INTERNATIONAL COURT OF ARBITRATION
INTERNATIONAL CHAMBER OF COMMERCE

ICC Case No. AAAAAAA

ACME Pharma, LTD.

Claimant,

-and-

XYZ Pharma, Inc.,

Respondent and Counterclaimant.

FINAL AWARD

The undersigned arbitrators, having been nominated in accordance with Article 16.1 of a certain License Agreement made and entered into as of December 31, 2007, and having duly heard the proofs and allegations of the parties, do hereby AWARD as follows:

I. THE PARTIES AND THEIR COUNSEL

1. Claimant Acme Pharma Ltd. ("Acme"), is a Delaware corporation in the business of commercializing, marketing, selling and distributing pharmaceuticals. Claimant has its principal place of business at [USA].

2. The Respondent, XYZ Pharma, Inc. ("XYZ"), is in the business of inventing, developing, licensing, commercializing, marketing and selling pharmaceuticals. Respondent has its principal place of business at [Portugal].

3. Stephen [], Rebecca [], [and] Gregory of the firm of [ ] acted as counsel to Claimant.

4. Respondent was represented by William[] of the firm of located at Washington, D.C. 20001, U.S.A.

II. THE CONTRACT, THE RULES, CHOICE OF LAW, AND THE AGREEMENT TO ARBITRATE

5. The agreement at issue is a certain license agreement effective December 31, 2007 ("the License Agreement" or "the LA") between two parties: [ABC Corp.], a Delaware corporation, on the one hand and XYZ on the other. ABC Corp. did business at [U.S.A.]. In 2009, ABC Corp. was acquired by [Nippon, Inc.], a Japanese pharmaceutical company ("Nippon"). In 2010, ABC Corp. changed its name to Acme. Acme continued to do business at the [U.S. state] premises. Witness Statement ("WS") of [Dr. Y] affirmed August 27, 2016 ("the Dr. Y WS"), para. 6.

6. Section 16.1(b) of the License Agreement calls for the arbitration of disputes in accordance with the Rules of Arbitration of the International Chamber of Commerce in effect on the date of filing of the arbitration. As this arbitration was commenced on 18 February 2016, the ICC Rules of Arbitration in force as from 1 January 2012 ("the ICC Rules") applied to the proceedings.

7. Section 16.8 of the License Agreement, entitled "Governing Law" states:

> All matters affecting the interpretation, validity, and performance of this Agreement will be governed by the laws of New York, U.S.A. without regard to its choice or conflict of law principles.

8. The License Agreement contains the following "Dispute Resolution" provisions in Section 16.1. That Section, in its entirety, reads as follows:

16.1 Dispute Resolution:

(a) Any dispute, controversy or claim arising out of or relating to the alleged breach, termination, or invalidity of this Agreement will be submitted in the first instance to the Chief Executive Officer ("CEO") of XYZ, or such person's designee of equivalent or superior position, and the CEO of Acme, or such person's designee of equivalent or superior position.

(b) If the CEO's cannot resolve the dispute within thirty (30) days of receipt by the CEO's, the Parties agree that either Party may submit the dispute for arbitration in accordance with the Rules of the International Chamber of Commerce ("ICC") in effect on the date of filing of the arbitration (the "Rules"), except as modified herein.

(c) If the amount in controversy, including claims and counterclaims, is less than five million dollars (US$5,000,000) or if only injunctive relief is requested, there will be one arbitrator, who will be selected jointly by Acme and XYZ within twenty (20) days of receipt by respondent of a copy of the demand for arbitration. Such arbitrator will have sixty (60) days from the date of appointment to render a decision. If the amount in controversy may be five million dollars (US$5,000,000) of more, or if the dispute involves the termination of this Agreement, there will be three neutral and impartial arbitrators, one appointed by Acme and one appointed by XYZ within twenty (20) days of receipt by respondent of a copy of the demand for arbitration, and the third arbitrator, who will serve as chair of the arbitral tribunal, will be appointed by agreement of the Party-appointed arbitrators within thirty (30) days of the appointment of the second arbitrator.

(d) Any arbitrator appointed in accordance with Section 16.1(c) will have significant experience with the arbitration of similar large, complex, commercial disputes between pharmaceutical companies. All arbitration proceedings will be conducted in the English language. The arbitration proceeding will be held and the award issued in London, England although the Parties may agree in writing to conduct the arbitration proceedings in a different location. The Parties agree that only documents directly relevant to the issues in dispute must be produced in any such arbitration. The arbitration will be conducted as expeditiously as practicable, and the Parties and the arbitrators will use their best efforts to hold the hearing on the merits no later than one hundred twenty (120) days after the appointment of the arbitration tribunal and the arbitrators will use their best efforts to issue a final award within twenty (20) days after the close of the hearing.

(e) In addition to damages, the arbitration tribunal may award any remedy provided for under applicable law and the terms of this Agreement, including, without limitation, specific performance or other forms of injunctive relief. The arbitration tribunal is not empowered to award damages in excess of compensatory damages, and each Party hereby irrevocably waives any right to recover punitive, exemplary, multiplied (including without limitation treble) consequential or similar damages with respect to any dispute.

The arbitration award must be in writing and will state, in English and in reasonable detail, the findings of fact and conclusions of law on which it is based. The arbitration award will be final and binding on the parties and will not be appealable except as otherwise provided for by applicable treaty or law and may be entered and enforced in any court having competent jurisdiction.

(f) Each Party will pay its own expenses of arbitration and the expenses of the arbitration tribunal and the ICC will be equally shared, except that if, in the opinion of the arbitration tribunal, any claim by a Party hereto or any defense or objection thereto by the other Party was unreasonable, the arbitration tribunal may in their discretion assess as part of the award all of or any part of the arbitration expenses of the other Party (including reasonable attorneys' fees) and the fees and expenses of the arbitration tribunal and the ICC against the Party raising such unreasonable claim, defense or objection.

III. OVERVIEW OF THE DISPUTES

9. The PREA Dispute. XYZ controlled certain patents and know-how relating to a proprietary compound known as [COMPOUND], otherwise known as [ACETATE], which is beneficial in the treatment of, among other conditions, epilepsy. Under the License Agreement, ABC Corp. (now known as Acme) acquired an exclusive license to market and distribute "Licensed Products" as defined in Section 1.32 of the License Agreement. The Licensed Products essentially include products containing [ACETATE]. Under the License Agreement, Acme also acquired a non-exclusive license to develop the Licensed Products in the United States and Canada.

10. On [date] The FDA sent an Approval Letter to Acme approving the use of [ACETATE] under the trade name [PRODUCT]®, as an adjunctive therapy for the treatment of partial onset epileptic seizures in adults (the "Adult Indication").[1] The FDA's approval, however, came with the proviso that the drug's sponsor conduct certain post-marketing studies including studies designed to comply with the provisions of a statute known as the Pediatric Research Equity Act,

[1] An "adjunctive therapy" is one used in combination with other medications.

21 U.S.C. Sec. 355c ("PREA"). PREA requires that all New Drug Applications ("NDAs") filed by sponsors such as, in this case, ACB Corp. (now known as Acme), contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients. The statute, however, permits the FDA to approve the marketing of the drug for use in adults while deferring the required PREA assessment of the pharmaceutical for use in pediatric patients. This is, in fact, what occurred when [PRODUCT]® was approved for use in adults.

11. The FDA's Approval Letter (Joint Ex. 2: Ex. C-12; Ex. R-2), which approved [PRODUCT]® for adult use, contained the proviso that the FDA's approval was contingent on Acme's prior commitment to complete the required PREA studies. As The Approval Letter stated:

> **REQUIRED PEDIATRIC ASSESSMENTS**
>
> Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regiments, or new routes of administration are required to contain an assessment of the safely and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.
>
> We are waiving the pediatric study requirement for ages less than one month old.
>
> We are deferring submission of your pediatric studies for ages one month to < 18 years old for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.
>
> Your deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the FDCA. . .

12. The Approval Letter then listed the required PREA studies. On the same day, and prior to the FDA's issuance of the Approval Letter, Acme, with XYZ's knowledge and acquiescence, agreed to conduct the required postmarketing studies. (Ex. C-42) The FDA then issued its Approval Letter permitting [PRODUCT]® to be marketed for the Adult Indication. All agree that the FDA's approval for the marketing of [PRODUCT]®

for the Adult Indication would not have been given had Acme not agreed to conduct the pediatric postmarketing studies in compliance with PREA. These PREA Studies are ongoing and may ultimately cost $100 million to complete.

13. The dispute between the parties involves the interpretation of two sections of the License Agreement, Sections 6.4(c) and 6.4(d). They provide:

> (c) The Parties will share equally the actual costs and expenses of conducting any studies required by the FDA to obtain the Approval of the [COMPOUND] Product for Adult Adjunct Partial Epileptic Seizures in the United States of America, provided that (i) ABC Corp. will be responsible for conducting such studies and (ii) prior to initiating any such study the Parties will mutually agree upon a budget for the study. Once approved, any modification to that study budget must also be mutually agreed upon by the Parties. The Parties acknowledge that the study budget will serve only as a good faith estimate of the study costs and expenses and will not limit the Parties obligations under this Section 6.4(c).
>
> (d) Except as provided for in Sections 6.4(a) and 6.4(c), ABC Corp. will be solely responsible and will bear the costs and expenses of all other studies necessary or useful for the Approval of the [COMPOUND] Product and/or Licensed Products within the Field and the Territory, as well as for any marketing or post-Approval studies.

14. The Claimant contends that Section 6.4(c) requires Respondent to pay one-half of the costs of the ongoing PREA studies. The Respondent on the other hand disputes Claimant's interpretation of the agreement and contends that Section 6.4(d) of the License Agreement controls with the result that Claimant is solely responsible for funding the PREA Studies.

15. Acme submitted several invoices to XYZ for payment of one-half of the costs of the ongoing PREA studies, and XYZ rejected the invoices. This arbitration followed.

16. The Trademark Dispute. Acme and its parent company, Nippon, Inc., own or control several [PRODUCT]® trademark registrations and numerous [PRODUCT] domain names.[2]

[2] According to Exhibits A and B to XYZ's Post-Hearing Brief, Acme presently holds Canadian trademark application No. ##### for [PRODUCT]®, along with all related goodwill and 24 [PRODUCT]® domain names. Also according to Exhibits A and B to XYZ's Post-Hearing Brief, [Nippon, Inc.] presently holds United States trademark registration No. ##### for [PRODUCT]®,

XYZ, in its Counterclaim, contends that these registrations and domain names properly belong to XYZ and asks for a declaration to that effect and an order from the Tribunal compelling Acme and Nippon, Inc. to cause these registrations and domain names to be transferred to XYZ.

17. In seeking this relief XYZ relies upon Section 2.3 of the License Agreement in which XYZ grants to ABC Corp. (now Acme) "an exclusive (even as to XYZ), royalty-free license to use the XYZ's Trademarks in connection with any Licensed Products that Acme uses, markets, promotes, distributes, imports, commercializes, offers for sale or sells within the Field and Territory . . ." XYZ also relies upon Sections 2.3(a) and 2.3(b) of the License Agreement which further provide:

> (a) The Parties will mutually agree upon the XYZ Trademarks. XYZ will own all right, title and interest in the XYZ Trademarks and the goodwill associated therewith and will be solely responsible for registering and maintaining such trademarks. If requested, Acme will assist and cooperate with XYZ in the selection, registration, and maintenance of the XYZ Trademarks.
>
> (b) Any marketing, sale or distribution of Licensed Products by Acme. . . will take place exclusively under the XYZ Trademarks, subject to each Party's rights set forth in Section 2.4. Acme will not file or obtain any trademark application or registration, or Internet domain name registration, comprised of or containing any XYZ Trademarks . . . without XYZ's express written permission. Acme will use the XYZ Trademarks only in accordance with guidelines mutually agreed upon by the Parties.

18. Acme on the other hand claims that XYZ has not proven its entitlement to the return of the [PRODUCT]® registrations and domain names held by either Acme or Nippon. Acme argues that Section 2.3 only refers to "XYZ Trademarks" which is a defined term in Section 1.11 of the License Agreement. "XYZ Trademarks" is there defined as those marks "listed in Exhibit B" to

---

Japanese trademark registration No. ##### for [PRODUCT]®, and European trademark registration No. ##### for [PRODUCT]. [Nippon, Inc.] also owns or controls 7 [PRODUCT]® domain names.

the License Agreement. "[PRODUCT]" is not listed in Exhibit B. Thus, argues Acme, "[PRODUCT]" is not an XYZ Trademark and XYZ has no claim of ownership to it.[3]

19. Second, Acme contends (as discussed further below) that XYZ's license only extends to the marketing and sale of Licensed Products within the "Field" and "Territory", which are also defined terms. "Territory" is defined in Section 1.47 of the License Agreement to mean "the United States of America and Canada." Thus, argues Claimant, Respondent is, at most, entitled to the [PRODUCT]® trademarks and domain names used in the U.S. and Canada but not elsewhere.

20. Finally, Acme points out that Nippon, a non-signatory to the License Agreement and a non-party to the arbitration, may own several trademark registrations and domain names that utilize the name "[PRODUCT]" but, as to those, the Tribunal lacks jurisdiction to issue any orders compelling Nippon to assign or transfer anything.

21. As will be explained in further detail below, XYZ counters with the argument, among others, that [PRODUCT]® is in fact an "XYZ Trademark" and that the parties' failure to amend Exhibit B to the License Agreement was caused solely by Acme's refusal to effect the amendment while the PREA dispute was pending. Respondent also contends that it is the sole owner of all [PRODUCT]® marks whether or not used in the "Territory" defined in the License Agreement.

IV. PRINCIPAL PROCEDURAL HISTORY

22. Claimant initiated this arbitration by filing a Request for Arbitration (the "Request") on 18 February 2016 with the Secretariat of the International Chamber of Commerce (the

[3] Section 1.11 further states: "For the avoidance of doubt, the term 'XYZ Trademarks' does not encompass . . . any marks, brand names and/or other indicators of source not specifically listed in Exhibit B."

"Secretariat"). Claimant duly nominated John McGoldrick residing at 25 Vandeventer Avenue, Princeton, New Jersey 08542, U.S.A. as co-arbitrator. By letter of 2 March 2016, the Secretariat notified the Respondent of the Request and informed Mr. McGoldrick that he had been nominated by Claimant as co-arbitrator.

23. By letter of 21 March 2016, counsel for Respondent requested an extension of time to submit Respondent's Answer to the Request and, in that same letter, designated the Hon. James Robertson (Ret.) of JAMS located at 555 13th Street, NW, Washington, D.C. 20004, U.S.A. as Respondent's party-appointed arbitrator.

24. By letter of 23 March 2016, Claimant's counsel objected to Respondent's application for a 30-day extension of time to file its Answer to the Request. Claimant, however, consented to an extension until 11 April 2016. The parties exchanged further correspondence on the matter of the requested extension.

25. On 25 March 2016, the Secretariat informed Judge Robertson that he had been nominated by Respondent for confirmation as co□arbitrator. Judge Robertson made a disclosure and the Claimant was given until 8 April 2016 to provide comments, if any. On that same date, Claimant informed the Secretariat that it had no objection to Judge Robertson acting as a co-arbitrator in the Arbitration.

26. By letter of 11 April 2016, the Secretariat advised the parties that, pursuant to Article 13(2) of the Rules, the Secretary General of the ICC had on the same day confirmed Mr. McGoldrick and Judge Robertson as co-arbitrators.

27. On 29 April 2016, Respondent transmitted to the Secretariat its Answer and Counterclaim filed in response to Claimant's Request. By letter of 10 May 2016 the Secretariat acknowledged its receipt of Respondent's Answer and Counterclaim.

28. On 9 May 2016 the two co-arbitrators advised the Secretariat of their joint nomination of Mr. Robert B. Davidson of JAMS located at The New York Times Building, 34th Floor, 620 Eighth Avenue, New York City, 10018, U.S.A. to be President of the arbitral tribunal (the "Tribunal").

29. By letter of 13 May 2016, the Secretariat informed Mr. Davidson of his nomination as President of the Tribunal, and, by letter of 3 June 2016 the Secretariat advised the parties that, pursuant to Article 13(2) of the Rules, the Secretary General of the ICC had confirmed Mr. Davidson's appointment.

30. By letter of 3 June 2016, the Secretariat transmitted the file to the arbitrators.

31. On 9 June 2016 Claimant filed its Reply to Respondent's Counterclaim

32. Pursuant to Article 24(1) of the ICC Rules, the Tribunal conducted a case management conference on 17 June 2016. On 28 June 2016, the Tribunal executed Procedural Order No. 1 as its procedural timetable pursuant to Articles 22(2) and 24(2) of the ICC Rules. Procedural Order No. 1 set forth the schedule for the arbitration.

33. The Parties and the arbitrators then executed Terms of Reference which were dated 5 July 2016. On 28 July 2016 the President of the Tribunal transmitted the Terms of Reference to the Secretariat. On 19 August, 2016 the Tribunal was advised that, pursuant to Article 23(2) of the ICC Rules, the Secretariat had transmitted the Terms of Reference to the International Court of Arbitration of the International Chamber of Commerce (the "Court") at its session of 18 August 2016. The Secretariat's correspondence of 19 August 2016 further advised the Tribunal of the time limit for the rendering of the Final Award, which was set as six months from 5 July 2016.

34. In accordance with paragraph 5 of Procedural Order No. 1 the parties served Requests for Production. Certain disagreements arose and the Tribunal resolved them in Procedural Order No. 2 dated July 29, 2016.

35. The parties, on August 31, 2016, again in accordance with the schedule set forth in Procedural Order No. 1, served their opening memorials together with supporting witness statements and expert reports. Each party served an answering memorial together with supporting statements on September 19, 2016. The parties served reply memorials and reply witness statements on September 26, 2016.

36. Certain prehearing motions were briefed and decided, and hearings were conducted in London at the offices of Reed Smith on October 10, 11 and 12, 2016. Counsel and the parties were present.

37. The following witnesses submitted witness statements and testified at the hearings: Mr. X, former Senior Vice President and Head of Global Quality Systems at Acme who retired in March 2016. He is now the principal at a consulting company called [ ]. Mr. X, a former FDA employee, supervised Acme's regulatory affairs and quality systems staff (Day 1, Tr. 79) and was a member of the [PRODUCT] Joint Steering Committee from 2008 through March of 2015 (Tr. 80). Mr. X submitted two witness statements. Dr. Y, the Executive Director of Product Management at Acme (Day 1, Tr. 129). Dr. Y also submitted two witness statements. He was responsible for preparing strategic plans and budget forecasts for the PREA studies relating to [PRODUCT]® *Id.*. Dr. A, a medical doctor, called as an expert by Acme, testified concerning the steps leading to the FDA's approval for [PRODUCT]® and their implications for the PREA studies. Ms. B, employed by Acme as an Executive Director in the financial planning and analysis department (Day 2, Tr. 6) testified on the second day of the hearings. She was the accounting and finance person at Acme with certain responsibilities for budgeting and billing the PREA study costs that Acme incurred. (Tr. 8). She filed two witness statements. Mr. XYZ's Director of Business Development, the Director of Business Development at XYZ, also submitted two witness statements. He was part of the team at XYZ that negotiated the License Agreement (Day 2, Tr. 35) and was the primary point of contact—called the

"Alliance Manager"—for XYZ relating to XYZ's performance under the License Agreement (Tr. 36). Mr. Peter [], Senior Counsel at the law firm of Covington & Burling (Day 3, Tr. 1), was called as an expert by XYZ on the issue of whether XYZ was required under the License Agreement to share the PREA study costs (Tr. 5).

38. Several additional witnesses filed witness statements but did not testify at the hearings. One of them, Prof. [ ] Leib, was a law professor and contracts expert. Mr. Leib submitted an expert report on behalf of XYZ in which he opined on New York contracts law and how it should be applied to the language of the License Agreement. Acme objected to his intended testimony on the basis that it would improperly impinge on the function of the Tribunal. At the Tribunal's suggestion Acme waived Prof. Leib's cross-examination (Day 1, Tr. 124) with the understanding that the Tribunal would accept Prof. Leib's statement as a legal brief only and would disregard any conclusory opinions. (Tr. 11).

39. Two other witnesses submitted witness statements but did not testify at the hearings when, with the permission of the Tribunal, their cross-examinations were waived. One of those witnesses, Ms. [employee in XYZ's legal department], works in XYZ's legal department and is primarily involved in managing the filing and prosecution of XYZ's patent portfolios and, in that capacity, also deals with trademarks. She dealt with XYZ's attempts to cause Acme to return the [PRODUCT] registrations and domain names to XYZ.

40. The other witness for whom Acme waived cross-examination was [NAME], XYZ's Director of Research and Development. He was one of the inventors of [COMPOUND] ([ACETATE]) and, as such, was involved in XYZ's partnership with Acme. His witness statement dealt with the various FDA applications that Respondent made and the studies conducted prior to the parties' entry into the License Agreement. He also rebutted allegations initially made by Claimant but not pursued at the hearings concerning a misrepresentation that Respondent allegedly made regarding [COMPOUND]'s

induction of a particular enzyme that adversely affected patients and made the drug less marketable.

41. The Tribunal heard final arguments, and the parties served post-hearing written submissions on October 31, 2016.

42. The Tribunal declared the hearings closed on 14 November 2016.

Issues for Decision

43. Paragraph 9 or the Terms of Reference listed the following issues for decision:

(a) Did XYZ breach the License Agreement by refusing to pay one-half of the costs and expenses of conducting the PREA Studies?

(b) Is Acme entitled to one-half of the costs and expenses incurred and to be incurred in connection with the PREA Studies?

1. Did Acme breach the License Agreement by failing to transfer or assign the disputed trademarks and domain names to XYZ?

2. Is XYZ entitled to have the [PRODUCT]® trademarks, trademark applications, and domain names assigned to XYZ?

(c) Assuming the answers to some or all of (a) through (b) above are affirmative, is the prevailing party entitled to compensatory damages or other relief (such as a trademark assignment) and, if so, in what amount and what relief?

(d) Assuming that compensatory damages are assessed, can XYZ recover interest on the amount(s) awarded, and, if so, on what date should such interest begin to accrue, and at what rate?

(e) Assuming that it prevails on its claim(s), is either party entitled to recover its costs, including the administrative costs of the ICC, the fees of the arbitrators and other costs of pursuing the arbitration. With respect to counsel fees, is either party entitled to such fees if it prevails on any of its claims; or, as Respondent contends, must each side

bear its own counsel fees for reasonable claims, defenses, and objections, regardless of the outcome on the merits. If the answer to either these questions is affirmative, can the prevailing party recover interest on the amount(s) awarded, and, if so, on what date should such interest begin to accrue, and at what rate?

44. As set forth in the analysis below, the Tribunal resolves the above issues as follows:

(a) XYZ did not breach the License Agreement by refusing to pay one-half of the PREA study costs;

(b) Acme is not entitled to one-half of the costs of the PREA studies incurred to date or to be incurred in the future;

(c) Acme breached the License Agreement by failing to transfer or assign the [PRODUCT] trademarks, trademark applications, and domain names to XYZ, and XYZ is entitled to have the [PRODUCT]® trademarks, trademark applications, and domain names assigned to it;

(d) XYZ is not entitled to any compensatory damages by reason of Acme's failure to transfer or assign the [PRODUCT]® trademarks, trademark registrations, and domain names. However, in view of such failure, XYZ is entitled to: (i) a Declaration that it is the owner of the [PRODUCT]® trademarks, trademark registrations, and domain names; and (ii) an Order compelling Acme to assign those trademarks, trademark registrations, and domain names to XYZ.

(e) As no compensatory damages are assessed, this issue need not be determined;

(f) Neither party shall recover its counsel fees from the other and each party will pay one-half of the expenses of the arbitral tribunal and one-half of the administrative fees of the ICC.

V. ANALYSIS

The PREA Claim

45. As set forth in Section 16.8 of the License Agreement, quoted above, the License Agreement is governed by the laws of New York, U.S.A. without regard to its choice of law principles.

46. Both sides argue that Section 6.4 of the License Agreement is unambiguous as a matter of law and that it should therefore be read and interpreted in strict accordance with its terms without reference to extrinsic evidence. New York law is well-settled that a court will not venture beyond the written language of the agreement, if the language is unambiguous. As New York's highest court explained: "[A] contract is to be interpreted so as to give effect to the intention of the parties as expressed in the unequivocal language employed." *Breed v. Insurance Co. of North America,* 46 N.Y.2d 351, 355 (1978), quoting *Morlee Sales Corp. v. Manufacturers Trust Co.,* 9 N.Y. 2d 16, 19 (1961). New York law requires that courts "must give the words and phrases employed [in contracts] their plain meaning." *Greenfield v. Philles Records, Inc.,* 98 N.Y.2d 562, 569 (2002); *Laba v. Carey,* 29 N.Y.2d 302, 308 (1971). If, however, contract language is ambiguous, then the trier of fact is entitled to consider extrinsic evidence in its quest to give effect to the parties' mutual intention at the time of their entry into the agreement. *See Greenfield, supra,* 98 N.Y.2d at 569-570.

47. While both sides argue that the contract language is unambiguous, they differ as to what it means. This does not, however, render the language ambiguous. Whether or not contract

language is "ambiguous" is a question of law for the Tribunal. *Id.* ("Extrinsic evidence of the parties' intent may be considered only if the agreement is ambiguous, which is an issue of law for the courts to decide")*; Hunt Ltd. v. Lifschultz Fast Freight, Inc.,* 889 F.2d 1274, 1277 (2d Cir. 1989).

48. Consistent with their legal positions that nothing more is required to determine the claim regarding PREA costs except the contract itself, neither side offered evidence of the License Agreement's negotiating history. No drafts of the License Agreement were offered, nor did any percipient witness testify about discussions that may have taken place involving either Section 6.4 or Section 2.3.[4] Each side, however, did enter evidence and discussed at some length the extrinsic evidence that would be relevant to the interpretation of the License Agreement in the event that the Tribunal found the contract language ambiguous.

49. The Tribunal's first task, therefore, is to determine whether the language of Section 6.4, quoted above, is or is not ambiguous.

50. Acme contends that the language of 6.4(c) unambiguously requires XYZ to pay one-half of the PREA study costs. The contract says quite clearly (argues Acme) that "The Parties will share equally the actual costs and expenses of conducting any studies required by the FDA to obtain the Approval of the [COMPOUND] Product for [the Adult Indication]" As the PREA studies were "required by the FDA to obtain the Approval", they are to be shared. Further, it is clear (argues Acme) that Section 6.4(c) trumps Section 6.4(d) that provides for Acme alone to bear the cost of "all other studies necessary or useful for the Approval" of the drug. This is evident from the beginning phrase of Section 6.4(d) that provides that 6.4(d) only applies:

[4] The Tribunal at one point asked Mr. [XYZ's Director of Business Development] about statements that may have been made during negotiations concerning Section 6.4 of the License Agreement. (Day 2, Tr. 156-158). The Tribunal, however, does not rely upon any negotiating history in reaching its conclusions.

"Except as provided in Sections 6.4(a) and 6.4(c)."

51. XYZ, advocating for a different interpretation, also contends that the language of the License Agreement is unambiguous. XYZ first points to the language of Section 6.4(c), quoted above, to wit: "The Parties will share equally the actual costs and expenses of conducting any studies required by the FDA to obtain the *Approval* of the [COMPOUND] Product for [the Adult Indication]" (emphasis added). The word "Approval" in that section is capitalized. It is a defined term in Section 1.3 of the License Agreement where it is there defined as "the receipt of all authorizations . . . required to market and sell a Licensed Product within the Field and the Territory." "Field" is also a defined term found in Section 1.27 of the License Agreement which provides that "'Field' means all . . . uses of the Licensed Products for adjunctive use in Adult Partial Epileptic Seizures . ." Thus, argues XYZ, the PREA studies do not fall under Section 6.4(c) because they were not required to obtain the authorization to market and sell [PRODUCT] for adjunctive use in adults.

52. According to XYZ, the Parties drew a clear line in the License Agreement between studies required for FDA approval of [COMPOUND] for the Adult Indication, and studies not required for such approval. According to XYZ, Section 6.4(c), quoted below, requires a sharing of study costs only for studies required by the FDA to obtain the "Approval of the [COMPOUND] Product for [the Adult Indication] . . ." In so contending, XYZ argues that there is a distinction between studies "required" by the FDA to obtain the FDA's approval of the drug for use in adults and a *commitment* to perform post-Approval studies after FDA approval. XYZ contends that Section 6.4(d) speaks to these marketing or post□Approval studies, such as the PREA studies.[5]

[5] XYZ contends that the language used in PREA also makes it clear that PREA studies are not "required" for FDA approval for adults. The PREA studies can be deferred, as happened here, until

53. XYZ also urges that the language used by the FDA in the Approval Letter (Joint Ex. 2; Ex. C-12; Ex. R-2) makes it clear that PREA studies are not required as a condition for such approval. The Approval Letter defers the PREA studies until a later date, but states that [PRODUCT]® is approved for marketing immediately for adult use. XYZ points out that, significantly, the Approval Letter refers to the PREA studies as "postmarketing studies" using a term synonymous with the language of Section 6.4(d) that expressly states that Acme will be solely responsible for all "marketing or post-Approval studies", and the prefatory phrase "Except a provided in Sections 6.4(a) and 6.4(c)" that appears in Section 6.4(d) of the License Agreement does not change that conclusion.

54. XYZ, as explained above, focuses on the phrase in Section 6.4(c)*:* "will share equally the actual costs and expenses of conducting any studies required by the FDA to obtain the Approval [for the Adult Indication]" and, in doing so, argues: "All that matters is whether the disputed costs were incurred **conducting** studies required **to obtain** FDA Approval of the Adult Indication." *Id.* (emphasis in original). Because the FDA did not "require" that any PREA studies be "conducted" to obtain FDA Approval for the Adult Indication, these costs (XYZ argues) do not fall under Section 6.4(c). The FDA gave its "Approval" for the marketing and sale of [PRODUCT]® without the need for the parties to complete the PREA studies. Thus, the PREA studies (argues XYZ) were not "required by the FDA *to obtain* the Approval [capital "A"] of [[PRODUCT]]" (Section 6.4(c), emphasis added). Such studies therefore fall under Section 6.4(d) and not Section 6.4(c). Again, the fact that the FDA required a commitment from Claimant to conduct PREA studies prior to the FDA's approval of [PRODUCT]® for adult use is

after the drug is approved, if the drug is ready for adult approval before the PREA studies have been completed or even begun. Indeed, PREA explicitly states that approval of the drug for adult use cannot be revoked for a failure to comply with PREA. 21 U.S.C. § 355c(d)(2).

not the same (argues XYZ) as requiring Acme to conduct PREA studies as a precondition to (capital "A") Approval.

55. After considering both Acme's and XYZ's interpretations of the contract language, a majority of the Tribunal concludes that Section 6.4 of the License Agreement is not unambiguous as to how post-Approval PREA study costs are to be treated and, specifically, whether such costs fall under Section 6.4(c) (and are to be shared) or Section 6.4(d) (and are to be borne solely by Acme). One member of the Tribunal believes that the language the parties used in Section 6.4(c) of the License Agreement unambiguously provides for the PREA study costs to be shared. A majority of the Tribunal, however, disagrees and finds the contract language ambiguous.

56. According to New York law:

> A contract is unambiguous if the language it uses has "a definite and precise meaning, unattended by danger of misconception in the purport of the [agreement] itself, and concerning which there is no reasonable basis for a difference of opinion" . . . Thus, if the agreement on its face is reasonably susceptible of only one meaning a court is not free to alter the contract to reflect its personal notions of fairness and equity . . ."

Greenfield v. Philles Records, Inc., supra, 98 N.Y.2d at 569-570 9 (citations omitted).

57. A majority of the Tribunal concludes that Sections 6.4(c) and 6.4(d), read together, are not unambiguous. Section 6.4(c) provides that "[t]he Parties will share equally the actual costs and expenses of conducting any studies required by the FDA to obtain the Approval of the [COMPOUND] Product for Adult Adjunct Partial Epileptic Seizures in the United States of America". The first part of that provision, read without reference to the rest of it or to other sections of the License Agreement, expresses an obligation to share costs. The majority concludes, however, that the phrase "required by the FDA to obtain the Approval . . .", as used in Section 6.4(c), renders the whole provision ambiguous. The word "required" is not a defined

term but the word "Approval" is a defined term. As explained in paragraph 51 above, "Approval" is a term that, in Section 1.3 of the License Agreement, refers to the marketing and sale of [PRODUCT] in the "Field", which is also a defined term. "Field" refers to Licensed Products for adjunctive use in Adult Partial Epileptic Seizures" (emphasis added), not for use in pediatric patients. Thus, Section 6.4(c)'s use of the defined term, "Approval" may well imply a sharing of costs only for those studies that the FDA requires prior to its approval for the marketing and sale of [PRODUCT] to adults.

58. A majority also finds ambiguity in the phrasing used in Section 6.4(c). That Section refers to the "actual" costs of "conducting" studies required to obtain "Approval" for the marketing and sale of the drug for use in adults. The PREA study costs had not yet been incurred when the License Agreement was executed. The only "actual" costs incurred at that point were the costs of the studies then relied upon by ABC Corp. (now known as Acme) to obtain FDA approval. Does the word "actual" refer only to those studies already conducted, or to any studies yet to be conducted after the FDA's "Approval"? See, paragraph 52 above.

59. Finally, there is ambiguity in the way the prefatory phrase to Section 6.4(d) ("Except as provided for in Sections 6.4(a) and 6.4(c)") should be interpreted. Is it intended to eliminate the possibility that Acme should bear the full cost of any and all post-Approval studies (such as the PREA studies) which were required by the FDA for the Approval of [PRODUCT]? Or, as XYZ contends, does it compel Acme to bear the full costs of the PREA studies because the costs of those "post-Approval" studies are not within the scope of Section 6.4(c)?

60. Thus, because the majority concludes that Section 6.4 is not unambiguous, the Tribunal will turn to the extrinsic evidence in its attempt to glean the parties' mutual intention at the time the contract was written. *Greenfield v. Philles Records, Inc., supra*.

61. As explained below, an examination of the extrinsic evidence leads to the conclusion that the parties mutually understood that Section 6.4(d) applies to the PREA study costs.

62. Acme's failure to submit budgets to XYZ. The first extrinsic fact that leads to the above conclusion relates to Acme's failure to submit PREA study cost budgets to XYZ prior to incurring such costs. Section 6.4(c) requires that Approval study costs be shared "provided that . . . (ii) prior to initiating any such study the Parties will mutually agree upon a budget for the study. Once approved, any modification to that study budget must also be mutually agreed upon by the Parties." It is undisputed that Acme embarked upon the PREA studies without ever sending XYZ a budget or soliciting its agreement on a budget. Acme first sent an invoice to XYZ for one-half of the ongoing PREA study costs in September 2015 (Day 2, [ ] Tr. 18). Acme failed to send a budget prior to tendering that invoice, or any of its subsequent invoices. If Acme truly thought that Section 6.4(c) applied to the costs of the PREA studies, it would have complied with the provisions of that section and sent a budget to XYZ for approval. The evidence presented demonstrated that the cost of these studies could approach or even exceed $100 million. *Id.* Tr.18-19. With that number in mind it is hard to reconcile Acme's failure to submit periodic budgets consistent with what it now claims is the correct interpretation of the contract.

63. Acme attempted to excuse its failure to submit budgets to XYZ for approval by claiming that a comment and follow up email from Mr. [XYZ's Director of Business Development], XYZ's alliance manager (Day 2, Mr. [XYZ's Director of Business Development] Tr. 36) on October 29, 2013 (Joint Ex. 7; Ex. C-51; Ex. R-10), constituted an anticipatory repudiation of XYZ's obligation to share the PREA study costs thus excusing strict performance by Acme. The Tribunal finds this argument unpersuasive. First, as acknowledged by [former Senior Vice President and Head of Global Quality Systems at Acme] in his testimony, alliance managers have

no "power or authority" to interpret an agreement on behalf of the parties (Day 1 Tr. 84, 92, 99-100). Thus, Mr. [XYZ's Director of Business Development]'s comment to [JILL], Acme's alliance manager at the time, would have been without legal significance even if it constituted a repudiation.[6] Second, Mr. [XYZ's Director of Business Development]'s actual statement would not have constituted a repudiation under New York law even if he had the authority to make such a statement. New York law requires that for a statement to constitute a repudiation it must be an "unequivocal, definite, and final expression of [ ] an intention not to perform." *Turner Constr. Co. v. US Framing Inc.,* 2015 N.Y.Slip Op. 51617(U) **5 (Sup. Ct. Albany Cty.), quoting *Children of America (Cortlandt Manor), LLC v. Pike Plaza Assoc., LLC,* 113 A.D.3d 583, 585 (2d Dep't 2014). Mr. [XYZ's Director of Business Development]'s conversation with his counterpart (Day 2, Tr. 36-37) and his subsequent email (Joint Ex. 7; Ex. C-51; Ex. R-10), constitutes no such unequivocal expression. After stating his view that the PREA costs were not to be shared, he states "I have not discussed this further so this is my opinion at this stage but I am pretty sure this correctly reflects the parties negotiations of the license, which as you know I was part of." This is not an unequivocal expression of an intention not to perform the License Agreement and is not, therefore, an anticipatory repudiation of that contract. There was no follow up to his email *Id.* Tr. 39. Moreover, a repudiation under New York law must be a repudiation of the entire agreement, not just a part of it. *De Lorenzo v. Bac Agency Inc.*, 681 N.Y.S.2d 846, 848 (3d Dep't 1998). In this situation, the License Agreement is an executory contract intended to continue whether or not XYZ shares in the PREA study costs. Acme's

[6] Section 5.7 of the License Agreement defines the role of the Alliance Managers. It provides in pertinent part: "The Alliance Managers will be the primary contact for the Parties regarding the activities contemplated by this Agreement and will facilitate all such activities hereunder. . . The Alliance Managers will not, in any manner, take over the role of the JSC [Joint Steering Committee] and will not have any rights, powers or discretion except as expressly granted to the Alliance Managers hereunder. In no event will the Alliance Managers have any power to modify or amend this Agreement."

Opening Mem. page 61. Acme's failure to send periodic budgets to XYZ for PREA study costs was, therefore, not excused by anything done or said by Mr. [XYZ's Director of Business Development].

64. Acme's Failure to Add the Costs of the PREA Studies in its 2015 Reconciliation. Another extrinsic fact that militates for the conclusion that the parties understood that 6.4(d) speaks to the PREA study costs can be found in a reconciliation of costs that Acme prepared in February 2015 (Ex. C-141). That reconciliation, which purported to be a "Reconciliation of costs incurred by XYZ and Acme up to December 31, 2014" failed to include the PREA costs incurred to date. There was no dispute that significant PREA costs had been incurred in 2014, See Day 2, Mr. [XYZ's Director of Business Development] Tr. 41.[7] If Acme believed that XYZ had an obligation to share in the PREA costs, those costs would have appeared in the 2015 reconciliation. Acme contended that the PREA costs were missing from the reconciliation because Acme's intent was to reconcile only the costs incurred to resubmit the required NDA (New Drug Application) to the FDA. *Id.* Tr. 14-15. The Tribunal also finds this reason unpersuasive. Mr. [XYZ's Director of Business Development] testified that the reconciliation was preceded by a letter agreement between the parties dated March 22, 2013 (Ex. R-5; Day 2, Mr. [XYZ's Director of Business Development] Tr. 40-41) in which the parties agreed to perform "a thorough analysis of their respective costs to date incurred in connection with the clinical study of [ACETATE] . . . including any other additional work required for the NDA submission as per the provisions of Clause 6.4 of the License Agreement . . ." Ex R-7 at paragraph 3. Mr. [XYZ's Director of Business Development]'s view of the situation followed in

[7] These costs were incurred after Mr. [XYZ's Director of Business Development] offered his opinion that the License Agreement did not require XYZ to share in the PREA study costs. See Joint Ex. 7 which is dated October 29, 2013.

October 2013 and the reconciliation of February 2015, which was prepared by Acme, followed after that. No PREA costs were sought to be reconciled.

65. Acme's inconsistent treatment of other postmarketing study costs. Finally, Acme's claim to 50% of the PREA study costs is flatly inconsistent with its conduct with regard to studies similarly situated. The FDA's Approval Letter (Joint Ex. 2; Ex. C-12; Ex. R-2) provides, as quoted above, that "Your [Acme's] deferred pediatric studies required by section 505B(a) of the FDCA are required postmarketing studies." *Id.* page 3. This is a reference to the PREA studies. Acme claims that XYZ is required to pay one-half of these studies pursuant to Section 6.4(c) of the License Agreement. However, the Approval letter also provides under the heading "**POSTMARKETING REQUIREMENTS UNDER 505(o)**" that "based on appropriate scientific data, FDA has determined that you are required to conduct the following: [listing three additional studies]" *Id.* pages 6-7. But Acme concededly paid all of the costs of these latter studies (presumably in the belief that Section 6.4(d) imposed that obligation) even though the Approval Letter states that they are also "required". Acme attempts to distinguish its conduct with respect to these Section 505(o) studies by pointing out that, unlike the PREA studies, the Section 505(o) studies are not required for approval under a statute such as PREA (Day 3, Tr. 80-83). The Tribunal fails to find a relevant distinction. Section 6.4 of the License Agreement simply refers to studies "required by the FDA to obtain Approval." (Section 6.4(c)) Whether or not "required" by statute or otherwise, the FDA's Approval Letter made clear that both the PREA studies and the Section 505(o) studies were "required" by the FDA as a condition to its approval of [PRODUCT]® for the Adult Indication. There is no reason why Section 6.4(c) should be interpreted to treat the 505(o) studies differently. Acme's voluntary payment for all of the costs of the 505(o) studies is simply inconsistent with its claim that the License Agreement

compels XYZ to pay for 50% of the PREA study costs. As Mr. [XYZ's Director of Business Development] testified: "Up until recently they [the PREA study costs] have been treated as post-market approval studies, like the other studies." (Day 2, Mr. [XYZ's Director of Business Development] Tr. 36).

66. For all the above reasons, the Tribunal finds that the parties' conduct in their performance of the License Agreement is consistent only with XYZ's interpretation that Acme must bear all of the costs of the PREA studies pursuant to Section 6.4(d) of the License Agreement.

The Trademark Claim

67. By its counterclaim, XYZ seeks an Order from the Tribunal: (i) declaring it to be the sole owner of all [PRODUCT] trademarks, trademark applications, and domain names that utilize the word "[PRODUCT]"; and (ii) compelling the present owners or holders of these marks, whether Acme or Nippon, to assign them to XYZ. XYZ's Answer, pages 15-16.

68. As explained above in the overview of the dispute, XYZ argues that Section 2.3 of the License Agreement clearly provides that XYZ owns the [PRODUCT]® trademark registrations and domain names.

69. In its defense to the counterclaim, Acme, also as explained above, relies upon the definition of "XYZ Trademarks" in Section 1.11 of the License Agreement which defines "XYZ Trademarks" as those "marks, brand names and/or other indicators of source listed in Exhibit B. . ." Because "[PRODUCT]" is not listed in Exhibit B, [PRODUCT] is not a "XYZ Trademark" and XYZ has no contractual right to the relief that it seeks.

70. XYZ counters that the reason that "[PRODUCT]" is not listed in Exhibit B to the License Agreement is simply because the parties had not yet (for the reasons discussed below) caused that Exhibit to be appropriately amended. Indeed, both sides—prior to the appearance of the

dispute over the payment of PREA study costs—agreed that the [PRODUCT]® registrations and domain names belonged to XYZ. XYZ's unwillingness to settle the matter of the PREA costs to Acme's satisfaction, however, caused Acme and its parent company to hold the [PRODUCT]® marks "hostage" pending a resolution of that dispute. XYZ's Reply Memorial, page 16.

71. Acme further argues that Section 2.3(b) only provides that "Any marketing, sale or distribution of Licensed Products by [Acme] . . . *under the license set forth in Section 2.1*, will take place exclusively under the XYZ Trademarks, . . ." (emphasis added). Section 2.1 provides that "XYZ grants to [Acme] an exclusive (even as to XYZ) license under the XYZ Patents and XYZ Know-How to use, market, distribute, import, commercialize, offer for sale and sell the Licensed Products under the XYZ Trademarks within the Field and the Territory." "Territory" is defined in Section 1.47 of the License Agreement to mean "the United States of America and Canada." Thus, at most, Acme argues that XYZ would be entitled to invoke Section 2.3 to claim ownership of the trademarks used in the U.S. and Canada, but not the marks that might be used elsewhere, specifically in Europe and Japan. (Day 1, Tr. 38-39; Day 3, Tr. 136-137).

72. Finally, Acme points out that Nippon, a non-signatory to the License Agreement and a non-party to the arbitration, owns several trademark registrations and domain names that utilize the name "[PRODUCT]®"[8] and, as to those, the Tribunal in any event lacks jurisdiction to issue any orders compelling Nippon to assign or transfer anything.[9]

---

[8] Exhibit B to XYZ's Post-Hearing Brief lists seven [PRODUCT] domain names presently owned by Nippon. They include: [PRODUCT].com; [PRODUCT].jp; [PRODUCT].net; [PRODUCT].org; [PRODUCT].biz; [PRODUCT].info and [PRODUCT].us. Exhibit A to XYZ's Post-Hearing Brief lists the following that are also controlled by Nippon: U.S. trademark registration No. #####; Japanese trademark registration No. ######; and European trademark registration No. ######.

[9] In that regard, Acme's counsel argued in his opening: "Nippon owns the trademark in Japan. . . Their [XYZ's] efforts to reach agreement on a license with Nippon never came to fruition. Nippon has signed no arbitration clause; it's not a party to this arbitration. They're trying to use this Tribunal to get around

73. The history of the parties' attempts to arrive at an acceptable name for [ACETATE] (eventually named [PRODUCT]®), and XYZ's attempts to obtain an assignment of the [PRODUCT]® registrations and domain names, is instructive and is set forth in detail in the Supplemental Witness Statement of Mr. [XYZ's Director of Business Development] ("Mr. [XYZ's Director of Business Development] Supp. WS") and in the Witness Statement of Ms. [employee in XYZ's legal department] dated August 31, 2016 ("Ms. [employee in XYZ's legal department] WS"). Acme waived the cross-examination of Ms. [employee in XYZ's legal department] and, with the Tribunal's consent, Ms. [employee in XYZ's legal department] never testified in person at the hearing. Under these circumstances, the Tribunal accepts her statement as uncontested.

74. Originally, and as reflected in Exhibit B to the License Agreement, the parties contemplated that [ACETATE] would be marketed and sold under either the name [eeee] or [oooo]. (Ex. B to the License Agreement, Joint Ex. 1; Ms. [employee in XYZ's legal department] WS, para. 6). In anticipation, ABC Corp. had registered these names as trademarks in both the United States and Canada and the registrations for [eeee] and [oooo] were therefore listed on Exhibit B. *Id.*

75. In 2009 the parties declined to pursue either [eeee] or [oooo] and instead agreed to submit the trademark "[iiii]" to the FDA for approval. Ms. [employee in XYZ's legal department] WS, para. 6; Ex, R-21).

76. As part of the agreement to select [iiii], and as required by Section 2.3 of the License Agreement, ABC Corp. on April 2, 2009 and without objection, assigned the [iiii] trademark applications to XYZ. Joint Ex. 11.

---

what they couldn't do through negotiations. You can't bring non-parties . . . and say that somehow we're going to ask you to force [Acme] to transfer over those Nippon-owned assets." (Day 1, Tr. 40).

77. At that time, the parties discussed updating Exhibit B to the License Agreement to add [iiii] and transferring the [iiii] related domain names to XYZ. Ms. [employee in XYZ's legal department] WS, para. 8.

78. While the parties were awaiting the FDA's consideration of the name [iiii][10], they considered potential back-up trademarks, for example, "[U]" and "[T]" *Id.,* para. 9; Ex. R-29). Acme (by that time, ABC Corp.'s name had been changed to Acme) agreed to assign those trademarks to XYZ if they were used instead of [iiii]. Ex. R-28.

79. In April 2013, XYZ learned of the FDA's intention to reject the [iiii] name. Ex. R-30. Several alternative names were discussed and "[aaaa]" was then selected by the parties to be submitted to the FDA. Ms. [employee in XYZ's legal department] WS, para. 10; Ex. R-31. [aaaa] was also rejected by the FDA on May 16, 2013. Joint Ex. 15.[11]

80. In response to these rejections, Acme, on July 26, 2013, provided XYZ with a shortlist of ten trademarks for consideration. Joint Ex. 19. [PRODUCT]® was on the list. *Id.* and Mr. [XYZ's Director of Business Development] Supp. WS, para. 6.

81. XYZ has an annual scheduled shutdown for three weeks every August. See, License Agreement, Section 5.7. As Acme was awaiting the FDA's Approval Letter permitting the marketing and sale of [ACETATE] for adult use, Acme was understandably anxious to obtain XYZ's approval for the potential trademarks prior to the shutdown. It would be extremely

[10] Trademarks for drugs approved by the FDA for sale must also be approved by the FDA to avoid the possibility of consumer confusion with other trademarked medications.

[11] The FDA thought that [aaaa] was too close to the name of a similar drug, "[aa]" *Id.* Apparently, Mr. [XYZ's Director of Business Development] did not learn of the FDA's rejection of [aaaa] until mid-August of 2013. Mr. [XYZ's Director of Business Development] Supp. WS, para. 10; Ex. C-86 at 01380374.

undesirable from a marketing perspective for a sponsor to have a drug approved for sale, but unable to sell it because a name for the drug had not yet been approved.

82. Mr. [XYZ's Director of Business Development] was the point person at XYZ for this effort and, by the time that he learned that [aaaa] had been rejected by the FDA in mid-August 2013, XYZ was in the midst of its annual shutdown. Mr. [XYZ's Director of Business Development] Supp. WS, para. 10. A flurry of emails ensued with Acme's alliance manager, [JILL] (Mr. [XYZ's Director of Business Development]'s counterpart at Acme) trying to reach Mr. [XYZ's Director of Business Development] to obtain his comments and approval and Mr. [XYZ's Director of Business Development] asking for more time to consider a new name for the drug. Finally, Acme, without awaiting XYZ's further input or consent, submitted the [PRODUCT]® name to the FDA on August 22, 2013. *Id.,* para. 12. Faced with a *fait accompli*, XYZ reluctantly approved of the [PRODUCT]® name at the end of August 2013. *Id.,* para. 13-14.

83. Following the FDA's approval of [PRODUCT]® on [date] (Joint Ex. 2), XYZ again raised the issue of the assignment of the [PRODUCT]® trademark. Ms. [employee in XYZ's legal department] WS, para. 13. Discussions with Acme ensued and XYZ initially took the position for technical reasons[12] that it did not want a direct assignment of the United States trademark but, instead, preferred that only the Canadian trademark application be assigned to it while the U.S. registration be held in trust by Nippon for XYZ pursuant to a so-called co-existence agreement. *Id.,* para. 14; Ex. R-41. At no time during those discussions did Acme dispute XYZ's right to own the [PRODUCT]® trademark and domain names. Indeed, at a

[12] At the time, XYZ had concerns that a direct assignment of the U.S. [PRODUCT] registration from Nippon to XYZ could be invalid and would jeopardize the [PRODUCT]® registration. Ms. [employee in XYZs legal department] WS, para. 14; Ex. R-37. Thus, it favored a "co-existence agreement" in lieu of an assignment.

teleconference of April 22, 2014, the parties agreed to update Exhibit B to the License Agreement to add [PRODUCT]® as a "XYZ Trademark". Ms. [employee in XYZ's legal department] WS, para. 14-15 and Ex. R-40 (Ms. [employee in XYZ's legal department]'s notes of the phone conversation). In May 2014, Ms. [employee in XYZ's legal department] reiterated to Acme's IP counsel, Ms. [counsel], the "need to update the License Agreement Exhibit to reflect [PRODUCT] as a XYZ Trademark." Ex. R-41. Acme never objected to that request but Exhibit B was never updated.

84. Further discussions followed with XYZ continuing to insist on the execution of a co-existence agreement and Acme wanting to execute a straight assignment. As Ms. [employee in XYZ's legal department] testified:

> XYZ did not agree with [Nippon's] proposal to assign the [PRODUCT] registration to Acme and informed Acme of its position. Ms. [employee in XYZ's legal department] November 24, 2104 Email to [Acme's IP counsel] (RX 35) ("XYZ does not accept assignment of the US registration of [PRODUCT] [from Nippon] to Acme."). It was clear to me that Acme had no objection to assigning the [PRODUCT] mark to XYZ at that time. [Acme's IP counsel] December 2, 2014 Email to Ms. [employee in XYZ's legal department] (RX 35) ("Acme has raised no issue of, and in fact proposed, transferring the US registration of [PRODUCT] to XYZ after that name was accepted by the FDA for the [[ACETATE]] product."); [Acme's in-house counsel] April 30, 2015 Email to Ms. [employee in XYZ's legal department] (RX 12) ("We [Acme] continue to believe that the direct assignment of the [PRODUCT] registration [to XYZ] . . . is the best way to effectuate both Acme's and XYZ's intent regarding ownership of the mark."

Ms. [employee in XYZ's legal department] WS, para. 18.

85. Finally, XYZ acquiesced in Acme's preference for a direct assignment of the U.S. trademark registration and, on September 7, 2015, XYZ drafted assignments for the various trademark rights and sent those to Acme for signature. Ex. R-13 and R-15; Ms. [employee in XYZ's legal department] WS, para. 21. After that date, Ms. [employee in XYZ's legal department] sent several reminders to Acme. *Id.* para. 22.

86. On October 19, 2015, [Acme's IP counsel] informed Ms. [employee in XYZ's legal department] that "Acme would not assign the trademarks or domain names to XYZ until a business decision is reached on the 'other matter' (i.e., sharing of costs for the PREA studies.)." Ms. [employee in XYZ's legal department] WS, para. 23.

87. It is clear from the facts set forth above, that Acme was prepared to assign the trademarks and domain names to XYZ as required by Section 2.3(a) of the License Agreement, and to amend Exhibit B to the License Agreement to add "[PRODUCT]®", but refused to do so because the parties were unable to resolve the matter of the PREA study costs. It is also clear that amending Exhibit B to the License Agreement to add "[PRODUCT]®" as a "XYZ Trademark" would have been a mere formality had the PREA dispute not arisen. Under these circumstances, the Tribunal will enforce the parties' intention, as expressed in Section 2.3(a), and compel Acme to assign the [PRODUCT]® trademarks, trademark registrations and domain names to XYZ notwithstanding the absence of "[PRODUCT]®" from Exhibit B to the License Agreement.

88. The conclusion above deals with all of the trademarks, trademark applications and domain names presently owned by Acme.[13]

89. Acme points out that the license that XYZ granted to it only applies in the "Territory", *i.e.* in the United States and Canada. (License Agreement, Section 2.1). That may be the case, but, because XYZ is the sole owner of the marks (License Agreement, Section 2.3(a)) and Acme has no competing claim to them, XYZ is entitled to their return, even if they are used outside of the "Territory". Thus, as against Acme, XYZ is entitled to a Declaration that it is the owner of the non-U.S. trademark registrations in Acme's name as well as the U.S. marks.

[13] These would include the Canadian [PRODUCT] trademark application No. ###### and the [PRODUCT] domain names identified on Exhibit B to XYZ's Post-Hearing Brief. These include: [list of products].

90. With respect to the domain names owned by Nippon, Acme is correct that the Tribunal has no jurisdiction to affect the rights of a party not before it. XYZ's counsel recognized this when he stated at the hearing: "We're not seeking an order against Nippon." (Day 3, Tr. 133). *See also*, page 13 of XYZ's Reply Memorial where XYZ states: "Respondent has no other adequate remedy in this arbitration, beyond what it requests—a declaration of the legal rights between Claimant and Respondent as to the trademark dispute. The issue of enforceability against Nippon of such a declaration, if necessary, is not before this Tribunal." [14]

91. That being said, however, XYZ, at pages 13-16 of its Reply Memorial, argues that Nippon should be bound by any declaration or order issued by this Tribunal. Nippon-- argues XYZ-- is Acme's principal and, as such, is bound by the promises and actions of its agent.[15] Nippon also (says XYZ) ratified Acme's entry into the License Agreement by giving written assurances to XYZ in connection with Nippon's acquisition of ABC Corp., that Nippon would abide by the terms of the License Agreement. *See*, ABC Corp.'s letter to XYZ dated August 19, 2009 (Ex. R-110, page 1) stating that "Nippon has confirmed to ABC Corp. that it will abide by the terms of the License Agreement." Nippon also gave that assurance directly in a letter that it sent to XYZ on August 25, 2009 confirming that "all of ABC Corp.'s obligations under its License Agreement with XYZ will be fully respected." Ex. R-111, page 1. It is apparent,

[14] The Terms of Reference make no claim for relief against Nippon.

[15] There is some evidence that an agency relationship in such things as Acme's agreement to cause the U.S. trademark registration to be transferred to XYZ. See, paragraphs 80-82 above. Nippon owns the U.S. trademark registration. See, Ex. A to XYZ's Post-Hearing Brief.

moreover, that Nippon is the driving force behind this dispute and, as Acme's parent, Nippon is the ultimate beneficiary of a favorable outcome.[16]

92. With the above in mind, XYZ, in Exhibit A to its Post-Closing Brief, requests an order from the Tribunal directing Acme to use its best efforts to cause the assignment or transfer to XYZ of the [PRODUCT]® marks presently held by Nippon. After due consideration, however, the Tribunal declines to issue such an order. While it appears that XYZ has a superior claim to the marks as against Nippon—based on, at least, the letter of assurance that Nippon gave to XYZ in connection with Nippon's acquisition of ABC Corp., Ex. R-111-- the Tribunal is in no position on this record to determine that issue factually,[17] and, indeed, has no jurisdiction given Nippon's absence from the arbitration. Whether, under all the circumstances, Nippon has a superior claim to the ownership of the marks will have to be resolved by the parties themselves or in further proceedings before an appropriate tribunal in which Nippon participates.

Expenses of the Arbitration Including the Parties' Expenses and the Expenses of the Tribunal

93. Section 16.1(f) of the License Agreement, quoted above, provides for each party to pay "its own expenses of arbitration" and to share the expenses of the arbitration tribunal and the ICC unless in the opinion of the arbitral tribunal, any claim or defense or objection thereto was "unreasonable". In that event, such fees and expenses can be assessed against the party that raised the unreasonable claim, defense or objection.

[16] Evidence was introduced that the top executives of both XYZ and Nippon met to discuss a global resolution of these disputes but were unable come to agreement. (Day 3, Tr. 137-138).

[17] For example, Acme points out that XYZ licensed [ACETATE] to a company named [Blank] Europe where it is marketed under the trade name [Blank]. Acme Defense to Counterclaim, Power Point slide No. 8.

94. XYZ, the prevailing party, asks for both its fees and expenses, including reimbursement of the ICC's administrative fees.

95. With respect to XYZ's own expenses and the expenses of the arbitration tribunal, the Tribunal finds that Acme advanced a plausible reading of Section 6.4 of the License Agreement and, with respect to its defense of the trademark counterclaim, pointed out the absence of the [PRODUCT]® name in Exhibit B to the License Agreement. The Tribunal is not prepared to characterize either of those positions as unreasonable. Thus, pursuant to Section 16.1(f) of the License Agreement, and in accordance with the discretion granted to the Tribunal in Article 37 of the ICC Rules, neither party will be awarded its expenses or the expenses of the arbitration tribunal.

The Expenses of the ICC

91. The Claimant and the Respondent have each paid the ICC's advance on costs of US $325,000. As quoted above, each side shall pay its own share of the ICC's administrative expenses unless, in the opinion of the Tribunal, any claim or defense or objection thereto is found to be unreasonable. For the reasons set forth above, the Tribunal does not characterize any of Acme's positions as unreasonable. Therefore, the parties shall share equally the ICC's administrative expenses.

92. The parties have an ongoing relationship that, but for these disputes, enjoyed close cooperation. The Tribunal is hopeful that the prompt resolution of these disputes will enable that cooperation to continue.

VI. RELIEF AWARDED

Wherefore, for the reasons set forth above, a majority of the Tribunal AWARDS the following relief:

A. DECLARES, that XYZ did not breach the License Agreement by refusing to pay one-half of the costs and expenses of conducting the PREA studies;

B. DECLARES, that Acme is not entitled to one-half of the costs of the PREA studies incurred to date or to be incurred in the future;

Wherefore, for the reasons set forth above, the full Tribunal AWARDS the following relief:

C. DECLARES that the [PRODUCT] trademarks are "XYZ Trademarks" as defined in Section 1.11 of the License Agreement, and, as such, XYZ owns all right, title and interest in the marks and in the goodwill associated with them. As a consequence, Acme is in breach of the License Agreement by failing to transfer or assign to XYZ the trademark application and domain names that it presently owns, to wit: [list of products].

D. ORDERS, that Acme assign to XYZ the Canadian trademark application and domain names set forth in Paragraph C. above, along with all related goodwill;

E. The parties shall each pay its own expenses and shall share equally the expenses of the arbitration tribunal;

F. Each party shall bear its own costs. At its session of 26 January 2017, the Court fixed the costs of arbitration at US $650,000.

G. All other requests and claims not expressly granted herein are rejected.

Place of Arbitration: London, England

Date: ____ February, 2017

_____
Robert B. Davidson, President

_____
John McGoldrick

_____

Hon. James Robertson (Ret.)