PROCEDURAL ORDER ON DOCUMENT PRODUCTION REGARDING THE PARTIES’ RESPECTIVE CLAIMS TO PRIVILEGE AND PRIVILEGE LOGS
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I. **Introduction**

1. Pursuant to Paragraph 14.2.7(v) of the First Procedural Order, the Claimants and the Respondent submitted to the Tribunal on 15 March 2013 disputes under their respective requests for document production for decision by the Tribunal as set out in their respective schedules (the “March Schedules”), such decision to be issued on 29 March 2013 in accordance with the procedural time-table fixed by Paragraph 14.2.7(vi) of the First Procedural Order.

2. On 29 March 2013, the Tribunal issued its Procedural Order with regard to the Parties’ respective requests for document production in these arbitration proceedings (the “March Order”).

3. The Tribunal there decided (inter alia) that as regards the privilege or privileges invoked or to be invoked by the Claimants and the Respondent, each side should prepare a privilege log identifying, by reference to any ordered document or (if not an identified document) any narrow and specific category of documentation, the particular privilege invoked by that side in relation to such document or documentation.

4. The Tribunal also decided that the requesting Party should have an opportunity to respond in writing to such privilege log, with the responding Party being afforded a brief opportunity to reply to such response, also in writing.

5. The Tribunal further requested the Parties to consult amongst themselves with a view to agreeing upon a time-table for the exchange of these privilege logs, further submissions and certifications.

6. On 26 April 2013, the Parties informed the Tribunal that they had agreed upon an approach to complete the procedure for document production, as well as a time-table for the exchange of privilege logs, further submissions and certifications. The Parties further agreed upon a time-table that they proposed to the Tribunal with dates remaining to be fixed. The Parties confirmed that the remainder of the procedural time-table (including the hearing dates), as fixed in paragraph 14.2.7 of the First Procedural Order would remain unchanged.
7. On 30 April 2013, the Tribunal accepted the Parties’ proposal of 26 April 2013. On 10 May 2013, the Parties informed the Tribunal of the agreed time-table and jointly requested the Tribunal to reflect that time-table in a procedural order.

8. On 13 May 2013, the Tribunal formalised the agreed time-table as procedural order, issued to the Parties on 14 May 2013 (the “May Order”).

9. As provided in the May Order, the Claimants filed on 24 May 2013 their Reply on the Merits and Counter-Memorial on Jurisdiction, addressing all documents produced on or before 19 April 2013.

10. On 28 May 2013, the Parties exchanged certifications (with copies to the Tribunal) that the tests for relevance and materiality under Articles 3(3)(b) and 9(2)(a) of the International Bar Association’s Rules on the Taking of Evidence 2010 (the “IBA Rules”) had been applied to documents not produced by the responding Party.

11. On 11 June 2013, the Parties simultaneously exchanged their replies to objections to privilege and provided such completed privilege logs to the Tribunal. Each privilege log was accompanied by a letter dated 11 June 2013. For ease of reference, the Claimants’ completed log is here attached as “Annex A” and the Respondent’s completed log as “Annex B” (neither with legal materials also supplied by the Parties), both such logs forming part of this procedural order. If and to the extent that full publication of this Order causes concern for any Party, the Tribunal will consider upon further consideration with the Parties redacting for publication any appropriate part of this Order’s text.

12. Having considered the Parties’ respective logs, letters dated 11 June 2013 and attached materials, the Tribunal makes the following procedural order in regard to the Parties’ respective assertions of privilege regarding the documentation ordered by the Tribunal in its March Order. This Order requires several preliminary explanations, as follows.

13. First, as decided in Paragraph 15.1 of the First Procedural Order, the Tribunal takes account of Articles 3 and 9 of the IBA Rules as an additional general guide to the exercise of its discretion under Article 41(2) of the ICSID Arbitration (Additional Facility) Rules, forming part of the Parties’ Arbitration Agreement.

14. Second, in Paragraph O of its March Order, the Tribunal decided that it was not minded to take into account deliberative process privilege, attorney-client privilege, attorney work-product doctrine privilege (or any other privilege or like impediment) as a matter of any applicable national law or rules of law, but rather as one or more factors falling
within Article 9(2) of the IBA Rules. The Tribunal continues here to apply this general principle to the Parties’ present dispute over document production.

15. Third, the Tribunal is conscious that both sides have undertaken the exercise of document production generally and the assertion of privilege specifically by engaging professional lawyers in the private and public sectors, owing a personal duty to their legal profession and also to this Tribunal within these arbitration proceedings. This exercise is required to be performed, of necessity, in a responsible and non-partisan manner; it is essentially (but not entirely) self-regulating; and in these arbitration proceedings the Tribunal is confident that the legal advisers for both sides have conducted themselves hitherto responsibly and with good faith in the performance of these duties. Of course, in the event that any party to an arbitration (whether by itself or by its legal representatives or advisers) should act irresponsibly, an arbitral tribunal may draw adverse inferences against that delinquent party at any time.

16. Fourth, this Tribunal considers that the Parties’ invocation of privilege in these arbitration proceedings relates not only to the non-production by the responding Party to a request for document production but also as a bar to the admission of such documentation into evidence by the requesting Party. Accordingly, the Tribunal being a final judge of factual issues in these arbitration proceedings, it is inappropriate for the Tribunal to examine for itself, ex parte, any document or part of a document for which privilege is invoked by a responding Party, quite apart from any question of due process. The Tribunal has considered appointing an independent and impartial referee to examine the disputed documents and redactions under Article 3(9) of the IBA Rules or its inherent procedural powers (such a referee would not suffer from the same predicament as the Tribunal); but, from concerns as to efficiency, time and cost, the Tribunal decided not to take that particular path in regard to this Order.

17. With these general explanations, it is appropriate next to address each of the Parties’ privilege logs in turn, beginning with the Claimants.
II. The Claimants’ Privilege Log

18. The Claimants invoked two forms of privilege to exclude the 353 documents enumerated in their privilege log: (i) attorney-client privilege as to 41 documents and (ii) work product doctrine as to all 353 documents. These documents comprise emails, letters, excel sheets, reports, memoranda and presentations exchanged between the Claimants, their Counsel (Buc & Beardsley, LLP which became Zuckerman Spaeder LLP, here the “Regulatory Counsel”) and their independent consultants on Current Good Manufacturing Practices or “cGMP” (Jeff Yuen & Associates and Paul Vogel Consulting Services LLC, together here the “Consultants”).

19. The Parties do not dispute that these two privileges fall within the IBA Rules. Their views diverge as to whether certain of the communications with the Consultants and the Regulatory Counsel and also certain other documents created by the Consultants fall in fact under the protection of either of these privileges.

20. In this respect, the Tribunal notes that the Parties have relied heavily upon United States legal sources to support their legal arguments. The Respondent also cites Article 9(3)(c) of the IBA Rules,¹ which provides that the Tribunal may take into account the expectations of the parties in assessing privilege.² The Respondent refers to the commentary on the IBA Rules, which states that “Article 9.3(c) expresses the guiding principle that expectations of the parties and their advisors at the time the legal impediment or privilege is said to have arisen should be taken into consideration. Often, these expectations will be formed by the approach to privilege prevailing in the home jurisdiction of such persons.”³ The Respondent also notes that while Apotex Inc. (the Second Claimant) is a Canadian company, the Claimants’ Regulatory Counsel and the Consultants were all based in the United States of America. Finally, the Respondent notes that New York (USA) is the legal place of this arbitration.⁴

21. The Tribunal considers that Article 9(3)(c) of the IBA Rules sufficiently provides for recognition of the expectations of the Parties and their advisers at any material time, as

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¹ Article 9(3)(c) of the IBA Rules provides that: “In considering issues of legal impediment or privilege under Article 9.2(b), and insofar as permitted by any mandatory legal or ethical rules that are determined by it to be applicable, the Arbitral Tribunal may take into account: […] (c) the expectations of the Parties and their advisors at the time the legal impediment or privilege is said to have arisen.”
² See Footnote 2 to Tab 1 to the Claimants’ privilege log.
³ The Commentary on the 2010 IBA Rules on the Taking of Evidence in International Arbitration at 25 (RLA-185).
⁴ See Footnote 2 to Tab 1 to the Claimants’ privilege log.
does Article 9(3)(e) of the IBA Rules on the need to maintain fairness and equality as between the Parties. The Parties’ reliance upon US law suggests both their expectations and the elements required to maintain fairness and equality between them. Nonetheless, as explained above, as an international arbitration tribunal, the Tribunal bases its decision directly upon the exercise of its discretionary powers under the IBA Rules and the ICSID Arbitration (Additional Facility) Rules, rather than national rules of law; and as already noted, the issues dividing the Parties arise from the application of the IBA Rules to the particular circumstances of this case, rather than the scope of those rules.

22. As to such issues of application, the Claimants submit (inter alia) that “[t]he Consultants were engaged by Apotex’s counsel to provide legal advice regarding regulatory compliance and to help respond to FDA. After putting Apotex on Import Alert, FDA informed Apotex that it must improve its cGMP compliance and have its facilities successfully re-inspected. However, FDA provided no guidance as to how Apotex should improve its compliance or what enhancements would be deemed sufficient at re-inspection. Thus, the Consultants performed a critical role in assisting the attorneys in creating a strategy for Apotex’s response, identifying areas for investigation, creating a review and remediation protocol, providing strategic input and analysis, and helping to formulate Apotex’s final responses to the multitude of issues raised by FDA. The Consultants’ assistance to Counsel in responding satisfactorily to FDA goes far beyond performing mere ‘technical research’. ” The Tribunal notes that, of course, the Consultants were not engaged themselves to provide any legal advice (not being lawyers); and accordingly the Tribunal interprets the Claimants’ submissions (as cited above and elsewhere) as meaning that the Consultants were engaged for the purpose of assisting the Claimants’ Regulatory Counsel in providing legal advice to the Claimants, both generally and also as regards the prospect of litigation with the Respondent or its agencies (including, primarily, FDA).

23. As noted above, the Claimants invoke attorney-client privilege in conjunction with the work product doctrine for 41 communications. The Claimants contend that attorney-client privilege covers communications made to agents of an attorney engaged to help translate the complicated landscape of technical subject matters, in this case FDA regulations. More specifically, “the Consultants gathered information through
confidential communications from Apotex and translated it into useable and understandable form for Counsel, in order for Counsel to render legal advice.”

24. The Respondent challenges the Claimants’ application of attorney-client or work product privilege to the communications with the Consultants. Regarding the documents produced by or involving Jeff Yuen & Associates (“JYA”), the Respondent contends that the engagement letter between Buc & Beardsley, LLP and JYA, dated 22 September 2009, is a mere veneer intended to cloak JYA’s work with ostensible privilege to which that work is not entitled. The Respondent invokes various facts in support of its allegation: the engagement letter is signed by the Claimants; the Claimants were made responsible to pay JYA’s fees directly; and the Claimants have pleaded in these proceedings that the Claimants themselves (not their Regulatory Counsel) had retained the services of an outside consulting group to guide the remediation process intended to remove the Import Alert.

25. The Respondent concludes that JYA was “not hired to assist in the provision of ‘legal advice,’ but rather [was] hired specifically to audit Apotex’s quality systems and provide corrective action plans to assist Apotex in returning to cGMP compliance. The attorney-client privilege does not extend to consultants hired to make scientific or business assessments, including consultants hired to achieve regulatory compliance.”

26. Alternatively, the Respondent maintains that the Claimants waived any privilege regarding documents concerning the same subject-matter by having selectively disclosed communications, audits, plans and documents of their consultants. In the words of the Respondent, the Claimants cannot use privilege both as a “sword and a shield”.

27. The Respondent advances similar arguments with respect to communications involving Paul Vogel Consulting Services LLC, which need not here be repeated.

28. In response, the Claimants state that their Regulatory Counsel did in fact retain the Consultants to assist them in providing legal advice to the Claimants in connection with the Claimants’ compliance with cGMP and the interaction with the FDA concerning

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5 Id. at para. 5.
6 See Tabs. 1 and 3 to the Claimants’ privilege log.
7 R-125.
8 See Tab. 1 to the Claimants’ privilege log.
9 The Claimants’ Memorial, paras. 248 and 550; The Claimants’ Reply, para. 77.
10 See Tab. 1 to the Claimants’ privilege log.
11 See Tab. 3 to the Claimants’ privilege log and R-124.
cGMP compliance and enforcement issues, including the prospect of litigation. This legal advice was then used to draft the Claimants’ various responses to FDA.  

29. The fact that the Claimants paid the Consultants’ fees directly does not demonstrate, according to the Claimants, that the Consultants were engaged by the Claimants, rather than by their Regulatory Counsel. In addition, the Claimants submit that documents dated on or before the engagement letters are still entitled to attorney-client privilege protection because an attorney-client relationship can and did commence prior to the date of signing of the retainer agreement.

30. With regard to the Respondent’s alternative case on waiver, the Claimants assert that they are not relying on any privileged communications to support their case. Rather than waiving privilege, the Claimants submit that they have relied only upon the final responses to the FDA, which are the by-product of the collaboration between the Consultants, the Regulatory Counsel and the Claimants.

31. Finally, Apotex notes that the US has not demonstrated any substantial and compelling need for these documents sufficient to overcome the attorney-client privilege.

32. US Courts, as also courts in other common law countries, have long recognized that attorney-client privilege can extend beyond the traditional relationship between an individual attorney and an individual client. The privilege may thus attach to communications with third parties acting as agents of an attorney, when the purpose of their work is to facilitate the provision of legal advice by that attorney. This approach recognises that lawyers in modern times for complex disputes need technical, financial or other expert consultants to “translate” difficult issues in order properly to advise their clients. In the Tribunal’s view, the critical question here is whether the principal purpose of the third-party communications was to provide for legal advice from the Regulatory Counsel to the Claimants.

33. In considering this question, the Tribunal observes that the factual burden of proof under both the IBA Rules and US law lies with the party asserting attorney-client privilege so as

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12 See Tab 4 to the Claimants’ privilege log, para. 2.
13 Id. at para. 3.
14 Id. at para. 4.
15 Id. at para. 8.
16 Id. at para. 10.
18 Id.
to exclude communications from the rule otherwise favouring disclosure,¹⁹ for which specific evidence is required by US courts. ²⁰ As asserted by the Respondent, communications with third-party consultants will not be privileged unless the asserting party can show that the underlying purpose was to assist in providing legal advice;²¹ thus, a formal engagement and an attorney’s use of a consultant’s particular knowledge point toward exclusion;²² but, on the other hand, where it is found that consultants were retained “primarily to provide technical services and not to interpret confidential client information,” the communications will be held discoverable under US law.²³

34. In this case, as regards the disputed 41 documents, the Tribunal accepts the Claimants’ statement that the Consultants were engaged in order to assist the Claimants’ Regulatory Counsel in providing legal advice to the Claimants. The Tribunal does not accept the Respondent’s unsupported factual allegation that the Claimants deliberately asked their Regulatory Counsel to issue letters of engagement for the Consultants for the sole purpose of protecting, as a “veneer”, their work from being produced in all future litigation or arbitration proceedings. That the Claimants also signed the engagement letters and directly paid the Consultants does not contradict, in the Tribunal’s view, the fact that the Consultants were retained in order to assist the Regulatory Counsel as the Claimants’ legal advisers.

35. The Tribunal now turns to these communications. Most of the documents for which the attorney-client privilege is invoked involve Ms. Kate Beardsley and Ms. Carmen Shepard, being lawyers at Buc & Beardsley, LLP and Zuckerman Spaeder LLP. The attorney-client privilege can therefore be confirmed as regards such documentation. The other communications (for which none of the lawyers seems to be named amongst the senders and addressees) are documents which the Claimants state were drafted at the request of the Regulatory Counsel or include chains of communications with Regulatory Counsel. The Tribunal considers that these communications are also protected by attorney-client

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privilege. Finally, the Tribunal accepts that attorney-client privilege can extend to communications with attorneys’ agents prior to signing any retainer agreement and therefore that communications pre-dating the Consultants’ formal engagement by letter here also benefits from attorney-client privilege.

36. The Tribunal does not consider that the Respondent has made out its claim of waiver of privilege in regard to any disputed document. Of course, a party cannot waive part of a document or part of related documentation so as to present incomplete and inaccurate materials; but the Tribunal is not persuaded that the Claimants have engaged in this subterfuge.

37. In conclusion, the Tribunal decides that the 41 documents listed the Claimants’ privilege log (for which the Claimants invoke attorney-client privilege) are not ordered to be produced by the Claimants to the Respondent, by reason of Article 9(2)(b) of the IBA Rules.

38. As regards work product doctrine, the Claimants assert that “Apotex engaged the Consultants to assist Counsel in providing legal advice regarding remediation efforts, which was motivated in part by a desire to avoid litigation. ‘Regulatory investigations by outside agencies present more than a mere possibility of future litigation, and provide reasonable grounds for anticipating litigation.’ Even if Apotex was ‘partially motivated by a business purpose, the privilege still protects these documents.’ […] [C]ommunications with the Consultants that relate to investigative efforts, analysis, and remediation planning are entitled to work product protections.”

39. The Respondent submits that the Claimants cannot withhold any documents on the basis of the work product doctrine because the doctrine protects only those documents that are prepared in anticipation of litigation. The Respondent notes that the Claimants have repeatedly stressed that the Consultants were engaged in order to improve the Claimants’ quality systems and implement plans for corrective action. The Respondent also contends that the Claimants repeatedly provided the Consultants’ reports to FDA and have relied upon those same documents to advance legal arguments in this arbitration. Therefore, so the Respondent concludes, the Claimants cannot rely upon any work product doctrine to

24 See Tab 4 to the Claimants’ privilege log, para. 9.
shield similar documents and to deny the Respondent an opportunity to challenge the Claimants’ arguments.\footnote{25 See Tab 2 to the Claimants’ privilege log.}


41. Under US law, it appears that the requirement for the relevant document to be prepared in anticipation of litigation does not limit the work product doctrine to documents prepared primarily or exclusively to assist in the litigation itself; and the broad language “in anticipation of” therefore includes documents created because litigation remained prospective.\footnote{29 RLA-193, ECDC Environmental v. New York Marine and General Insurance Co., 1998 WL 614478 (S.D.N.Y. 4 June 1998) at *4.} What matters is that a reasonable likelihood or “substantial probability” of litigation existed at the time the document was created.\footnote{30 RLA-193, ECDC Environmental v. New York Marine and General Insurance Co., 1998 WL 614478 (S.D.N.Y. 4 June 1998) at *11-12 citing United States v. Adlman, 68 F.3d 1495, 1499 (2d Cir.1995) at 1202.}

42. As with attorney-client privilege, the Tribunal recognises that the responding party bears the burden, under the IBA Rules and US law, of showing that the withheld documents fall within the work product doctrine’s protection.\footnote{31 CLA-616, Garrett v. Metropolitan Life Ins. Co., 1996 WL 325725, (S.D.N.Y. 12 June 1996) at *4-5; CLA-617, In re Woolworth Corp. Sec. Class Action Litigation, 1996 WL 306576, (S.D.N.Y. 7 June 1996), at *3. Fed.Rule.Civ.Proc. 26(b)(3).} The NAFTA tribunal in \textit{Glamis Gold}, after considering US law on the work product doctrine, observed that the party asserting the privilege must “show the subject matter of the document relates to a likely lawsuit by an identifiable adversary in respect of a specific dispute.”\footnote{32 CLA-480, Glamis Gold, Ltd. v. United States, NAFTA/UNCITRAL, Decision on Parties’ Request for Production of Documents Withheld on Grounds of Privilege of 17 November 2005, para. 31.} The Tribunal considers the application of this practical test appropriate in this arbitration.
43. The description of the documents in the Claimants’ Log “quality system assessment”, “corrective action plan”, “quality systems gap and remediation”, does not indicate, one way or the other, whether any these documents were prepared in anticipation of litigation.

44. In its Memorial, the Claimants pleaded that “Apotex had ‘retained an independent expert consultant to assist in executing corrective actions and ongoing monitoring for effectiveness.’ The planned quality system improvements were designed to assure that all products manufactured by Apotex for US distribution met or exceeded the requirements of the GMP regulations […].”33 When describing the reports of the Consultants sent to FDA on 17 March 2010, the Claimants pleaded “Jeff Yuen & Associates, Inc. presented its independent review of Apotex quality structures and processes, taking into account all findings from numerous regulatory inspections conducted in 2008 and 2009. Finally, Paul Vogel Consulting Services LLC assisted Apotex in producing a corrective action plan (CAP) and a global quality systems enhancement program.”34 The Claimants also pleaded: “[w]ith respect to the corrective action plan, Apotex explained that the objective of this ambitious program was a comprehensive cGMP enhancement of the quality systems across all development and manufacturing sites of Apotex.”35

45. Based on these statements, it appears to the Tribunal that these disputed documents were prepared in order to remove or qualify a measure imposed by the Respondent’s agency (the Import Alert of 28 August 2009). They were prepared at times when a litigious dispute against the Respondent or its agencies was more than a possibility, but (as transpired) a substantial probability. The Parties dispute whether the documents were prepared in anticipation of such litigation or rather to respond to FDA’s immediate regulatory requirements. However, as indicated above (paragraph 21), under Article 9 of the IBA Rules, the expectations of the parties and considerations of fairness should be taken into account in assessing a claim of privilege. These documents were produced pursuant to engagements with Claimants’ regulatory counsel clearly indicating the participants’ expectations that they would be privileged.

33 The Claimants’ Memorial, para. 195.
34 Id. at para. 228.
35 Id. at para. 234.
46. In these circumstances, the Tribunal concludes that the work product doctrine applies to the 312 disputed documents listed in the Claimants’ privilege log (beyond the 41 also subject to attorney-client privilege).

47. Accordingly, for these reasons, the Tribunal does not order the Claimants to produce these 312 documents to the Respondent, by reason of Article 9(2)(b) of the IBA Rules. (The Tribunal, as already indicated above, does not here seek to base its decision upon US law or the application of US law to this case, as if it were a US Court. It does consider, however, that at all material times the expectations in regard to US law of the Claimants (with their several advisers), however much now disputed by the Respondent as a matter of US law, are consistent with this decision of the Tribunal under the IBA Rules).

III. The Respondent’s Privilege Log

48. Out of the 35 documents contained in the Respondent’s privilege log, there is only one disputed document. (The Tribunal addresses the disputed redactions separately below). For the other 34 documents, the Claimants do contest that a domestic privilege, such as the deliberative process privilege or exemptions under the Freedom of Information Act (FOIA), is applicable in these international arbitration proceedings; but, to the Tribunal’s understanding, the Claimants do not now object to the Respondent withholding these documents from production under Articles 9(2)(b) and Article 9(2)(f) of the IBA Rules.

49. The disputed document is described by the Respondent as a Draft Information Advisory, entitled “Subject: Warning Letter to Apotex Inc.” prepared for internal briefing purposes only for the US Secretary of Health and Human Services. The Respondent states that three versions of this same document were inadvertently produced to the Claimants and that as an advisory prepared for internal use and briefing purposes only, the information advisory was not intended to be made public, and in any event it was not, as a draft, finalised even for internal briefing purposes. The Respondent also states that draft advisories are internal, pre-decisional communications that form part of a government agency’s decision-making process, are protected by deliberative process privilege under US law and are therefore excluded from production under Article 9(2)(b) of the IBA Rules (for legal impediment or privilege) and/or Article 9(2)(f) of the IBA Rules (on grounds of special political or institutional sensitivity). Lastly, the Respondent submits
that it has not waived the privilege attaching to these documents and requests the immediate return of the inadvertently produced draft(s).\textsuperscript{36}

50. The Claimants object to the Respondent’s withholding this document from production and do not consent to returning its produced version(s) because, in their submission, the document is not privileged under US law or the IBA Rules, and even if it were, the Respondent has waived any such privilege. The Claimants note that the Respondent has produced three nearly identical versions of the same document to the Claimants during these arbitration proceedings in two separate procedures (the US’s 8\textsuperscript{th} and 10\textsuperscript{th} document productions of 10 and 24 May 2013, respectively). The Claimants also note that the version marked US007470-71 was the “Confidential” Exhibit C-365 to the Claimants’ Reply Memorial of 24 May 2013. Accordingly, the Claimants request the Tribunal to overrule the US’s assertion of privilege, to order the production of the withheld document and not to order the return of its produced versions, one of these now forming the Claimants’ Exhibit C-365.\textsuperscript{37}

51. The Tribunal accepts that the document was inadvertently produced by the Respondent to the Claimants in three versions under two procedures for document production within these arbitration proceedings and that, subsequently, the Claimants referred to one version in their Reply Memorial as a confidential exhibit relevant to its case in this arbitration.

52. Paragraph 62 of the Claimants’ Reply Memorial states: “Apotex immediately became a subject of discussion at the highest levels of FDA. The company was discussed at a meeting between the FDA Commissioner and her executive staff on Tuesday, June 9, 2009. On June 24, 2009, FDA informed the Secretary of the US Department of Health and Human Services of the impending Etobicoke warning letter.” The next Paragraph 63 states that: “Elevation to political levels of the issuance of a warning letter is highly unusual. Political officers are informed of CDER action typically only when, due to the significance of the underlying issues, FDA expects high level of publicity to be associated with its proposed action.” The Tribunal understands that the Etobicoke Warning Letter was eventually issued on 25 June 2009 (which is not a disputed document).

53. In these circumstances, the Tribunal concludes that the Respondent has waived any privilege in regard to the three versions of the draft letter produced to the Claimants, including the version now adduced in evidence by the Claimants as Exhibit C-365.

\textsuperscript{36} See the Respondent’s privilege log, Row 29, Column Explanation/Comments on Privilege Determination.

\textsuperscript{37} See the Respondent’s privilege log, Row 29, Column Responses/Objections to Privilege Determinations.
Accordingly, the Tribunal rejects the Respondent’s request for the return of the produced versions.

54. As regards redacted documentation, the Claimants complain that the Respondent has inconsistently, heavily, and improperly redacted more than 550 documents on the basis of attorney-client privilege, deliberative process privilege and other legal exemptions. The Claimants submit that these heavily redacted documents should have been included in a privilege log. The Claimants submit that by failing to describe the basis for asserting a privilege, the Respondent has made it impossible for the Claimants to determine whether the assertion of privilege in the form of such redactions is justifiable. The Claimants also note that there appears to be inconsistencies in the type of material the Respondent has redacted, namely information redacted under the deliberative process privilege and information relating to third parties. According to the Claimants, the ostensible deficiency in applying consistent standards calls into serious question whether any of the Respondent’s redactions can be justified.

55. Accordingly, the Claimants request the Tribunal to order the unredacted production of 20 documents. These 20 documents fall into two main categories: (i) the heavily redacted documents (under the deliberative process privilege and the attorney-client privilege); and (ii) the documents redacted inconsistently (under the deliberative process privilege and third party information).

56. Regarding the first category of documents, the Claimants submit that the basis for redacting information based on privilege is not self-evident and that as a consequence the Respondent “has eschewed its ‘burden of proving that such privilege applies to each document’.”38 The Respondent contends that these documents contain ample information justifying privilege; and, as regards deliberative process privilege, the Respondent asserts that privilege applies by virtue of Articles 9(2)(b) and 9(2)(f) of the IBA Rules, as recognised by several NAFTA Chapter Eleven tribunals.

57. Regarding the second category of documents, the Claimants claim that the Respondent has redacted material on an inconsistent basis, causing the Claimants to question whether the Respondent is using the deliberative process privilege (by itself or under the IBA Rules) as both a sword and a shield, by choosing to redact information when that information would be helpful to the Claimants and by choosing not to redact information

38 The Claimants’ Letter of 11 June 2013, p. 2.
when conversely that information would be helpful to the Respondent.\textsuperscript{39} The Claimants express similar concerns with regards to third party information, as follows: “[i]n its privilege log, the US has asserted that US law prohibits the US from releasing trade secret or confidential commercial information. However, the US has selectively redacted confidential information related to third parties. As with the deliberative process privilege, it appears that the US may be redacting information on the basis of how helpful it is, rather than applying redactions on a consistent basis. This approach finds no support in the IBA Rules or in US law and should be rejected by the Tribunal.”\textsuperscript{40}

58. The Respondent replies that each of the “B(5)” designations, which is a FOIA designation for pre-decisional and deliberative documents, should be understood to refer to Articles 9(2)(b) and 9(2)(f) of the IBA Rules.\textsuperscript{41} Regarding the alleged inconsistencies, the Respondent notes that it made extraordinary efforts to comply with the Claimants’ massive document requests in the very short time allotted under the Tribunal’s procedural time-table. According to the Respondent, it has produced 3,559 documents totaling over 13,800 pages. The Respondent contends that, if and to the extent that there were minor inconsistencies in redactions to the produced documents, they were solely the result of the expedited process involving multiple reviewers.\textsuperscript{42}

59. Regarding the heavily redacted documents, the Tribunal accepts from their face their treatment as privileged by reason of Articles 9(2)(b) and (f) of the IBA Rules. It might have been easier for the Tribunal if the Respondent had addressed such redacted privilege seriatim in its privilege log; but the Tribunal is satisfied that the Claimants were not thereby prejudiced from presenting their case in this current dispute over document production. By itself, the Tribunal cannot of course check upon these redactions; but, as indicated earlier, the Tribunal must here trust the good faith and professionalism of the Respondent’s legal advisers. It sees no good reason now to do otherwise.

60. With respect to the allegedly inconsistent redactions, the Tribunal acknowledges that the enormous exercise with such a relatively short period of time required of the Respondent to meet the Claimants’ extensive requests for document production led inevitably to the apparent inconsistencies of which the Claimants now complain. Far from establishing a scheme to take unfair advantage of redactions (as alleged by the Claimants), the Tribunal

\textsuperscript{39} Id. at pp. 3 and 4.
\textsuperscript{40} Id. at p. 5.
\textsuperscript{41} The Respondent’s letter of 11 June 2013, p. 2.
\textsuperscript{42} Id. at p. 3.
infers the contrary: these particular inconsistencies establish the good faith of the Respondent’s multiple reviewers which would be absent from a nefarious forensic scheme to use redactions “as a sword and a shield”. The Tribunal therefore sees no good reason now to initiate any procedure to check upon the work of the Respondent's own reviewers.

61. Accordingly, for all these reasons, the Tribunal rejects the Claimants’ request in regard to these 20 disputed redacted documents.
IV. The Tribunal’s Order

62. In regard to the Claimants’ claims to privilege and their privilege log, the Tribunal dismisses all the Respondent’s applications;

63. In regard to the Respondent’s claims to privilege and its privilege log, the Tribunal dismisses all the Claimants’ applications; and

64. Subject to any further application by the Parties and order by the Tribunal, the current procedural time-table (including the hearing dates), as set out in Paragraph 14.2.7 of the First Procedural Order, remains unchanged, as summarised below:

20 or 27 September 2013 – The Respondent to file its Rejoinder on the Merits and Reply on Jurisdiction (the earlier date if the Claimants do not file a supplement to their Reply of 24 May 2013 and the later date if they do);

11 or 18 October 2013 – The Claimants to file their Rejoinder on Jurisdiction (ditto);

25 October 2013 - The Claimants and the Respondent to notify names of any factual and expert witnesses to be cross-examined at the oral hearing;

31 October 2013: The pre-hearing organisational meeting (by telephone conference), here tentatively arranged (subject to further confirmation) for 0800 hours (DC time) equivalent to 1400 hours (Paris time); and

18 -26 November 2013: The oral hearing in Washington DC, with a reserve day of Saturday 23 November 2013.

Dated 5 July 2013

Signed for the Tribunal:

/signed/

V.V. Veeder (President of the Tribunal)
June 11, 2013

BY EMAIL

V.V. Veeder, QC
J. William Rowley, QC
Mr. John R. Crook

c/o Ms. Eloise Obadia
Secretary of the Tribunal
International Centre for Settlement
of Investment Disputes
The World Bank
1818 H Street, N.W.
MSN U3-301
Washington, D.C. 20433
United States of America

Re: Apotex Holdings Inc. and Apotex Inc. v. United States (ICSID Case No. ARB(AF)/12/1)

Dear Members of the Tribunal:

On behalf of claimants Apotex Holdings Inc. and Apotex Inc. (collectively, "Apotex"), and pursuant to the Tribunal’s Procedural Order on the Schedule Regarding the Parties’ Respective Privilege Logs, Further Submissions and Certifications, dated May 14, 2013, we enclose Apotex’s reply to Respondent the United States of America’s objections to Apotex’s privilege log.

In addition, we submit this letter to address certain redactions made by the US to documents it has produced in the above-referenced arbitration proceeding, but which were not included on the US’s privilege log.

As described more fully below, the US has inconsistently, heavily, and improperly redacted more than 550 documents on the basis of attorney-client privilege, deliberative process privilege, and under US FOIA law exemptions. Apotex believes the failure to include heavily redacted documents on a privilege log demonstrates non-compliance with the Tribunal’s Procedural Order dated March 29, 2013, instructing the parties to prepare a privilege log. By failing to include these documents on a privilege log and describe the basis for asserting a privilege, the US has made it impossible for Apotex to determine whether the assertion of privilege is reasonable. In addition, there appears to be inconsistencies in the type of material the US has redacted, namely information redacted under the deliberative process privilege and information relating to third parties. The apparent lack of consistent standards calls into question whether any of the US’s redactions are defensible.

By letter dated June 4, 2013, Apotex raised these objections with the US. The parties conferred on June 5 and 10, 2013 about each party’s objections to the other’s privilege logs and redactions. Through these conversations, the parties were able to resolve some issues. However, the parties were unable to resolve their disagreement regarding the US’s redactions.
1. Failure to Log Heavily Redacted Documents

In addition to Apotex's prior objections to the US's assertion of attorney-client or deliberative process privilege, Apotex objects to a number of documents produced by the US that contain significant, and in many cases, complete redactions of substantive information based on the US's assertion of attorney-client and/or deliberative process privilege under 5 USC § 552(b)(5).

Apotex provided the US several examples of heavily-redacted documents that it believes should have been properly logged. The extent of the US's redactions renders the documents entirely content-free and thus is functionally equivalent to not producing these documents. It is impossible for Apotex to assess whether the US's assertion of privilege is justified because Apotex has insufficient information about these documents. See, e.g., US010525 (redacting all of the email chain except the words "Carmelo" and "Christina" (the names of the author and recipient of the first email in the chain) and "Thanks CR" in the second email in the chain).

During the parties' conferences, the US disagreed that the heavily-redacted documents belonged on a privilege log because Apotex could purportedly figure out the basis for the privilege from the context or the email subject line. The US largely dismissed the examples Apotex provided as being self-evident, but did agree to add to its privilege log two documents that were redacted on the basis of attorney-client privilege. Apotex disagrees that the basis for redacting information based on privilege is self-evident, particularly because the subject line may not accurately describe the content of the email discussions themselves as parties may introduce new topics into the discussion. In fact, at times, the subject line raises further questions. For example, the US redacted an email produced as US011956 on the basis of attorney-client privilege. The email's subject line reads “FW: Apotex Signet RAI letter May 20 2011”. However, because the email was sent four days after sending a letter dated May 20, 2011 to Apotex about its Signet facilities, Apotex cannot discern the basis for claiming privilege over a finalized document, let alone one that was disclosed to Apotex.

By taking the position that Apotex should be able to figure out the basis for the US's redactions, the US has eschewed its "burden of proving that such privilege applies to each document." Apotex believes the Tribunal should overrule the US's assertion of privilege with respect to the following documents and order their unredacted production.

Deliberative Privilege

US010525
US003091
US006106
US008799
US012576

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1 As described in its March 15, 2013 reply to the US's objections to Apotex's document requests and its submission de bene esse dated March 22, 2013, Apotex believes that the US errs in relying on the deliberative process privilege under US law and has not demonstrated that international law recognizes this privilege.

2 Legal Authority CLA-480, Glimis Gold, Ltd. v. United States, Decision on Parties' Request for Production of Documents Withheld on Grounds of Privilege, para. 23 (Nov. 17, 2005).
2. Inconsistent Redactions

a. Deliberative Process Privilege

For the reasons Apotex stated in its March 15, 2013 reply to the US’s objections to Apotex’s document requests and its submission de bine esse dated March 22, 2013, Apotex disputes that a domestic privilege, such as the FOIA exemption for deliberative process privilege, is applicable in international arbitration proceedings.

Moreover, paragraph O of the Tribunal’s Procedural Order on the Parties’ Respective Requests for Document Production, dated March 29, 2013, states that “the Tribunal is minded not to take into account deliberative process privilege ... as a matter of any applicable law or rules of law, but rather as one or more factors falling within Article 9(2) of the IBA Rules.” Thus, the US was required to do more than merely cite to a provision of US law relating to a privilege recognized domestically. Rather, the US was required to explain how the deliberative process privilege is embraced in international law and encompassed by the IBA Rules. The failure to explain in more detail why the US’s redactions are appropriate constitutes a failure to comply with the Tribunal’s order.

Even if the deliberative process privilege may be asserted in international arbitration, the US has redacted purportedly “deliberative” material on an inconsistent basis. As an example of the US’s inconsistent redaction policy, the US produced as US007154 an email from Carmelo Rosa to Irma Rivera dated June 10, 2009 in which Mr. Rosa states:

Allow me to pass the proposed date through my management here. There is a big issue and interest in this case, and we (CDER) need to brief Canada Health on the upcoming WL and concerns we have with this firm. This has been taken to the level of Deb Autor and Janet Woodcock. The new commissioner is also being briefed. Just to let you know. I should get back to you by tomorrow. Thanks.

The US produced as US007799-7780 the same email, but redacted the words in bold below as being entitled to deliberative process privilege under FOIA exemption (b)(5):

Allow me to pass the proposed date through my management here. There is a big issue and interest in this case, and we (CDER) need to brief Canada Health on the upcoming WL and concerns we have with this firm. This has been taken to the level of Deb Autor and Janet Woodcock. The new commissioner is also being briefed. Just to let you know. I should get back to you by tomorrow. Thanks.

The bolded language does not reflect privileged information. It does not describe what FDA’s concerns were; it does not reflect deliberation, evaluation, or assessment undertaken before taking an agency action; and it does not express any opinion or recommendation on legal or policy matters. As such, it is not entitled to protection from disclosure. See, e.g., Legal Authority CLA-488, N.L.R.B. v. Sears,
Roebuck & Co., 421 U.S. 132, 158-9 (1975) (documents relating to the agency’s final decision were not protected by DPP, while documents relating to a non-final decision were); Legal Authority CLA-489, Coastal States Gas Corp. v. Dep’t of Energy, 617 F.2d 854, 867 (D.C. Cir. 1980) (Deliberative documents “reflect the give-and-take of the consultative process” and include “subjective documents which reflect the personal opinions of the writer rather than the policy of the agency.”).

By way of another example, the US redacted a portion of US012572 which was a quotation from a letter from FDA to Apotex. The unredacted portion of the email states that the letter “[l]ooks really good! One comment. I think this [redacted] sentence has an inaccuracy.” This context demonstrates that the redacted portion was factual, rather than deliberative, which the deliberative process privilege does not cover. See, e.g., Legal Authority CLA-490, In re Subpoena Served Upon Comptroller of Currency, and Secretary of Bd. of Governors of Federal Reserve System, 967 F.2d 630, 634 (D.C. Cir. 1992). Although Apotex does not believe the Tribunal should permit the assertion of deliberative process privilege, to the extent it is allowed, the US must apply it correctly.

As these two examples demonstrate, the US’s decision to redact such information calls into question the basis for other material redacted pursuant to 5 USC § 552(b)(5). Because the US has not logged heavily redacted documents, Apotex is unable to assess whether the US’s redactions are reasonable. The US’s response to Apotex’s concerns in this regard was to merely assert that these redaction decisions do not reflect an inconsistent policy.

Likewise, the documents that the US has chosen to produce in unredacted form also cast doubt on the reliability of the US’s redactions, as Apotex has identified unredacted documents that reflect FDA’s decision-making process. Apotex believes that the US’s inconsistent approach constitutes a waiver as to deliberative, pre-decisional information. For example, the same email chain quoted above contains unredacted references to FDA’s strategy, decision-making hierarchy, and proposed next steps. According to the email, the “case has reached very high levels, including the preparation of an advisory paper” and FDA was “interested in revising the original strategy ... .” See US007799.

Similarly, the US produced US011286-91, which discusses whether Apotex should recall a particular product. The email details FDA’s evaluation of Apotex’s response to a warning letter, how ICB was “considering expanding the Import Alert ... ” and its plan to “contact the firm ... to discuss these FARs ... " US011288-89. It discusses whether to initiate a “new” and “innovative” type of import alert against Apotex and the rationale behind doing so. Despite producing all of this information, the US redacts a portion of the email discussing this “innovative approach”. Such an approach is internally inconsistent and Apotex can discern no uniform standard for redacting information. The US’s explanation was simply to assert that it saw no inconsistency.

The US has even produced documents that are marked as “Privileged, Confidential, and Pre-Decisional” without redacting any purportedly deliberative information. See, e.g., US011500-08; See also US011626-27 (failing to redact what FDA “may decide”). This inconsistency causes Apotex to question whether the US is using the deliberative process privilege (to the extent it should be recognized by this Tribunal) as both a sword and a shield, by redacting information when it would be helpful to Apotex and choosing not to redact information when it would be helpful to the US.

Despite identifying to the US the following documents that were redacted on the basis of deliberative privilege but for which Apotex is unable to determine whether such privilege was properly asserted, the US did not sufficiently explain its apparently inconsistent approach to redacting material:

US011286
US011627
US012119
US013191

Because of the US's inconsistent application of the deliberative process privilege, the Tribunal should reject the application of that privilege to any document in this case and order the US to produce documents withheld or redacted on the basis of deliberative process privilege in an unredacted form.

b. Third Party Information

In its privilege log, the US has asserted that US law prohibits the US from releasing trade secret or confidential commercial information. However, the US has selectively redacted confidential information related to third parties. As with the deliberative process privilege, it appears that the US may be redacting information on the basis of how helpful it is, rather than applying redactions on a consistent basis. This approach finds no support in the IBA Rules or in US law and should be rejected by the Tribunal.

For example, US011971 fails to redact the names of companies who would receive warning letters, yet redacts third-party information about recalls and press updates which are presumably final and public FDA actions, among other things. US011918 fails to redact NDA numbers and company names, yet contains information about third parties' pending applications. This information presumably would be precisely the sort of confidential commercial information protected under US law, yet this information was not redacted.

In contrast, other documents are almost entirely redacted on the basis that they contain information related to third parties. Additionally, Apotex has identified multiple versions of what appear to be two types of periodic reports that contain information related to third parties. See, e.g., US011520 and US011517.³

The US explained these inconsistencies by saying that for documents reflecting third party information, a final agency determination was made or subsequently approved. However, the US did not explain why, under this logic, it continues to assert deliberative process privilege over documents relating to Apotex, despite already having taken final action against the company.

Information related to third parties is relevant to Apotex's arguments concerning like treatment of comparators. Thus, the US is not entitled to selectively redact information related to comparators.

As a result of the US's inconsistent redaction policy, it is impossible for Apotex to determine whether the periodic reports and other documents contain information related to comparators and other third parties and have been appropriately redacted. In addition to these reports and the documents identified above, Apotex has also identified the following documents which suffer from the same uncertainty:

US011622
US011624
US011825

³ As further evidence of the US's inconsistent redaction policies, the US has at times redacted these periodic reports as containing third-party information, but at others, redacts the report based on deliberative process privilege. Apotex is hard-pressed to understand the basis for redacting these periodic reports because the US's professed justification is a moving target. Compare US003091 and US011517.
In light of the above, Apotex respectfully requests that the Tribunal order the US to provide copies of the periodic reports described above and copies of the documents listed above, in an unredacted form as to any identified comparator.

* * *

For all of the foregoing reasons, Apotex respectfully requests that the Tribunal reject the US's objections and order the production of unredacted versions of the above-referenced documents as described more fully above.

Respectfully submitted,

John J. Hay
Partner
Salans FMC SNR Denton Europe LLP

cc: Jeremy Sharpe and Lisa Grosh, US Department of State
    Barton Legum and Anne-Sophie Dufêtre, Salans FMC SNR Denton Europe LLP
2 Oct. 9, 2000 Arto Harte Diane Cason, Bruce Clark; Lance Loevner; Pradeep Sanghe; R. Royster; Larry Rock; Tish Anger; John Speake, Carol Austey; Julie Farber; Paul Farber; Mohamed Chah; Jeremy Senior; Paul Gordon Jeff Fass; Terri Dodell; Dan Harringer; Phil Russ; Sue Lee Chan; Janet Burke; Calvin Kemsar; E. Mohlich; Elaine Bush XONSHARE: Latest Update Gap Assessment 10-09 Read Attorney Client: Work Product Communication concerning factual investigation and assessment of various quality systems undertaken at the request of Apotex's legal counsel, Bar & Boardsey, LLP ("Counsel") pursuant to an engagement letter dated September 22, 2000, between Counsel and Jeff Fass & Associates ("Y&P"). Y&P was retained to work under Counsel's direct supervision and provide Counsel with necessary information and evaluations (the "Engagement"), in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken in response to FDA concerns and to prevent regulatory enforcement actions. Information provided by Y&P was used by Counsel to tailor Apotex's response to, and communications with, FDA. (See Objections and Replies) **See Reply**.

2 Oct. 11, 2000 Arto Harte Diane Cason, Bruce Clark; Lance Loevner; Pradeep Sanghe; R. Royster; Larry Rock; Tish Anger; John Speake, Carol Austey; Julie Farber; Paul Farber; Mohamed Chah; Jeremy Senior; Paul Gordon Jeff Fass; Terri Dodell; Dan Harringer; Phil Russ; Sue Lee Chan; Janet Burke; Calvin Kemsar; E. Mohlich; Elaine Bush XONSHARE: Latest Update Gap Assessment 10-09 Read Attorney Client: Work Product Communication concerning factual investigation and assessment of various quality systems undertaken at the request of Apotex's legal counsel, Bar & Boardsey, LLP ("Counsel") pursuant to an engagement letter dated September 22, 2000, between Counsel and Jeff Fass & Associates ("Y&P"). Y&P was retained to work under Counsel's direct supervision and provide Counsel with necessary information and evaluations (the "Engagement"), in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken in response to FDA concerns and to prevent regulatory enforcement actions. Information provided by Y&P was used by Counsel to tailor Apotex's response to, and communications with, FDA. (See Objections and Replies) **See Reply**.

2 Oct. 28, 2000 Arto Harte Diane Cason, Bruce Clark; Lance Loevner; Pradeep Sanghe; R. Royster; Larry Rock; Tish Anger; John Speake, Carol Austey; Julie Farber; Paul Farber; Mohamed Chah; Jeremy Senior; Paul Gordon; Elizabeth Ricci Jeff Fass; Terri Dodell; Dan Harringer; Phil Russ; Sue Lee Chan; Janet Burke; Calvin Kemsar; E. Mohlich; Elaine Bush XONSHARE: Latest Update Gap Assessment 10-09 Read Attorney Client: Work Product Communication concerning factual investigation and assessment of various quality systems undertaken at the request of Apotex's legal counsel, Bar & Boardsey, LLP ("Counsel") pursuant to an engagement letter dated September 22, 2000, between Counsel and Jeff Fass & Associates ("Y&P"). Y&P was retained to work under Counsel's direct supervision and provide Counsel with necessary information and evaluations (the "Engagement"), in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken in response to FDA concerns and to prevent regulatory enforcement actions. Information provided by Y&P was used by Counsel to tailor Apotex's response to, and communications with, FDA. (See Objections and Replies) **See Reply**.

2 Nov. 10, 2000 Arto Harte Diane Cason, Bruce Clark; Lance Loevner; Pradeep Sanghe; R. Royster; Larry Rock; Tish Anger; John Speake, Carol Austey; Julie Farber; Paul Farber; Mohamed Chah; Jeremy Senior; Paul Gordon; Elizabeth Ricci Jeff Fass; Terri Dodell; Dan Harringer; Phil Russ; Sue Lee Chan; Janet Burke; Calvin Kemsar; E. Mohlich; Elaine Bush XONSHARE: Latest Update Gap Assessment 10-09 Read Attorney Client: Work Product Communication concerning factual investigation and assessment of various quality systems undertaken at the request of Apotex's legal counsel, Bar & Boardsey, LLP ("Counsel") pursuant to an engagement letter dated September 22, 2000, between Counsel and Jeff Fass & Associates ("Y&P"). Y&P was retained to work under Counsel's direct supervision and provide Counsel with necessary information and evaluations (the "Engagement"), in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken in response to FDA concerns and to prevent regulatory enforcement actions. Information provided by Y&P was used by Counsel to tailor Apotex's response to, and communications with, FDA. (See Objections and Replies) **See Reply**.

2 Nov. 16, 2000 Arto Harte Diane Cason, Bruce Clark; Lance Loevner; Pradeep Sanghe; R. Royster; Larry Rock; Tish Anger; John Speake, Carol Austey; Julie Farber; Paul Farber; Mohamed Chah; Jeremy Senior; Paul Gordon; Elizabeth Ricci Jeff Fass; Terri Dodell; Dan Harringer; Phil Russ; Sue Lee Chan; Janet Burke; Calvin Kemsar; E. Mohlich; Elaine Bush XONSHARE: Latest Update Gap Assessment 10-09 Read Attorney Client: Work Product Communication concerning factual investigation and assessment of various quality systems undertaken at the request of Apotex's legal counsel, Bar & Boardsey, LLP ("Counsel") pursuant to an engagement letter dated September 22, 2000, between Counsel and Jeff Fass & Associates ("Y&P"). Y&P was retained to work under Counsel's direct supervision and provide Counsel with necessary information and evaluations (the "Engagement"), in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken in response to FDA concerns and to prevent regulatory enforcement actions. Information provided by Y&P was used by Counsel to tailor Apotex's response to, and communications with, FDA. (See Objections and Replies) **See Reply**.

2 Nov. 16, 2000 Arto Harte Diane Cason, Bruce Clark; Lance Loevner; Pradeep Sanghe; R. Royster; Larry Rock; Tish Anger; John Speake, Carol Austey; Julie Farber; Paul Farber; Mohamed Chah; Jeremy Senior; Paul Gordon; Elizabeth Ricci Jeff Fass; Terri Dodell; Dan Harringer; Phil Russ; Sue Lee Chan; Janet Burke; Calvin Kemsar; E. Mohlich; Elaine Bush XONSHARE: Latest Update Gap Assessment 10-09 Read Attorney Client: Work Product Communication concerning factual investigation and assessment of various quality systems undertaken at the request of Apotex's legal counsel, Bar & Boardsey, LLP ("Counsel") pursuant to an engagement letter dated September 22, 2000, between Counsel and Jeff Fass & Associates ("Y&P"). Y&P was retained to work under Counsel's direct supervision and provide Counsel with necessary information and evaluations (the "Engagement"), in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken in response to FDA concerns and to prevent regulatory enforcement actions. Information provided by Y&P was used by Counsel to tailor Apotex's response to, and communications with, FDA. (See Objections and Replies) **See Reply**.
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<td>Communication concerning internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apothe, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and/or prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>11/24/2000</td>
<td>Amy Daddis</td>
<td>Janice Lowstock</td>
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<td>Product</td>
<td>Communication concerning product remediation and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apothe, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and/or prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 4.</td>
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<td>11</td>
<td>11/18/2009</td>
<td>Paul Vogel</td>
<td>Mohammad Chari</td>
<td>Note 6</td>
<td>Product</td>
<td>Communication with Apothe and Counsel concerning gap assessment of various quality systems and cGMP compliance with respect to Apothe's legal counsel, Bus &amp; Beaudry, LLP (&quot;Counsel&quot;) pursuant to an engagement letter dated September 16, 2009, between Counsel and Paul Vogel Consulting Services LLC. Paul Vogel Consulting Services LLC was retained to work under Counsel's direct supervision and provide Counsel with necessary information and evaluations (the &quot;Engagement&quot;). In order to assist Counsel in providing legal and regulatory advice to Apothe, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and/or prevent regulatory enforcement actions. Information provided by Paul Vogel Consulting Services LLC was used by Counsel to tailor Apothe's response to, and communications with, FDA.</td>
<td>See Objectives 3 and 4.</td>
<td>See Reply.</td>
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<td>Pradeep Sanghi</td>
<td>Note 8</td>
<td>Product</td>
<td>Communication concerning gap assessment of various quality systems and cGMP compliance with respect to Apothe's legal counsel, Bus &amp; Beaudry, LLP (&quot;Counsel&quot;) pursuant to an engagement letter dated September 16, 2009, between Counsel and Paul Vogel Consulting Services LLC. Paul Vogel Consulting Services LLC was retained to work under Counsel's direct supervision and provide Counsel with necessary information and evaluations (the &quot;Engagement&quot;). In order to assist Counsel in providing legal and regulatory advice to Apothe, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and/or prevent regulatory enforcement actions. Information provided by Paul Vogel Consulting Services LLC was used by Counsel to tailor Apothe's response to, and communications with, FDA.</td>
<td>See Objectives 3 and 4.</td>
<td>See Reply.</td>
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<td>13</td>
<td>12/23/2009</td>
<td>WP Yuen</td>
<td>Jeremy Deceau</td>
<td>Note 7</td>
<td>Product</td>
<td>Communication reflecting mental impressions and assessment of conceptual framework for corrective action efforts and global product quality assessment undertaken at the request of Counsel pursuant to the Engagement, and anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apothe legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.</td>
<td>See Objectives 1 and 2.</td>
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<td>Kris Hatle</td>
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<td>Communication plan between FDA, Apothe, and Counsel concerning quality assessment report prepared at the request of Counsel pursuant to the Engagement and anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apothe legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.</td>
<td>See Objectives 1, 2, and 3.</td>
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* U.S. Objectives 1, 2 and 3 are located at Tab 1, 2, and 3 to Claimants' Privilege Log.
** Apotex's Reply is located at Tab 4 to Claimants' Privilege Log.
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<td>Priv. Resp: Bruce Stark; Chris Harte; HP Audit</td>
<td>Email</td>
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<td>Communication concerning assessment of various quality systems undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>HP - Bruce Clark</td>
<td>Priv. Resp: Jeff Yuen; Some Material</td>
<td>Email</td>
<td>Work Product</td>
<td>Communication concerning remediation efforts and attaching documents concerning same, prepared at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>22</td>
<td>Nov. 5, 2009</td>
<td>HP - Bruce Clark</td>
<td>PRIV: DOCUMENT Update to Assessment D-09</td>
<td>Email</td>
<td>Work Product</td>
<td>Class of communications containing Corrective Action Plan, cGMP compliance, proposed corrective actions, and factual investigation and assessment of various quality systems, conducted at request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
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<td>Jan. 26, 2010</td>
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<td>Priv. Resp: Jeff Yuen; Some Material</td>
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<td>Work Product</td>
<td>Communication concerning assessment of various quality systems undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding compliance, corrective action remediation plans of products quality systems undertaken solely in response to Health Canada (&quot;HC&quot;) concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>24</td>
<td>Feb. 17, 2010</td>
<td>HP - Bruce Clark</td>
<td>Priv. Resp: Jeff Yuen; Some Material</td>
<td>Email</td>
<td>Work Product</td>
<td>Observations, mental impressions, factual investigation, and compliance evaluations regarding various quality systems, prepared at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>25</td>
<td>Apr. 16, 2009</td>
<td>HP - William Clark; Bruce Stark</td>
<td>Priv. Resp: Jeff Yuen; Some Material</td>
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<td>Class of communication containing corrective action plans, regulatory compliance, proposed corrective actions, and factual investigation and assessment of various quality systems, conducted at request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, regulatory compliance, and corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
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<td>HP - Bruce Clark; Carol Austin</td>
<td>Priv. Resp: Brad Cangari; Karo Schwartz</td>
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<td>Communication concerning initial impressions and legal advice concerning communication with Canada's Health Products and Food Branch inspections (&quot;VSHI&quot;) and compliance with Canadian regulatory framework, prepared at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters.</td>
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<td>Priv. Resp: Heather Syrett; John Beresley; Bruce Clark; Paul Vogel</td>
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<td>Class of communications between Apotex, councillors, and Counsel concerning review of supplements undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions, prepared at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans of products.</td>
<td>See Objectives 1 and 3.</td>
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<td>Priv. Resp: Heather Syrett; John Beresley; Bruce Clark; Paul Vogel</td>
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<td>Communications with Counsel and Apotex concerning factual investigation and assessment of various quality systems undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
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<td>Review of supplement communications, including communications with counsel, concerning the factual investigation and concern over supplements undertaken at the request of counsel pursuant to the Engagement, in order to assist counsel in providing legal and regulatory advice to Apaxes, including considering FDA enforcement actions, cGMP compliance, and corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
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<td>Nov. 16, 2009</td>
<td>Paul Vogel</td>
<td>Review</td>
<td>Product</td>
<td>Initial response to request for review of supplements undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions, prepared at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apollos legal advice regarding regulatory compliance matters, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans.</td>
<td>See Objections 3 and 4.</td>
<td>See Reply.</td>
<td>See Reply.</td>
<td>See Reply.</td>
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<td>See Objections 3 and 4.</td>
<td>See Reply.</td>
<td>See Reply.</td>
<td>See Reply.</td>
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<td>7</td>
<td>Nov. 22, 2009</td>
<td>Jeff Yuen</td>
<td>Review</td>
<td>Product</td>
<td>Communication reflecting involvement of counsel's communications with Counsel, concerning amendment to GPC-1 supplement, reflecting observations and mental impressions, prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apollos legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objections 2 and 3.</td>
<td>See Reply.</td>
<td>See Reply.</td>
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<td>8</td>
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<td>Jeff Yuen</td>
<td>Review</td>
<td>Product</td>
<td>Communication reflecting involvement of counsel's communications with Counsel, concerning amendment to GPC-1 supplement, reflecting observations and mental impressions, prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apollos legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objections 2 and 3.</td>
<td>See Reply.</td>
<td>See Reply.</td>
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<td>Jeff Yuen</td>
<td>Review</td>
<td>Product</td>
<td>Communication reflecting involvement of counsel's communications with Counsel, concerning amendment to GPC-1 supplement, reflecting observations and mental impressions, prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apollos legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objections 2 and 3.</td>
<td>See Reply.</td>
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<td>Nov. 22, 2009</td>
<td>Jeff Yuen</td>
<td>Review</td>
<td>Product</td>
<td>Communication reflecting involvement of counsel's communications with Counsel, concerning amendment to GPC-1 supplement, reflecting observations and mental impressions, prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apollos legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objections 2 and 3.</td>
<td>See Reply.</td>
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<td>11</td>
<td>Nov. 22, 2009</td>
<td>Jeff Yuen</td>
<td>Review</td>
<td>Product</td>
<td>Communication reflecting involvement of counsel's communications with Counsel, concerning amendment to GPC-1 supplement, reflecting observations and mental impressions, prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apollos legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objections 2 and 3.</td>
<td>See Reply.</td>
<td>See Reply.</td>
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* U.S. Objections 1, 2 and 3 are located at Tabs 1, 2, and 3 to Claimant's Privilege Log.

** Apollos' Reply is located at Tab 4 to Claimants' Privilege Log.
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<td>AGM meeting for 2010-2011</td>
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<td>Chain of communications reflecting mental impressions and advice concerning review of compliance and remediation efforts, in connection with Canadian regulatory framework and CAP audit, provided at the request of Counsel pursuant to the engagement.</td>
<td>See Objectives 1 and 2.</td>
<td>Am Reply.</td>
<td>See Reply.</td>
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<td>11/27, 2000</td>
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<td>Predeep Sangiels, Catherine Roemer</td>
<td>Bruce Clark</td>
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<td>Work Product</td>
<td>Communication reflecting observations and advice concerning compliance efforts with respect to a particular product, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>Am Reply.</td>
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<td>11/16, 2009</td>
<td>Paul Vogel</td>
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<td>Communication with Apotex and counsel regarding review and analysis of retrospective reviews of various products, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>Am Reply.</td>
<td>See Reply.</td>
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<td>27</td>
<td>12/3, 2010</td>
<td>Paul Vogel</td>
<td>Bernice Tao</td>
<td>JF Benardis, Bruce Clark; Paul Vogel; Carmen Shepard</td>
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<td>Email</td>
<td>Work Product</td>
<td>Communication with Apotex and Counsel, reflecting recommendations and observations with respect to proposed manufacturing supplement cover letter, at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>Am Reply.</td>
<td>See Reply.</td>
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<td>JF Benardis, Bruce Clark; Paul Vogel; Carmen Shepard</td>
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<td>Work Product</td>
<td>Chain of communications with Apotex and Counsel, reflecting legal/regulatory advice with respect to proposed manufacturing supplement cover letter, at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 2 and 3.</td>
<td>Am Reply.</td>
<td>See Reply.</td>
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<td>Bernice Tao</td>
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<td>Email</td>
<td>Work Product</td>
<td>Chain of communications between Apotex, consultants, and counsel (reflecting legal/advisory advice with respect to review of supplements undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans.</td>
<td>See Objectives 2 and 3.</td>
<td>Am Reply.</td>
<td>See Reply.</td>
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<td>Chris Harte</td>
<td>Bruce Clark</td>
<td>Jeff Yuan</td>
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<td>Work Product</td>
<td>Communication concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.</td>
<td>See Objectives 2 and 3.</td>
<td>Am Reply.</td>
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<td>1/24, 2010</td>
<td>Jeff Yuan</td>
<td>Bruce Clark, Jeff Barns, Michael Barns, Amy Barns; Jeff Barns; Michael Barns; Amy Barns</td>
<td>Bruce Clark</td>
<td>PDPKsky</td>
<td>Email</td>
<td>Work Product</td>
<td>Communication regarding recommendations concerning FDA inspection, provided at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>Bruce Clark; Jeff Barns; Bernice Tao; Sandra Doss; Michael Barns</td>
<td>Jeff Yuan</td>
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<td>Work Product</td>
<td>Chain of Communications concerning preparations for FDA inspection report, and reflecting mental impressions and comments concerning same, which were provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>Am Reply.</td>
<td>See Reply.</td>
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<td>Jeff Yuan</td>
<td>Barry Sherman, Andrew Hess, Nestor Pinciaro, Bruce Clark</td>
<td>Barry Kay; Craig Baster; Rachael Ufaluhy</td>
<td>PRESENTATION OUTLINE FOR FDA MEETING</td>
<td>Email</td>
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<td>Communications between Apotex, Counsel, and FDA reflecting mental impressions, analysis, and compliance advice concerning upcoming meeting with FDA, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>Am Reply.</td>
<td>See Reply.</td>
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<td>Sep 6, 2010</td>
<td>Jeff Yuan</td>
<td>Bruce Clark; Brice Clark; Lance Lovelock</td>
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<td>PRESENTATION OUTLINE FOR FDA MEETING</td>
<td>Read</td>
<td>Work Product</td>
<td>Chain of communications between FDA, Apotex and counsel reflecting material impressions, analysis, and compliance advice concerning upcoming meeting with FDA, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2. Even if Apotex proved that its Counsel requested Apotex's cGMP consultants and that the cGMP consultants' work was prepared in anticipation of litigation, its privilege can attach to documents dated prior to such engagement. This document is dated prior to September 22, 2008, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuan &amp; Associates. Therefore, the document is not privileged.</td>
<td>See Reply.</td>
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<td>25</td>
<td>Jan 1, 2010</td>
<td>Jeff Yuan</td>
<td>Paul Gordon; Bruce Clark; Jim Butzulis; Larry Rock; Paul Forrest; Peter Eulzinger; Priyesh Sanghvi; Ron Davidson; Sheila Warner; Calvin Kramer; Stephen Edely; Carol Austin; Sue Gabdullin; Sabrina Doss; Sarah Papadopoulos; Paolo Farina; Joanne Kampschull; Phil Tackett; Ann Holder; Diane Zipper; Anthony Khan; Katherine Runny; Chris Harle</td>
<td></td>
<td>Q3: Eckels' focus review - Meeting Minutes</td>
<td>Read</td>
<td>Work Product</td>
<td>Communication reflecting material impressions and advice concerning corrective actions, continuous improvement initiatives, and cGMP prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>Feb 14, 2010</td>
<td>Jeff Yuan</td>
<td>Bernie Tao</td>
<td>Bruce Clark; Kiran Krishnan</td>
<td>Q3: Question</td>
<td>Email</td>
<td>Work Product</td>
<td>Communication concerning regulatory compliance with respect to raw material inspection; provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>Feb 17, 2010</td>
<td>Jeff Yuan</td>
<td>Ann Holden</td>
<td>Priyesh Sanghvi; Chris Harle; Bruce Clark</td>
<td>Q3: R&amp;D to Commercial CAP Document</td>
<td>Email</td>
<td>Work Product</td>
<td>Observations, material impressions, and compliance evaluations regarding cGMP prepared at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>28</td>
<td>Jul 11, 2010</td>
<td>Jeff Yuan</td>
<td>Sarah Papiadopoulos; Larry Shemtov; Bruce Clark; Jeremy Deas; Jim Butzulis; Jack Kay; Priyesh Sanghvi; Jeff Bracken; Gordon Winters; Peter Hird; Craig Baker; Steven Lapham</td>
<td></td>
<td>Q3: Recall Committee via Email</td>
<td>Email</td>
<td>Work Product</td>
<td>Chain of communications reflecting recommendations and observations related to product analysis, provided at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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74 | Apr. 16, 2009 | JF Yuen | James Lawlorick; Bruce Clark | Kel Murray | EC: Requesting between submitted Process Product Formats | Email | Work Product | Communication reflecting observations, related impressions, and complete evaluations related to requested product, provided at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and IQMF compliance, and to respond to FDA concerns. | See Objections 1 and 2. | See Reply. |

75 | Oct. 22, 2009 | Paul Vogel | Jennifer Tao | Bruce Clark; Jeremy Desai; Kate Beadshady; Carmen Shepard | EC: Request for supplement | Email | Work Product; Attorney Client | Chain of communication with Apotex and Counsel regarding and reflecting observations and legal/regulatory advice regarding supplements, provided at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and IQMF compliance, and to respond to FDA concerns. | See Objections 1 and 3. | See Reply. |

76 | Oct. 28, 2009 | Paul Vogel | Jennifer Tao | Bruce Clark; Jeremy Desai; Kate Beadshady; Paul Vogel; Carmen Shepard | EC: Request for supplement | Email | Work Product; Attorney Client | Chain of communication with Apotex and Counsel regarding and reflecting observations and legal/regulatory advice regarding supplements, provided at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and IQMF compliance, and to respond to FDA concerns. | See Objections 1 and 3. | See Reply. |

77 | Feb. 4, 2010 | JF Yuen | Paul Gorden; Bruce Clark; Karin Ruzicka; Larry Rock; Paul Forbes; Peter Exchanger; Padmapriya Senghale; Ron Davidson; Sheila Manner; Calvin Manner; Stephen Krausty; Carol Austri; Sue Szabo; Sabrina Davis; Sarah Papadopoulos; Paolo Berti; Janeen Campbell; Anthony Hran; Phil Tambor; Ari Holden; Elaine Copay; Catherine Rumby; Chris Harbor; Jeff Barragh | JJ: Resources For SAP Audit | Email | Work Product | Chain of communications concerning SAP audit, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and IQMF compliance, and to respond to FDA concerns. | See Objections 1 and 2. | See Reply. |

78 | Feb. 5, 2010 | JF Yuen | Padmapriya Senghale; Carol Ruzicka; Jeremy Desai; Bruce Clark | JF/Ru; Elisabeth Knows | EC: Response to PwC Inquiry | Email | Work Product | Communications providing regulatory and compliance advice with respect to observations and related impressions, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and IQMF compliance. | See Objections 1 and 2. | See Reply. |

79 | Oct. 1, 2009 | Paul Vogel | Jennifer Tao | Jennifer Tao | EC: Response to your email | Email | Work Product; Attorney Client | Communication with Apotex and Counsel concerning evaluation of steps taken to address compliance and regulatory issues, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and IQMF compliance. | See Objections 2 and 3. | See Reply. |

90 | Feb. 10, 2010 | JF Yuen | Padmapriya Senghale; Karin Ruzicka; Bruce Clark; Paul Ross | Jennifer Desai | EC: Preparing Form Process Proposal | Email | Work Product | Communication reflecting observations, related impressions, and complete evaluations related to requested product, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and IQMF compliance, and to respond to FDA concerns. | See Objections 1 and 2. | See Reply.
21 Feb 22, 2009 RR Yuen Bruce Clark, Celine Kameer; Paul Gordon; Jeremy Doce; Carol Audic; Tom Miller; Ray Cossen; Jeff Berraglia; Phil Buss; Ron Rupley; Paula Forbes; Tad Anger; John Hanke

21: RADMD 7 Apex Oil Quality System Corrective Action Plan CE1 Email Work Product Communication concerning review and analysis of CAP, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexes legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns. See Objections 1 and 2. Am Reply.

22 Feb 12, 2009 RR Yuen Barbara Tate; Steven Padmanan; Jeff Berraglia; Paul Forbes; Brian Long; Jeremy Doce; Bruce Clark; Santro D'oppi; Carol Audic

21: HPLC list of avoiding products, recommendations after meeting Email Work Product Chain of communications evaluating preparation for TGA pre-approval inspection and cGMP inspection, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexes legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns. See Objections 1 and 2. Am Reply.

23 Feb 12, 2009 RR Yuen Bilkley, slaghty; Bruce Clark, Rupley Carol Audic

21: Summary from HPLC visit Feb 11/10 Email Work Product Chain of communications concerning quality control procedures and processes, relative to regulatory compliance matters and cGMP compliance, in connection with legal and regulatory guidance provided at the request of Counsel pursuant to the Engagement. See Objections 1 and 2. Am Reply.

24 Dec 8, 2008 Paul Vogel Carmen Shepard Brian Doce; Brian Tate; Bruce Clark; Kate Blochley

21: Telephone interview re: OME supplement review process Email Work Product - Attorney/Client Communication with Apexes and Counsel reflecting initial impressions and analysis relating to review protocols and reporting to FDA, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexes legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns. See Objections 1 and 2. Am Reply.

25 Dec 12, 2009 RR Yuen Sabrina Davis Bruce Clark

21: URGENT >> Renton Controls Email Work Product Chain of communications relating to evaluation of CAP, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexes legal advice regarding regulatory compliance matters and to address FDA concerns. See Objections 1 and 2. Am Reply.

26 Feb 16, 2010 RR Yuen Bruce Clark Kym Hardie

T/A Email Work Product Communication concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexes legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns. See Objections 1 and 2. Am Reply.

27 Dec 4, 2009 RR Yuen Bruce Clark Celine Kameer

T/A Email Work Product Communication concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexes legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns. See Objections 1 and 2. Am Reply.

28 Sep 11, 2009 RR Yuen Jeremy Doce Anouk Lavens; Ron Rupley; Bruce Clark; Terri Waddell; Donald Harrington; Dick Hanke

T/A Email Work Product Communication concerning review and analysis of quality systems gap assessments and remediation efforts, and outlining spreadsheet regarding the same, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexes legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests. See Objections 1 and 2. Am Reply.

29-2 Apexes Request for Key Process Quality Systems Gap AND Remediation Support at 29

29-2 Email Work Product Spreadsheet reflecting observations concerning remediation efforts in the areas of production controls, facilities and equipment, and quality systems. See Objections 1 and 2. Am Reply.

30 Jan 16, 2010 Anet Burke Jeff Geraghty

T/A Email Work Product Chain of communications concerning factual investigation and compliance evaluation regarding various quality systems, undertaken at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexes legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation. See Objections 1 and 2. Am Reply.

31 May 20, 2010 RR Yuen Jeff Geraghty

T/A Email Work Product Chain of communications concerning compliance evaluation regarding various quality systems, undertaken at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexes legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation. See Objections 1 and 2. Am Reply.
| Doc ID | Date & Time | Email From | Email To | Email CC | Email Subject | File | Role Type | Privilege Basis (Alt/MP) | Privilege Remarks/Comments | Responses/Objectives to Privilege Determination | Replies to Objectives to Privilege Determinations | Board's Decision |
|--------|-------------|------------|---------|-----------|-------------|------|-----------|-------------------------|--------------------------------|------------------------------------------------|--------------------------------------------------|----------------|}

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* Apology's Reply is located at Tab 4 to Claimants' Privilege Log.
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<td>INTERNAGLOBAL REPORTS</td>
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<td>Product</td>
<td>Gennaeu</td>
<td>Gennaeu</td>
<td>After conducting routine and observations resulting from internal investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apetx, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>See Objectives 1 and 2.</td>
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<td>See Objectives 1 and 2.</td>
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<td>Review and analysis of deficiencies concerning FDA inspections, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apax legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
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<td>Review and analysis of deficiencies concerning FDA inspections, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apax legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objections 1 and 2.</td>
<td>See Reply.</td>
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* U.S. Objections 1, 2 and 3 are located at Tab 1, 2, and 3 to Claimant's Privilege Log. ** Apax's Reply is located at Tab 4 to Claimant's Privilege Log. *Document ID numbers preceded by a dash indicate attachments to emails.
Communication concerning internal E elimination and/or investigation, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel in providing legal and regulatory advice to Apexis, including regarding FDA enforcement actions, GAAP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objectives 1 and 2.

See Reply.

Communication concerning quality control procedures and compliance with regulatory requirements, including GAAP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexis legal advice regarding regulatory compliance matters and GAAP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

Communication concerning quality control procedures, gap analysis, and compliance with regulatory requirements, including GAAP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexis legal advice regarding regulatory compliance matters and GAAP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

Communication concerning evaluation and remediation of quality control procedures and compliance with regulatory requirements, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexis legal advice regarding regulatory compliance matters and GAAP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

Communication reflecting initial impressions, analysis, recommendations and observations concerning Confidential, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexis legal advice regarding regulatory compliance matters and GAAP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

Communication reflecting initial impressions, analysis, recommendations and observations concerning Confidential, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexis legal advice regarding regulatory compliance matters and GAAP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

Communication reflecting initial impressions, analysis, recommendations and observations concerning Confidential, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexis legal advice regarding regulatory compliance matters and GAAP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

Communication reflecting initial impressions, analysis, recommendations and observations concerning Confidential, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexis legal advice regarding regulatory compliance matters and GAAP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

Communication reflecting initial impressions, analysis, recommendations and observations concerning Confidential, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexis legal advice regarding regulatory compliance matters and GAAP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

Communication reflecting initial impressions, analysis, recommendations and observations concerning Confidential, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apexis legal advice regarding regulatory compliance matters and GAAP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.
May 4, 2010
Jeff Derragh

Work Product

Draft plan for communications concerning evaluation and remediation of quality control procedures and compliance with regulatory requirements, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Axopra legal advice regarding regulatory compliance matters and GxMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2: See Reply.

March 8, 2010
Jeff Derragh

Work Product

Email

Work Product

Communication reflecting mental impressions and observations concerning FDA filing, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Axopra legal advice regarding regulatory compliance matters and GxMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2: See Reply.

Feb. 10, 2010
Cynthia Lee

Work Product

Email

Work Product

Communication concerning quality control procedures and compliance with regulatory requirements, including GxMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Axopra legal advice regarding regulatory compliance matters and GxMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2: See Reply.

July 10, 2010
Jeff Derragh

Work Product

Email

Work Product

Communication concerning internal audit and factual investigation undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Axopra, including regarding FDA enforcement actions, GxMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objectives 1 and 2: See Reply.

July 14, 2010
Jeff Derragh

Work Product

Email

Work Product

Communication conveying mental impressions and evaluation of internal audit and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Axopra, including regarding FDA enforcement actions, GxMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objectives 1 and 2: See Reply.

July 26, 2010
Jeff Derragh

Work Product

Email

Work Product

Draft plan for communications concerning internal audit and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel in providing legal and regulatory advice to Axopra, including regarding FDA enforcement actions, GxMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objectives 1 and 2: See Reply.

Mar. 5, 2010
Jeff Derragh

Work Product

Email

Work Product

Communication reflecting mental impressions and advice concerning corrective actions and continuous improvement initiatives, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Axopra legal advice regarding regulatory compliance matters and GxMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2: See Reply.

May 11, 2010
Stephen Simmons; Jeff Derragh

Work Product

Email

Work Product

Draft plan for communications concerning preparations for FDA preapproval inspection, and reflecting mental impressions and comments concerning same, which were provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Axopra legal advice regarding regulatory compliance matters and GxMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2: See Reply.

May 20, 2010
Jeff Derragh

Work Product

Email

Work Product

Draft plan for communications concerning factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Axopra, including regarding FDA enforcement actions, GxMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objectives 1 and 2: See Reply.

May 20, 2010
Jeff Derragh

Work Product

Email

Work Product

Communications providing regulatory guidance and concerning factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Axopra, including regarding FDA enforcement actions, GxMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objectives 1 and 2: See Reply.

May 11, 2010
Jeff Derragh

Work Product

Email

Work Product

Draft plan for communications concerning facility remediation and quality control evaluation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Axopra, including regarding FDA enforcement actions, GxMP compliance, and corrective action remediation plans undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objectives 1 and 2: See Reply.
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<th>To</th>
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<td>Jeff Derragh</td>
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<td>175</td>
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<td>177</td>
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<td>178</td>
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<td>179</td>
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<td>See Objectives 1 and 2.</td>
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<td>See Objectives 1 and 2.</td>
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* U.S. Objectives 1, 2 and 3 are located at Tabs 1, 2, and 3 to Claimsants' Privilege Log.
* Apotex's Reply is located at Tab 4 to Claimsants' Privilege Log.
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<td>Bid</td>
<td>Work Product</td>
<td>Communication concerning, internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>J46</td>
<td>April 13, 2010</td>
<td>Jeff Kearagh</td>
<td>WC, Vital GMP Assessment</td>
<td>Bid</td>
<td>Work Product</td>
<td>Communication concerning, internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>J47</td>
<td>July 22, 2010</td>
<td>Sandra Olsip</td>
<td>Jeff Kearagh</td>
<td>Joint Burke, Sue Lee-Chan</td>
<td>Work Product</td>
<td>Communication concerning, internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>J48</td>
<td>March 16, 2010</td>
<td>Jeff Kearagh</td>
<td>WC, Investigation report</td>
<td>Bid</td>
<td>Work Product</td>
<td>Chain of communications concerning factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>J49</td>
<td>May 14, 2010</td>
<td>Jeff Kearagh</td>
<td>WC, FDA CONSULTANTS</td>
<td>Bid</td>
<td>Work Product</td>
<td>Chain of communications concerning, internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>J50</td>
<td>Oct. 22, 2010</td>
<td>Jeff Kearagh</td>
<td>Meeting Minutes</td>
<td>Bid</td>
<td>Work Product</td>
<td>Communication concerning, internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>J51</td>
<td>Mar. 23, 2010</td>
<td>Jeff Kearagh</td>
<td>Meeting Minutes</td>
<td>Bid</td>
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<td>Communication concerning, internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>J52</td>
<td>April 7, 2010</td>
<td>Jeff Kearagh, Sue Lee-Chan</td>
<td>Cynthia Lee</td>
<td>WC, murch method review report</td>
<td>Work Product</td>
<td>Communication concerning, internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
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<td>J53</td>
<td>June 3, 2010</td>
<td>Ari Muchnick</td>
<td>Jeff Kearagh</td>
<td>Bid</td>
<td>Work Product</td>
<td>Chain of communications concerning, internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
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<td>June 8, 2010</td>
<td>Jeff Kearagh</td>
<td>Meeting minutes</td>
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<td>Chain of communications concerning, internal audit program and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotes, including regarding FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>276</td>
<td>Mar 26, 2010</td>
<td>Jeff Derrick, Jeff Derrick, Bensoo Tan</td>
<td>Michael Baker, Amy Mary Yi Chu</td>
<td>Bruce Clark</td>
<td>W: FA</td>
<td>Preparation</td>
<td>Read</td>
<td>Work Product</td>
<td>Communication concerning quality control procedures, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and dCMMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>277</td>
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<td>Jeff Derrick</td>
<td>Michael Baker, Amy Mary Yi Chu</td>
<td>Bruce Clark</td>
<td>W: FA</td>
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<td>Work Product</td>
<td>Communication concerning quality control procedures, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and dCMMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>278</td>
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<td>Jeff Derrick</td>
<td>Michael Baker, Amy Mary Yi Chu</td>
<td>Bruce Clark</td>
<td>W: FA</td>
<td>Preparation</td>
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<td>Work Product</td>
<td>Chain of communications reflecting recommendations and observations concerning compliance with regulatory requirements, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and dCMMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>279</td>
<td>Mar 24, 2010</td>
<td>Jeff Derrick</td>
<td>Bruce Clark, Jeff Derrick, Bensoo Tan</td>
<td>Michael Baker, Amy Mary Yi Chu</td>
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<td>Work Product</td>
<td>Communication concerning communication with Messrs. Li et al. (including responses to sample identification). Communications concerning quality control procedures, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and dCMMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>280</td>
<td>Mar 30, 2010</td>
<td>Jeff Derrick</td>
<td>Jeff Derrick</td>
<td>Bruce Clark</td>
<td>W: FA</td>
<td>Preparation</td>
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<td>Work Product</td>
<td>Chain of communications concerning communications for FDA preapproval inspection, and reflecting mental impressions and concerns concerning same, which were provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and dCMMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>Jeff Derrick</td>
<td>Jeff Derrick</td>
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<td>Chain of communications concerning communications for FDA preapproval inspection, and reflecting mental impressions and concerns concerning same, which were provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and dCMMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>282</td>
<td>Apr 20, 2010</td>
<td>Jeff Derrick</td>
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<td>Jeff Derrick</td>
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<td>Product Data - Final- With sample identified in colour attachment</td>
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<td>Communication concerning quality control procedures, gap review, and compliance with regulatory requirements, including dCMMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>283</td>
<td>May 20, 2010</td>
<td>Jeff Derrick, Stephen Graham</td>
<td>Bensoo Tan</td>
<td>Bensoo Tan</td>
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<td>Product Data</td>
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<td>Work Product</td>
<td>Review and analysis of recommendations concerning submission to FDA, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>284</td>
<td>May 30, 2010</td>
<td>Jeff Derrick</td>
<td>Jeff Derrick, Jonet Barlow, Akin Kinnear</td>
<td>Bensoo Tan</td>
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<td>Work Product</td>
<td>Chain of communication concerning quality control procedures and compliance with regulatory requirements, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>285</td>
<td>Jun 1, 2010</td>
<td>Jeff Derrick</td>
<td>Jeff Derrick, Jonet Barlow</td>
<td>Bensoo Tan</td>
<td>W: FA</td>
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<td>Work Product</td>
<td>Chain of communication concerning quality control procedures and compliance with regulatory requirements, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
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<td>286</td>
<td>July 22, 2010</td>
<td>Jeff Derragh, Stephen Simmons</td>
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<td>Brad</td>
<td>Work-Product</td>
<td>Chain of communications concerning factual investigation and quality control procedures to undertake at the request of counsel pursuant to the Engagement, in order to assist counsel in providing legal and regulatory advice to Apesix, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems, undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>287</td>
<td>April 20, 2010</td>
<td>Jeff Derragh, Stephen Simmons, Sanaa Sow, Phil Russ</td>
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<td>Brad</td>
<td>Work-Product</td>
<td>Chain of communications concerning quality control procedures and reflecting regulatory guidance, provided at the request of counsel pursuant to the Engagement, in order to assist counsel in providing legal and regulatory advice to Apesix, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>288</td>
<td>March 5, 2010</td>
<td>Jeff Derragh, Stephen Simmons</td>
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<td>Brad</td>
<td>Work-Product</td>
<td>Chain of communications concerning evaluation and remediation of quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of counsel pursuant to the Engagement, in order to assist counsel in providing legal and regulatory advice to Apesix, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>289</td>
<td>Feb 28, 2010</td>
<td>Jeff Derragh</td>
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<td>Work-Product</td>
<td>Chain of communications concerning facility remediation and factual investigation, undertaken at the request of counsel pursuant to the Engagement, in order to assist counsel in providing legal and regulatory advice to Apesix, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>290</td>
<td>March 5, 2010</td>
<td>Tracy Roberts, Frederick Mayer, Cheryl McAdoo; Jeff Derragh, Phil Russ, Stephen Simmons</td>
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<td>Brad</td>
<td>Work-Product</td>
<td>Observations, market impressions, factual investigations, and compliance evaluations regarding various unique systems, prepared at the request of counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist counsel to provide Apesix legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>291</td>
<td>March 8, 2010</td>
<td>Jeff Derragh</td>
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<td>Work-Product</td>
<td>Communication concerning corporate actions, continuous improvement initiatives, and cGMP, provided at the request of counsel pursuant to the Engagement, and to anticipate regulatory enforcement actions, in order to assist counsel to provide Apesix legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>March 30, 2010</td>
<td>Jeff Derragh</td>
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<td>Communication concerning GSK's response to FDA warning letter, provided at the request of counsel pursuant to the Engagement, in order to assist counsel in providing legal and regulatory advice to Apesix, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>293</td>
<td>Oct 18, 2010</td>
<td>Jeff Derragh</td>
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<td>Work-Product</td>
<td>Communication reflecting internal discussions and advice concerning corrective actions, continuous improvement initiatives, and cGMP, provided at the request of counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist counsel to provide Apesix legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>294</td>
<td>Oct 30, 2010</td>
<td>Jeff Derragh</td>
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<td>Work-Product</td>
<td>Communication reflecting internal discussions and advice concerning regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>Nov 3, 2010</td>
<td>Jeff Derragh</td>
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<td>Work-Product</td>
<td>Communication reflecting internal discussions and advice concerning regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>296</td>
<td>June 11, 2010</td>
<td>Janet Burke</td>
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<td>Work-Product</td>
<td>Chain of communications concerning factual investigation, undertakend at the request of counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist counsel to provide Apesix legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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* U.S. Objectives 1, 2 and 3 are located at Tabs 1, 2, and 3 to Claimant's Privilege Log.
** Apesix's Reply is located at Tab A to Claimant's Privilege Log.
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<td>Jul 14, 2010</td>
<td>Jeff Derragh;</td>
<td>PTH Dodds</td>
<td>Chain of communications concerning evaluation of quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>Email</td>
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<td>Chain of communications concerning evaluation of quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>Terri Dodds</td>
<td>Chain of communications concerning evaluation of quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>Email</td>
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<td>Chain of communications concerning evaluation of quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>252</td>
<td>Jul 18, 2010</td>
<td>Dr. Anthony Reid</td>
<td>Bob Spectrum</td>
<td>Chain of communications concerning evaluation of quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>Email</td>
<td>Work Product</td>
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<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>253</td>
<td>Mar 9, 2010</td>
<td>Stephen Simmons; Jeff Derragh</td>
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<td>Communication providing advice on quality control procedures and compliance with regulatory requirements, including cGMP compliance, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>Email</td>
<td>Work Product</td>
<td>Communication providing advice on quality control procedures and compliance with regulatory requirements, including cGMP compliance, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>Work Product</td>
<td>Communication providing advice on quality control procedures and regulatory requirements, including cGMP compliance, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>255</td>
<td>Jun 8, 2010</td>
<td>Jeff Derragh; Paul Ross; Chris Curry; Gamba Sow; Cheryl Meach; Elaine Cappy</td>
<td>Gail Raglue; Stephen Simmons</td>
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<td>Chain of communications concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>256</td>
<td>May 14, 2010</td>
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<td>Chain of communications concerning factual investigation, remediation efforts and regulatory compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>Jun 30, 2010</td>
<td>Jeff Derragh; Jeremy Sosul; Bruce Clark</td>
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<td>Communication concerning factual investigation, remediation efforts and regulatory compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>258</td>
<td>Aug 10, 2010</td>
<td>Jeff Derragh</td>
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<td>Evaluation of and recommendation concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
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<td>See Objectives 1 and 2.</td>
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<td>Sarah Popadopoulos, Jeff Derragh</td>
<td>Stephen Simmons</td>
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<td>Communication reflecting recommendations and observations concerning FAH filing, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
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<td>See Reply.</td>
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<td>Feb 12, 2010</td>
<td>Jeff Yuen</td>
<td>Patricia Hart; Phil Russ; Carol Austin; Sarah Papadopoulos</td>
<td>Certification, implementation, and verification of various quality systems undertaken at the request of Counsel pursuant to the engagement, in order to assist Counsel in providing legal and regulatory advice to Apetes, including regarding FDA enforcement actions; GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
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<td>Stephen Simmonds; Carol Austin; Jeff Derragh</td>
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<td>Paul Gordon, Phil Russ; Jeremy Doux</td>
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<td>Chris Hartle; Carol Austin; Tam Dang; Tracy Roberts; Gevven Kumar; Rohini Roy; Sarah Papadopoulos; Claudia Vare; Phil Russ; Paul Gordon</td>
<td>Certification, implementation, and verification of various quality systems undertaken at the request of Counsel pursuant to the engagement, in order to assist Counsel in providing legal and regulatory advice to Apetes, including regarding FDA enforcement actions; GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
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111 June 18, 2010 JF York Sarah Popadopoulos Dr. Nicole Fish, Stephen Simmons Product: Product 20 Work Product Chain of communications concerning regulatory compliance and proposed corrective actions, conducted at request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apple, including regarding FDA regulatory compliance and corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2; See Reply.

112 May 20, 2010 JF York Sarah Popadopoulos Email Work Product Chain of communications reflecting mental impressions, factual investigation, recommendations and observations related to Covi’s quality control processes, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apple, including regarding FDA enforcement actions, eGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2; See Reply.

113 Nov. 3, 2009 JF York Pradeep Sanghai, Jeff Barron, Blaine Westerfield, Kevin Murphy Email Work Product Chain of communications concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apple legal advice regarding regulatory compliance matters and cGMP compliance, and/or to request for FDA concerns.

See Objections 1 and 2; See Reply.

114 Feb. 28, 2010 JF York Pradeep Sanghai Email Work Product Communication concerning facility remediation and factual investigation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apple, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2; See Reply.

115 Sep. 6, 2009 JF York Jane Lowiek, Don Binninger, Pradeep Sanghai Email Work Product Chain of communications concerning recommendations and observations, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apple legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.

See Objections 1 and 2; See Reply.

116 Jan. 25, 2010 JF York Pradeep Sanghai Elizabeth Kowes Email Work Product Communication concerning recommendations approach to remediation/compliance, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apple, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2; See Reply.

117 May 4, 2010 JF York Joseph Simmons, Rob Ross, Cheryl Meade, Linda Sive, Jeff Barron Email Work Product Communication in connection with various undertakings at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apple legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.

See Objections 1 and 2; See Reply.

118 Nov. 7, 2009 JS Buettner and Factor; Robert Bristow Paul Feroker, Paolo Flaminio Email Work Product Communication concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel to provide Apple legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.

See Objections 1 and 2; See Reply.
July 27, 2010
Erika Goffin
Paul Forbes
Jeff Chenough
SC: FDA Presentation
Work Product
Draft communications reflecting initial impressions, analysis, recommendations and observations concerning upcoming meeting with FDA, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.
See objections 1 and 2.
See Reply.

July 28, 2010
Erika Goffin
Paul Forbes
Jeff Chenough
Jeff Faes
Erik Linder
SC: FDA Presentation
Work Product
Written comments on the FDA’s draft Guidance for Industry “Labeling of Premarket Approval (PMA) and Abbreviated New Drug Application (ANDA) Products: Requirements for Listing Active Pharmaceutical Ingredients (APIs)”
See objections 1 and 2.
See Reply.

July 28, 2010
Erika Goffin
SC: FDA Presentation
Work Product
Written comments on the FDA’s draft Guidance for Industry “Labeling of Premarket Approval (PMA) and Abbreviated New Drug Application (ANDA) Products: Requirements for Listing Active Pharmaceutical Ingredients (APIs)”
See objections 1 and 2.
See Reply.

July 28, 2010
Erika Goffin
Paul Forbes
Jeff Chenough
SC: FDA Presentation
Work Product
Reproduction of Kelley & Eversolo’s view of the FDA’s draft Guidance for Industry “Labeling of Premarket Approval (PMA) and Abbreviated New Drug Application (ANDA) Products: Requirements for Listing Active Pharmaceutical Ingredients (APIs)”
See objections 1 and 2.
See Reply.

July 28, 2010
Erika Goffin
Paul Forbes
Jeff Chenough
SC: FDA Presentation
Work Product
Communication containing factual information collected and observations regarding various quality systems, prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns for remediation.
See objections 1 and 2.
See Reply.

July 28, 2010
Erika Goffin
Paul Forbes
Jeff Chenough
SC: FDA Presentation
Work Product
Communication containing factual information collected and observations regarding various quality systems, prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns for remediation.
See objections 1 and 2.
See Reply.

July 28, 2010
Erika Goffin
Paul Forbes
Jeff Chenough
SC: FDA Presentation
Work Product
Communication containing factual information collected and observations regarding various quality systems, prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns for remediation.
See objections 1 and 2.
See Reply.

July 28, 2010
Erika Goffin
Paul Forbes
Jeff Chenough
SC: FDA Presentation
Work Product
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See objections 1 and 2.
See Reply.
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<td>Chair of communications reflecting mental impressions and suggestions related to clients' quality control processes, provided at the request of Counsel pursuant to the Engagement, to avoid assisting Counsel in providing legal and regulatory advice to Apexis, including providing FDA enforcement actions, GMP compliance, and corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
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<td>Chair of communications with Apexis and Counsel reflecting mental impressions, factual investigation, and legal/regulatory advice related to clients' quality control processes, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apexis, including providing FDA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
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Apexus Holdings Inc. and Apetus Inc. v. United States

KND Case No. ARW1/21

Claimants' Privilege Log

June 11, 2013

Doc # 264
Date 24 Sep 2009
Type Email
From Ars Hurtle
To Janice Lawless
Subject APUS Update to Blaxx

Observed Work Product

Observations, comments, and corrective recommendations concerning various quality control systems, undertaken at request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apetus, including regarding FDA enforcement actions, cGMP compliance, and corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

To see objections 1 and 2, see reply.

Doc # 265
Date 24 Sep 2009
Type Email
From Ars Hurtle
To Janice Lawless
Subject Advanced Analytics (AAA)

Work Product

Communication concerning interim report, undertaken at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel in providing legal and regulatory advice to Apetus, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

To see objections 1 and 2, see reply.

Doc # 266
Date 20 Oct 2009
Type Email
From Paul Vogel
To Anthony Duce, Lance Lawless
Subject Interim Report

Work Product

Final reflecting observations, mental impressions, and recommendations related to client's response to FDA concerns, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apetus, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

To see objections 1 and 2, see reply.

Doc # 267
Date 30 Oct 2009
Type Email
From Ars Hurtle
To Janice Lawless
Subject Quality Policy

Work Product

Draft reflecting mental impressions, recommendations and observations related to client's quality control processes, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apetus, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

To see objections 1 and 2, see reply.

Doc # 268
Date 7 Nov 2009
Type Email
From RR Yune
To Janice Lawless
Subject Interim Report

Work Product

Communication concerning quality control processes, provided at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.

To see objections 1 and 2, see reply.

Doc # 269
Date 6 Nov 2009
Type Email
From Paul Vogel
To Janice Lawless
Subject Interim Report

Work Product

Communication between Consultant, client, and Counsel concerning quality control processes, undertaken at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.

To see objections 1 and 2, see reply.

Doc # 270
Date 5 Nov 2009
Type Email
From RR Yune
To Janice Lawless
Subject Interim Report

Work Product

Communication providing guidance concerning upcoming FDA meeting, provided at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.

To see objections 1 and 2, even if Apetus replied to Counsel's request for guidance and the cGMP consultants' work was prepared in anticipation of litigation, no privilege can attach to documents dated prior to such engagement. This document is dated prior to September 22, 2009, the date of the alleged engagement letter between Apetus's Counsel and Jeff Ivan & Associates. Therefore, the document is not privileged.

Doc # 271
Date 24 Nov 2009
Type Email
From RR Yune
To Jeremy Knowl
Subject Update

Work Product

Plan of communications concerning compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.

To see objections 1 and 2, see reply.

Doc # 272
Date 25 Nov 2009
Type Email
From RR Yune
To Jeremy Knowl
Subject Update

Work Product

Final plans of communications concerning compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.

To see objections 1 and 2, see reply.

Doc # 273
Date 6 Dec 2009
Type Email
From RR Yune
To Janice Lawless, Larry Bish, Ther Rayshyk
Subject: Materials

Work Product

Communication concerning quality control processes and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.

To see objections 1 and 2, see reply.

Doc # 274
Date 24 Dec 2009
Type Email
From RR Yune
To Janice Lawless
Subject: Materials

Work Product

Communication concerning quality control processes and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.

To see objections 1 and 2, see reply.

Doc # 275
Date 24 Dec 2009
Type Email
From RR Yune
To Janice Lawless
Subject: Materials

Work Product

Communication concerning quality control processes and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apetus legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.

To see objections 1 and 2, see reply.
<table>
<thead>
<tr>
<th>Doc ID</th>
<th>Date</th>
<th>From:</th>
<th>To:</th>
<th>Subject:</th>
<th>File:</th>
<th>Access Type</th>
<th>Access Basis</th>
<th>Privilege Remains/Comments</th>
<th>Responses/Objections to Privilege Determinations</th>
<th>Repl. to Objections to Privilege Determinations</th>
<th>Board’s Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td>661</td>
<td>Sep 2, 2009</td>
<td>Teri Dodds</td>
<td>Jamie Lawlock</td>
<td>PR: Observation and $</td>
<td>Email</td>
<td>Work Product</td>
<td>Communication concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.</td>
<td>See Objections 1 and 2.</td>
<td>Even if Apotex proved that its Counsel provided Apotex’s cGMP consultants and that the cGMP consultants’ work was prepared in anticipation of litigation, no privilege can attach to documents dated prior to such engagement. This document is dated prior to September 22, 2008, the date of the alleged engagement letter between Apotex’s Counsel and Jeff Yuan &amp; Associates. Therefore, the document is not privileged.</td>
<td>See Reply.</td>
<td></td>
</tr>
<tr>
<td>662</td>
<td>Sep 21, 2009</td>
<td>Jeff Yuan</td>
<td>Jamie Lawlock</td>
<td>N/A</td>
<td>Email</td>
<td>Work Product</td>
<td>Communication concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.</td>
<td>See Objections 1 and 2.</td>
<td>See Reply.</td>
<td></td>
<td></td>
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<tr>
<td>663</td>
<td>Sep 24, 2009</td>
<td>Aric Hartle</td>
<td>Jamie Lawlock</td>
<td>C Formal</td>
<td>Email</td>
<td>Work Product</td>
<td>Communication concerning quality control procedures, gap review, and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.</td>
<td>See Objections 1 and 2.</td>
<td>See Reply.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>664</td>
<td>Sep 1, 2009</td>
<td>Jeff Yuan</td>
<td>Jamie Lawlock, Carol Roush</td>
<td>N/A</td>
<td>Email</td>
<td>Work Product</td>
<td>Communication concerning quality control procedures and systems and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.</td>
<td>See Objections 1 and 2.</td>
<td>See Reply.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>665</td>
<td>Oct 17, 2009</td>
<td>Jeff Yuan</td>
<td>Tony Roush; Julie Carney; Elaine Copps; John Snape; Seipree Bunan; Tish Anger</td>
<td>N/A</td>
<td>Email</td>
<td>Work Product</td>
<td>Cover email attaching training presentation, as described below.</td>
<td>See Objections 1 and 2.</td>
<td>See Reply.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>666</td>
<td>Oct 8, 2009</td>
<td>Jeff Yuan</td>
<td>N/A</td>
<td>Email</td>
<td>Work Product</td>
<td>Presentation on quality control processes and regulations, created at the request of Counsel pursuant to the engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.</td>
<td>See Objections 1 and 2.</td>
<td>See Reply.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>667</td>
<td>Sep 30, 2009</td>
<td>Jeff Yuan</td>
<td>Rick Russ; Julie Carney; Jamie Lawlock; Jeremy Deen; Chris Harra</td>
<td>Email</td>
<td>Work Product</td>
<td>Observations and compliance evaluations regarding various quality systems, prepared at the request of Counsel pursuant to the engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.</td>
<td>See Objections 1 and 2.</td>
<td>See Reply.</td>
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<td></td>
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</tr>
<tr>
<td>668</td>
<td>Feb 23, 2010</td>
<td>Jeff Yuan</td>
<td>Jeremy Deen; Tony Roush</td>
<td>Email</td>
<td>Work Product</td>
<td>Chain of communications concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.</td>
<td>See Objections 1 and 2.</td>
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<tr>
<td>669</td>
<td>Feb 17, 2010</td>
<td>Jeff Yuan</td>
<td>Rich Harri; Paul Gandon; Jeremy Deen</td>
<td>Email</td>
<td>Work Product</td>
<td>Chain of communications concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.</td>
<td>See Objections 1 and 2.</td>
<td>See Reply.</td>
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<td></td>
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</tr>
</tbody>
</table>
Email: rrupey@apexus.com
Subject: Privacy

Dear Board:

I am writing to provide an update on our ongoing efforts to ensure that our company's operations are compliant with the General Data Protection Regulation (GDPR) and other relevant data protection legislation.

Recent developments:

1. The GDPR went into effect on May 25, 2018. Since then, we have been working closely with our legal team to ensure that all necessary changes to our policies and procedures have been implemented.

2. In addition to GDPR compliance, we have also been reviewing our data protection procedures to align with the new requirements of the California Consumer Privacy Act (CCPA).

3. Our IT department has completed a comprehensive review of our data processing activities to identify any potential gaps or areas for improvement.

4. We have implemented new training programs for all employees to raise awareness of GDPR and CCPA compliance.

Next steps:

1. We will continue to monitor regulatory changes and best practices to ensure that our policies stay up-to-date.

2. We will conduct regular audits to assess the effectiveness of our data protection measures.

3. We will provide ongoing training to our employees to ensure they remain informed about the latest developments.

I appreciate your continued support and encouragement as we work to meet our obligations under these new regulations.

Sincerely,

[Your Name]
210 Feb 17, 2010 JF Yuan Paul Goldstein; Elisabeth Kowas; Bernie Tao; Robert Parfet; Yu Goldberg

Shinya Omura; BST Kreis; Frederick Mayer; Cheryl Mood

Email Work Product

E-mail: Communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

211 Feb 23, 2010 JF Yuan Pradeep Sanghvi Elisabeth Kowas

Email Work Product

E-mail: Chain of communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

212 May 10, 2010 JF Yuan Stephen Simonsen; PhD Rush

Pradeep Sanghvi; Elisabeth Kowas

Email Work Product

E-mail: Chain of communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

213 Dec. 16, 2009 JF Yuan Olivia Kowas; Elisabeth Kowas; Pradeep Sanghvi; Jan-Chan; Janet Barker

Email Work Product

E-mail: Chain of communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

214 Feb 14, 2010 JF Yuan Pradeep Sanghvi Elisabeth Kowas; Larry Rock; Rosana Adam; Chris Curry

Email Work Product

E-mail: Chain of communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

215 Dec. 16, 2009 JF Yuan Elisabeth Kowas; Pradeep Sanghvi; Calvis Kowas

Ditt Curry; Larry Rock

Email Work Product

E-mail: Communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

216 Jul. 11, 2010 JF Yuan Elaine Capowy; Elisabeth Kowas

Email Work Product

E-mail: Chain of communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

217 Oct. 16, 2010 JF Yuan Elisabeth Kowas

N/A Email Work Product

Email: Chain of communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

218 Dec. 23, 2009 JF Yuan Elisabeth Kowas

N/A Email Work Product

Email: Chain of communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

219 Oct. 9, 2008 JF Yuan Pradeep Sanghvi

Email Work Product

E-mail: Communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.

See Reply.

220 May 10, 2010 JF Yuan Elaine Capowsy

Elisabeth Kowas; Wan King; San-Lee Chen; Cynthia Lee; Stephen Simonsen; PhilMusic; Sarita Sow; Jeff Cemuga; Bruce Clark

Email Work Product

E-mail: Communications concerning quality control procedures and compliance with regulatory requirements, including GMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and GMP compliance, and to respond to FDA concerns.

See Objectives 1 and 2.
<table>
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<th>RevType</th>
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<th>Privilege Remarks/Comments</th>
<th>Reponses/Objectives to Privilege Determination</th>
<th>Reply to Objectives to Privilege Determination</th>
<th>Board's Decisions</th>
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<tbody>
<tr>
<td>211</td>
<td>8/6/2009</td>
<td>Jeff Yuen</td>
<td>Isabel Boucau, Sally Burke, Richard Sugino</td>
<td>8%</td>
<td>email</td>
<td>Work Product</td>
<td>Report letter reflecting observations, material impressions, factual investigation, advice regarding manufacturing quality systems and assessments of compliance with cGMP, prepared at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>Communication concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
<td></td>
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<tr>
<td>213</td>
<td>8/2/2009</td>
<td>Erim Dodds</td>
<td>Carol Audson</td>
<td>8%</td>
<td>email</td>
<td>Work Product</td>
<td>Claim of communications regarding recommendations and observations related to client’s response to FDA inspections, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
<td></td>
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<tr>
<td>214</td>
<td>8/3/2009</td>
<td>Erim Dodds</td>
<td>Carol Audson</td>
<td>8%</td>
<td>email</td>
<td>Work Product</td>
<td>Email regarding mental impressions and recommendations related to client’s response to FDA inspection, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
<td></td>
<td></td>
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<tr>
<td>215</td>
<td>8/10/2010</td>
<td>Paul Vogel</td>
<td>Jeremy Denic; Stephen Salmi; Carol Audson; Marc Schaner; Carmen Russell; Kate Burnside; Paul Vogel; Bruce Clark</td>
<td>8%</td>
<td>email</td>
<td>Work Product; Attorney Client</td>
<td>Communication with Counsel and Apotex reflecting observations, mental impressions, and recommendations advice related to client’s response to FDA warning letter, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>8/4/2010</td>
<td>Jeff Yuen</td>
<td>Carol Audson</td>
<td>8%</td>
<td>email</td>
<td>Work Product</td>
<td>Communication concerning quality control procedures and compliance with regulatory requirements, including cGMP compliance, undertaken at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td>217</td>
<td>8/2/2009</td>
<td>Erim Dodds</td>
<td>Chris Carr, Lance Treadwell</td>
<td>8%</td>
<td>email</td>
<td>Work Product</td>
<td>Communication reflecting observations, mental impressions, and corrective recommendations related to client’s response to FDA warning letter, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Apotex, including regarding FDA enforcement actions, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.</td>
<td>See Objectives 1 and 2.</td>
<td>See Reply.</td>
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<td></td>
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</tbody>
</table>
211 Feb 11, 2010 Jeff Yuan Chris Lurcy, Friedrich Mayer, Cheryl Meade; Carol Austin 46333 00:15:50 Subject: SAN 1586 - CFP: San Francisco, CA February 25, 2010 Email Work Product Communication: reflecting observations, material impressions, and recommendations related to client's response to FPA inspection, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Aponte, including regarding FPA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2. See Reply.

212 Feb 13, 2009 Chrissie Harte Carol Austin 46333 00:15:50 Subject: HCP - Subcategories Email Work Product Lists of communications containing observations, material impressions, and recommendations related to client's response to FPA inspection, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Aponte, including regarding FPA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2. See Reply.

213 Feb 10, 2009 Chrissie Harte Peri Diodati, Lackle Lawrence; Tabi Angel 46333 00:15:50 Subject: CFP: San Francisco, CA February 25, 2010 Email Work Product Communication: reflecting material impressions and recommendations related to client’s response to FDA, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Aponte, including regarding FPA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2. See Reply.

214 Feb 3, 2009 Jeff Yuan Carol Austin; Terri Dodds; Jeff Yuan 46333 00:15:50 Subject: observations - 11 draft response Email Work Product Observations, material impressions, factual investigations, and compliance evaluations regarding various quality systems, prepared at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Aponte legal advice regarding regulatory compliance matters and FDA compliance, and to respond to FDA requests for remediation.

See Objections 1 and 2. Even if Aponte proved that its Counsel retained Aponte’s GMP consultants and that the GMP consultants’ work was prepared in anticipation of litigation, no privilege can attach to documents dated prior to such engagement. This document is dated prior to September 22, 2008, the date of the alleged engagement letter between Aponte’s Counsel and Jeff Yuan & Associates. Therefore, the document is not privileged.

215 Mar. 5, 2010 Jeff Yuan Tracey Roberts Carol Austin; Friedrich Mayer; Cheryl Meade; Jeff Derragh; Phil Bucz; Stephen Simmons 46333 00:15:50 Subject: CFP - Overview of CFP Audit - Proposal to City-over to New Initial Schedule Apr 2010 - Mar 2011 Email Work Product Observations, material impressions, factual investigations, and compliance evaluations regarding various quality systems, prepared at the request of Counsel pursuant to the Engagement and in anticipation of regulatory enforcement actions, in order to assist Counsel to provide Aponte legal advice regarding regulatory compliance matters and FDA compliance, and to respond to FDA requests for remediation.

See Objections 1 and 2. See Reply.

216 Feb 5, 2010 Jeff Yuan Chris Harte Calvin Kramer; Carol Austin 46333 00:15:50 Subject: CFP: San Francisco, CA - Resources for CFP Audit Email Work Product Communication: reflecting observations, material impressions, and corrective recommendations related to client’s response to FDA, provided at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Aponte, including regarding FPA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2. See Reply.

217 Jan. 1, 2009 Terri Dodd Carol Austin 46333 00:15:50 Subject: CFP: San Francisco, CA Email Work Product Communication: providing review and analysis of client’s response to FPA inspection, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Aponte, including regarding FPA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2. Even if Aponte proved that its Counsel retained Aponte’s GMP consultants and that the GMP consultants’ work was prepared in anticipation of litigation, no privilege can attach to documents dated prior to such engagement. This document is dated prior to September 22, 2008, the date of the alleged engagement letter between Aponte’s Counsel and Jeff Yuan & Associates. Therefore, the document is not privileged.

218 Oct. 4, 2009 Neal Vogel Alice Tao 46333 00:15:50 Subject: Protocol for retrospective review Email Work Product Communication: reflecting evaluation and analysis of client’s draft protocol in response to FDA observation, undertaken at the request of Counsel pursuant to the Engagement, in order to assist Counsel in providing legal and regulatory advice to Aponte, including regarding FPA enforcement actions, GMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions.

See Objections 1 and 2. See Reply.
June 11, 2013

By email

V.V. Veeder, QC
J. William Rowley, QC
Mr. John R. Crook
c/o Ms. Eloïse Obadia
Secretary of the Tribunal
International Centre for Settlement
of Investment Disputes
1818 H Street, N.W.
MSN U3-301
Washington, D.C. 20433

Re: Apotex Holdings Inc. and Apotex Inc. v. United States of America,
ICSID Case No. ARB(AF)/12/1

Dear Members of the Tribunal:

Pursuant to the Tribunal’s May 14, 2013 Procedural Order on the Schedule Regarding the Parties’ Respective Privilege Logs, Further Submissions and Certifications, attached please find the United States’ privilege log, which includes the United States’ replies to Apotex’s objections.

The parties have worked diligently and in good faith to narrow the issues of disagreement. In addition to those identified on the parties’ logs, three issues remain unresolved.

1. U.S. Redactions

In a June 4, 2013 letter (Attachment A), Apotex objected to various U.S. redactions for attorney-client and deliberative-process privileges. Although we subsequently explained the bases for these redactions, Apotex informed us that it intends to maintain its objections, on three grounds.

First, Apotex contends that several documents were too heavily redacted, and thus should have been placed on the U.S. privilege log. The parties had expressly agreed, however, to log only

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1 See IBA Rules on the Taking of Evidence in International Arbitration (IBA Rules), arts. 9(2)(b) and 9(2)(f). In a separate letter, also dated June 4, 2013, Apotex requested additional information regarding a number of documents produced by the United States. In a June 5 teleconference and in subsequent emails, the United States responded to these requests. We understand that Apotex is satisfied and thus is not pursuing these requests further.

2 The United States understands that Apotex intends to submit a letter to the Tribunal raising these or similar points. If Apotex’s new letter raises additional points, examples, or arguments, we may request an opportunity to respond.

3 See Attachment A, at 1-2.
fully withheld documents. In any event, the documents that Apotex identified contain ample information justifying the asserted privilege. For example, emails redacted to protect FDA’s deliberative process identify the author, recipients, date, and subject matter. Additionally, the subject lines or unredacted text of those emails indicate the reason for the redactions. Most of the examples identified by Apotex concern draft language for official agency correspondence, which is inherently deliberative and protected by privilege. Similarly, the emails redacted for attorney-client privilege contain, in unredacted portions, threats by Apotex’s counsel to sue FDA. The subsequent emails are internal discussions between FDA lawyers and their policy clients, which on their face are privileged.

Second, Apotex objects to our use of a U.S. Freedom of Information Act (FOIA) designation, rather than the corresponding IBA Rules designation. In particular, Apotex objects to our use of the “b(5)” FOIA designation, which is for pre-decisional and deliberative documents. The b(5) designation, however, provides more precise information than the comparable IBA Rules designation. While the IBA Rules generally refer to “legal impediment or privilege” and “special political or institutional sensitivity,” the b(5) designation specifically refers to the deliberative process privilege. In any event, as explained to Apotex, each of the b(5) designations may be understood to refer to Articles 9(2)(b) and 9(2)(f) of the IBA Rules.

Third, Apotex asserts that some U.S. redactions are inconsistent, and that this inconsistency suggests that the United States was “redacting information when it would be helpful to Apotex and choosing not to redact information when it would be helpful to the US.” This claim is baseless, and we reject it categorically. The United States made extraordinary efforts to comply with Apotex’s massive document request in the very short time allotted. To do so, the United States required the assistance of three individuals from FDA’s Division of Information Disclosure Policy to review (and potentially redact) nearly 14,000 pages for deliberative process and confidential commercial and trade secret information. A team of State Department lawyers then independently checked the redactions and, when necessary, reverted to FDA to resolve

4 In discussions with Apotex, the United States acknowledged two exceptions. Both were emails subject to attorney-client privilege (US012032 and US012049). These two documents have since been placed on the U.S. privilege log.

5 Apotex does not object to the assertion of attorney-client privilege on the United States’ privilege log, implicitly acknowledging the proper application of that privilege. The United States, by contrast, has objected to Apotex’s assertion of attorney-client and work product privileges for documents prepared by Apotex’s cGMP consultants. See U.S. Objections 1, 2 and 3 to Claimants’ privilege log. Apotex’s assertions go well beyond what previous NAFTA Chapter Eleven tribunals have recognized as the outer bounds of those privileges. See, e.g., Vito G. Gallo v. Government of Canada, NAFTA/UNCITRAL, Procedural Order No. 3 ¶ 47 (Apr. 8, 2009) (applying four requirements for the solicitor-client privilege: (1) the document must be drafted by a lawyer acting in that capacity, (2) a solicitor-client relationship based on trust must exist, (3) the document must have been created for the purpose of giving or obtaining legal advice, and (4) the parties must have acted in the expectation that the advice would be kept confidential) [RLA-188]; Glamis Gold, Ltd. v. United States of America, NAFTA/UNCITRAL, Decision on Parties’ Requests for Production of Documents Withheld on Grounds of Privilege ¶ 31 (Nov. 17, 2005) (recognizing that the work product privilege requires that a document be prepared in anticipation of litigation, and finding that a withholding party must explain “how the subject matter of the document relates to a likely lawsuit by an identifiable adversary in respect of a specific dispute.”) [CLA-480].

6 See Attachment A, at 3.


8 See Attachment A, at 3.
inconsistencies. To the extent there were minor inconsistencies in the produced documents, they were solely the result of the expedited redaction process involving multiple reviewers. These inconsistencies do not indicate any scheme on the part of the United States or constitute a waiver of any asserted privilege. Apotex’s accusation is all the more unjustified when considered in light of each party’s document production. Apotex produced 365 documents and withheld 353 for privilege. The United States, by contrast, produced 3,559 documents and withheld 32 for privilege. Apotex’s criticism of minor inconsistencies in the United States’ vastly larger document production thus is not only objectionable but wholly misplaced.

2. **Deliberative Process Privilege**

In Apotex’s objections to the U.S. privilege log and in its June 4 letter, Apotex “disputes that a domestic privilege, such as the FOIA exemption for deliberative process privilege, is applicable in international arbitration proceedings.”\(^9\) While domestic law on privilege is not directly applicable,\(^11\) the deliberative process privilege applies to these proceedings by virtue of Articles 9(2)(b) (legal impediment or privilege) and 9(2)(f) (special political or institutional sensitivity) of the IBA Rules. Indeed, when applying the IBA Rules, several NAFTA Chapter Eleven tribunals have specifically recognized the deliberative process privilege. The *Gallo* tribunal, for example, recognized the need to protect “information exchanged during deliberative and policy making processes” in order to protect frank and uninhibited advice provided to and exchanged by government decision-makers.\(^12\) The *Merrill & Ring* tribunal similarly explained, in recognizing that the IBA Rules protect deliberative materials:

> Paragraph 9(2)(f) of the IBA Rules on the Taking of Evidence in International Commercial Arbitration, includes within the concept of ‘special political or institutional sensitivity’ the kind of privileged information to which the Canadian legislation refers. Even if such information is not formally classified as ‘secret’, the purpose of the privilege is quite evidently to prevent disclosure of documents containing information which is sensitive by its nature. There is thus no conflict in this case between international law and a domestic law that might be inconsistent with its provisions.\(^13\)

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\(^9\) As noted on its log, the United States withheld multiple versions or copies of several documents.

\(^10\) See Attachment A, at 3.

\(^11\) Domestic law may provide guidance on matters of privilege. See, e.g., *William Ralph Clayton et al. v. Canada*, NAFTA/UNCITRAL, Procedural Order No. 12 ¶ 17 (May 2, 2012) (“In accordance with NAFTA Articles 1131(1) and 1120(2), the Tribunal will apply any relevant provisions of NAFTA, international law, and the UNCITRAL Rules in resolving the Disputing Parties’ disagreement regarding their privilege claims. As the Disputing Parties note, the Tribunal has previously decided that the IBA Rules on the Taking of Evidence in International Commercial Arbitration of 1999 (‘IBA Rules’) serve as guidelines in this arbitration. The Tribunal further observes that other NAFTA tribunals have considered national law, as well, for guidance on matters of privilege.”) (citing, e.g., *Gallo and Glamis*) [RLA-204]; *Glamis Gold, Ltd. v. United States*, NAFTA/UNCITRAL, Decision on Parties’ Request for Production of Documents Withheld on Grounds of Privilege ¶¶ 19-20 (Nov. 17, 2005) ) (noting that while the law of the United States was not “directly applicable,” the parties agreed to look to U.S. privilege law as “guidance”) [CLA-480].

\(^12\) *Vito G. Gallo v. Government of Canada*, NAFTA/UNCITRAL, Procedural Order No. 3 ¶ 54 (Apr. 8, 2009) [RLA-188].

\(^13\) *Merrill & Ring Forestry L.P. v. Canada*, NAFTA/UNCITRAL, Decision of the Tribunal on Production of Documents ¶ 18 (July 18, 2008) [CLA-481].
The UPS and Glamis tribunals reached the same conclusion.\(^\text{14}\) There is no reason for this Tribunal to depart from the well-established application of the deliberative process privilege in NAFTA Chapter Eleven arbitrations.

3. **Apotex Redactions**

Apotex redacted various documents related to Tunnell Consulting on the basis of “commercial or technical sensitivity” (IBA Rules, art. 9(2)(e)). The United States objected to these redactions in a letter dated June 4, 2013 (Attachment B), observing that Apotex’s commercial and technical information is sufficiently protected by the Confidentiality Agreement and Order. In a June 10 teleconference, Apotex agreed to produce these documents without many of the redactions. But Apotex stated that some of the redactions, including redactions for information Apotex deems non-responsive, will remain. The United States will review these documents once they are produced. If the United States continues to object to the remaining redactions, the United States will promptly bring those redactions to the Tribunal’s attention for resolution.

Sincerely,

Jeremy K. Sharpe  
Chief, Investment Arbitration  
International Claims and Investment Disputes

Copies (by email):  
Barton Legum, Esq.  
John J. Hay, Esq.  
Kristen B. Weil, Esq.  
Anne-Sophie Dufêtre, Esq.  
Ulyana Bardyn, Esq.

\(^{14}\) See, e.g., *United Parcel Serv. of America v. Canada*, NAFTA/UNCITRAL, Decision of the Tribunal Relating to Canada’s Claim of Cabinet Privilege ¶ 11 (Oct. 8, 2004) (“[S]tate practice does support the protection of information falling within the deliberative and policy making processes at high levels of government[,]”) [CLA-478]; *Glamis Gold, Ltd. v. United States*, NAFTA/UNCITRAL, Decision on Parties’ Request for Production of Documents Withheld on Grounds of Privilege ¶ 36 (Nov. 17, 2005) (adopting the parties’ positions on deliberative process and clarifying the scope of the privilege) [CLA-480].
Attachment A
BY EMAIL

Jeremy K. Sharpe, Esq.
Chief, Investment Arbitration
Office of International Claims and
Investment Disputes
U.S. Department of State
2430 E Street, NW, Suite 203
Washington, D.C. 20037

June 4, 2013

Re: Apotex Holdings Inc. and Apotex Inc. v. United States (ICSID Case No. ARB(AF)/12/1)

Dear Jeremy:

On behalf of claimants Apotex Holdings Inc. and Apotex Inc. (collectively, "Apotex"), we write to object to certain redactions made by Respondent the United States of America to documents it has produced in the above-referenced arbitration proceeding. Apotex has identified more than 500 redacted documents, but has limited its objections to the categories discussed below.

Apotex seeks to resolve these issues amicably and hopes that the parties are able to reach a resolution without the Tribunal's assistance.

1. Failure to Log Heavily Redacted Documents

   a. Deliberative Process Privilege

Apotex objects to a number of documents produced by the US that contain significant, and in many cases, complete redactions of substantive information based on the US's assertion of deliberative process privilege under 5 USC § 552(b)(5). As discussed further below, Apotex believes the US's assertion of deliberative process privilege is inappropriate for two reasons: first, the US has not sufficiently explained how application of this privilege to particular documents falls within the IBA Rules, and second, the US's inconsistent use of redactions shakes Apotex's confidence that the US has a justifiable basis for excluding certain information from production.

However, even assuming, arguendo, that deliberative process privilege may be properly asserted in this proceeding, Apotex believes that the US redacted substantive information and produced these documents so that the US would not be required to include them on a privilege log. See, e.g., US010525 (redacting all of the email chain except the words "Carmelo" and "Christina" (the names of the author and recipient of the first email in the chain) and "Thanks CR" in the second email in the chain).

Apotex believes this demonstrates non-compliance with the Tribunal's order dated March 29, 2013, instructing the parties to prepare a privilege log. By failing to include these documents on a privilege log and describe the basis for asserting a privilege, the US has made it impossible for Apotex to determine whether the assertion of privilege is reasonable.

Apotex has identified the following non-exhaustive list of documents that were heavily redacted and that should have been included on the US's privilege log instead:

NewYork 1598080.1
b. Attorney-Client Privilege

Similarly, the US heavily redacted documents purportedly containing information protected by the attorney-client privilege rather than withholding these documents and including them on a privilege log. The extent of the US’s redactions renders the documents entirely content-free and thus is functionally equivalent to not producing these documents. By failing to include these documents on a privilege log and describe the basis for asserting a privilege, Apotex is unable to determine whether the assertion of privilege is reasonable. Apotex believes the US’s failure to include these documents on a privilege log demonstrates non-compliance with the Tribunal’s order.

Apotex has identified the following as documents that were heavily redacted and that should have been included on the US’s privilege log instead:

US004392
US004499
US004505
US004510
US004553
US007644
US008719
US011956
US011974
US012007
US012032
US012049
US012174
US013108

2. Inconsistent Redactions

Apotex is also concerned by inconsistencies in the type of material the US has redacted, namely information redacted under the deliberative process privilege and information relating to third parties, as discussed below. The apparent lack of consistent standards calls into question whether any of the US’s redactions are defensible.

a. Deliberative Process Privilege
For the reasons Apotex stated in its March 15, 2013 reply to the US’s objections to Apotex’s document requests, Apotex disputes that a domestic privilege, such as the FOIA exemption for deliberative process privilege, is applicable in international arbitration proceedings.

Moreover, paragraph O of the Tribunal’s Procedural Order on the Parties’ Respective Requests for Document Production, dated March 29, 2013, states that “the Tribunal is minded not to take into account deliberative process privilege … as a matter of any applicable law or rules of law, but rather as one or more factors falling within Article 9(2) of the IBA Rules.” Thus, the US was required to do more than merely cite to a provision of US law relating to a privilege recognized domestically. Rather, the US was required to explain how the deliberative process privilege is embraced in international law and encompassed by the IBA Rules. The failure to explain in more detail why the US’s redactions are appropriate constitutes a failure to comply with the Tribunal’s order.

Even if the deliberative process privilege may be asserted in international arbitration, the US has redacted purportedly “deliberative” material on an inconsistent basis. This inconsistency causes Apotex to question whether the US is using the deliberative process privilege (to the extent it should be recognized by this Tribunal) as both a sword and a shield, by redacting information when it would be helpful to Apotex and choosing not to redact information when it would be helpful to the US. As an example of the US’s inconsistent redaction policy, the US produced as US007154 an email from Carmelo Rosa to Irma Rivera dated June 10, 2009 in which Mr. Rosa states:

Allow me to pass the proposed date through my management here. There is a big issue and interest in this case, and we (CDER) need to brief Canada Health on the upcoming WL and concerns we have with this firm. This has been taken to the level of Deb Autor and Janet Woodcock. The new commissioner is also being briefed. Just to let you know. I should get back to you by tomorrow. Thanks.

The US produced as US007799-7780 the same email, but redacted the words in bold below as being entitled to deliberative process privilege under FOIA exemption (b)(5):

Allow me to pass the proposed date through my management here. There is a big issue and interest in this case, and we (CDER) need to brief Canada Health on the upcoming WL and concerns we have with this firm. This has been taken to the level of Deb Autor and Janet Woodcock. The new commissioner is also being briefed. Just to let you know. I should get back to you by tomorrow. Thanks.

The bolded language does not reflect privileged information. It does not describe what FDA’s concerns were; it does not reflect deliberation, evaluation, or assessment undertaken before taking an agency action; and it does not express any opinion or recommendation on legal or policy matters. As such, it is not entitled to protection from disclosure. See, e.g., Legal Authority CLA-488, N.L.R.B. v. Sears, Roebuck & Co., 421 U.S. 132, 158-9 (1975) (documents relating to the agency’s final decision were not protected by DPP, while documents relating to a non-final decision were); Legal Authority CLA-489, Coastal States Gas Corp. v. Dept’ of Energy, 617 F.2d 854, 867 (D.C. Cir. 1980) (Deliberative documents “reflect the give-and-take of the consultative process” and include ‘subjective documents which reflect the personal opinions of the writer rather than the policy of the agency.’).

By way of another example, the US redacted a portion of US012572 which was a quotation from a letter from FDA to Apotex. The unredacted portion of the email states that the letter “[l]ooks really good! One comment. I think this [redacted] sentence has an inaccuracy.” This context demonstrates that the redacted portion was factual, rather than deliberative, which the deliberative process privilege does not
cover. See, e.g., Legal Authority CLA-490, In re Subpoena Served Upon Comptroller of Currency, and Secretary of Bd. of Governors of Federal Reserve System, 967 F.2d 630, 634 (D.C. Cir. 1992). Although Apotex does not believe the Tribunal should permit the assertion of deliberative process privilege, to the extent it is allowed, the US must apply it correctly.

As these two examples demonstrate, the US’s decision to redact such information calls into question the basis for other material redacted pursuant to 5 USC § 552(b)(5). Because the US has not logged heavily redacted documents, Apotex is unable to assess whether the US’s redactions are reasonable.

Likewise, the documents that the US has chosen to produce in unredacted form also cast doubt on the reliability of the US’s redactions, as Apotex has identified unredacted documents that reflect FDA’s decision-making process. Apotex believes that the US’s inconsistent approach constitutes a waiver as to deliberative, pre-decisional information. For example, the same email chain quoted above contains unredacted references to FDA’s strategy, decision-making hierarchy, and proposed next steps. According to the email, the “case has reached very high levels, including the preparation of an advisory paper” and FDA was “interested in revising the original strategy ... “. See US007799.

Similarly, the US produced US011286-91, which discusses whether Apotex should recall a particular product. The email details FDA’s evaluation of Apotex’s response to a warning letter, how ICB was “considering expanding the Import Alert ... ” and its plan to “contact the firm ... to discuss these FARs ... ” US011288-89. It discusses whether to initiate a “new” and “innovative” type of import alert against Apotex and the rationale behind doing so. Despite producing all of this information, the US redacts a portion of the email discussing this “innovative approach”. Such an approach is internally inconsistent and Apotex can discern no uniform standard for redacting information.

The US has even produced documents that are marked as “Privileged, Confidential, and Pre-Decisional” without redacting any purportedly deliberative information. See, e.g., US0011500-08; See also US11626-27 (failing to redact what FDA “may decide”). The US’s approach to redacting allegedly deliberative information is troubling to Apotex.

Apotex has identified the following as documents that were redacted on the basis of deliberative privilege but for which Apotex is unable to determine whether such privilege was properly asserted, based on the US’s inconsistent approach to redacting material:

US009006
US011286
US011627
US012119
US013127
US013191

b. Third Party Information

In its privilege log, the US has asserted that US law prohibits the US from releasing trade secret or confidential commercial information. However, the US has selectively redacted confidential information related to third parties. As with the deliberative process privilege, it appears that the US may be redacting information on the basis of how helpful it is, rather than applying redactions on a consistent basis. This approach finds no support in the IBA Rules or in US law.

For example, US011971 fails to redact the names of companies who would receive warning letters and US11918 fails to redact NDA numbers and company names. US011918 contains information about third
parties’ pending applications. This information presumably would be precisely the sort of confidential commercial information protected under US law, yet this information was not redacted.

In contrast, other documents are almost entirely redacted on the basis that they contain information related to third parties. See, e.g., US007660, US011345, US011571.

Information related to third parties is relevant to Apotex’s arguments concerning like treatment of comparators. Thus, the US is not entitled to selectively redact information related to comparators.

Apotex has identified multiple versions of what appear to be two types of periodic reports that contain information related to third parties. See, e.g., US011517 and US011520. As a result of the US’s inconsistent redaction policy, it is impossible for Apotex to determine whether these documents contain information related to comparators and other third parties and have been appropriately redacted. In addition to these reports, Apotex has also identified the following documents which suffer from the same uncertainty:

US009468
US011076
US011356
US011622
US011624
US011825
US011918
US011971
US012113

By simply citing domestic US law, including FOIA, rather than explaining why the US believes it is entitled to redact certain information under the IBA Rules, the US did not comply with the Tribunal’s Procedural Order. Accordingly, and for reasons stated in Apotex’s March 15, 2013 reply to the US’s objections to Apotex’s document requests, Apotex believes the Tribunal should reject the US’s application of deliberative process privilege wholesale and order the production in unredacted form of all information redacted on this basis. However, at the very least, Apotex suggests that if the parties cannot resolve these issues between themselves, that the Tribunal review in camera the limited number of redacted documents specifically identified above.

Sincerely,

John J. Hay
Partner
Salans FMC SNR Denton Europe LLP

cc: Lisa Grosh; Barton Legum; Anne-Sophie Dufêtre
Attachment B
June 4, 2013

By email

John J. Hay
Dentons
Rockefeller Center
620 Fifth Avenue
New York, New York 10020-2457
john.hay@dentons.com

Re: Apotex Holdings Inc. and Apotex Inc. v. United States, ICSID Case No. ARB(AF)/12/1 – U.S. Objections to Apotex’s Redacted Documents

Dear John,

With reference to our email agreement of May 21, 2013, we write to express our objections to redactions included in your production of Apotex documents.

Apotex has heavily redacted documents evidencing communications between itself and other entities, including one of its cGMP consultants, Tunnell Consulting, APO000698 – APO-002746. Almost every document in this set contains some redactions; in several the substance of the communications is redacted in full. With two exceptions, these redactions fall entirely into one of two categories: redactions based on Article 9(2)(e) of the 2010 IBA Rules on the Taking of Evidence in International Arbitration, or redactions with no identified basis.¹

Unless Apotex is protecting commercially sensitive information supplied by third parties, there is no foundation for Apotex to redact on the basis of Article 9(2)(e). Apotex’s commercial and technical information is sufficiently protected by the Confidentiality Agreement and Order dated July 24, 2012, which includes “confidential commercial and financial information” and “trade secret information” in its definition of “confidential information.” The United States has agreed to treat “confidential information” in the manner detailed in the Agreement and Order, including by, inter alia, agreeing not to disclose “confidential information” to third parties (paragraph 4), limiting the information’s dissemination to certain individuals (paragraph 5), and destroying “confidential information” following the termination of the arbitration (paragraph 16). There is therefore no “compelling” basis for redacting this information per Article 9(2)(e).

Many of the Article 9(2)(e) redactions appear to shield from disclosure names of Apotex products or projects. To the extent these overlap with products that were investigated by FDA or

¹ The sole exceptions to these two categories are APO-001745 & APO-001747, in which the redactions are labeled “non-responsive.”
were otherwise of concern to FDA, the quality assessment and remediation undertaken by Tunnell Consulting and Apotex’s other consultants is highly relevant. Notably, Apotex has not asserted that this information is irrelevant or immaterial to this arbitration.

The remainder of the redactions contains no indication of a redaction basis. To the extent these are also redacted on the basis of Article 9(2)(e), the redactions are improper for the reasons discussed above. To the extent that there is another basis for redaction (for example, attorney-client privilege), the basis should be identified in the document. The United States requests that Apotex identify the basis as soon as possible, and in any event the United States must reserve its right to object once the basis is so identified.

In accordance with the parties’ agreement, we look forward to discussing these matters tomorrow with the goal of resolving as many issues as possible prior to presenting our respective objections and replies to the Tribunal on June 11.

Sincerely,

Nicole C. Thornton
Attorney-Adviser
Office of International Claims and Investment Disputes

Cc: Barton Legum, Esq.
    Ulyana Bardyn, Esq.
    Anne-Sophie Dufêtre, Esq.
    Kristen Weil, Esq.
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<td>Draft of blockbuster hearing letter. See 200-08-08 (multiple versions).</td>
<td>Supporting materials and all communications that have part of a government agency's decision-making process and are protected by deliberation process privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or to a legal privilege or for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege.</td>
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<td>Supporting materials and all communications that have part of a government agency's decision-making process and are protected by deliberation process privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or to a legal privilege or for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege. The drafts are available to the US (See 200-08-08) for legal incorporation or privilege.</td>
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<td>PCT-116</td>
<td>10/09/2021</td>
<td>Draft Letter to Apotex Canada</td>
<td>Confidential</td>
<td>Microsoft Word</td>
<td>2021-10-10</td>
<td>NA, Rule 47(b),</td>
<td>Draft of blockbuster hearing letter. See 200-08-08 (multiple versions).</td>
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Apotex Holdings Inc. and Apotex Inc. v. United States

Respondent's Privilege Log

June 11, 2013

Page 1
Drafts of the 2011 Deposition(s): (multiple documents submitted). See the attached Deposition(s) for the full texts and context.

For the reasons set out in the Notice to T.J. O’Donnell dated April 20, 2011, the Respondent seeks to exclude 18,498 lines of the 2011 Depositions. The Respondent is not seeking to exclude any documents, other than the 2011 Depositions, as Exhibit(s) or Evidence(s) in this proceeding.

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