INTERNATIONAL CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES
(ICSID Case No. ARB(AF)/12/1)

(1) APOTEX HOLDINGS INC.

(2) APOTEX INC.

Claimants

v.

UNITED STATES OF AMERICA

Respondent

PROCEDURAL ORDER ON DOCUMENT PRODUCTION REGARDING THE PARTIES' RESPECTIVE CLAIMS TO PRIVILEGE AND PRIVILEGE LOGS

The Tribunal:

J. William Rowley, Arbitrator;
John R. Crook, Arbitrator; and
V.V. Veeder, President.

The Secretary to the Tribunal:
Eloïse M. Obadia

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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

[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."[5]

24. The Respondent challenges the Claimants' application of attorney-client or work product privilege to the communications with the Consultants.[6] 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,[7] is a mere veneer intended to cloak JYA's work with ostensible privilege to which that work is not entitled.[8] 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.[9]

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."[10]

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,[11] 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

[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.[12]

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.[13] 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.[14]

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.[15]

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.[16]

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.[17] 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.[18] 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

[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.
[17] CLA-609, *United States v. Kovel*, 296 F.2d 918 (2d Cir. 1961); CLA-610, *MBIA Ins. Corp. v Countrywide Home Loans, Inc*., 35 Misc. 3d 1205(A), (N.Y. Sup. Ct. 2011) at *6-7.
[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

[19] 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. 23.
[20] RLA-192, *Spread Enters. v. First Data Merchant Services Corp.*, 2013 WL 618744, (E.D.N.Y. 19 Feb. 2013) at *3.
[21] RLA-193, *ECDC Environmental v. New York Marine and General Insurance Co*, 1998 WL 614478 (S.D.N.Y. 4 June 1998) at *8.
[22] CLA-610, *MBIA Ins. Corp. v Countrywide Home Loans, Inc*., 35 Misc. 3d 1205(A), (N.Y. Sup. Ct. 2011) at *6-7.
[23] RLA-193, *ECDC Environmental v. New York Marine and General Insurance Co*, 1998 WL 614478 (S.D.N.Y. 4 June 1998) at *8, citing *United States Postal Service v. Phelps Dodge Ref. Corp.,* 852 F.Supp. 156 (E.D.N.Y.1994).

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."[24]

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.[25]

40. The Tribunal notes that US law, as under many common law systems (albeit there labeled differently), a party may invoke the work product doctrine to protect from disclosure documents that are "prepared in anticipation of litigation."[26] This privilege is intended to keep litigation planning private and thereby prevent its unfair use by an opposing party.[27] Similar to attorney-client privilege, the work-product doctrine extends beyond work created by an attorney to cover the work of consultants and others engaged to assist a party's lawyers.[28]

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.[29] What matters is that a reasonable likelihood or "substantial probability" of litigation existed at the time the document was created.[30]

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.[31] The NAFTA tribunal in *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."[32] The Tribunal considers the application of this practical test appropriate in this arbitration.

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[25] See Tab 2 to the Claimants' privilege log.
[26] Fed.Rule.Civ.Proc. 26(b)(3); CLA-616, *Garrett v. Metropolitan Life Ins. Co*.,1996 WL 325725, (S.D.N.Y. 12 June 1996) at *3.
[27] CLA-616, *Garrett v. Metropolitan Life Ins. Co*.,1996 WL 325725, (S.D.N.Y. 12 June 1996) at *3.
[28] CLA-616, *Garrett v. Metropolitan Life Ins. Co*.,1996 WL 325725, (S.D.N.Y. 12 June 1996) at *3; CLA-618, *Travelers Indem. Co. v. Northrop Grumman Corp*., 2013 U.S. Dist. LEXIS 58856, (S.D.N.Y. 22 Apr. 2013) at *7-8. RLA-193, *ECDC Environmental v. New York Marine and General Insurance Co*, 1998 WL 614478 (S.D.N.Y. 4 June 1998) at *4.
[29] 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.
[30] 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.
[31] Fed.Rule.Civ.Proc. 26(b)(3).
[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.

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).[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 8th and 10th 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.[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.

[36] See the Respondent's privilege log, Row 29, Column Explanation/Comments on Privilege Determination.
[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.[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."[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.[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.[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 inconsistences of which the Claimants now complain. Far from establishing a scheme to take unfair advantage of redactions (as alleged by the Claimants), the Tribunal

[39] *Id*. at pp. 3 and 4.
[40] *Id*. at p. 5.
[41] The Respondent's letter of 11 June 2013, p. 2.
[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)

DENTONS

John J. Hay
Partner

john.hay@dentons.com
D +1 (212) 632-8457
M +1 (203) 536-6758
F +1 (212) 307-3397

Salans FMC SNR Denton Europe LLP
Rockefeller Center
620 Fifth Avenue
New York, NY 10020-2457

T +1 (212) 632-5500
F +1 (212) 632-5555

Salans FMC SNR Denton
dentons.com

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
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,[1] 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" and purports to attach a document titled "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."[2] 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**, *Glamis Gold, Ltd. v. United States*, Decision on Parties' Request for Production of Documents Withheld on Grounds of Privilege, para. 23 (Nov. 17, 2005).

Attorney-Client Privilege

US007644
US011956
US012007
US013108

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 bene 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

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[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

Claimants' Privilege Log

Doc ID	DocDate & Time	Email. From	Email.To	Email.cc	Email. Subject	Author	Title	DocType	Privilege Basis [AC/WP]	Privilege Reasons/Comments	Responses/Objections to Privilege Determinations	Replies to Objections to Privilege Determinations	Tribunal's Decisions
1	Oct. 9, 2009	Chris Hartle	Elaine Copsey; Bruce Clark; Lance Lovelock; Pradeep Sanghvi; Ihor Ruzycky; Larry Rock; Tish Anger; John Snape; Carol Austin; Julie Carriere; Paul Forbes; Mohamed Chan; Jeremy Desai; Paul Gordon	Jeff Yuen; Terri Dodds; Don Harrigan; Phil Russ; Sue Lee-Chan; Janet Burke; Calvin Koerner; Ken Muhvich; Elaine Bunch	EXCHANGE: Latest Update Gap Assessment 10-02			Email	Attorney Client; Work Product	Communication concerning factual investigation and assessment of various quality systems undertaken at the request of Apotex's legal counsel, Buc & Beardsley, LLP ("Counsel") pursuant to an engagement letter dated September 22, 2009, between Counsel and Jeff Yuen & Associates ("JYA"). JYA 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, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions. Information provided by JYA was used by Counsel to tailor Apotex's response to, and communications with, FDA.	See Objections 1 and 2.*	See Reply.**	
1-1							Apotex Update 10-02.xlsx	Excel	Work Product	Observations, mental impressions, factual investigation, and compliance evaluations concerning 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.	See Objections 1 and 2.	See Reply.	
2	Oct. 11, 2009	Chris Hartle	Elaine Copsey; Bruce Clark; Lance Lovelock; Pradeep Sanghvi; Ihor Ruzycky; Larry Rock; Tish Anger; John Snape; Carol Austin; Julie Carriere; Paul Forbes; Mohamed Chan; Jeremy Desai; Paul Gordon	Jeff Yuen; Terri Dodds; Don Harrigan; Phil Russ; Sue Lee-Chan; Janet Burke; Calvin Koerner; Ken Muhvich; Elaine Bunch	EXCHANGE: Latest Update Gap Assessment 10-09			Email	Attorney Client; Work Product	Communication 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, 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.	
2-1							Apotex Update 10-09.xlsx	Excel	Work Product	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 requests for remediation	See Objections 1 and 2.	See Reply.	
2-2							Apotex Update 10-09.xlsx	Excel	Work Product	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 requests for remediation	See Objections 1 and 2.	See Reply.	
3	Oct. 28, 2009	Chris Hartle	Elaine Copsey; Bruce Clark; Lance Lovelock; Pradeep Sanghvi; Ihor Ruzycky; Larry Rock; Tish Anger; John Snape; Carol Austin; Julie Carriere; Paul Forbes; Mohamed Chan; Jeremy Desai; Paul Gordon; Elisabeth Kovacs	Jeff Yuen; Terri Dodds; Don Harrigan; Phil Russ; Sue Lee-Chan; Janet Burke; Calvin Koerner; Ken Muhvich; Elaine Bunch	Exchange: Latest Update Gap Assessment Oct-09			Email	Attorney Client; Work Product	Communication 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, 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.	
3-1							Apotex Update 10-26 (includes Class Categories).xlsx-	Excel	Work Product	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 requests for remediation.	See Objections 1 and 2.	See Reply.	
3-2							Apotex Update 10-26 (includes Class Categories).xlsx	Excel	Work Product	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 requests for remediation.	See Objections 1 and 2.	See Reply.	

* U.S. Objections 1, 2 and 3 are located at Tabs 1, 2, and 3 to Claimants' Privilege Log.
** Apotex's Reply is located at Tab 4 to Claimants' Privilege Log.

Document ID numbers preceded by a dash indicate attachments to emails.

Claimants' Privilege Log

Doc ID	DocDate & Time	Email. From	Email.To	Email.cc	Email. Subject	Author	Title	DocType	Privilege Basis [AC/WP]	Privilege Reasons/Comments	Responses/Objections to Privilege Determinations	Replies to Objections to Privilege Determinations	Tribunal's Decisions
4	Nov. 13, 2009	Calvin Koerner	Christ Hartle; Carol Austin; Paul Gordon		Here is the JYA observations categorized			Email	Work Product	Communication 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, 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.	
4-1							Quality subsystems for categorizing observations	Document	Work Product	Reflecting mental impressions and conceptual framework of quality systems to be evaluated 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.	See Objections 1 and 2.	See Reply.	
4-2							Copy of JYA Master FINAL Presentation Order.xlsx	Excel	Work Product	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 requests for remediation.	See Objections 1 and 2.	See Reply.	

* U.S. Objections 1, 2 and 3 are located at Tabs 1, 2, and 3 to Claimants' Privilege Log.
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Doc ID	DocDate & Time	Email. From	Email.To	Email.cc	Email. Subject	Author	Title	DocType	Privilege Basis [AC/WP]	Privilege Reasons/Comments	Responses/Objections to Privilege Determinations	Replies to Objections to Privilege Determinations	Tribunal's Decisions
5	Oct. 9, 2009	Chris Hartle	Elaine Copsey; Bruce Clark; Lance Lovelock; Pradeep Sanghvi; Ihor Ruzycky; Larry Rock; Tish Anger; John Snape; Carol Austin; Julie Carriere; Paul Forbes; Mohamed Chan; Jeremy Desai; Paul Gordon	Jeff Yuen; Terri Dodds; Don Harrigan; Phil Russ; Sue Lee-Chan; Janet Burke; Calvin Koerner; Ken Muhvich; Elaine Bunch	Re: EXCHANGE: Latest Update Gap Assessment 10-02			Email	Attorney Client; Work Product	Communication 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, 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.	
5-1							Apotex Update 10-02.xls	Excel	Work Product	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 requests for remediation.	See Objections 1 and 2.	See Reply.	
6	Oct.12, 2009	Jeff Yuen	Chris Hartle; Elaine Copsey; Bruce Clark; Lance Lovelock; Pradeep Sanghvi; Ihor Ruzycky; Larry Rock; Tish Anger; John Snape; Carol Austin; Julie Carriere; Paul Forbes; Mohamed Chan; Jeremy Desai; Paul Gordon	Terri Dodds; Don Harrigan; Phil Russ; Sue Lee-Chan; Janet Burke; Calvin Koerner; Ken Muhvich; Elaine Bunch	Re: EXCHANGE: Latest Update Gap Assessment 10-09			Email	Work Product	Chain of communication concerning FDA re-inspection, 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, 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.	

* U.S. Objections 1, 2 and 3 are located at Tabs 1, 2, and 3 to Claimants' Privilege Log.
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Doc ID	DocDate & Time	Email. From	Email.To	Email.cc	Email. Subject	Author	Title	DocType	Privilege Basis [AC/WP]	Privilege Reasons/Comments	Responses/Objections to Privilege Determinations	Replies to Objections to Privilege Determinations	Tribunal's Decisions
7	Oct.17, 2009	Jeff Yuen	Lance Lovelock	Ihor Ruzycky; Julie Carriere; Elaine Copsey; John Snape; Sanjeev Kumar; Tish Anger	N/A			Email	Work Product	Communication attaching presentation concerning FDA standards for cGMP compliance, investigations into deviations of quality systems, and conceptual framework for assessment of quality systems to be 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, 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.	
7-1							Apotex QS + Deviation Training – October 2009.ppt	PowerPoint	Work Product	Presentation regarding FDA standards for cGMP compliance and conceptual framework for assessment of quality systems, prepared in order to assist Counsel in providing legal and regulatory advice to Apotex pursuant to the Engagement.	See Objections 1 and 2.	See Reply.	
8	Sept. 24, 2009	Chris Hartle	Lance Lovelock	Jeff Yuen; Don Harrigan; Phil Russ; Terri Dodds	Interim Report			Email	Attorney Client; Work Product	Chain of communication concerning interim gap assessment, 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.	See Objections 1 and 2.	See Reply.	
9	Oct.16, 2009	Elaine Bunch	Carol Austin		Internal Audit Program			Email	Attorney Client; Work Product	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 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.	See Objections 1 and 2.	See Reply.	
10	Nov. 3, 2009	Terri Dodds	Carol Austin	Jeff Yuen	N/A			Email	Attorney Client; Work Product	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 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.	See Objections 1 and 2.	See Reply.	
11	Nov.18, 2009	Paul Vogel	Mohamed Chan	Jeremy Desai; Pradeep Sanghvi; Carmen Shepard; Kate Beardsley; Calvin Koerner	Re: [redacted]			Email	Attorney-Client; Work Product	Communication with Apotex and Counsel concerning gap assessment of various quality systems and cGMP compliance with respect to [redacted] undertaken at the request of Apotex's legal counsel, Buc & Beardsley, LLP ("Counsel") pursuant to an engagement letter dated September 18, 2009, between Counsel and Paul Vogel Consulting Services LLC. Paul Vogel Consulting Services LLC as 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, cGMP compliance, corrective action remediation plans of products quality systems undertaken solely in response to FDA concerns and to prevent regulatory enforcement actions. Information provided by Paul Vogel Consulting Services LLC was used by Counsel to tailor Apotex's response to, and communications with, FDA.	See Objections 2 and 3.	See Reply.	
12	Nov.12, 2009	Paul Vogel	Pradeep Sangvhi		Re: [redacted]			Email	Work Product	Communication concerning gap assessment of various quality systems and cGMP compliance with respect to [redacted] 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 requests for remediation.	See Objections 2 and 3.	See Reply.	
13	Sept. 23, 2009	Jeff Yuen	Lance Lovelock	Jeremy Desai	Re: Global Product Quality Assessment			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
14	Nov.10, 2009	Chris Hartle	Jeremy Desai	Patricia Lochhead; Barry Sherman; Jack Kay; Jeff Yuen; Carmen Shepard; Kate Beardsley; Paul Vogel	Re: Third Party Quality System Assessment – FINAL REPORT			Email	Work Product; Attorney-Client	Communication chain between JYA, Apotex, and Counsel concerning quality assessment report 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.	See Objections 1, 2, and 3.	See Reply.	

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16	Nov. 9, 2009	Chris Hartle	Jeremy Desai	Patricia Lochhead; Barry Sherman; Jack Kay; Jeff Yuen	Third Party Quality System Assessment – FINAL REPORT			Email	Work Product	Communication attaching quality assessment report 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.	See Objections 1 and 2.	See Reply.	
16-1							Cover Letter to QSA Report.pdf	Letter	Work Product	Letter from Jeff Yuen & Associates to Apotex and Counsel concerning quality site assessments provided at request of Counsel.	See Objections 1 and 2.	See Reply.	
16-2							Final Apotex QSA Report.pdf	Report	Work Product	Report reflecting observations, mental impressions, factual investigation, advice concerning Quality System Assessment Protocol 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.	See Objections 1 and 2.	See Reply.	
16-3							Attachment A.pdf	Report	Work Product	Attachment to report reflecting observations, mental impressions, factual investigation, advice concerning Quality System Assessment Protocol 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.	See Objections 1 and 2.	See Reply.	
16-4							Attachment B.pdf	Report	Work Product	Attachment to report reflecting observations, mental impressions, factual investigation, advice concerning Quality System Assessment Protocol 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.	See Objections 1 and 2.	See Reply.	
16-5							Attachment C.pdf	Report	Work Product	Attachment to report reflecting observations, mental impressions, factual investigation, advice concerning Quality System Assessment Protocol 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.	See Objections 1 and 2.	See Reply.	
16-6							Attachment D.pdf	Report	Work Product	Attachment to report reflecting observations, mental impressions, factual investigation, advice concerning Quality System Assessment Protocol 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.	See Objections 1 and 2.	See Reply.	
17	Jan. 7, 2010	Chris Hartle	Jeremy Desai; Jeff Yuen		QSA Executive Summary Report FINAL			Email	Work Product	Communication attaching report concerning Quality System Assessment Protocol and cGMP compliance, 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.	See Objections 1 and 2.	See Reply.	
17-1								Report	Work Product	Report concerning Quality System Assessment Protocol 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.	See Objections 1 and 2.	See Reply.	
19	Feb. 9, 2010	Chris Hartle	Jeremy Desai; Paul Gordon; Jeff Yuen		Fully Signed CAP Audit Protocol			Email	Work Product	Chain of communication concerning Corrective Action Plan Protocol, 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.	See Objections 1 and 2.	See Reply.	
19-1							JYA QSA Protocol - Signed.pdf	Report	Work Product	Report concerning Corrective Action Plan 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.	See Objections 1 and 2.	See Reply.	

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20	Feb. 2, 2010	Chris Hartle	Paul Gordon; Jeremy Desai	Jeff Yuen	CAP Audit Notification/Confirmation			Email	Work Product	Communication attaching memoranda concerning Corrective Action Plan Protocol, cGMP compliance, and factual investigation and assessment of various quality systems, undertaken 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.	See Objections 1 and 2.	See Reply.	
20-1		Chris Hartle	Jeremy Desai; Paul Gordon	Don Harrigan; Terri Dodds; Sue Lee-Chan; C. Lee			Protocol: JYA-CAP-2010-04	Memorandum	Work Product	Memorandum concerning Corrective Action Plan Protocol, cGMP compliance, and factual investigation and assessment of various quality systems, undertaken 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.	See Objections 1 and 2.	See Reply.	
20-2		Chris Hartle	Jeremy Desai; Paul Gordon	Don Harrigan; Terri Dodds; Sue Lee-Chan; C. Lee			Protocol: JYA-CAP-2010-04	Memorandum	Work Product	Memorandum concerning Corrective Action Plan Protocol, cGMP compliance, and factual investigation and assessment of various quality systems, undertaken 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.	See Objections 1 and 2.	See Reply.	
22	Sept. 29, 2009					Terri Dodds	Observations_Doing_Signet_2009_09_29 final.doc	Report	Work Product	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 requests for remediation.	See Objections 1 and 2.	See Reply.	
24							JYA Observations.doc	Report	Work Product	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 requests for remediation.	See Objections 1 and 2.	See Reply.	
25	Sept. 4, 2009	Jeff Yuen	Jeremy Desai					Letter	Work Product	Letter concerning factual investigation and compliance evaluations of manufacturing processes for [redacted], prepared 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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
26	Oct. 9, 2009	Chris Hartle	Elaine Copsey; Bruce Clark; Lance Lovelock; Pradeep Sanghvi; Ihor Ruzycky; Larry Rock; Tish Anger; John Snape; Carol Austin; Julie Carriere; Paul Forbes; Mohamed Chan; Jeremy Desai; Paul Gordon	Jeff Yuen; Terri Dodds; Don Harrigan; Phil Russ; Sue Lee-Chan; Janet Burke; Calvin Koerner; Ken Muhvich; Elaine Bunch	EXCHANGE: Latest Update Gap Assessment 10-02			Email	Work Product	Communication 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, 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.	
26-1							Apotex Update 10-02.xlsx	Excel	Work Product	Observations, mental impressions, factual investigation, and compliance evaluations concerning 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.	See Objections 1 and 2.	See Reply.	
29	Feb. 26, 2010	Chris Hartle	Jeremy Desai	Jeff Yuen; Paul Gordon; Christopher Hartle; Bruce Clark; Sheila Marner	CAP Audit Status for Feb 26			Email	Work Product	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	See Objections 1 and 2.	See Reply.	

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30	Feb. 11, 2010	Jeff Yuen	Carol Austin; Sarah Papadopoulas; Sabrina Davis	Phil Russ; Bruce Clark; Chris Hartle	CAP Audits			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
31	Oct. 9, 2009	Jeff Yuen	Bruce Clark		FW: Attn: Jeff Yuen - Some Material			Email	Work Product	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 concerns.	See Objections 1 and 2.	See Reply.	
32	Nov. 5, 2009	Jeff Yuen	Bruce Clark		FW: EXCHANGE: Latest Update Gap Assessment 10-09			Email	Work Product	Chain of communication concerning 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.	See Objections 1 and 2.	See Reply.	
33	Jan. 25, 2010	Jeff Yuen	Bruce Clark		FW: [redacted]			Email	Work Product	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 ("HC") concerns.	See Objections 1 and 2.	See Reply.	
34	Feb. 17, 2010	Jeff Yuen	Bruce Clark		FW: [redacted]			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
35	Sept. 16, 2009	Jeff Yuen	Lance Lovelock; Bruce Clark	Ihor Ruzycky	FW: Repacking Between Approved Finished Product Formats			Email	Work Product	Chain of communication concerning corrective action plan, 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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
36	Feb. 4, 2010	Jeff Yuen	Jeremy Desai: Bruce Clark; Carol Austin	Phil Russ; Pradeep Sanghvi	FW: Response to Phone Inquiry			Email	Work Product	Communication reflecting mental impressions and legal advice concerning communication with Canada's Health Products and Food Branch Inspectorate ("HPFBI") 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.	See Objections 1 and 2.	See Reply.	
37	Dec. 3, 2009	Paul Vogel	Carmen Shepard	Kate Beasley; Bruce Clark	Fwd: CBE-30 Meeting Today			Email	Work Product; Attorney-Client	Chain of communications between Apotex, consultants, 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.	See Objections 2 and 3.	See Reply.	
38	June 16, 2010	Paul Vogel	Bernice Tao	Kate Beasley; Carmen Shepard; Bruce Clark; Paul Vogel	Re:			Email	Work Product; Attorney-Client	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.	See Objections 2 and 3.	See Reply.	

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39	Sept. 18, 2009	Jeff Yuen	Bruce Clark	Jeremy Desai	Re: Actions from FDA Meeting			Email	Work Product; Attorney-Client	Chain of communications, including communications with Counsel, concerning factual investigation and concerning review of supplements 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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
40	Sept. 28, 2009	Paul Vogel	Bruce Clark	Kate Beardsley; Carmen Shepard	Re: Another Apotex E-mail			Email	Work Product; Attorney-Client	Chain of communications, including communications with Counsel, concerning factual investigation and concerning review of supplements 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.	See Objections 2 and 3.	See Reply.	
40-1						Paul Vogel	B. Clark CBE Matter	Letter	Work Product; Attorney-Client	Letter provided to Apotex and Counsel regarding assessment of supplement submissions to FDA in 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 Apotex.	See Objections 2 and 3.	See Reply.	
41	4/23/2010	Paul Vogel	Jeremy Desai	Jack Kay; Stephen Simmons; Bruce Clark; Carmen Shepard; Kate Beasley; Paul Vogel; R. Sturgeon; J. Yuen	Re: APOTEX MEETING-MARCH 31ST - FDA Slides - HIGHLY CONFIDENTIAL-PLEASE DO NOT FORWARD			Email	Work Product; Attorney-Client	Observations, mental impressions, factual investigation, and compliance evaluations regarding various quality systems provided to Apotex and Counsel, prepared 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.	See Objections 1, 2, and 3.	See Reply.	
42	April 17, 2010	Paul Vogel	Carol Austin	Bruce Clark; Stephen Simmons; Jeremy Desai; Carmen Shepard; Marc Scheineson; Kate Beardsley; Paul Vogel	Re: Apotex Warning Letter Response - Final			Email	Work Product; Attorney-Client	Communication with Apotex and Counsel concerning response to FDA concerns, 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, solely in response to FDA concerns and to prevent/respond to regulatory enforcement actions.	See Objections 2 and 3.	See Reply.	
43	April 15, 2010	Paul Vogel	Stephen Simmons	Carol Austin; Marc Scheineson; Carmen Shepard; Kate Beardsley; Paul Vogel; Bruce Clark; Jeremy Desai	Re: Apotex Warning Letter Response			Email	Work Product; Attorney-Client	Chain of communications, including communications with Counsel, concerning response to warning letter, 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.	See Objections 2 and 3.	See Reply.	
44	April 15, 2010	Paul Vogel	Jeremy Desai; Stephen Simmons	Carol Austin; Marc Scheineson; Carmen Shepard; Kate Beardsley; Paul Vogel; Bruce Clark	Re: Apotex Warning Letter Response			Email	Work Product; Attorney-Client	Communication to Apotex and Counsel concerning response to FDA warning letter, 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.	See Objections 2 and 3.	See Reply.	
45	Oct. 9, 2009	Jeff Yuen	Bruce Clark		RE: Attn: Jeff Yuen - Some Material			Email	Work Product; Attorney-Client	Communication concerning remediation efforts, 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.	See Objections 1 and 2.	See Reply.	
46	Nov. 16, 2009	Paul Vogel	Bernice Tao	Carmen Shepard; Bruce Clark	Re: CBE-30 retrospective reviews			Email	Work Product; Attorney-Client	Email to Apotex 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.	See Objections 2 and 3.	See Reply.	
47	Nov. 16, 20009	Paul Vogel	Bernice Tao	Carmen Shepard; Bruce Clark	Re: CBE-30 retrospective reviews			Email	Work Product; Attorney-Client	Email to Apotex and Counsel enclosing attachments with observations, mental impressions, and compliance evaluations concerning review of supplements undertaken solely in response to FDA concerns, 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.	See Objections 2 and 3.	See Reply.	

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48	Nov. 16, 2009	Paul Vogel	Bernice Tao	Carmen Shepard; Bruce Clark	Re: CBE-30 retrospective reviews				Work Product; Attorney-Client	Email to Apotex and Counsel providing observations and recommendations 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.	See Objections 2 and 3.	See Reply.	
49	Nov. 16, 2009	Paul Vogel	Bernice Tao	Carmen Shepard; Bruce Clark	Re: CBE-30 retrospective reviews			Email	Work Product; Attorney-Client	Email to Apotex and Counsel enclosing attachments with observations, mental impressions, and compliance evaluations concerning review of supplements undertaken solely in response to FDA concerns, 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.	See Objections 2 and 3.	See Reply.	
50	Dec. 29, 2009	Jeff Yuen	Calvin Koerner; Barry Sherman	Bruce Clark; Pradeep Sanghvi; Jeremy Desai; Elisabeth Kovacs; Colin D'Cunha; Phil Russ; Jeff Derraugh; Ruth Moses-Kogut	RE: [redacted]			Email	Work Product	Communication reflecting mental impressions and assessment of conceptual framework for corrective action efforts, cGMP compliance, and global product quality assessment 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.	See Objections 1 and 2.	See Reply.	
51	Oct. 27, 2009	Paul Vogel	Bernice Tao; Kate Beardsley; Bruce Clark; Carmen Shepard; Jeremy Desai		Re: Cover letter			Email	Work Product; Attorney-Client	Chain of communications, including communications with Counsel, concerning amendment to CBE-30 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA.	See Objections 2 and 3.	See Reply.	
52	Nov. 20, 2009	Paul Vogel	Bruce Clark; Carmen Shepard; Jeremy Desai; Bernice Tao	Kate Beardsley	Re: Draft Executive Summary - manufacturing supplements			Email	Work Product; Attorney-Client	Email to Apotex and Counsel, reflecting legal advice in connection with proposed revisions/updates to FDA reporting requirements, provided at the request of Counsel pursuant to the Engagement, and in anticipation of regulatory enforcement actions	See Objections 2 and 3.	See Reply.	
53	Nov. 20, 2009	Paul Vogel	Jeremy Desai; Carmen Shepard	Kate Beardsley; Bruce Clark; Bernice Tao	Re: Draft Executive Summary - manufacturing supplements			Email	Work Product; Attorney-Client	Email to Apotex and Counsel enclosing attachments with observations, mental impressions, and compliance evaluations concerning review of supplements undertaken solely in response to FDA concerns, 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.	See Objections 2 and 3.	See Reply.	
54	Sept. 5, 2009	Jeff Yuen	Jeremy Desai; Lance Lovelock; Bruce Clark; Sheila Marner; Pradeep Sanghvi; Anthony Khan		RE: FDA SLIDES VERSION 1 - HIGHLY CONFIDENTIAL			Email	Work Product	Observations, mental impressions, and comments regarding global corrective action plan, 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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
55	Oct. 23, 2009	Paul Vogel	Bruce Clark; Carmen Shepard		Re: Follow up to your request			Email	Work Product; Attorney-Client	Email to Apotex 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.	See Objections 2 and 3.	See Reply.	
56	Nov. 18, 2009	Jeff Yuen	Chris Curry; Jeff Derraugh; Carol Austin; Bruce Clark	Calvin Koerner	Re: Follow up to FDA 483 response			Email	Work Product	Communication reflecting review and analysis of requalification protocol in connection with regulatory commitments, 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.	See Objections 1 and 2.	See Reply.	
57	Nov. 20, 2009	Paul Vogel	Bernice Tao	Bruce Clark; Jeremy Desai; Carmen Shepard	Re: Format of Product Summaries - Strike 3?			Email	Work Product; Attorney-Client	Chain of communications between Apotex, consultants, 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.	See Objections 2 and 3.	See Reply.	

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58	Feb. 5, 2010	Jeff Yuen	Bruce Clark		Re: GQCELT Agenda for meeting on 10-February			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
59	Nov. 17, 2009	Jeff Yuen	Pradeep Sangvhi; Calvin Koerner	Jeremy Desai; Bruce Clark	RE: [redacted]			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
60	Nov. 16, 2009	Paul Vogel	Bernice Tao	Carmen Shepard; Jeremy Desai; Bruce Clark	Re: Last five reviews			Email	Work Product; Attorney-Client	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.	See Objections 2 and 3.	See Reply.	
61	June 21, 2010	Paul Vogel	Bernice Tao	Kate Beardsley; Bruce Clark; Paul Vogel; Carmen Shepard	Re: Manufacturing Supplement Cover Letter (version 1) - please review this one includes PQAs			Email	Work Product; Attorney-Client	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.	See Objections 2 and 3.	See Reply.	
62	June 19, 2010	Paul Vogel	Bernice Tao	Kate Beardsley; Bruce Clark; Paul Vogel; Carmen Shepard	Re: Manufacturing Supplement Cover Letter (version 1) - please review this one includes PQAs			Email	Work Product; Attorney-Client	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.	See Objections 2 and 3.	See Reply.	
63	June 18, 2010	Paul Vogel	Bernice Tao	Kate Beardsley; Bruce Clark; Paul Vogel; Carmen Shepard	Re: Manufacturing Supplement Cover Letter			Email	Work Product; Attorney-Client	Chain of communications between Apotex, consultants, and Counsel reflecting legal/regulatory advice with respect to 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.	See Objections 2 and 3.	See Reply.	
64	Nov. 4, 2009	Chris Hartle	Bruce Clark	Jeff Yuen	RE: Materials Questions			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 Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
65	Feb. 24, 2010	Jeff Yuen	Gina Sirianni; Jeff Derraugh; Bernice Tao; Michael Balon; Amy Man Yi Chiu	Bruce Clark	RE: PAI Preparation			Email	Work Product	Communication regarding recommendations concerning FDA preapproval 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.	See Objections 1 and 2.	See Reply.	
66	Jan. 20, 2010	Jeff Yuen	Bruce Clark; Jeff Derraugh	Bernice Tao; Sandra Ostojic; Michael Balon	RE: PAI Preparation			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
67	Sept. 6, 2009	Jeff Yuen	Barry Sherman; Jeremy Desai; Lance Lovelock; Bruce Clark	Jack Kay; Craig Baxter; Shashank Upadhye	Re: PRESENTATION OUTLINE FOR FDA MEETING			Email	Work Product	Communications between Apotex, Counsel, and JYA 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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	

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68	Sept. 6, 2009	Jeff Yuen	Bruce Clark: Jeremy Desai; Lance Lovelock		Re: PRESENTATION OUTLINE FOR FDA MEETING			Email	Work Product	Chain of communications between JYA, Apotex and Counsel 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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
69	Jan. 31, 2010	Jeff Yuen	Paul Gordon; Bruce Clark; Ihor Ruzycky; Larry Rock; Paul Forbes; Peter Eichinger; Pradeep Sanghvi; Ron Davidson; Sheila Marner; Calvin Koerner; Stephen Coady; Carol Austin; Sue Gadsby; Sabrina Davis; Sarah Papadopoulos; Paolo Fiorino; Joanne Campbell; Phil Tackett; Ann Holden; Elaine Copsey; Anthony Khan; Catherine Rumsby; Chris Hartle	Jeremy Desai	RE: Q6 Etobicoke Focus Review - Meeting Minutes			Email	Work Product	Communication reflecting mental impressions and advice concerning corrective actions, continuous improvement initiatives, and CAP, 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.	
71	Feb. 24, 2010	Jeff Yuen	Bernice Tao	Bruce Clark; Kiran Krishnan	RE: Question			Email	Work Product	Communication concerning regulatory compliance with respect to preapproval 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.	See Objections 1 and 2.	See Reply.	
72	Feb. 17, 2010	Jeff Yuen	Ann Holden	Pradeep Sanghvi; Chris Hartle; Bruce Clark	RE: R&D to Commercial CAP Document			Email	Work Product	Observations, mental impressions, and compliance evaluations regarding CAP, 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.	See Objections 1 and 2.	See Reply.	
73	Feb. 11, 2010	Jeff Yuen	Sarah Papadopoulos; Barry Sherman; Bruce Clark; Jeremy Desai; Ihor Ruzycky; Jack Kay; Pradeep Sanghvi; Jeff Watson; Gordon Fahner; Peter Hardwick; Craig Baxter; Steven Lydeamore	Phil Russ; Carol Austin; Yana Kaspariants; Jeff Derraugh	RE: Recall Committee via Email			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	

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74	Sept. 16, 2009	Jeff Yuen	Lance Lovelock; Bruce Clark	Ihor Ruzycky	RE: Repacking Between Approved Finished Product Formats			Email	Work Product	Communication reflecting observations, mental impressions, and compliance evaluations related to repacked 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
75	Oct. 22, 2009	Paul Vogel	Bernice Tao	Bruce Clark, Jeremy Desai; Kate Beardsley; Carmen Shepard	Re: Request for supplement			Email	Work Product; Attorney-Client	Chain of communication with Apotex and Counsel requesting 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 cGMP compliance, and to respond to FDA concerns.	See Objections 2 and 3.	See Reply.	
76	Oct. 18, 2009	Paul Vogel	Bernice Tao	Bruce Clark; Jeremy Desai; Kate Beardsley; Paul Vogel; Carmen Shepard	Re: Request for supplement			Email	Work Product; Attorney-Client	Chain of communication with Apotex and Counsel requesting 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 cGMP compliance, and to respond to FDA concerns.	See Objections 2 and 3.	See Reply.	
77	Feb. 4, 2010	Jeff Yuen	Paul Gordon; Bruce Clark; Ihor Ruzycky; Larry Rock; Paul Forbes; Peter Eichinger; Pradeep Sanghvi; Ron Davidson; Sheila Marner; Calvin Koerner; Stephen Coady; Carol Austin; Sue Gadsby; Sabrina Davis; Sarah Papadopoulos; Paolo Fiorino; Joanne Campbell; Anthony Khan; Phil Tackett; Ann Holden; Elaine Copsey; Catherine Rumsby; Chris Hartle; Jeff Derraugh	Jeremy Desai	RE: Resources For CAP Audit			Email	Work Product	Chain of communications concerning CAP 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
78	Feb. 5, 2010	Jeff Yuen	Pradeep Sanghvi; Carol Austin; Jeremy Desai; Bruce Clark	Phil Russ; Elisabeth Kovacs	RE: Response to Phone Inquiry			Email	Work Product	Communications providing regulatory and compliance advice with respect to [redacted], 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.	See Objections 1 and 2.	See Reply.	
79	Oct. 1, 2009	Paul Vogel	Bruce Clark	Carmen Shepard	RE: 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 cGMP compliance.	See Objections 2 and 3.	See Reply.	
80	Feb. 25, 2010	Jeff Yuen	Pradeep Sanghvi; Ihor Ruzycky; Bruce Clark; Phil Russ	Jeremy Desai	RE: Restricted Product Process Proposal			Email	Work Product	Communication reflecting mental impressions and conceptual framework of quality systems to be evaluated 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.	

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81	Nov. 22, 2009	Jeff Yuen	Bruce Clark; Calvin Koerner; Paul Gordon; Jeremy Desai; Carol Austin; Tom Mitten; Ray Coates; Jeff Derraugh; Phil Russ; Ihor Ruzycky; Paul Forbes; Tish Anger; Chris Hartle		RE: REVISED ^ Apotex Q6 Quality System Corrective Action Plan CK1			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
82	Feb. 12, 2010	Jeff Yuen	Bernice Tao; Steven Lydeamore; Jeff Derraugh; Paul Forbes; Wan Jiang; Jeremy Desai; Bruce Clark; Sandra Ostojic;		RE: RH list of pending products - Recommend-ations after meeting			Email	Work Product	Chain of communications evaluating preparation for FDA preapproval 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
83	Feb. 23, 2010	Jeff Yuen	Pradeep Sanghvi; Bruce Clark; Ihor Ruzycky	Carol Austin	RE: Summary from HPFBI Visit Feb 22/10			Email	Work Product	Chain of communications concerning quality control procedures and processes, related 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.	See Reply.	
84	Dec. 8, 2009	Paul Vogel	Carmen Shepard	Jeremy Desai; Bernice Tao; Bruce Clark; Kate Beardsley	Re: Telephone interview re: CMC supplement review process			Email	Work Product; Attorney-Client	Communication with Apotex and Counsel reflecting mental 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 2 and 3.	See Reply.	
85	Mar. 12, 2010	Jeff Yuen	Sabrina Davis	Bruce Clark	RE: URGENT >> Interim 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 Apotex legal advice regarding regulatory compliance and to address FDA concerns.	See Objections 1 and 2.	See Reply.	
88	Feb. 16, 2010	Jeff Yuen	Bruce Clark	Chris Hartle	N/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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
89	Nov. 4, 2009	Jeff Yuen	Bruce Clark	Calvin Koerner	N/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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
90	Sept. 22, 2009	Jeff Yuen	Jeremy Desai	Lance Lovelock; Ihor Ruzycky; Bruce Clark; Terri Dodds; Donald Harrigan; Chris Hartle	N/A			Email	Work Product	Communication concerning review and analysis of quality systems gap assessments and remediation efforts, and enclosing 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
90-1							Apotex Request for Key Personnel - Quality Systems Gap AND Remediation Support.xls	Excel	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.	See Reply.	
93	June 10, 2010	Janet Burke	Jeff Derraugh		[redacted]			Email	Work Product	Chain of communications concerning factual investigation and compliance evaluations 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.	See Objections 1 and 2.	See Reply.	
94	May 20, 2010	Jeff Yuen	Jeff Derraugh		FW:			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.	See Objections 1 and 2.	See Reply.	

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95	Mar. 5, 2010	Jeff Yuen	Jeremy Desai; Paul Gordon	Jeff Derraugh; Stephen Simmons; Steven Lydeamore	N/A			Email	Work Product	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, 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.	
96	Feb. 22, 2010	Jeff Yuen	Cynthia Lee; Jeff Derraugh		Fw:			Email	Work Product	Communication concerning quality control procedures, gap review, 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 Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
97	May 20, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons		FW:			Email	Work Product	Chain of communications reflecting evaluations and observations with respect to recent changes to US, Australian, and EU law, 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.	See Objections 1 and 2.	See Reply.	
98	May 17, 2010	Jeff Yuen	Jeff Derraugh		FW:			Email	Work Product	Communication concerning quality control procedures, implementation of CAP, 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.	See Objections 1 and 2.	See Reply.	
99	July 20, 2010	Jeff Yuen	Stephen Simmons	Jeff Derraugh; Bruce Clark; Bernice Tao	FW:			Email	Work Product	Chain of communications concerning investigation and report 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 and to address FDA concerns.	See Objections 1 and 2.	See Reply.	
100	March 5, 2010	Jeff Yuen	Jeff Derraugh	Phil Russ	FW: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
100-1							RE: CCP Concurrence - SOD update	Email	Work Product	Communication 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
101	Sept. 30 , 2010	Jeff Yuen	Stephen Simmons; Jeff Derraugh		FW: [redacted]			Email	Work Product	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 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.	
102	July 21, 2010	Jeff Yuen	Jeff Derraugh	Sandra Ostojic; Janet Burke; Sue Lee-Chan	FW: INTERNAL AUDIT REPORTS			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
102-1							ApotexRH_Feb2010_CJL_-_Feb._2010internalauditreport.doc	Document	Work Product	Letter containing observations, mental impressions and recommendations regarding audit of Client, 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.	See Objections 1 and 2.	See Reply.	
102-2							ApotexRH_June2010_CJL_internalauditreport.doc	Document	Work Product	Letter containing observations, mental impressions and recommendations regarding audit of Client, 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.	See Objections 1 and 2.	See Reply.	

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102-3							ApotexRH_Mar2010_CJL_labnotebookreviewinternalauditreport.xlsx	Excel	Work Product	Spreadsheet containing comments and observations resulting from factual investigation, 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.	See Objections 1 and 2.	See Reply.	
102-4							ApotexRH_Mar2010_CJLinternalauditreport.doc	Document	Work Product	Letter containing results of audit/factual investigation, 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.	See Objections 1 and 2.	See Reply.	
103	July 22, 2010	Jeff Yuen	Jeff Derraugh; Sandra Ostojic	FW: INTERNAL AUDIT REPORTS				Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
105	June 27, 2010	Terri Dodds	Jeff Derraugh		FW: nagging questions			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
107	Feb. 23, 2010	Jeff Yuen	Jeremy Desai	Jeff Derraugh	FW: PAI Preparation 2010 Deficiency list.xlsx			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
107-1							PAI Preparation 2010 Deficiency list.xlsx	Excel	Work Product	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.	See Objections 1 and 2.	See Reply.	
108	June 29, 2010	Calvin Koerner	Jeff Derraugh		Re: PAI Product List for FDA			Email	Work Product	Review and analysis of and recommendations concerning submission to FDA, 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.	See Objections 1 and 2.	See Reply.	
109	April 8, 2010	Jeff Yuen	Cynthia Lee; Jeff Derraugh		FW: Response(Draft) to JYA Internal Audit Report			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
110	March 11, 2010	Jeff Yuen	Jeff Derraugh		Re:			Email	Work Product	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, 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.	
111	July 25, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons		RE: 285 Garyray			Email	Work Product	Chain of communications 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
112	July 22, 2010	Jeff Yuen	Jeff Derraugh		Re: airlock dwgs 1340 2309			Email	Work Product	Chain of communications concerning quality control procedures and facility remediation, 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.	See Objections 1 and 2.	See Reply.	

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113	Aug. 13, 2010	Jeff Yuen	Jeff Derraugh		RE: FDA PAI review			Email	Work Product	Communication regarding observations concerning regulatory 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
116	June 25, 2010	Sue Lee-Chan	Jeff Derraugh; Janet Burke	Jeff Yuen	Re: PAI Product List for FDA			Email	Work Product	Review and analysis of and recommendations concerning submission to FDA, 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.	See Objections 1 and 2.	See Reply.	
117	Nov. 1, 2010	Jeff Yuen	Jeff Derraugh		Re: Question			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations 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.	See Objections 1 and 2.	See Reply.	
118	July 22, 2010	Jeff Yuen	Jeff Derraugh		Re: [redacted]			Email	Work Product	Chain of communications 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
119	July 25, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons		RE: [redacted]			Email	Work Product	Observations and mental impressions concerning factual investigation and compliance evaluations regarding various quality systems, 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 requests for remediation.	See Objections 1 and 2.	See Reply.	
120	Mar. 9, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	Chain of communications 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
121	July 25, 2010	Jeff Yuen	Cynthia Lee	Jeff Derraugh	N/A			Email	Work Product	Communication 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
122	July 12, 2010	Jeff Yuen	Jeff Derraugh		RE: Discussion			Email	Work Product	Chain 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
123	Mar. 1, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	Communication 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
124	July 22, 2010	Jeff Yuen	Jeff Derraugh		RE: Heads Up			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, 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.	
125	July 23, 2010	Jeff Yuen	Jeff Derraugh		RE: PAI Product List - Final - With Gaps Identified with colour.xlsx			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	

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127	Mar. 7, 2010	Elaine Bunch	Jeff Yuen	Jeff Derraugh	Notebook review			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
128	Mar. 9, 2010	Jeff Yuen	Jeff Derraugh		RE:			Email	Work Product	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, 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.	
130	Feb. 22, 2010	Jeff Yuen	Jeff Derraugh		RE:			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
131	May 20, 2010	Jeff Yuen	Wan Jiang	Jeff Derraugh	Re:			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
132	Mar. 5, 2010	Jeff Yuen	Jeff Yuen; Jeremy Desai; Paul Gordon	Stephen Simmons; Steven Lydeamore; Paul Forbes; Wan Jiang	RE:			Email	Work Product	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, 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.	
134	Mar. 10, 2010	Jeff Yuen	Jeff Derraugh		RE:			Email	Work Product	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, 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.	
135	July 21, 2010	Jeff Yuen	Jeff Derraugh; Sharon Botes	Stephen Simmons; Sarah Papadopoulos	RE: [redacted]			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations concerning [redacted], 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.	
136	July 21, 2010	Jeff Yuen	Sarah Papadopoulos; Stephen Simmons; Jeff Derraugh; Sharon Botes		RE: [redacted]			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations concerning [redacted], 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.	
137	July 20, 2010	Jeff Yuen	Stephen Simmons; Sharon Botes; Jeff Derraugh	Sarah Papadopoulos	RE: [redacted]			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations concerning [redacted], 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.	
138	July 20, 2010	Jeff Yuen	Jeff Derraugh; Sue Lee-Chan		FW:			Email	Work Product	Chain of communications concerning investigation and report 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 and to address FDA concerns.	See Objections 1 and 2.	See Reply.	
139	Oct. 19, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	Chain of communications concerning quality control procedures and providing guidance on 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
140	July 26, 2010	Jeff Yuen	Jeff Derraugh; Terri Dodds		RE: another question			Email	Work Product	Chain of communications concerning quality control procedures and providing guidance on 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	

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141	May 3, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
142	March 8, 2010	Jeff Yuen	Jeff Derraugh		RE Apotex Field Alert - Follow Up - [redacted]			Email	Work Product	Communication reflecting mental impressions recommendations and observations concerning FAR 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
143	Feb. 20, 2010	Cynthia Lee	Jeff Derraugh	Jeff Yuen	RE: Apotex report			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 Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
144	July 30, 2010	Jeff Yuen	Jeff Derraugh	Stephen Simmons	RE: [redacted]		Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
145	July 14, 2010	Jeff Yuen	Sue Lee-Chan; Jeff Derraugh		RE: [redacted]			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 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.	See Objections 1 and 2.	See Reply.	
146	July 26, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons	Cynthia Lee	RE: [redacted]			Email	Work Product	Chain of communications 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 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.	See Objections 1 and 2.	See Reply.	
147	Mar. 5, 2010	Jeff Yuen	Jeff Derraugh		Re: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
148	May 11, 2010	Jeff Yuen	Stephen Simmons; Jeff Derraugh	Bruce Clark	RE: Construction at RH Site			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
149	May 20, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted] for 2:30 PM meeting today			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
150	May 20, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted] for 2:30 PM meeting today			Email	Work Product	Chain of 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 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.	See Objections 1 and 2.	See Reply.	
151	May 11, 2010	Jeff Yuen	Jeff Derraugh		RE: Design of Air Direction for sterile/non sterile			Email	Work Product	Communication 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 Apotex, 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.	

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152	July 12, 2010	Jeff Yuen	Jeff Derraugh		RE: Discussion			Email	Work Product	Chain of communications reflecting recommendations and observations 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
153	June 11, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons		RE: Discussion over JYA report for RH site			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations concerning regulatory 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
154	May 28, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	Chain of communications reflecting mental impressions, analysis, recommendations and observations concerning regulatory 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
155	June 29, 2010	Jeff Yuen	Jeff Derraugh; Cynthia Lee		RE: [redacted] in logbooks			Email	Work Product	Chain of communications reflecting mental impressions, analysis, recommendations and observations concerning regulatory 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
156	July 23, 2010	Jeff Yuen	Jeff Derraugh		RE: Emailing: [redacted]			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations concerning regulatory 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
157	Mar. 29, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
158	Aug. 13, 2010	Jeff Yuen	Jeff Derraugh		RE: FDA PAI review			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations concerning regulatory 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
159	April 1, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons		RE: [redacted] GMP Investigation Report update - CONFIDENTIAL			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
160	April 1, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted] GMP Investigation Report update - CONFIDENTIAL - Update			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
161	June 15, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons	Bruce Clark	RE: Follow-up to the Deviation report in R&D			Email	Work Product	Chain of communications concerning evaluation of quality control procedures, internal audit 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.	See Objections 1 and 2.	See Reply.	
162	July 9, 2010	Jeff Yuen	Calvin Koerner; Amir Siddiqui; Jeff Derraugh		RE Gap List			Email	Work Product	Chain of communications concerning implementation of quality control procedures, remediation efforts, 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.	See Objections 1 and 2.	See Reply.	

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164	April 11, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
165	July 14, 2010	Jeff Yuen	Jeff Derraugh		RE: Higher GMP consciousness			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
166	April 3, 2010	Jeff Yuen	Jeff Derraugh		RE: Initial GMP Assessment			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
167	July 22, 2010	Jeff Yuen	Sandra Ostojic; Jeff Derraugh	Janet Burke; Sue Lee-Chan	RE: INTERNAL AUDIT REPORTS			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
168	March 16, 2010	Jeff Yuen	Jeff Derraugh		RE: Investigation Report - [redacted]			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
169	May 14, 2010	Jeff Yuen	Jeff Derraugh		RE: JYA CONSULTANTS			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
170	Oct. 22, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted] Meeting Minutes			Email	Work Product	Communication containing recommendations and observations concerning regulatory 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
171	Mar. 21, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted] March 22			Email	Work Product	Communication reflecting recommendations and observations concerning regulatory compliance and internal audits, 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.	
172	April 7, 2010	Jeff Yuen	Jeff Derraugh; Sue Lee-Chan	Cynthia Lee	RE: march method review report			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 Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
173	June 3, 2010	Ken Muhvich	Jeff Derraugh		RE: [redacted] Update			Email	Work Product	Chain of communications reflecting mental impressions and evaluation of factual investigation, 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.	See Objections 1 and 2.	See Reply.	
174	June 8, 2010	Jeff Yuen	Jeff Derraugh		RE: Meeting to discuss [redacted]			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	

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175	March 29, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
176	March 5, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
177	Sept. 15, 2010	Jeff Yuen	Jeff Derraugh		Re: [redacted]			Email	Work Product	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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
178	Feb. 24, 2010	Jeff Yuen	Jeff Derraugh		RE: PAI Preparation			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
179	Feb. 24, 2010	Jeff Yuen	Gina Sirianni; Jeff Derraugh; Bernice Tao; Michael Balon; Amy Man Yi Chiu	Bruce Clark	RE: PAI Preparation (4)			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
180	Feb. 23, 2010	Jeff Yuen	Bernice Tao; Jeff Derraugh; Michael Balon; Amy Man Yi Chiu	Gina Sirianni	RE: PAI Preparation 2			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
181	Feb. 23, 2010	Jeff Yuen	Jeff Desai	Jeff Derraugh	RE: PAI Preparation 2010 Deficiency list.xlsx			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
182	July 23, 2010	Jeff Yuen	Jeff Derraugh		RE: PAI Product List - Final - With Gaps Identified with colour.xlsx			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
183	June 29, 2010	Jeff Yuen	Sue Lee-Chan; Jeff Derraugh; Janet Burke; Calvin Koerner	Terri Dodds	RE: PAI Product List for FDA			Email	Work Product	Review and analysis of and recommendations concerning submission to FDA, 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.	See Objections 1 and 2.	See Reply.	
184	Aug. 11, 2010	Jeff Yuen	Jeff Derraugh; Sharon Botes		Re: [redacted]			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
185	May 19, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons		RE: [redacted]			Email	Work Product	Chain of communications concerning factual investigation and quality control procedures to [redacted], 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.	See Objections 1 and 2.	See Reply.	

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186	July 22, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons		RE: [redacted]			Email	Work Product	Chain of communications concerning factual investigation and quality control procedures to [redacted], 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.	See Objections 1 and 2.	See Reply.	
187	April 6, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons; Kant Ragbeer; Samba Sow; Phil Russ		RE: [redacted]			Email	Work Product	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 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.	See Objections 1 and 2.	See Reply.	
188	March 5, 2010	Jeff Yuen	Jeff Derraugh	Stephen Simmons	RE: [redacted]			Email	Work Product	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, 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.	
189	Feb. 28, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted] update Feb 27th update 1			Email	Work Product	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 Apotex, 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.	
190	March 5, 2010	Jeff Yuen	Tracey Roberts	Carol Austin; Frederick Mayer; Cheryl Meads; Jeff Derraugh; Phil Russ; Stephen Simmons	RE: Q6 - Overdue APRs - Proposal to Carry-over to New Annual Schedule (Apr 2010 - Mar 2011)			Email	Work Product	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 requests for remediation.	See Objections 1 and 2.	See Reply.	
191	March 8, 2010	Jeff Yuen	Jeff Derraugh		RE: Q6 Update			Email	Work Product	Communication concerning corrective actions, continuous improvement initiatives, and CAP, 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.	
192	March 30, 2010	Jeff Yuen	Jeff Derraugh		RE Quality Leadership Meeting			Email	Work Product	Communication concerning 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.	See Objections 1 and 2.	See Reply.	
193	Oct. 18, 2010	Jeff Yuen	Jeff Derraugh		RE: Quality Signatures on Documents			Email	Work Product	Communication reflecting mental impressions and advice concerning corrective actions, continuous improvement initiatives, and CAP, 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.	
194	Oct. 30, 2010	Jeff Yuen	Jeff Derraugh		Re: Question			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations 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.	See Objections 1 and 2.	See Reply.	
195	March 24, 2010	Jeff Yuen	Jeff Derraugh		Re: Quick opinion			Email	Work Product	Communication reflecting recommendations and observations concerning compliance with regulatory requirements, 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.	
196	June 11, 2010	Janet Burke	Jeff Derraugh		Re: Re:			Email	Work Product	Chain of communications concerning factual investigation, 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.	See Objections 1 and 2.	See Reply.	

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197	May 20, 2010	Jeff Yuen	Jeff Derraugh		Re: Re:			Email	Work Product	Chain of 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
198	April 14, 2010	Terri Dodds	Lan Huong Duong	Jeff Yuen; Jeff Derraugh	RE: [redacted] - weekly meeting			Email	Work Product	Communication concerning factual investigation and compliance evaluations, 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.	See Objections 1 and 2.	See Reply.	
199	Feb. 23, 2010	Jeff Yuen	Jeff Derraugh; Cynthia Lee	Sue Lee-Chan	RE: Richmond Hill			Email	Work Product	Communication concerning factual investigation and review of quality control procedures, 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.	See Objections 1 and 2.	See Reply.	
200	May 10, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	Communication concerning recommendations and observations related to facility remediation, 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 requests for remediation.	See Objections 1 and 2.	See Reply.	
201	July 25, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons		RE: [redacted] Review			Email	Work Product	Observations and mental impressions concerning factual investigation and compliance evaluations regarding various quality systems, 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 requests for remediation.	See Objections 1 and 2.	See Reply.	
202	May 12, 2010	Jeff Yuen	Jeff Derraugh		RE [redacted]			Email	Work Product	Communication concerning recommendations and observations related to facility remediation, 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 requests for remediation.	See Objections 1 and 2.	See Reply.	
203	Aug. 31, 2010	Jeff Yuen	Sharon Botes	Carol Austin; Jeff Derraugh	RE: Scanned Documents			Email	Work Product	Communication concerning response to FDA concerns, 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, solely in response to FDA concerns and to prevent/respond to regulatory enforcement actions.	See Objections 1 and 2.	See Reply.	
204	March 27, 2010	Jeff Yuen	Jeff Derraugh	Stephen Simmons	RE: [redacted]			Email	Work Product	Communication 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 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.	See Objections 1 and 2.	See Reply.	
205	March 26, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	Communication reflecting recommendations and observations, 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.	See Objections 1 and 2.	See Reply.	
206	April 28, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	Communication concerning evaluation of quality control procedures, 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.	See Objections 1 and 2.	See Reply.	
207	July 19, 2010	Jeff Yuen	Jeff Derraugh		Re: [redacted]			Email	Work Product	Mental impressions concerning quality control procedures and regulatory 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
208	July 16, 2010	Jeff Yuen	Jeff Derraugh; Stephen Simmons	Terri Dodds; Douglas Reid; Sharon Botes	Re: [redacted] (2)			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	

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209	July 15, 2010	Jeff Yuen	Jeff Derraugh	Terri Dodds	Re: [redacted](3)			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
210	July 15, 2010	Jeff Yuen	Jeff Derraugh; Terri Dodds		Re: [redacted] (4)			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
211	July 19, 2010	Jeff Yuen	Douglas Reid	Jeff Derraugh; Bob Sjostrom	Re: [redacted] (5)			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
212	July 17, 2010	Jeff Yuen	Jeff Derraugh; Terri Dodds		Re: [redacted] 4			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
213	March 4, 2010	Jeff Yuen	Stephen Simmons; Jeff Derraugh		RE: Strategic Thoughts on the [redacted]			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
214	May 29, 2010	Jeff Yuen	Jeff Derraugh		RE: Third Party Auditing			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
215	June 9, 2010	Jeff Yuen	Jeff Derraugh; Phil Russ; Chris Curry; Samba Sow; Cheryl Meads; Elaine Copsey	Kant Ragbeer; Stephen Simmons	RE: [redacted]position paper			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, 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.	
216	May 14, 2010	Jeff Yuen	Jeff Derraugh		RE: Update on [redacted]			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
218	June 30, 2010	Jeff Yuen	Jeff Derraugh; Jeremy Desai; Bruce Clark	Stephen Simmons; Wan Jiang	RE: Warning Letter			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
220	Aug. 16, 2010	Jeff Yuen	Jeff Derraugh		RE: [redacted]			Email	Work Product	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
221	March 15, 2010	Jeff Yuen	Sarah Papadopoulos; Jeff Derraugh	Stephen Simmons	RE: General FAR Questions			Email	Work Product	Communication reflecting recommendations and observations concerning FAR 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	

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223	Feb. 22, 2010	Jeff Yuen	Tracey Roberts	Carol Austin; Frederick Mayer; Cheryl Meads; Jeff Derraugh; Phil Russ	RE: Q6 - Overdue APRs - Proposal to Carry-over to New Annual Schedule (Apr 2010 - Mar 2011)			Email	Work Product	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 requests for remediation.	See Objections 1 and 2.	See Reply.	
225	July 10, 2010	Jeff Yuen	Jeff Derraugh	Stephen Simmons; Sue Lee-Chan; Cynthia Lee; Janet Burke; Wan Jiang; Bruce Clark; Pradeep Sanghvi	N/A			Email	Work Product	Cover email attaching summary of site inspection and audit, as described below.	See Objections 1 and 2.	See Reply.	
225-1							Apotex - PrePAI Trip Report - July 2010 - JLB.doc	Document	Work Product	Letter reflecting mental impressions and observations, and summarizing results of site inspection 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 to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.	See Objections 1 and 2.	See Reply.	
226	May 19, 2010	Jeff Yuen	Elaine Copsey	Elisabeth Kovacs; Wan Jiang; Sue Lee-Chan; Cynthia Lee; Stephen Simmons; Phil Russ; Samba Sow; Jeff Derraugh; Bruce Clark				Email	Work Product	Communication reflecting mental impressions, recommendations and observations concerning procedures and compliance with 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.	See Objections 1 and 2.	See Reply.	
226-1						Sue Lee-Chan	RH Internal Audit - Labs 2010.PDF	Document	Work Product	Letter summarizing reviews of various method validation packages, 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.	See Objections 1 and 2.	See Reply.	
228	March 5, 2010	Jeff Yuen	Jeremy Desai; Paul Gordon	Jeff Derraugh; Stephen Simmons; Steven Lydeamore	N/A			Email	Work Product	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, 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.	
228-1							PAI Gap List 030410.xls	Excel	Work Product	Spreadsheet incorporating evaluation of and recommendations 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.	See Objections 1 and 2.	See Reply.	
229	March 2, 2010	Jeff Yuen	Jeff Derraugh		N/A				Work Product	Communication 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, 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.	
230	March 24, 2010	Janet Burke	Jeff Derraugh		N/A			Email	Work Product	Cover email attaching summary of results of audit/factual investigation, as described below.	See Objections 1 and 2.	See Reply.	
230-1						Janet Burke	PrePAI Report Apotex Feb 2010 - JLB.doc	Document	Work Product	Letter presenting summary of results of audit/factual investigation, and recommendations for corrective actions, 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.	See Objections 1 and 2.	See Reply.	
230-2						Janet Burke	February 2010 jibv sig page.pdf	PDF	Work Product	Letter presenting summary of results of audit/factual investigation, and recommendations for corrective actions, 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.	See Objections 1 and 2.	See Reply.	
300	Jan. 28, 2010				Global Research, Development & Quality	Calvin Koerner		Letter	Work Product	Letter evaluating quality control procedures and providing guidance concerning ongoing quality control initiatives, 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.	See Objections 1 and 2.	See Reply.	

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401	Feb. 12, 2010	Jeff Yuen	Sabrina Davis; Phil Russ; Carol Austin; Sarah Papadopoulos	Frederick Mayer; Chris Hartle; Bruce Clark	RE: CAP Audits			Email	Work Product	Chain of communications 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	See Objections 1 and 2.	See Reply.	
402	May 19, 2010	Jeff Yuen	Stephen Simmons; Carol Austin; Jeff Derraugh	Sarah Papadopoulos	RE: [redacted]			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations concerning FAR 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
403	Feb. 5, 2010	Jeff Yuen	Phil Russ; Sarah Papadopoulos; Carol Austin		Re: [redacted]			Email	Work Product	Chain of communications concerning quality control procedures and compliance with regulatory requirements, including [redacted], 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.	See Objections 1 and 2.	See Reply.	
404	Feb. 16, 2010	Jeff Yuen	Paul Gordon; Phil Russ; Jeremy Desai	Sarah Papadopoulos; Catherine Rumsby	RE: Q6 Team Escalation: Deviations / CAPA			Email	Work Product	Chain of communications 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	See Objections 1 and 2.	See Reply.	
405	Feb. 17, 2010	Jeff Yuen	Chris Hartle; Carol Austin; Tam Dang; Tracey Roberts; Sanjeev Kumar; Rohini Roy; Sarah Papadopoulos; Claudia Vari; Phil Russ; Paul Gordon		RE: Quality Systems Team			Email	Work Product	Chain of communications concerning assessment and implementation of CAPA 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	See Objections 1 and 2.	See Reply.	
406	Feb. 5, 2010	Jeff Yuen	Carol Austin; Chris Hartle	Calvin Koerner; Calvin Koerner; Tam Dang, Tracey Roberts; Rohini Roy; Claudia Vari; Sarah Papadopoulos; Phil Russ; Sanjeev Kumar	RE: Resources For CAP Audit			Email	Work Product	Chain of communications concerning CAP 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
410	May 4, 2010	Jeff Yuen	Sarah Papadopoulos; Jeff Derraugh	Stephen Simmons	RE: Complaint Resources [redacted]			Email	Work Product	Chain of communications 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
411	Sep. 15, 2010	Jeff Yuen	Sarah Papadopoulos		RE: [redacted]s leaving			Email	Work Product	Chain of communications 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 cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
412	Feb. 10, 2010	Jeff Yuen	Jeff Derraugh; Sarah Papadopoulos	Steven Lydeamore; Bob Sjostrom; Roger Diamond	RE: [redacted]			Email	Work Product	Communication reflecting mental impressions, analysis, recommendations and observations concerning [redacted], 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.	
414	Feb. 2, 2010	Jeff Yuen	Phil Russ; Sarah Papadopoulos; Carol Austin	Ihor Ruzycky; Jeremy Desai; Rohini Roy	RE: [redacted]			Email	Work Product	Chain of communications concerning quality control procedures and compliance with regulatory requirements, [redacted] 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.	See Objections 1 and 2.	See Reply.	
415	Feb. 5, 2010	Jeff Yuen	Sarah Papadopoulos; Phil Russ; Carol Austin		RE: [redacted]			Email	Work Product	Chain of communications concerning quality control procedures and compliance with regulatory requirements, including [redacted], 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.	See Objections 1 and 2.	See Reply.	

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417	June 13, 2010	Jeff Yuen	Sarah Papadopoulos	Grimolda Botelho; Stephen Simmons	RE: Recall/Field Alert Workshops			Email	Work Product	Chain of communication 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 Apotex, 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.	
418	May 20, 2010	Jeff Yuen	Sarah Papadopoulos		RE: [redacted]			Email	Work Product	Chain of communications reflecting mental impressions, factual investigation, 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 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.	See Objections 1 and 2.	See Reply.	
421	Nov. 3. 2009	Jeff Yuen	Pradeep Sanghvi; Jeff Derraugh; Bruce Clark	Ihor Ruzycky; Larry Rock; Calvin Koerner	RE: [redacted] facilities			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, 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.	
422	May 2, 2010	Jeff Yuen	Pradeep Sanghvi		RE: Couple of Questions			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 Apotex, 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.	
423	Feb. 23, 2010	Jeff Yuen	Pradeep Sanghvi		RE: [redacted]			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, 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.	
424	Sep. 8, 2009	Jeff Yuen	Lance Lovelock; Don Harrigan; Pradeep Sanghvi	Jeremy Desai; Ihor Ruzycky; Chris Curry	RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
425	Feb. 23, 2010	Jeff Yuen	Pradeep Sanghvi	Elisabeth Kovacs	RE: [redacted]			Email	Work Product	Communication concerning recommended 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 Apotex, 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.	
427	May 5, 2010	Jeff Yuen	Stephen Simmons; Phil Russ; Cheryl Meads; Samba Sow; Jeff Derraugh	Jeremy Desai; Ihor Ruzycky; Bruce Clark; Pradeep Sanghvi	N/A			Email	Work Product	Communication in connection with services 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.	See Objections 1 and 2.	See Reply.	
428	Nov. 7, 2009	Terri Dodds	Ken Factor; Robert Brunton; Paul Forbes; Paolo Fiorino		RE: FDA observation on Master Packaging Documents			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, 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.	

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429	July 17, 2010	Terri Dodds	Paul Forbes	Jeff Derraugh	RE: FDA Presentation				Work Product	Chain of communications reflecting mental 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.	
430	Nov. 5, 2009	Jeff Yuen	Paul Gordon; Terri Dodds	Paolo Fiorino; Paul Forbes	RE: Group Meetings			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, 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.	
431	Dec. 18, 2009	Chris Hartle	Paolo Fiorino; Paul Gordon; Chris Hartle	Catherine Rumsby; Paul Forbes	RE: Info your requested			Email	Work Product	Chain of communications reflecting 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 requests for remediation.	See Objections 1 and 2.	See Reply.	
432	Dec. 14, 2009	Chris Hartle	Paul Gordon; Paolo Fiorino	Terri Dodds; Paul Forbes	RE: Production / Packaging & Labelling Observations			Email	Work Product	Chain of communications reflecting 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 requests for remediation.	See Objections 1 and 2.	See Reply.	
434	Jan. 25, 2010	Jeff Yuen	Paul Gordon; Paul Forbes	Steven Lydeamore; Jeff Derraugh; Calvin Koerner; Jeremy Desai	RE: Q6 Etobicoke Focus			Email	Work Product	Chain of communications 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 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.	See Objections 1 and 2.	See Reply.	
438	Jan. 22, 2010	Terri Dodds	Paul Forbes		request			Email	Work Product	Communication pertaining to 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.	See Objections 1 and 2.	See Reply.	
439	Jan. 8, 2010	Terri Dodds	Paolo Fiorino; Paul Gordon	Jeff Yuen; Jeff Derraugh	Schedule Meetings			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
440	Jan. 21, 2010	Terri Dodds	Paul Forbes	Jeff Derraugh	Urgent!!!			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
441	Oct. 28, 2009	Chris Hartle	Elaine Copsey; Bruce Clark; Lance Lovelock; Pradeep Sanghvi; Ihor Ruzycky; Larry Rock; Tish Anger; John Snape; Carol Austin; Julie Carriere; Paul Forbes; Mohamed Chan; Jeremy Desai; Paul Gordon; Elisabeth Kovacs	Jeff Yuen; Terri Dodds; Don Harrigan; Phil Russ; Sue Lee-Chan; Janet Burke; Calvin Koerner; Ken Muhvich; Elaine Bunch	EXCHANGE: Latest Update Gap Assessment Oct-09			Email	Work Product	Communication 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, 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.	
441-1							Apotex Update 10-26 (includes Class Categories).xls	Excel	Work Product	GAP assessment incorporating observations, mental impressions, and corrective recommendations related to various systems and procedures, undertaken 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.	See Objections 1 and 2.	See Reply.	

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441-2							Apotex Update 10-26 (includes Class Categories).xlsx	Excel	Work Product	GAP assessment incorporating observations, mental impressions, and corrective recommendations related to various systems and procedures, undertaken 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.	See Objections 1 and 2.	See Reply.	
442	Nov. 15, 2009	Paul Vogel	Pradeep Sanghvi	Mohamed Chan	Re: Doc2 [redacted] (2).doc			Email	Work Product	Chain of communications 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 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.	See Objections 2 and 3.	See Reply.	
445	Nov. 18, 2009	Paul Vogel	Mohamed Chan	Jeremy Desai; Pradeep Sanghvi; Carmen Shepard; Kate Beardsley; Calvin Koerner	Re: [redacted]			Email	Work Product; Attorney-Client	Chain of communications with Apotex and Counsel reflecting mental impressions, factual investigation, and legal/regulatory advice 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 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.	See Objections 2 and 3.	See Reply.	
449	Oct. 28, 2009	Phil Russ	Jeremy Desai	Ihor Ruzycky; Calvin Koerner; Mohamed Chan; Pradeep Sanghvi; Bruce Clark; Bernice Tao; Rekha Panchal	RE: [redacted]			Email	Work Product	Chain of communications reflecting mental impressions, factual investigation, 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 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.	See Objections 1 and 2.	See Reply.	
450	Feb. 9, 2010	Jeff Yuen	Larry Rock	Chris Curry; Tom Mitten; Elaine Copsey; Pradeep Sanghvi; Jill Lau	RE: [redacted] Results			Email	Work Product	Chain of communications 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.	See Objections 1 and 2.	See Reply.	
451	Aug. 24, 2010	Paul Vogel	Jeremy Desai	Carmen Shepard; Kate Beardsley; Ihor Ruzycky; Larry Rock; Stephen Simmons	N/A			Email	Work Product; Attorney-Client	Chain of communications with Apotex and Counsel 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.	See Objections 2 and 3.	See Reply.	
452	July 8, 2010	Jeff Yuen	Larry Rock	Stephen Simmons	Re: [redacted]			Email	Work Product	Chain of communications 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.	See Objections 1 and 2.	See Reply.	
453	Feb. 19, 2010	Jeff Yuen	Larry Rock	Chris Hartle	RE: CAPA Sign Off's			Email	Work Product	Communication reflecting mental impressions and advice concerning corrective actions, continuous improvement initiatives, and CAP, 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.	
454	Feb. 17, 2010	Jeff Yuen	Larry Rock		Re: [redacted]			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
455	Apr. 8, 2010	Jeff Yuen	Larry Rock		Re: [redacted] Equipment and Services			Email	Work Product	Communication concerning quality control procedures and systems and compliance with regulatory requirements, including cGMP compliance, and containing guidance with respect to same, 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 to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	

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456	Mar. 20, 2010	Jeff Yuen	Larry Rock		Re: Duct Cleaning			Email	Work Product	Communication reflecting mental impressions concerning and evaluation of 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.	See Objections 1 and 2.	See Reply.	
457	Oct. 12, 2009	Jeff Yuen	Larry Rock	Lance Lovelock; Jeremy Desai	Re: HVAC Description - 150 Signet			Email	Work Product	Chain of communications 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.	See Objections 1 and 2.	See Reply.	
458	Feb. 10, 2010	Jeff Yuen	Larry Rock		Re: [redacted]			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
459	Sept. 24, 2009	Jeff Yuen	Larry Rock		Re: [redacted]			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
460	Sep. 21, 2009	Jeff Yuen	Larry Rock	Don Harrigan; Lance Lovelock; Jeremy Desai; Ihor Ruzycky	Re: [redacted]			Email	Work Product	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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
462	Mar. 14, 2010	Jeff Yuen	Larry Rock	Chris Curry	N/A			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
464	Oct. 29, 2009	Jeff Yuen	Calvin Koerner; Phil Russ	Jeremy Desai; Ihor Ruzycky; Larry Rock	N/A			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
467	Oct. 11, 2009	Chris Hartle	Elaine Copsey; Bruce Clark; Lance Lovelock; Pradeep Sanghvi; Ihor Ruzycky; Larry Rock; Tish Anger; John Snape; Carol Austin; Julie Carriere; Paul Forbes; Mohamed Chan; Jeremy Desai; Paul Gordon	Jeff Yuen; Terri Dodds; Don Harrigan; Phil Russ; Sue Lee-Chan; Janet Burke; Calvin Koerner; Ken Muhvich, Elaine Bunch	EXCHANGE: Latest Update Gap Assessment 10-09			Email	Work Product	Communication 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, 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.	
467-1							Apotex Update 10-09.xls	Excel	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 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.	See Objections 1 and 2.	See Reply.	

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467-2							Apotex Update 10-09.xlsx	Excel	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 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.	See Objections 1 and 2.	See Reply.	
469	Sep. 24, 2009	Chris Hartle	Lance Lovelock		Re: Developing Plan for Quality Systems			Email	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 to provide Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.	See Objections 1 and 2.	See Reply.	
471	Oct. 20, 2009	Paul Vogel	Jeremy Desai; Lance Lovelock	Kate Beardsley; Carmen Shepard	Re: [redacted] Interim Report			Email	Work Product; Attorney-Client	Email 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 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.	See Objections 2 and 3.	See Reply.	
472	Sep. 30, 2009	Chris Hartle	Lance Lovelock		Quality Policy			Email	Work Product	Email 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 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.	See Objections 1 and 2.	See Reply.	
473	Oct. 7, 2009	Jeff Yuen	Lance Lovelock	Paul Gordon; Jeremy Desai	N/A			Email	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.	See Objections 1 and 2.	See Reply.	
474	Oct. 6, 2009	Paul Vogel	Lance Lovelock	Jeremy Desai; Carmen Shepard	Re: Apotex [redacted]			Email	Work Product; Attorney-Client	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.	See Objections 2 and 3.	See Reply.	
475	Sep. 9, 2009	Jeff Yuen	Lance Lovelock	Jeremy Desai	Re: Apotex/FDA Meeting September 11, 2009			Email	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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA requests for remediation.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
476	Sep. 24, 2009	Jeff Yuen	Lance Lovelock	Chris Curry	RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
477	Aug. 30, 2009	Jeff Yuen	Jeremy Desai	Lance Lovelock	RE: EMC PRESENTATION			Email	Work Product	Chain 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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
480	Oct. 6, 2009	Jeff Yuen	Lance Lovelock; Larry Rock; Ihor Ruzycky		RE: Micro. Methods			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 Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	

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481	Sep. 2, 2009	Terri Dodds	Lance Lovelock		RE: observaiton [sic] 5			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 Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
483	Aug. 31, 2009	Jeff Yuen	Lance Lovelock		N/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 Apotex legal advice regarding regulatory compliance matters, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
484	Sep. 22, 2009	Chris Hartle	Lance Lovelock	Sheri Horton; Tish Anger; Elaine Copsey	RE: Today's Meeting			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
485	Sep. 1, 2009	Jeff Yuen	Lance Lovelock; Carol Austin	Terri Dodds; Don Harrigan; Phil Russ; Chris Hartle; Jeremy Desai; Ihor Ruzycky	N/A			Email	Work Product	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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
486	Oct. 17, 2009	Jeff Yuen	Lance Lovelock	Ihor Ruzycky; Julie Carriere; Elaine Copsey; John Snape; Sanjeev Kumar; Tish Anger	N/A			Email	Work Product	Cover email attaching training presentation, as described below.	See Objections 1 and 2.	See Reply.	
486-1	Oct. 9, 2009						Apotex QS + Deviation Training - October 2009.ppt	Presentation	Work Product	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.	See Objections 1 and 2.	See Reply.	
487	Sep. 30, 2009	Jeff Yuen	Phil Russ; Julie Carriere; Lance Lovelock; Jeremy Desai; Chris Hartle		Re: SOP for [redacted]			Email	Work Product	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.	See Objections 1 and 2.	See Reply.	
488	Feb. 23, 2010	Jeff Yuen	Jeremy Desai	Ihor Ruzycky	Re: Etobicoke [redacted]			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, 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.	
489	Jan. 22, 2010	Jeff Yuen	Chris Hartle; Paul Gordon; Jeremy Desai	Ihor Ruzycky	Re: Focus on Etobicoke			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, 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.	

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490	Sep. 1, 2009	Jeff Yuen	Ihor Ruzycky; Jeremy Desai	Lance Lovelock	Re: MEETING ON THURSDAY			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, 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. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
491	Sep. 18, 2009	Jeff Yuen	Ihor Ruzycky	Larry Rock; Don Harrigan; Lance Lovelock; Jeremy Desai	Re: [redacted]			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, 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. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
492	Apr. 21, 2010	Jeff Yuen	Wan Jiang; Elisabeth Kovacs	Cynthia Lee	[redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
494	May 19, 2010	Jeff Yuen	Elisabeth Kovacs; Pradeep Sanghvi		FW: [redacted] Compliance Strategy			Email	Work Product	Chain of communications regarding recommendations and observations related to client's compliance methods and strategy, 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.	See Objections 1 and 2.	See Reply.	
495	Dec. 14, 2009	Chris Hartle	Elisabeth Kovacs		JYA Report Observations Teleconference			Meeting Invitation	Work Product	Calendar item 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.	See Objections 1 and 2.	See Reply.	
496	Mar. 9, 2010	Janet Burke	Elisabeth Kovacs		Re: additional assistance			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
497	Mar. 4, 2010	Jeff Yuen	Bernice Tao; Phil Russ; Samba Sow	Elisabeth Kovacs; Chetan Doshi; Mohamed Chan; Claire Mackenzie	RE: Blend Uniformity Testing Criteria			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
498	Feb. 25, 2010	Jeff Yuen	Pradeep Sanghvi; Elisabeth Kovacs	Chris Curry	RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
499	Dec. 4, 2009	Jeff Yuen	Pradeep Sanghvi; Jeff Derraugh; Elisabeth Kovacs; Jagdev Bahra	Calvin Koerner	RE: [redacted] reports			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	

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500	Jan. 27, 2010	Jeff Yuen	Jenn Cross	Elisabeth Kovacs; Pradeep Sanghvi; Sue Lee-Chan; Barry Sherman	RE: [redacted] - MOST URGENT			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
501	Feb. 15, 2010	Jeff Yuen	Barry Sherman	Pradeep Sanghvi; Sue Lee-Chan; Yuri Goldberg; Jeremy Desai; Elisabeth Kovacs;	RE: [redacted] - MOST URGENT			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
502	Dec. 30, 2009	Jeff Yuen	Elisabeth Kovacs		RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
503	Feb. 17, 2010	Jeff Yuen	Elisabeth Kovacs; Larry Rock; Jill Lau	Tom Mitten; Chris Curry; Pradeep Sanghvi	RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
504	Feb. 17, 2010	Jeff Yuen	Chris Curry; Jill Lau	Pradeep Sanghvi; Elisabeth Kovacs	RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
505	Apr. 26, 2010	Jeff Yuen	Wan Jiang; Elisabeth Kovacs; Cynthia Lee		RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
506	Feb. 23, 2010	Jeff Yuen	Chris Curry; Frederick Mayer; Elisabeth Kovacs; Cheryl Meads; Carol Austin; Rohini Roy; Bo Lei	Patti Semple; Phil Russ	RE: HC February 25 Site Visit Agenda to include [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
507	Feb. 22, 2010	Jeff Yuen	Elisabeth Kovacs		RE: [redacted]			Email	Work Product	Communication providing regulatory/legal guidance 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.	See Objections 1 and 2.	See Reply.	
508	Sep. 8, 2009	Jeff Yuen	Lance Lovelock; Don Harrigan; Pradeep Sanghvi	Jeremy Desai; Ihor Ruzycky; Chris Curry	Re: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
509	Feb. 18, 2010	Jeff Yuen	Elisabeth Kovacs; Jeremy Desai; Phil Russ	Pradeep Sanghvi	RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	

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510	Feb. 17, 2010	Jeff Yuen	Paul Gordon; Elisabeth Kovacs; Bernice Tao; Rekha Panchal; Yuri Goldberg	Jeremy Desai; Phil Russ; Frederick Mayer; Cheryl Meads	RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
511	Feb. 23. 2010	Jeff Yuen	Pradeep Sanghvi	Elisabeth Kovacs	RE: [redacted]			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, 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.	
512	May 19, 2010	Jeff Yuen	Stephen Simmons; Phil Russ	Pradeep Sanghvi; Elisabeth Kovacs	RE: [redacted] Compliance Strategy			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, 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.	
513	Dec. 14, 2009	Jeff Yuen	Calvin Koerner; Elisabeth Kovacs; Pradeep Sanghvi; Sue Lee-Chan; Janet Burke		Re: [redacted] testing			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, 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.	
514	Feb. 14, 2010	Jeff Yuen	Pradeep Sanghvi	Elisabeth Kovacs; Larry Rock; Ravena Adani; Chris Curry	RE: [redacted]			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, 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.	
516	Dec. 24, 2009	Jeff Yuen	Elisabeth Kovacs; Pradeep Sanghvi; Calvin Koerner	Chris Curry; Larry Rock	RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
517	Jun. 11, 2010	Jeff Yuen	Elaine Copsey; Elisabeth Kovacs		Re: [redacted]			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, 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.	
518	Mar. 16, 2010	Jeff Yuen	Elisabeth Kovacs		N/A			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, 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.	
519	Dec. 23, 2009	Jeff Yuen	Elisabeth Kovacs		N/A			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, 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.	
520	Dec. 8, 2009	Jeff Yuen	Elisabeth Kovacs	Pradeep Sanghvi	N/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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
521	May 19, 2010	Jeff Yuen	Elaine Copsey	Elisabeth Kovacs; Wan Jiang; Sue Lee-Chan; Cynthia Lee; Stephen Simmons; Phil Russ; Samba Sow; Jeff Derraugh; Bruce Clark	N/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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	

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521-1							RH Internal Audit - Labs - 2010.PDF	Document	Work Product	Report letter reflecting observations, mental 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.	See Objections 1 and 2.	See Reply.	
522	Mar. 8, 2010	Jeff Yuen	Elisabeth Kovacs; Janet Burke; Pradeep Sanghvi		N/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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
602	Sept. 2, 2009	Terri Dodds	Carol Austin		FW: Response 5 --- [redacted]			Email	Work Product	Chain of communications regarding recommendations and observations 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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
604	Sept. 1, 2009	Terri Dodds	Jeff Yuen	Carol Austin	My review of Carol's responses			Email	Work Product	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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
607	Apr. 15, 2010	Paul Vogel	Jeremy Desai; Stephen Simmons	Carol Austin; Marc Scheineson; Carmen Shepard; Kate Beardsley; Paul Vogel; Bruce Clark	Re: Apotex Warning Letter Response			Email	Work Product; Attorney-Client	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.	See Objections 2 and 3.	See Reply.	
609	Feb. 4, 2010	Jeff Yuen	Carol Austin		RE: [redacted]			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 Apotex legal advice regarding regulatory compliance matters and cGMP compliance, and to respond to FDA concerns.	See Objections 1 and 2.	See Reply.	
610	Sept. 2, 2009	Terri Dodds	Chris Curry; Lance Lovelock	Carol Austin	RE: [redacted] response			Email	Work Product	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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	

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Doc ID	DocDate & Time	Email. From	Email.To	Email.cc	Email. Subject	Author	Title	DocType	Privilege Basis [AC/WP]	Privilege Reasons/Comments	Responses/Objections to Privilege Determinations	Replies to Objections to Privilege Determinations	Tribunal's Decisions
612	Feb. 23, 2010	Jeff Yuen	Chris Curry; Frederick Mayer; Cheryl Meads; Carol Austin	Phil Russ	Re: HC February 25 Site Visit Agenda to include [redacted]			Email	Work Product	Communication reflecting observations, mental impressions, and 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.	See Objections 1 and 2.	See Reply.	
613	Nov. 13, 2009	Chris Hartle	Carol Austin		RE: HELP-Subcategories			Email	Work Product	Chain of communications concerning observations, 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.	See Objections 1 and 2.	See Reply.	
614	Oct. 2, 2009	Chris Hartle	Paul Gordon; Lance Lovelock; Tish Anger	Jeff Yuen	RE: JYA Team			Email	Work Product	Communication concerning observations, 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.	See Objections 1 and 2.	See Reply.	
615	Sept. 1, 2009	Jeff Yuen	Carol Austin; Terri Dodds; Jeff Yuen		RE: Observations 11 draft response			Email	Work Product	Communication reflecting mental 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 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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
618	Mar. 5, 2010	Jeff Yuen	Tracey Roberts	Carol Austin; Frederick Mayer; Cheryl Meads; Jeff Derraugh; Phil Russ; Stephen Simmons	RE: Q6 - Overdue APRs - Proposal to Carry-over to New Annual Schedule (Apr 2010 - Mar 2011)			Email	Work Product	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 requests for remediation.	See Objections 1 and 2.	See Reply.	
620	Feb. 5, 2010	Jeff Yuen	Chris Hartle	Calvin Koerner; Carol Austin	RE: Resources For CAP Audit			Email	Work Product	Communication reflecting observations, mental 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 Apotex, including regarding FDA enforcement actions, cGMP compliance, CAP audit, 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.	
627	Sept. 1, 2009	Terri Dodds	Carol Austin	N/A				Email	Work Product	Communication providing review and analysis of client's response to FDA inspection, 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.	See Objections 1 and 2. Even if Apotex proved that its Counsel retained 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, 2009, the date of the alleged engagement letter between Apotex's Counsel and Jeff Yuen & Associates. Therefore, the document is not privileged.	See Reply.	
700	Oct. 6, 2009	Paul Vogel	Bernice Tao	Bruce Clark	Re: 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 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.	See Objections 2 and 3.	See Reply.	

* U.S. Objections 1, 2 and 3 are located at Tabs 1, 2, and 3 to Claimants' Privilege Log.
** Apotex's Reply is located at Tab 4 to Claimants' Privilege Log.

Document ID numbers preceded by a dash indicate attachments to emails.

United States Department of State

Washington, D.C. 20520

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.[1] Although we subsequently explained the bases for these redactions, Apotex informed us that it intends to maintain its objections, on three grounds.[2]

First, Apotex contends that several documents were too heavily redacted, and thus should have been placed on the U.S. privilege log.[3] The parties had expressly agreed, however, to log only

[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.[4] 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.[5]

Second, Apotex objects to our use of a U.S. Freedom of Information Act (FOIA) designation, rather than the corresponding IBA Rules designation.[6] In particular, Apotex objects to our use of the "b(5)" FOIA designation, which is for pre-decisional and deliberative documents.[7] 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."[8] 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.

[7] *See* 5 U.S.C. § 552(b)(5) (2006) [RLA-187].

[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.[9] 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."[10] 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:

> [P]aragraph 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]

---

[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.[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

DENTONS

John J. Hay
Partner

john.hay@dentons.com
D +1 (212) 632-8457
M +1 (203) 536-6758
F +1 (212) 307-3397

Salans FMC SNR Denton Europe LLP
Rockefeller Center
620 Fifth Avenue
New York, NY 10020-2457

T +1 (212) 632-5500
F +1 (212) 632-5555

Salans FMC SNR Denton
dentons.com

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:

US003091
US006092
US006106
US008799
US010525
US010526
US010814
US011970
US012303
US012419
US012574
US012576

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. 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.

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 (ASBW)

John J. Hay
Partner
Salans FMC SNR Denton Europe LLP

cc: Lisa Grosh; Barton Legum; Anne-Sophie Dufêtre

Attachment B

United States Department of State

Washington, D.C. 20520

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 Abritration, 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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PRIV-US000001	PRIV-US000005			Draft Warning Letter	molinah		Microsoft Word 2003	3/31/2009 13:55	3/31/2009 9:16	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft of Etobicoke Warning Letter No. 320-09-06 (multiple versions/copies). The draft letters are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege. The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts are exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final version of this Warning Letter, sent contemporaneously to Apotex, was produced by Claimants (C-41). The Tribunal, moreover, rejected Claimants' document request no. 3 for "[a]ll documents generated within FDA regarding the Warning Letter No. 320-09-06."	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000006	PRIV-US000012			Draft Warning Letter	JBowers	DHHS Letterhead	Microsoft Word 2003	3/24/2010 19:31	3/24/2010 19:49	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft of Signet Warning Letter No. 320-10-003 (multiple versions/copies). The draft letters are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege. The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts are exempt from disclosure under U.S. law. 5 U.S.C. §552(b)(5); 21 C.F.R. §20.62. The final version of this Warning Letter, sent contemporaneously to Apotex, was produced by Claimants (C-138). The Tribunal, moreover, rejected Claimants' request no. 17 for "[a]ll documents generated within FDA regarding the Warning Letter No. 320-10-003."	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000013	PRIV-US000020			Draft Letter to Apotex Counsel	JBowers	DHHS Letterhead	Microsoft Word 2003	12/23/2010 12:21	12/23/2010 13:37	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft letter from Deborah Autor, Director, Center for Drug Evaluation and Research - Office of Compliance (CDER/OC) to Apotex counsel, Carmen Shepard and Kate Beardsley (multiple versions/copies). The draft letters are internal, pre-decisional communications forming part of a government agency's decision-making process and are protected by deliberative process privilege. The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts are exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final version of this letter, sent contemporaneously to Apotex's counsel, was produced by Claimants (C-186).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000021	PRIV-US000022			Draft FDA Letter to Apotex	huertasa	28-Jun-07	Microsoft Word 2003	5/1/2011 16:06	5/1/2011 16:27	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft letter from FDA to Apotex enclosing a copy of the Establishment Inspection Report (EIR) from the 2011 Etobicoke inspection. The draft letter is an internal, pre-decisional communication forming part of a government agency's decision-making process and is protected by deliberative process privilege. The draft is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft letter is exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final version of the letter, sent contemporaneously to Apotex, was produced by Claimants (C-233).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000023	PRIV-US000026			Draft FDA Letter to Apotex	huertasa	28-Jun-07	Microsoft Word 2003	5/19/2011 16:34	5/19/2011 16:33	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft of FDA letter to Apotex requesting additional information following the 2011 Signet inspection (multiple versions/copies). The draft letters are internal, pre-decisional communications forming part of a government agency's decision-making process and are protected by deliberative process privilege. The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts are exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final version of this letter, sent contemporaneously to Apotex, was produced by Claimants (C-237).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	

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PRIV-US000027	PRIV-US000028			Draft Import Alert Recommendation	Carole Jones	Date	Microsoft Word 2003	5/22/2009 10:56	5/22/2009 10:58	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft recommendation from the Director of CDER, Division of Manufacturing and Product Quality (DMPQ), to the Director of the Division of Import Operations and Policy (DIOP), requesting an Import Alert for all finished pharmaceutical products for human use manufactured at the Etobicoke facility (dated May 22, 2009). The draft request was not finalized, and represents an internal, pre-decisional communication forming part of the government's decision-making process. The draft request is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft request is exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The Tribunal, moreover, rejected Claimants' document request no. 2(m) for documents concerning CDER's evaluation as to "whether to initiate any enforcement actions" following the 2008 Etobicoke inspection.	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000029	PRIV-US000032			Draft Import Alert Recommendation	Carole Jones	Date	Microsoft Word 2003	5/22/2009 10:56	8/20/2009 12:17	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft request from the Director of CDER/DMPQ to the Director of DIOP to revise Import Alert 66-40 to include future shipments of all finished drug products manufactured at the Apotex Inc. Etobicoke and Signet sites (dated August 20, 2009). The draft document is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft is exempt from disclosure under U.S. law for deliberative process privilege and reflects an internal, pre-decisional communication forming part of the government's decision-making process. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. A final version of this request is in the record (C-64).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000033	PRIV-US000034			Draft Import Alert Removal Recommendation	CDER User		Microsoft Word 2003	5/6/2011 17:25	5/6/2011 17:32	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft memorandum from Carmelo Rosa (CDER) to the Director of DIOP recommending the revision of Import Alert 66-40 to remove Apotex Inc. (Etobicoke). As a draft memorandum, the document is an internal, pre-decisional communication forming part of a government agency's decision-making process and is protected by deliberative process privilege. The draft is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft memorandum also is exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final memorandum was produced by Claimants (C-234).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000035	PRIV-US000035			Draft Import Alert, Removal Recommendation			Rich Text Format	5/3/2013 10:29	7/8/2011 7:52	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft memorandum from Carmelo Rosa (CDER) to the Director of DIOP recommending the revision of Import Alert 66-40 to remove Apotex Inc. (Signet). The draft memorandum is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft is an internal, pre-decisional communication that forms part of a government agency's decision-making process and is protected by deliberative process privilege under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final version of the memorandum was produced by Claimants (C-250).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000036	PRIV-US000048			Draft CDER PowerPoint Presentation (Sept. 11, 2009 regulatory meeting)	rparrill	Slide 1	Microsoft PowerPoint 97/98	9/10/2009 14:09	9/10/2009 14:51	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft CDER PowerPoint slide presentation from the Sept. 11, 2009 regulatory meeting with Apotex. This draft presentation is an internal, pre-decisional communication that forms part of a government agency's decision-making process and is protected by deliberative process privilege. It is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft is exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. Claimants have already produced a final version of the CDER presentation (C-93).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000049	PRIV-US000083			Draft CDER PowerPoint Presentation (Mar. 2010)	saccone, helen	Division of Compliance Risk Management & Surveillance (DCRMS)	Microsoft PowerPoint 97/98	4/4/2013 4:08	3/9/2010 16:11	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(4); (b)(5)	Draft PowerPoint presentation by Richard Friedman, Director, CDER/DMPQ, dated Mar. 10-11, 2010. The draft presentation was prepared for internal delivery only to the FDA Field Drug Committee. Apotex is discussed on one slide. The draft is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The presentation contains trade secret and/or confidential commercial information (TS/CCI) about a variety of companies that is prohibited from release under U.S. law. 18 U.S.C. § 1905; *see also* 5 U.S.C. § 552(b)(4); 21 C.F.R. § 20.61. The draft presentation constitutes an internal, pre-decisional communication forming part of a government agency's decision-making process and is protected by deliberative process privilege. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62.	The parties have discussed this document and the US has agreed to produce the final version of this document in redacted form. 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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules, but does reserve its right to challenge the redactions made by the US.	The United States produced the final, redacted version of this document (US013809-35) on June 10, 2013. No reply required at this time.	

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PRIV-US000084	PRIV-US000096			Draft CDER PowerPoint Presentation (Mar. 31, 2010 regulatory meeting)	rparrill	Slide 1	Microsoft PowerPoint 97/98	4/3/2013 15:55	7/20/2010 14:06	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft version of CDER PowerPoint presentation delivered during the March 31, 2010 regulatory meeting with Apotex (multiple versions/copies). The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft presentations are internal, pre-decisional communications that form part of a government agency's decision-making process and are subject to deliberative process privilege. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final version of this presentation was produced by the United States (R-55).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000097	PRIV-US000100			Draft FDA PowerPoint Presentation (undated)	Maan	Slide 1	Microsoft PowerPoint 97/98	1/24/2011 13:54	1/26/2011 13:38	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft internal FDA slides from an undated PowerPoint presentation concerning general information on Warning Letters, Untitled Letters and Field Alert Reports (FARs). Apotex is mentioned on one slide. The draft slides are internal, pre-decisional communications that form part of a government agency's decision-making process and are subject to deliberative process privilege. The document is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The document is also exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62.	The parties have discussed this document and the US has represented that the slides produced as US011963-67 contain substantively the same information as this document. 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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, and based on the US's representations, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000101	PRIV-US000125			Draft CDER PowerPoint Presentation (June 2011)	Raphael Brykman	ICB Overview-2011-05-02	Microsoft PowerPoint 97/98	6/6/2011 12:04	6/15/2011 16:54	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft PowerPoint presentation by Carmelo Rosa (CDER) entitled "FDA International GMP Inspection and Compliance Issues," dated June 19, 2011. Apotex is mentioned on two slides in the context of recalls and FARs. The draft presentation is an internal, pre-decisional communication that forms part of a government agency's decision-making process and is protected by deliberative process privilege. The document is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft presentation is exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62.	The parties have discussed this document and the US has represented that the slides produced as US011963-67 contain substantively the same information as this document. 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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, and based on the US's representations, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000126	PRIV-US000131			Draft Establishment Inspection Report (EIR)		RA Chem Pharma Ltd	Microsoft Word 2003	2/12/2009 21:28	2/6/2009 15:17	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft section of the 2008 Etobicoke EIR (multiple versions/sections). These drafts are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege. The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts are exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. A section of this EIR was inadvertently produced (US006519-24); however, the United States has not waived the privilege attaching to these drafts and requests the immediate return of the section accidentally produced. The final version of the Etobicoke 2008 EIR was produced by the United States (R-26). The Tribunal rejected, moreover, Claimants' document request no. 2(l) "regarding preparing and finalizing Forms 483 and EIRs for the inspection."	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules and agrees to return this document to the US.	No reply required. Claimants have agreed not to use and to destroy all versions of US006519-24.	
PRIV-US000132	PRIV-US000146			Draft Establishment Inspection Report (EIR)	carmel	SUMMARY OF FINDINGS:	Microsoft Word 2003	4/15/2013 11:25	8/27/2009 11:07	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft section of the 2009 Signet EIR (multiple versions/sections). The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final version of the EIR was produced by the United States (R-42). The Tribunal rejected, moreover, Claimants' document request no. 6(l) "regarding preparing and finalizing Forms 483 and EIRs for the inspection."	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000147	PRIV-US000150			Draft Establishment Inspection Report (EIR)	fguidry		Microsoft Word 2003	2/16/2011 16:02	3/3/2011 15:57	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft section of the 2011 Signet EIR (multiple versions/sections). The drafts are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege. The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts are exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final version of the EIR was produced by the United States (R-71).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	

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PRIV-US000151	PRIV-US000159			Draft Establishment Inspection Report (EIR)	Mike Goga	Administrative	Microsoft Word 2003	3/24/2011 20:13	3/24/2011 20:13	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft section of the 2011 Etobicoke EIR (multiple versions/sections). These drafts are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege. The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts are exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R § 20.62. The final version of the EIR was produced by the United States (R-72).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000160	PRIV-US000161			Draft Form 483	Brian Perry		Microsoft Word 2003	1/5/2009 6:34	12/19/2008 14:52	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft section of the 2008 Etobicoke Form 483. This draft section of the Form 483 may be excluded under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft 483 is an internal, pre-decisional communication forming part of a government agency's decision-making process and is protected by deliberative process privilege. The draft is exempt from disclosure under U.S. law. 5 USC § 552(b)(5); 21 C.F.R. § 20.62. The final Form 483 for the 2008 Etobicoke inspection was provided to Apotex at the close of the inspection and produced by Claimants (C-34). The Tribunal rejected, moreover, Claimants' document request no. 2(l) "regarding preparing and finalizing Forms 483 and EIRs for the inspection."	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000162	PRIV-US000175			Draft Form 483	kzielny		Microsoft Word 2003	8/12/2009 18:43	8/12/2009 22:46	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft section of the 2009 Signet Form 483. The draft is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft is an internal, pre-decisional communication that forms part of a government agency's decision-making process and is privileged as deliberative process. The draft is exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final version of the 2009 Signet Form 483 was provided to Apotex at the close of the inspection and produced by Claimants (C-61). The Tribunal rejected, moreover, Claimants' document request no. 6(l) with respect to documents "regarding preparing and finalizing Forms 483 and EIRs for the inspection."	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000176	PRIV-US000176			Draft Form 483	smcmulle	Etobicoke 483 Item:	Microsoft Word 2003	4/19/2013 19:13	2/10/2011 22:13	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft section of the 2011 Etobicoke Form 483 (multiple versions/sections). The drafts are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege. They are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. They are exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final Form 483 from the 2011 Etobicoke inspection was provided to Apotex at the close of the inspection and produced by Claimants (C-193).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000177	PRIV-US000186			Draft Form 483	smcmulle	Signet 483 Items:	Microsoft Word 2003	4/19/2013 19:13	3/1/2011 12:33	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft section of the Signet 2011 Form 483 (multiple versions/sections). These drafts are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege. The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The documents are exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The final Form 483 was provided to Apotex at the close of the inspection and produced by Claimants (C-194).	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	

Priv.BegBates	Priv.EndBates	Email . From	Email . To	Subject	Metadata . Author	Metadata . Title	Metadata . Header Doc Type	Metadata . Date Created	Metadata . Date Last Modified	Privilege Determination - Bases	Explanation/Comments on Privilege Determination	Responses/Objections to Privilege Determinations	Replies to Objections to Privilege Determinations	Tribunal's Decisions
PRIV-US000187	PRIV-US000190			Quality Assurance Feedback Forms	DSHAFFER	INSPECTIONAL/INVESTIGATIONAL EVENT REPORT	Microsoft Word 2003	9/28/2009 8:52	9/28/2009 8:52	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(2); (b)(5); (b)(6)	Quality Assurance Feedback Form concerning the 2008 Etobicoke inspection (multiple versions and amendments). The "form is to be used by HQ, Center and Field Personnel to report any highly successful operations and/or problems encountered during inspections/investigations/sample collection operations. This information will be held confidential and is intended only for purposes of establishing any new procedures, guidance, business practices, and/or improvements or additions to training which may be warranted." The form is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The forms may be withheld from public disclosure under 5 U.S.C. § 552(b)(2) and 21 C.F.R. § 20.66 as they relate solely to the internal personnel rules and practices of an agency, and 5 U.S.C. § 552(b)(6) because they contain evaluations of personnel performance held in strict confidence by the FDA. The forms are internal recommendations concerning training and foreign inspections and are protected by deliberative process privilege. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The Tribunal rejected, moreover, Claimants' document request nos. 2(j) and 2(m) concerning FDA/CDER's review of the inspectors' findings and the inspection package from the 2008 Etobicoke inspection.	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000191	PRIV-US000193			Quality Assurance Feedback Forms, Internal DFI Review	laskas	The A	Microsoft Word 2003	12/17/2010 22:38	12/17/2010 23:38	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(2); (b)(4); (b)(5); (b)(6)	Internal review of Quality Assurance Feedback Forms provided to the Division of Foreign Inspections (DFI). QA Feedback Forms pertaining to the 2008 Apotex inspection are discussed, together with several other, non-Apotex inspections. The QA Feedback Forms are privileged and excludable under the IBA Rules, as well as exempt from disclosure under U.S. law, as explained above. The internal review, discussing the content of these Forms is privileged and excludable for the same reasons (IBA Rules, art. 9(2)(b) and/or art. 9(2)(f); 5 U.S.C. §§ 552(b)(2), (b)(5), and (b)(6); 21 C.F.R. §§ 20.62 and 20.66). The internal review also contains trade secret and/or confidential commercial information (TS/CCI) pertaining to other companies, the release of which is prohibited under U.S. law. 18 U.S.C. § 1905; 5 U.S.C. § 552(b)(4); 21 C.F.R. § 20.61.	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000194	PRIV-US000195	Tave, Steven	Friedman, Rick L	RE: Apotex			Microsoft Outlook Message File	4/19/2010 8:50	4/19/2010 8:50	IBA Rules, art. 9(2)(b); 9(2)(f); Attorney-client; FOIA (b)(5)	Email chain containing confidential attorney-client and pre-decisional communications between Steven J. Tave, Associate Chief Counsel for Enforcement, and Rick Friedman (CDER). The confidential emails discuss the 2010 Signet Warning Letter and are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. As confidential attorney-client communications, the emails are protected by attorney-client privilege. *See, e.g.* , *Upjohn Co. v. United States* , 449 U.S. 383, 389 (1981) ("The attorney-client privilege is the oldest of the privileges for confidential communications known to the common law. 8 J. Wigmore, Evidence 2290 (McNaughton rev. 1961). Its purpose is to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice."). As pre-decisional communications forming part of a government agency's decision-making process, they are also protected as deliberative process and exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62.	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000196	PRIV-US000198	Rogers, Michael	Tyler, Ralph; Elder, David K.	Re: Inspection status -- Apotext [*sic*]			Microsoft Outlook Message File	4/27/2011 17:19	4/27/2011 17:19	IBA Rules, art. 9(2)(b); Attorney-client	April 2011 email chain containing confidential attorney-client communications to or from Ralph Tyler, then Chief Counsel of the U.S. Food and Drug Administration, concerning the status of FDA's review of the January-February 2011 inspections of Etobicoke and Signet. Confidential attorney-client communications are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and are protected by attorney-client privilege under U.S. law. *See, e.g., Upjohn Co. v. United States* , 449 U.S. 383, 389 (1981) ("The attorney-client privilege is the oldest of the privileges for confidential communications known to the common law. 8 J. Wigmore, Evidence 2290 (McNaughton rev. 1961). Its purpose is to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice.").	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	

Priv.BegBates	Priv.EndBates	Email . From	Email . To	Subject	Metadata . Author	Metadata . Title	Metadata . Header Doc Type	Metadata . Date Created	Metadata . Date Last Modified	Privilege Determination - Bases	Explanation/Comments on Privilege Determination	Responses/Objections to Privilege Determinations	Replies to Objections to Privilege Determinations	Tribunal's Decisions
PRIV-US000199	PRIV-US000202	Tyler, Ralph	Laska, Susan F; Rogers, Michael; Elder, David K.	Re: Inspection status -- Apotext [*sic*]			Microsoft Outlook Message File	4/28/2011 6:47	4/28/2011 6:47	IBA Rules, art. 9(2)(b); Attorney-client	April 2011 email chain containing confidential attorney-client communications to or from Ralph Tyler, then Chief Counsel of the U.S. Food and Drug Administration, concerning the status of FDA's review of the January-February 2011 inspections of Etobicoke and Signet. Confidential attorney-client communications are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and are protected by attorney-client privilege under U.S. law. *See, e.g., Upjohn Co. v. United States* , 449 U.S. 383, 389 (1981) ("The attorney-client privilege is the oldest of the privileges for confidential communications known to the common law. 8 J. Wigmore, Evidence 2290 (McNaughton rev. 1961). Its purpose is to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice.").	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000203	PRIV-US000204			Draft Information Advisory	Elizabeth A. Giaquinto	Date: May 29, 2009	Microsoft Word 2003	6/3/2009 10:16	6/4/2009 11:17	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft Information Advisory, "Subject: Warning Letter to Apotex Inc." prepared for internal briefing purposes only for the Secretary of Health and Human Services (multiple versions/copies). Three versions of this document were inadvertently produced (US007470-7471, US07488-89 and US013072-73). 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 was not finalized even for internal briefing purposes. The draft advisories are internal, pre-decisional communications that form part of a government agency's decision-making process, are protected by deliberative process privilege, and are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts are exempt from disclosure under U.S. law. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. The United States has not waived the privilege attaching to these documents and requests the immediate return of the inadvertently produced draft advisories (*i.e.* , US007470-71, US007488-89 and US013072-73).	Apotex objects to the US withholding these documents and does not consent to returning them because these documents are not privileged, and even if they were, the US has waived any such privilege. First, 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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Even if the deliberative process privilege does apply in this proceeding, the documents at issue do not reflect pre-decisional deliberation. The information contained in the Draft Information Advisories is not provided for use in making an internal decision. Rather, the documents purport to provide relevant facts and to inform high-level FDA officials of a final agency decision to send a warning letter to Apotex that had already been made. Although the US indicates these documents were not finalized, they are not marked as drafts and do not appear incomplete on their face. As Apotex has previously noted, deliberative process privilege does not apply to factual material or material that underpins a final agency decision. Second, the US also fails to explain why this document constitutes a "special political or institutional sensitivity" under IBA Rules, art. 9(2)(f). The US's description does not explain what compelling sensitivity exists or how this document reflects compelling political interests. Instead, it describes the advisory only as providing internal briefing, which generally constitutes factual background. Third, even if these documents were entitled to deliberative process privilege or protection from disclosure due to the sensitivity of the information contained therein, the US has waived privilege as to these documents through multiple productions of this document and is not entitled to their return. The US produced three nearly identical version of the same document to Apotex. These documents were produced after undergoing separate review by both FDA and the US, and were included in two separate document production sets (the US's 8th and 10th document productions, produced on May 10 and 24, 2013, respectively). The US did not notify Apotex that any documents had been inadvertently produced at any time prior to exchanging privilege logs on May 28, 2013 and the parties do not have a pre-existing "clawback" agreement relating to inadvertently produced documents. Apotex has included US007470-71 as Exhibit C-365 to its Reply, submitted on May 24, 2013, and has designated this exhibit as "Confidential". Accordingly, Apotex asks the Tribunal to overrule the US's assertion of privilege and order that the production of these documents was proper.	*See* Tab 1-Reply to PRIV-US000203	
PRIV-US000205	PRIV-US000210			Draft CDER Report: "Summary of Emerging Drug Product Quality Concerns"	METAYERA	Mass Seizure: Various Prescription Drugs	Microsoft Word 2003	6/17/2009 8:08	6/17/2009 8:13	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(4); (b)(5)	Draft CDER/OC report entitled "Summary of Emerging Drug Product Quality Concerns" (multiple versions/copies). The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The drafts contain trade secret and/or confidential commercial information (TS/CCI) about a variety of companies that is prohibited from release under U.S. law. 18 U.S.C. § 1905; *see also* 5 U.S.C. § 552(b)(4); 21 C.F.R. § 20.61. The draft reports are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62. Several final versions of these periodic reports, redacting the non-Apotex TS/CCI, have been produced to the Claimants by the United States. *See, e.g .,* US007674-79; US010915-18.	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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, Apotex does not object to the US withholding these documents under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000211	PRIV-US000220			Draft FDA Letter to GAO	JBowers	DHHS Letterhead	Microsoft Word 2003	5/13/2010 23:56	5/14/2010 6:24	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft FDA letter responding to an "ongoing audit of FDA's foreign drug inspection program" conducted by the Government Accountability Office (GAO). The undated draft letter describes a series of initiatives and improvements made by the Agency to its foreign drug inspection program, one paragraph of which mentions Apotex. The draft letter is excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft is a pre-decisional communication that forms part of a government agency's decision-making process and is protected by deliberative process privilege. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62.	The parties have discussed this document and the US has represented that the document produced as US011612-21 is the final version of this document and that the text concerning Apotex is identical to the version produced. 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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, and based on the US's representations, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	

Priv.BegBates	Priv.EndBates	Email . From	Email . To	Subject	Metadata . Author	Metadata . Title	Metadata . Header Doc Type	Metadata . Date Created	Metadata . Date Last Modified	Privilege Determination - Bases	Explanation/Comments on Privilege Determination	Responses/Objections to Privilege Determinations	Replies to Objections to Privilege Determinations	Tribunal's Decisions
PRIV-US000221	PRIV-US000226			Draft FDA Updates (GAO)	ehrlichd	Name of Study	Microsoft Word 2003	3/9/2011 17:55	3/9/2011 18:55	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft, internal FDA updates in chart form concerning GAO recommendations made in its 2008 report entitled "Drug Safety--Better Data Management and More Inspections are Needed to Strengthen FDA's Foreign Drug Inspection Program (GAO-08-970)" (multiple versions/copies). The draft charts discuss Apotex in one paragraph. The draft charts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft charts are internal, pre-decisional communications that form part of a government agency's decision-making process and are protected by deliberative process privilege. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62.	The parties have discussed this document and the US has represented that it contains text concerning Apotex that is identical to text contained in the document produced as US013799-US013808. 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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, and based on the US's representations, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
PRIV-US000227	PRIV-US000234			Draft FDA Updates (GAO)	grilloc	Title of Final Report	Microsoft Word 2003	8/30/2011 18:17	8/30/2011 18:25	IBA Rules, art. 9(2)(b); 9(2)(f); FOIA (b)(5)	Draft FDA updates in narrative form responding to the GAO's 2008 Report entitled, "Drug Safety: Better Data Management and More Inspections Are Needed to Strengthen FDA's Foreign Drug Inspection Program (GAO-08-970)" (multiple versions/copies). The narratives discuss Apotex in one paragraph. The drafts are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and/or art. 9(2)(f) on grounds of special political or institutional sensitivity. The draft narratives are pre-decisional communications forming part of a government agency's decision-making process and are protected by deliberative process privilege. 5 U.S.C. § 552(b)(5); 21 C.F.R. § 20.62.	The parties have discussed this document and the US has represented that the document produced as US013799-US013808 is the final version of this document and that the text concerning Apotex is identical to the version produced. 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 deliberative process privilege or FOIA exemptions, is applicable in international arbitration proceedings. Nonetheless, and based on the US's representations, Apotex does not object to the US withholding this document under articles 9(2)(b) and/or 9(2)(f) of the IBA Rules.	No reply required.	
Supplemental Entries As Agreed by Parties (6/5/13)														
US012032	US012034	Stern, Michael	Rosa, Carmelo; Vaid, Sonal	Re: Amphastar Pharmaceuticals v. FDA et al., No. 10-1800 (D.D.C.)			Microsoft Outlook Message File	6/15/2011 12:50	6/15/2011 12:50	IBA Rules, art. 9(2)(b); Attorney-Client; Work Product	Email chain containing confidential attorney-client communications to or from Michael Stern, FDA Associate Chief Counsel. The emails discuss a change in regulatory policy concerning "close-out" letters in connection with a matter raised by counsel for Amphastar in the context of unrelated litigation between Amphastar and the Agency. Confidential attorney-client communications and communications containing attorney work product are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and are protected under U.S. law. *See, e.g., Upjohn Co. v. United States* , 449 U.S. 383, 389 (1981) ("The attorney-client privilege is the oldest of the privileges for confidential communications known to the common law. 8 J. Wigmore, Evidence 2290 (McNaughton rev. 1961). Its purpose is to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice."); *Hickman v. Taylor* , 329 U.S. 495, 509-511 (1947) (recognizing qualified immunity from discovery for attorney work product); Fed.R.Civ.P. 26(b)(3) (codifying the work product doctrine) .	Apotex does not object to the US withholding this document under article 9(2)(b) of the IBA Rules.	No reply required.	
US012049	US012051	Lynn, Steven	Rosa, Carmelo; Stearn, Douglas	Re: Amphastar Pharmaceuticals v. FDA et al., No. 10-1800 (D.D.C.)			Microsoft Outlook Message File	6/14/2011 21:27	6/14/2011 21:27	IBA Rules, art. 9(2)(b); Attorney-Client; Work Product	Email chain containing a confidential attorney-client communication from Michael Stern, FDA Associate Chief Counsel, and emails between Mr. Stern's clients (Steven Lynn, Carmelo Rosa and Douglas Stearn) discussing counsel's communication. The emails discuss a change in regulatory policy concerning "close-out" letters in connection with a matter raised by counsel for Amphastar in the context of unrelated litigation between Amphastar and the Agency. Confidential attorney-client communications and communications containing attorney work product are excludable under the IBA Rules, art. 9(2)(b) for legal impediment or privilege and are protected under U.S. law. *See, e.g., Upjohn Co. v. United States* , 449 U.S. 383, 389 (1981) ("The attorney-client privilege is the oldest of the privileges for confidential communications known to the common law. 8 J. Wigmore, Evidence 2290 (McNaughton rev. 1961). Its purpose is to encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice."); *Hickman v. Taylor* , 329 U.S. 495, 509-511 (1947) (recognizing qualified immunity from discovery for attorney work product); Fed.R.Civ.P. 26(b)(3) (codifying the work product doctrine) .	Apotex does not object to the US withholding this document under article 9(2)(b) of the IBA Rules.	No reply required.	