INTERNATIONAL COURT OF ARBITRATION

INTERNATIONAL CHAMBER OF COMMERCE

ICC Case No. AAAAAA

ACME Pharma, LTD.,

Claimant,

-and-

XYZ Pharma, Inc.,

Respondent and Counterclaimant.

TERMS OF REFERENCE

1. Introduction. This arbitration arises under an agreement in writing, namely a License Agreement made and entered into as of December 31, 2007 ("the License Agreement") between ABC Corp., a Delaware Corporation, on the one hand and the Respondent, XYZ Pharma, Inc. ("XYZ") on the other. ABC Corp. was the predecessor company to the Claimant, Acme Pharma, Ltd. ("Acme"), in this arbitration. In October 2009, ABC Corp. was acquired by [Nippon, Inc.], a Japanese pharmaceutical company ("Nippon"), and, in late 2010, ABC Corp. changed its name to Acme. Article 16.1 of the License Agreement calls for the arbitration of disputes in accordance with the Rules of Arbitration of the International Chamber of Commerce ("ICC Rules") 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", reference to which will be to

"Art. __" or "Article__") shall apply. These Terms of Reference are entered into by the parties and the Arbitral Tribunal in accordance with ICC Rules Art. 23. The Tribunal is separately executing a Procedural Timetable pursuant to Art. 24 as its provisional timetable.

2. Parties and Counsel: The parties to this arbitration are identified in the caption and are represented as follows:

Counsel for Claimant:
[name]
[firm]
[address]
[Telephone, fax, email]

-and-
[name]
[firm]
[address]
[Telephone, fax, email]

Counsel for Respondent-Counterclaimant:
[name]
[firm]
[address]
[Telephone, fax, email]

All communications in this arbitration shall be made to the representatives of the parties as set forth above. Copies of all communications shall be transmitted to the Administrator identified below.

3. Arbitrators.

John McGoldrick
25 Vandeventer Avenue
Princeton, New Jersey 08542
United States of America
Email: jmcgold7@gmail.com

Hon James Robertson (Ret.
JAMS
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JAMS
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4. Administration.

The ICC Administrators are:

Mr. Tunde Ogunseitan
Counsel to the Secretariat of the ICC International Court of Arbitration
Ms. Anne de Mazieres
Deputy Counsel
33-43 avenue du President Wilson
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5. Background.

The brief narrative that follows is included in these Terms of Reference in order to set the claims and issues in context. It contains no findings by the Tribunal and does not bind the Tribunal or the parties in any way.

(a) Claimant, Acme, is a corporation organized and existing under the laws of Delaware with its principal office located at [U.S. Address]. Acme is a pharmaceutical company engaged in the business of developing, marketing, manufacturing and selling pharmaceuticals.

(b) Respondent and Counterclaimant, XYZ, is a corporation organized and existing under the laws of Portugal, with its principal office located at [Portugal Address]. XYZ is also a pharmaceutical company engaged in the business of developing, marketing, manufacturing and selling pharmaceuticals.

(c) This dispute arises out of the License Agreement whereby XYZ granted to Acme's predecessor a non-exclusive license to develop and an exclusive license (with the right to sublicense in Canada only) to use, market, distribute, import, commercialize, offer for sale and sell certain defined Licensed Products in the United States and Canada. Those products included a pharmaceutical known as the prescription drug, [PRODUCT]®, ([ACETATE]) used to treat epileptic seizures.

(d) On [date] the U.S. Food and Drug Administration (the "FDA") approved [PRODUCT]® for the treatment of "Adult Adjunct Partial Epileptic Seizures in the United States of America" (the "Adult indication").

(e) The Pediatric Research Equity Act ("PREA", codified at 21 U.S.C. Sec. 355c) provides that all New Drug Applications ("NDAs") filed with the FDA contain an assessment of the drug candidate's safety and efficacy in pediatric subjects, even if the drug will be indicated for use only in adults.

(f) PREA allows FDA to defer submission of some or all assessments required under PREA until after the approval of the drug for use only in adults. In compliance with PREA, the Claimant obtained an extension of time to complete these studies (consistent with protocols to be later agreed with the FDA). Acme contends that such studies (the "PREA Studies") are now

ongoing, and that these studies will continue through approximately 2025.

(g) Acme contends that the License Agreement, and, in particular, Clause 6.4(c), requires XYZ to pay an equal share of the costs and expenses of the PREA Studies. Respondent disagrees and contends that it has no obligation under the License Agreement or otherwise to fund any part of the PREA Studies. Acme alleges that the total costs and expenses of the PREA Studies may reach $150 million, and that Respondent's share of these costs would, therefore, be $75 million, or such other amount as would equal one-half of the costs and expenses. XYZ, while denying any obligation to fund the PREA Studies, disputes the total amount suggested by Acme.

(h) In addition to denying any liability to Acme under the License Agreement or otherwise, XYZ asserts a counterclaim based on the Acme's alleged failure to take the steps needed to assign certain U.S. and Canadian [PRODUCT]® trademarks and domain names to XYZ as required by Section 2.3 of the License Agreement. Acme denies that it is contractually obligated to assign such trademarks and domain names.

6. Agreement to Arbitrate.

Section 16.1 of the License Agreement states in relevant part:

> 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 ABC Corp., 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 ABC Corp. 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 ABC Corp. 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 us 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 or 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.

The parties agree that the claims and the counterclaim asserted herein are arbitrable and that the Arbitral Tribunal has been established consistent with the parties' agreement.

7. <u>Procedural History</u>

(a) The arbitration was commenced on 18 February 2016 when the Secretariat of the International Court of Arbitration of the International Chamber of Commerce (the "Secretariat") received the Claimant's Request for Arbitration (the "Request"). By letter of 2 March 2016, the Secretariat notified the Respondent of the Request.

(b) On 2 March 2016, the Secretariat informed Mr. John McGoldrick of Princeton, New Jersey, USA that he had been nominated by Claimant for confirmation as co-arbitrator.

(c) 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.) as Respondent's party-appointed arbitrator.

(d) 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.

(e) On 25 March 2016, the Secretariat informed Judge James Robertson (ret.) of Washington, D.C., USA 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.

(f) By letter of 11 April 2016, the ICC Administrators named above 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.

(g) On 29 April 2016, Respondent transmitted to the ICC its Answer and counterclaim filed in response to Claimant's Request. By letter of 10 May 2016 the Secretariat acknowledged its receipt on 9 May 2016 of Respondent's Answer and counterclaim.

(h) On 9 May 2016 the two co-arbitrators advised the Administrators named above of their joint nomination of Mr. Robert B. Davidson of New York City, USA to be president of the arbitral tribunal.

(i) By letter of 13 May 2016, the Secretariat informed Mr. Davidson of his nomination as president of the arbitral tribunal.

(j) On 20 May 2016, the Secretariat wrote to counsel enclosing a copy of Mr. Davidson's Statement of Acceptance, Availability, Impartiality and Independence, as well as his cv.

(k) On 3 June 2016, the Secretariat notified the parties and the arbitrators that, pursuant to Article 13(2), the Secretary General had on 1 June 2016 confirmed Mr. Davidson as president of the arbitral tribunal. On the same day the Secretariat transmitted the file to the arbitrators.

(l) On 9 June 2016, Claimant sent its Reply to Counterclaim to the ICC for filing in accordance with Article 5(6) of the ICC Rules.

8. Contentions and Claims.

The purpose of the following summaries is to satisfy the requirements of Article 23(1)(c)

of the ICC Rules, without prejudice to any other or further allegations, arguments, and contentions contained in the pleadings or submissions already filed and in such submissions as will be made in the course of this arbitration. No statement or omission in the following summaries is to be interpreted as a waiver of any issue of fact or law by any party. The Tribunal shall be entitled, subject to Articles 19, 22 and 23(4) of the ICC Rules and other applicable procedural requirements, to take into consideration further allegations, arguments, contentions, and oral or written submissions. By signing these Terms of Reference, neither party subscribes to, or acquiesces in, the contentions of the other party set forth below. These Terms of Reference are intended to enable the Tribunal and the parties to focus on the issues in this arbitration; they are not to be understood as foreclosing the making of arguments or the introduction of evidence not expressly referred to herein.

The Claimant requests the Tribunal to assess that:

1. Pursuant to Section 6.4(c) of the License Agreement, XYZ is obligated to "share equally the actual costs and expenses of conducting any studies required by the FDA to obtain the Approval of the [ ] Product for Adult Adjunct Partial Epileptic Seizures . . ." (the "Adult indication").

2. Studies for which XYZ is obligated to share costs include those required by FDA under the Pediatric Research Equity Act ("PREA"). PREA provides that each New Drug Application ("NDA") must contain data adequate to assess the safety and effectiveness, and to support dosing and administration, of the drug product for the claimed indications in all relevant pediatric subpopulations, even if the drug will be indicated only for use in adults. *See* 21 U.S.C. §355c(a)(2)(A).

3. PREA permits FDA to defer submission of pediatric assessments until after the drug is marketed for use in adults. *See* 21 U.S.C. §355c(a)(3)(A). If an Applicant fails to make its required pediatric submissions, however, the drug is misbranded and may be enjoined from sale and/or seized by the federal government. *See* 21 U.S.C. §§355c(d)(2), 332(a); 334(a).

4. Prior to FDA's November 8, 2013 approval of [PRODUCT]® for the Adult indication, Acme and FDA had extensive discussions about PREA studies that FDA would require as a condition of approval. Prior to issuing its Approval Letter, FDA extracted Acme's commitment to perform certain PREA studies. XYZ was fully aware of and participated in this process.

5. In its Approval Letter, FDA memorialized Acme's commitment to perform the PREA studies, and specified that Acme complete eight (8) PREA studies as a condition of [PRODUCT]®'s approval. As authorized under PREA, FDA deferred the timing of study completion until after the drug was marketed for use in adults.

6. Since November 8, 2013, FDA and Acme have discussed whether the number of FDA-required PREA studies would be reduced through consolidation. Although Acme has not yet received formal confirmation from FDA, the current budget (PREA costs and expenses) totals approximately $105 million USD (with XYZ's share being approximately $52.5 million).[1] Acme expects to receive formal confirmation from FDA in the near future, and the amount of PREA costs and expenses, reduced to present value, will be established during the course of this proceeding. XYZ was aware of the interactions with FDA and participated in at least one meeting with FDA regarding consolidation of certain PREA studies.

[1] In its Request for Arbitration, Acme stated that the PREA budget for costs and expenses would total approximately $150 million USD (with XYZ's equal share being $75 million). That number was accurate at the time of the filing of the Request.

7. XYZ expressly repudiated its cost-sharing obligation under Section 6.4(c) of the Agreement and has refused to accept Acme's invoices for XYZ's share of PREA costs and expenses. After XYZ's repudiation of its obligations under Section 6.4(c), Acme opted to proceed with the PREA studies and seek damages through arbitration. XYZ's share of PREA study costs and expenses through March, 2016 totals $5,861,363.69 USD. XYZ's repudiation amounted to an anticipatory breach of the License Agreement, relieving Acme of the burden to futilely seek XYZ's agreement on PREA study budgets. Nonetheless, Acme kept XYZ informed of the scope, design and status of the PREA studies.

8. With respect to XYZ's Counterclaim, Acme denies that it is contractually obligated to assign the [PRODUCT]® trademarks and domain names to XYZ. Further, XYZ cannot pursue its counterclaim because XYZ itself is in breach of the Agreement by failing to share PREA costs and expenses pursuant to Section 6.4(c).

The Claimant further requests that the Tribunal, having determined the above, to award the following relief:

A. A declaration that XYZ has breached Clause 6.4(c) of the Agreement by failing to pay and expressly repudiating its obligation to pay an equal share of PREA study costs and expenses;

B. Actual damages for XYZ's breach of Clause 6.4(c) of the Agreement, plus interest, in an amount to be established during the course of this proceeding;

C. The costs and expenses of this arbitration, including Acme's attorneys' fees, plus interest; and,

D. Further and other relief in favor of Acme that the Tribunal deems is just and proper.

The Respondent requests the Tribunal to assess that:

1. These disputes between Acme and XYZ are issues of contract interpretation.

2. The PREA Regulations were in place at the time the License Agreement was negotiated and the Parties were fully aware of their requirements.

3. The Parties drew a clear line in the License Agreement between studies required for adult approval and studies not required for adult approval. Section 6.4(c) relates to studies required to obtain FDA approval for adult use and § 6.4(d) relates to marketing or post-Approval studies, such as PREA studies. It is also clear, when reading the License Agreement in its entirety, that the Parties drew a distinction between Adult and Pediatric use of the drug.

4. The language used in PREA makes it clear that its studies are not "required" for FDA approval for adults. The PREA studies can be deferred, as happened here, until after the drug is approved, if the drug is ready for adult approval before the PREA studies have been completed or even started. PREA explicitly states that approval cannot be revoked for a failure to comply with PREA. 21 U.S.C. § 355c(d)(2).

5. The language used by the FDA in the NDA Approval Letter and other correspondence makes it clear that the PREA studies are not required for approval and are not a condition for approval. The NDA Approval Letter defers the PREA studies until a later date, but states that [PRODUCT]® is approved for marketing for adult use immediately. The NDA Approval Letter also refers to the PREA studies as "postmarketing studies." Section 6.4(d) of the License Agreement expressly states that Acme will be responsible for all "marketing or post-Approval studies".

6. PREA studies are not required for adult approval. Therefore, the studies fall under § 6.4(d) and Acme is solely responsible for the costs of such PREA studies.

7. Acme's failure to raise the issue of the costs of the PREA studies during a two year reconciliation process and to present XYZ with a PREA studies budget for its approval, as required by § 6.4(c), prior to initiating any such study, supports XYZ's position that: (1) it was the intent of the Parties when entering into the License Agreement that the PREA studies were not encompassed by § 6.4(c); and (2) both Parties performed under the License Agreement in accordance with that intention until September 2015.

8. Section 2.3 of the License Agreement requires any marketing, sale, or distribution of the Licensed Products by Acme to take place exclusively under the XYZ Trademarks. The License Agreement stipulates that the Parties will mutually agree upon the XYZ Trademarks and that XYZ will own all right, title, and interest in the XYZ Trademarks.

9. Despite the License Agreement's mandate, Acme's marketing, sale, and distribution of the Licensed Products is conducted under the [PRODUCT]® mark, trademark applications and registrations for which are currently held in Canada and the United States by Acme and Nippon. The Parties agreed to the transfer of the [PRODUCT]® mark, as they had done previously with [aaaa]® when they thought this would be the approved trademark for the License Products, and XYZ sent the draft assignment agreements to Acme on September 7, 2015, but Acme has since refused to comply.

10. Acme's allegations of misrepresentation and failure to disclose material facts (e.g., regarding the liver enzyme known as [bbbb]) are irrelevant to this proceeding, premature, and not ripe for arbitration.

The Respondent further requests that the Tribunal, having determined the above, award the following relief:

A. A declaration that XYZ has not breached § 6.4(c) of the License Agreement and is not responsible for 50% of the costs and expenses of any studies to be conducted by Acme under PREA.

B. A declaration that Acme is entirely responsible for the costs and expenses of the PREA studies, which are marketing or post-Approval studies under § 6.4(d).

C. Assuming, *arguendo*, that the Tribunal finds that § 6.4(c) does encompass the PREA Studies, XYZ requests a declaration that Acme relinquished its compensation rights under § 6.4(c) by failing to obtain XYZ's budget approval before proceeding with such studies and allegedly incurring millions of dollars in costs.

D. Assuming, *arguendo*, that the Tribunal finds XYZ liable for half of the costs and expenses of the PREA studies, then XYZ requests a declaration that it is outside the Tribunal's purview to determine such amounts and/or damages and should order the parties to agree on budgets for such studies before they are performed, as the License Agreement requires.

E. A declaration that Acme and Nippon are required by § 2.3 of the License Agreement to assign the [PRODUCT]® trademarks, trademark applications, and domain names to XYZ.

F. A declaration that Acme is required to pay its own attorneys' fees, as required by § 16.1(f) of the License Agreement.

G. Acme's breach of contract claim is clearly unreasonable under the express terms of the License Agreement and in view of the Parties' actions and course of conduct. XYZ therefore requests an award of XYZ's arbitration expenses, including XYZ's attorneys' fees, and the fees and expenses of the Tribunal and the ICC, under § 16.1(f) of the License Agreement.

H. In view of the irrelevant nature of the allegations of misrepresentation and failure to disclose material facts raised in Acme's Request for Arbitration, XYZ requests reimbursement of its expenses in researching and responding to such statements under § 16.1(f) of the License Agreement.

I. A declaration that interest shall not be awarded on any damages or other award.

9. Issues for Decision.

The issues to be determined by the Arbitral Tribunal shall be those resulting from the Parties' submissions, including forthcoming submissions, and which are relevant to the adjudication of the Parties' respective claims and defenses. The identification of the issues below is intended to facilitate the resolution of this arbitration; it is not to be understood or construed as foreclosing the presentation or consideration of other factual or legal issues necessary for a complete resolution of this arbitration by the Tribunal. The following issues have been identified by the Parties:

(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?

(c) 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?

(d) Assuming the answers to some or all of (a) through (c) 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?

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

(f) 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?

10. Applicable Substantive Law.

Clause 16.8 of the License Agreement states in part: "[a]ll 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."

11. The Seat and Language of the Arbitration.

By the terms of Clause 16.1(d) of the License Agreement, "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."

Deemed Executed at London, England
June___, 2016

_____
John McGoldrick

_____
Hon. James Robertson (Ret.)

_____
Robert B. Davidson
Arbitrators

_____ _____
[Firm] Date

Attorneys for Claimant

_____ _____
[FIRM] Date

Attorneys for Respondent