the Echo 1 and Echo 2 studies were insufficient to qualify as Phase III studies. Indeed, the purpose of Ferring's May 1, 2014

meeting with the FDA was "to discuss the impact of the investigational drug supply error on the on-going phase 3 trials."

133. Additionally, the License Agreement defined a Phase III trial as "a Clinical Trial as defined in 21 C.F.R. § 312.21(c)," which in turn contains no requirement that the FDA accept the results of a study.

134. If the parties had contemplated adding such a requirement, they could have and would have included it in the detailed written agreement already spanning well over 100 pages.

135. The License Agreement contains no language requiring that the FDA accept the results of a study to render the study a Phase III study.

136. The milestone payment for achieving the Phase III CIC milestone was €5 million.

137. Ferring was required to make this payment in early 2015. With accrued interest and at current exchange rates, the amount currently owed is approximately US$6.5 million.

Ferring Failed to Use Commercially Reasonable Efforts

138. By the time that Ferring had failed to make the milestone payment described above, Ferring was already in breach of the License Agreement in several other respects.

139. To begin with, Ferring's caused patients to be exposed to incorrect doses of study drug, in violation of one or more sections of the License Agreement.

140. The first violation concerns Section 4.1.4 ("Development Diligence Obligations"), which provides:

> Licensee shall use Commercially Reasonable Efforts to Develop Products for CIC [Chronic Idiopathic Constipation] and IBS-C [Irritable Bowel Syndrome with Constipation] in the Territory. Each Party shall use Commercially Reasonable Efforts to implement and conduct the Development activities assigned to such Party under the Global Development Plan, and to cooperate with and provide reasonable support to the other Party in such other Party's conduct of Development activities under the Global Development Plan.

141. Under Section 1.28, the Agreement defines Commercially Reasonable Efforts (CRE) as

> those efforts and resources that a similarly situated pharmaceutical company would reasonably devote to a product or compound owned by it or to which it has rights of the type it has hereunder, which is of similar market potential at a similar stage in its development or product life, taking into account the competitiveness of the global and local marketplace, the pricing and launching strategy for the respective product, the proprietary position of the product, the profitability and the relative potential safety and efficacy of the product and other relevant factors, including technical, legal, scientific, regulatory or medical factors.

142. Ferring exposed patients enrolled in a clinical trial to the wrong drug supply, without detecting or curing the critical errors before patients began to receive study medication.

143. Ferring's own root cause analysis showed that it caused the mix-up, and Ferring took no commercially reasonable measures to detect, identify, return, or destroy mislabeled drug products.

144. While perhaps convenient and low cost, Ferring's use of mislabeled study drug with no inspection, reconciliation, and tracking utterly lacked the "efforts and resources" that a similarly situated company would have devoted, especially one that

held itself out as a global leader in research, development, and commercialization of compounds in various therapeutic areas.

145. Ferring's approach toward the use of study drug supply was not commercially reasonable.

Ferring Failed to Employ Good Clinical Practice, Good Laboratory Practice, and Good Manufacturing Practice

146. Similarly, Ferring also violated Section 4.1.2 ("Development Activities") of the License Agreement, which provides in relevant part that "[e]ach Party shall, and shall cause its Affiliates, Sublicensees, and Licensees, to undertake its respective Development activities in accordance with GCP [Good Clinical Practice], GLP [Good Laboratory Practice], GMP [Good Manufacturing Practice], and Applicable Laws."

147. GCP requires the sponsor to "verify[] … that the investigational product(s) are supplied only to subjects who are eligible to receive it and at the protocol specified dose." GCP § 5.18.4.

148. Ferring failed to conform to these requirements.

149. As a result, specific study sites were supplied with Elobixibat at the incorrect dose, in violation of GCP § 5.18.4.

150. GCP § 5.18.4 provides that "[t]he sponsor should ensure that the investigational product(s) ... is coded and labelled in a manner that protects blinding, if applicable. The labelling should also comply with applicable regulatory requirement(s)."

151. Here, Ferring violated FDA requirements for accurate dosing of subjects and precise recordkeeping of the treatment doses received.

152. In a three-arm, blinded study such as the Echo trials, each treatment group should have been the subject of a separate packaging/labeling batch record, with separate operations to minimize the chance of mix-ups. Once packaged, Ferring needed to inspect, reconcile, and track the drugs before patients were exposed to the drugs. Ferring failed to take these required actions before patients were exposed to study medication.

153. The avoidance of patient exposure to adulterated, misbranded, or mislabeled drugs is a central concern of GMP as well.

154. If a company fails to comply with GMP regulations, any drugs it makes are considered "adulterated" under the law. Regulatory actions against companies with poor GMPs are meant to prevent the possibility of unsafe and/or ineffective drugs.

155. By some estimates, the most common single preventable cause of adverse events in medication practice is exposure of patients to a medication error, such as a drug mix-up caused by labeling or packaging errors. Indeed, in FY2017 alone, 14% of all FDA drug product recalls were due to labeling and packaging errors.[3]

156. GMP regulations, as codified in 21 C.F.R. Part 211, provide explicit requirements to ensure that patients take medicine which meets quality standards so that they will be safe and effective. These requirements include the use of procedures that incorporate the following features:

[3] *See* U.S. Food & Drug Admin., *Drug Recalls*, *www.fda.gov/drugs/drugsafety/drugrecalls/default.htm* (last visited Feb. 18, 2019).

a. Pursuant to 21 C.F.R. § 211.130 (a): "Prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products."

b. Pursuant to 21 C.F.R. § 211.134 (a): "Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the lot have the correct label."

c. Pursuant to 21 C.F.R. § 211.134 (b): "A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling."

d. Pursuant to 21 C.F.R. § 211.125 (c): "Procedures ***shall be used to reconcile the quantities of labeling issued, used, and returned***, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with 211.192." (emphasis added).

e. Pursuant to 21 C.F.R. § 211.192: "All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages

established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, ***whether or not the batch has already been distributed***. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy." (emphasis added).

157. Based on Ferring's own root cause analysis, Ferring fell short of GMP requirements.

158. Ferring exposed patients to 10-mg drug supplies that had been commingled with 5-mg drug supplies, and were not subject to inspection or reconciliation that would have intercepted the error in time to avoid patient exposure and potential harm.

159. Ferring also failed to reject or destroy the incorrect labels before they exposed patients to the study medication, in violation of 21 C.F.R. § 211.122 (a), (e).

Damages Caused by Ferring

160. The License Agreement provides for the availability of direct or general damages, which include the value of the very performance promised, *i.e.*, the money that Ferring as the breaching party agreed to pay under the contract. These general damages are the natural and probable consequence of Ferring's breaches of a contract.

161. Ferring's drug mix-up deprived Elobix of the CIC milestone payments that the Parties clearly contemplated in the License Agreement.

162. First, Elobix was entitled to receive a €5 million CIC Phase III development milestone payment for completion of a positive Phase III study, which—even if such milestone had not already become due and payable (which it had)—would in any event have occurred in the absence of Ferring's breach.

163. Second, Elobix was entitled to receive a €5 million regulatory milestone payment merely for the submission of a New Drug Application ("NDA") for CIC in the United States, something that would have occurred in the absence of Ferring's breach.

164. Under Section 5.2.2 of the License Agreement, this payment would be due regardless of the outcome of the NDA.

165. Similarly, Ferring would have paid a €2 million regulatory milestone payment upon submission of an MAA.

166. Based on the results of all completed trials for Elobixibat demonstrating efficacy for treating CIC, as well as the Japanese approval of Elobixibat for CIC, it is more probable than not that the FDA would have approved an NDA for CIC, in which case Ferring would then have owed an additional €25 million regulatory milestone payment.

167. Empirical data shows that 85% of NDAs are approved.[4]

168. In summary, Ferring's breaches have cost Elobix development and regulatory milestone payments worth in excess of €37 million. At the current exchange rate, total damages are no less than $42.7 million, exclusive of interest.

[4] BIO, Biomedtracker & Amplion, *Clinical Development Success Rates 2006-2015*, at 7 (2016), *available at* https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

169. To the extent that Ferring's breaches were willful, the damages caused by such willful misconduct are no less than $42.7 million, exclusive of interest.

CAUSES OF ACTION

COUNT I
Breach of Contract for Failure to Pay Earned Milestone Payment

170. Plaintiff re-alleges the allegations of paragraphs 1-169 herein.

171. At all times and in all respects material hereto, Elobix and Albireo adequately performed under the License Agreement.

172. Sections 1.114 and 5.2.1 of the License Agreement required Ferring to pay Elobix a Phase III CIC development milestone of €5 million.

173. Ferring sent Elobix Tables, Listings, and Figures for Echo 1 demonstrating that there was a statistically significant difference versus placebo for the 5-mg group on the primary endpoint (p=0.0286).

174. In a later email sent on June 22, 2015, Ferring confirmed that the Tables, Listings, and Figures constituted the statistical report for the Phase III study.

175. Therefore, the final Phase III CIC development milestone payment was due and payable.

176. Ferring was required to make this payment in early 2015.

177. With accrued interest, and at the prevailing conversion rate, the amount currently owed is in excess of US$6.5 million.

178. Ferring did not make payment for the Phase III CIC development milestone, which was due and payable.

179. As a result of this willful breach, Elobix has been injured in an amount no-less than US$6.5 million.

COUNT II
Breach of Contract for Failure to Use Good Clinical Practices, Good Laboratory Practices, and Good Manufacturing Practices

180. Plaintiff re-alleges the allegations of paragraphs 1-179 herein.

181. At all times and in all respects material hereto, Elobix and Albireo adequately performed under the License Agreement.

182. Section 4.1.2 of the License Agreement required Ferring to undertake all development activities in accordance with Good Clinical Practice, Good Laboratory Practice, and Good Manufacturing Practice.

183. Ferring failed to conform to Good Clinical Practice, Good Laboratory Practice, and Good Manufacturing Practice to achieve various development and regulatory milestones, as set forth in paragraphs 55–67, 83–95, and 146–159 above.

184. These failures resulted in Ferring depriving Elobix of contractually specified milestone payments which otherwise would have been met.

185. These milestones were an essential part of the License Agreement and represented the direct and immediate fruits of the contract that Albireo AB bargained for extensively.

186. These milestones were the value of the very performance that Ferring promised as stated and clearly contemplated in the License Agreement, and they represent the amounts that Ferring agreed to pay under the contract.

187. At the prevailing conversion rate (but without taking into account accrued interest), the value of the very performance of which Ferring deprived Elobix is more than US$42.7 million. This sum represents the natural, probable, and foreseeable consequence of Ferring's breach and are profits lost by reason of Ferring's failure to honor its contractual commitments.

188. In light of the recent Japanese approval of Elobixibat for CIC, approval of an NDA for Elobixibat for CIC would have been more probable than not.

189. As a result of Ferring's breaches, Ferring did not make payment of various milestones that would have been met had Ferring not breached the contract. Therefore, Elobix has suffered damages.

190. As a result of these breaches, Elobix has been injured in an amount no-less than US$42.7 million.

COUNT III

Breach of Contract for Failure to Use Commercially Reasonable Efforts

191. Plaintiff re-alleges the allegations of paragraphs 1-190 herein.

192. Section 4.1.4 of the License Agreement required Ferring to use commercially reasonable efforts in the development of Elobixibat.

193. Section 12.3 of the License Agreement required Ferring to use commercially reasonable efforts to make registrations, filings, and applications and to do "all other things necessary or desirable for the consummation of the transactions as contemplated" under the License Agreement.

194. At all times and in all respects material hereto, Elobix and Albireo adequately performed under the License Agreement.

195. Ferring failed to use commercially reasonable efforts to achieve various Development and Regulatory Milestones, as set forth in paragraphs 96–123 and 138–145 above.

196. These failures resulted in Ferring depriving Elobix of contractually specified milestone payments which otherwise would have been met.

197. These milestones were an essential part of the License Agreement and represented the direct and immediate fruits of the contract that Albireo AB bargained for extensively.

198. These milestones were the value of the very performance that Ferring promised as stated and clearly contemplated in the License Agreement, and they represent the amounts that Ferring agreed to pay under the contract.

199. At the prevailing conversion rate (but without taking into account accrued interest), the value of the very performance that Ferring deprived Elobix is more than US$42.7 million. This sum represents the natural, probable, and foreseeable consequence of Ferring's breach and are profits lost by reason of Ferring's failure to honor its contractual commitments.

200. In light of the recent Japanese approval of Elobixibat for CIC, approval of an NDA for Elobixibat for CIC would have been more probable than not.

201. As a result of Ferring's breaches, Ferring did not make payments for various milestones that would have been met had Ferring not breached the contract. Therefore, Elobix has suffered damages.

202. As a result of these willful breaches, Elobix has been injured in an amount no-less than US$42.7 million.

COUNT IV

Violation of the Implied Covenant of Good Faith and Fair Dealing

203. Plaintiff re-alleges the allegations of paragraphs 1-202 herein.

204. The parties agreed in Section 12.1.1 of the License Agreement that the "interpretation and construction of this [License] Agreement shall be governed by the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this [License] Agreement to the substantive law of another jurisdiction."

205. New York law implies a covenant of good faith and fair dealing in all contracts in the course of the performance of the contract, through which each contracting party covenants and agrees that it will do nothing that will have the effect of destroying or injuring the right of the other party to receive the fruits of the contract.

206. Under the implied covenant of good faith and fair dealing, a party cannot exercise a contractual right as part of a scheme to deprive the other party of the fruits of its bargain.

207. Under the implied covenant of good faith and fair dealing, a party must exercise any contractual discretion in good faith and may not exercise contractual discretion in bad faith, even when that discretion is vested solely in that party.

208. Under the implied covenant of good faith and fair dealing, where a party has contractual discretion it may not exercise that discretion arbitrarily or irrationally.

209. At all times and in all respects material hereto, Elobix and Albireo adequately performed under the License Agreement.

210. At all times and in all respects material hereto, Elobix and Albireo acted in good faith.

211. In May 2014, Ferring belatedly realized that a new clinical trial program would be required. This requirement was brought about by Ferring's decision to terminate the Echo trials without first receiving feedback from the FDA.

212. Ferring knew that its decision had negatively affected the commercialization of Elobixibat, and it decided to take advantage of its superior size and resources to force economic concessions on Elobix.

213. Although Ferring made various proposals for new clinical trial programs or for new Phase III CIC studies that would have preserved Elobix's prospects of receiving milestone payments, Ferring without warning informed Elobix that it would not move forward with Elobixibat unless Elobix agreed to renegotiate the License Agreement to provide Ferring with more favorable terms. Ferring took these actions in bad faith and as part of a scheme to deprive Elobix of the fruits of the License Agreement.

214. A December 2014 term sheet reflects these concessions, wherein Ferring insisted on massive, across-the-board reductions of milestone and royalty payments due under the License Agreement.

215. For example, Ferring insisted that Albireo agree to reduce the Phase III CIC milestone payment by 60%, from €5 million to €2 million. Ferring similarly insisted

that the milestone for filing an NDA for CIC be reduced from €5 million to €2 million. Ferring also insisted that the milestone payment for approval of the CIC NDA be reduced 80%, from €25 million to €5 million. Ferring also insisted that sales milestones be slashed, with reductions ranging from 23% to 80% depending on the level of sales achieved. Ferring took these actions in bad faith and as part of a scheme to deprive Elobix of the fruits of the License Agreement.

216. With little choice, Elobix grudgingly indicated that it would agree to the reduced milestone payout structure. Ferring informed Elobix that its board would need to approve the new terms, and the board could still decide to terminate the license despite the renegotiated terms.

217. By no later than December 19, 2014, Ferring knew that the milestone for the first milestone payment as described in the preceding paragraphs had been satisfied and would come due and payable.

218. Alternatively, if Ferring had not satisfied the milestone, Ferring intentionally slowed its performance under the License Agreement to avoid satisfying the milestone and deprive Elobix of the fruits of the License Agreement.

219. Ferring abruptly terminated the License Agreement on or about March 27, 2015 without any explanation because it did not want to pay the milestone, even at the reduced rate. Ferring did not pay the milestone payment that was due and payable, and Ferring terminated the contract in the hopes that Elobix would either mistakenly believe that its rights to the milestone payment would be similarly terminated, or it would be deterred by the prospect of challenging the more economically powerful Ferring. Even

though the License Agreement gave Ferring discretion to terminate the License Agreement, the implied covenant of good faith and fair dealing prohibited Ferring from exercising this right of termination as part of a scheme to deprive Elobix of the fruits of the License Agreement.

220. Shortly after the termination, Ferring drafted a "termination agreement" which, under the guise of accelerating the performance of its existing obligations, attempted to obtain Elobix's agreement to waive its rights to obtain payment milestone payments that were due and payable and release Ferring from any claims for breach of contract.

221. These actions constituted a scheme by Ferring to deprive Elobix of the fruits of the License Agreement.

222. Through these actions, Ferring defeated the reasonable expectations for which Elobix bargained in the License Agreement and evaded the spirit and purpose of the parties' agreement to remunerate Elobix for licensing elobixibat.

223. Through these actions, Ferring breached the implied covenant by attempting and in fact succeeding to prevent performance of the License Agreement and to withhold its benefits from Elobix.

224. As a direct, proximate, and foreseeable result of Ferring's breaches of the covenant of good faith and fair dealing, Elobix has been damaged in an amount to be determined at trial plus interest.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that the Court grant the following relief:

a. On Count I, a judgment that Ferring breached the License Agreement by failing to make the Phase III CIC Milestone payment and that the Plaintiff is entitled to a damages award in an amount to be determined at trial plus interest, but in no event less than $6.5 million;

b. On Count II, a judgment that Ferring breached the License Agreement with respect to the Developmental and Regulatory Milestones and that the Plaintiff is entitled to a damages award in an amount to be determined at trial plus interest, but in no event less than $42.7 million;

c. On Count III, a judgment that Ferring breached the License Agreement with respect to the Developmental and Regulatory Milestones and that the Plaintiff is entitled to a damages award in an amount to be determined at trial plus interest, but in no event less than $42.7 million;

d. On Count IV, a judgment that Ferring breached the implied covenant of good faith and fair dealing and that Plaintiff is entitled to a damages award in an amount to be determined at trial plus interest; and

e. Any such other and further relief as the Court may deem just, equitable, and proper.

Respectfully submitted,
MILLIGAN RONA DURAN & KING LLC

Dated: April 26, 2019

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