

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PLAINTIFF,	:	
	:	
Plaintiff,	:	
	:	
v.	:	Civil Action No. []
	:	ANDA CASE
DEFENDANT,	:	
	:	
Defendant.	:	

**SCHEDULING ORDER FOR
HATCH-WAXMAN PATENT INFRINGEMENT CASES¹**

This __ day of _____, 20 __, the Court having conducted an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b), and the parties having determined after discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration:

IT IS ORDERED that:

1. Caption Modification. The Caption shall be modified to include the words “ANDA CASE” immediately below the Civil Action Number.

¹ This form order is to be used in cases arising under 21 U.S.C. § 355 where all patents alleged to be infringed were the subject of a Paragraph IV certification of noninfringement and/or invalidity by Defendant(s).

2. Relevant Deadlines and Dates. All relevant deadlines and dates established by this Order are set forth in the chart attached as Exhibit A. The expiration date(s) of any applicable 30-month period(s) imposed pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) are set forth in the first row(s) of the chart.

3. Rule 26(a)(1) Initial Disclosures. Unless otherwise agreed to by the parties, the parties shall make their initial disclosures required by Federal Rule of Civil Procedure 26(a)(1) within five days of the date of this Order.

4. Production of the ANDA(s) and/or NDA(s). As required by the Court's Standing Order Regarding Hatch-Waxman Cases in Which Infringement Is Alleged, upon the filing of a responsive pleading to the Complaint, Defendant(s) shall produce to Plaintiff(s) the entire Abbreviated New Drug Application(s) or New Drug Application(s) that is(are) the basis of the alleged infringement.

5. Preliminary Disclosure of Asserted Claims. No later than seven days after the date of this Order, Plaintiff(s) shall serve Defendant(s) with a "Preliminary Disclosure of Asserted Claims" that lists each claim of each patent alleged to be infringed by Defendant(s), including for each claim the applicable statutory subsections of 35 U.S.C. § 271 asserted. Unless otherwise agreed to by the parties, Plaintiff(s) may assert no more than ten claims of any one patent and no more than 32 claims in total against any one Defendant. Plaintiff(s) shall produce with the Preliminary Disclosure of Asserted Claims a copy of the file

history for each asserted patent, all documents evidencing ownership of the asserted patent rights by Plaintiff(s), and all agreements, including licenses, transferring an interest in any asserted patent.

6. Noninfringement Contentions. Unless otherwise agreed to by the parties, no later than 30 days after service of the Preliminary Disclosure of Asserted Claims, Defendant(s) shall serve on Plaintiff(s) “Noninfringement Contentions” that shall set forth any defense of noninfringement and include a claim chart that identifies each claim at issue in the case, each limitation of each claim at issue, and any and all claim limitations that are literally absent from the Abbreviated New Drug Application(s) or New Drug Application(s) accused of infringement. Defendant(s) shall produce with the Noninfringement Contentions any document or thing that Defendant(s) intend(s) to rely upon in defense of any infringement allegations by Plaintiff(s).

7. Invalidity Contentions and Preliminary Disclosure of Asserted Prior Art. Unless otherwise agreed to by the parties, no later than 30 days after service of the Preliminary Disclosure of Asserted Claims, Defendant(s) shall serve on Plaintiff(s) “Invalidity Contentions” that shall contain the following information:

- (a) The identity of no more than 12 prior art references for any one patent and no more than 30 prior art references in total that Defendant(s) allege(s) anticipates each asserted claim or renders the claim obvious (the

“Preliminary Disclosure of Asserted Prior Art”). Each prior art patent shall be identified by its number, country of origin, and date of issue. Each prior art publication shall be identified by its title, date of publication, and, where feasible, author and publisher. Each alleged sale or public use shall be identified by specifying the item offered for sale or publicly used or known, the date the offer or use took place or the information became known, and the identity(ies) of the person(s) or entity(ies) that made the use or made and received the offer, or the person(s) or entity(ies) that made the information known or to whom it was made known. For pre-AIA claims, prior art under 35 U.S.C. § 102(f) shall be identified by providing the name of the person(s) from whom and the circumstances under which the invention or any part of it was derived. For pre-AIA claims, prior art under 35 U.S.C. § 102(g) shall be identified by providing the identity(ies) of the person(s) or entity(ies) involved in and the circumstances surrounding the making of the invention before the patent applicant(s);

(b) Whether each item of prior art anticipates each asserted claim or renders it obvious. If obviousness is alleged, an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness;

(c) A chart identifying specifically where and how in each alleged item of prior art each limitation of each asserted claim is found, including, for each limitation that such party contends is governed by 35 U.S.C. § 112(f), the identity of the structure(s), act(s), or material(s) in each item of prior art that performs the claimed function; and

(d) Any grounds of invalidity based on 35 U.S.C. § 101, indefiniteness under 35 U.S.C. § 112(b), or lack of enablement or insufficient written description under 35 U.S.C. § 112(a) of any of the asserted claims.

8. Document Production Accompanying Invalidity Contentions. With the Invalidity Contentions, Defendant(s) shall produce or make available for inspection and copying a copy or sample of the prior art identified pursuant to paragraph 7(a) that does not appear in the file history of the asserted patent(s). To the extent any such item is not in English, an English translation of the portion(s) relied upon shall be produced.

9. Infringement Contentions. Unless otherwise agreed to by the parties, no later than 45 days after service of the Noninfringement Contentions, Plaintiff(s) shall serve on Defendant(s) “Infringement Contentions.” Separately for each Defendant, the Infringement Contentions shall contain the following information:

(a) Each claim of each asserted patent that Plaintiff(s) allege(s) Defendant(s) infringe(s), including for each claim the applicable statutory subsections of 35 U.S.C. § 271 asserted;

(b) Separately for each asserted claim, each accused apparatus, product, device, process, method, act, or other instrumentality (“Accused Instrumentality”) of each Defendant of which Plaintiff(s) is(are) aware. This identification shall be as specific as possible. Each product, device, and apparatus shall be identified by name or model number, if known. Each method or process shall be identified by name, if known, or by any product, device, or apparatus that, when used, allegedly results in the practice of the claimed method or process;

(c) A chart identifying specifically where and how each limitation of each asserted claim is found within each Accused Instrumentality, including for each limitation that such party contends is governed by 35 U.S.C. § 112(f), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function;

(d) For each claim alleged to have been indirectly infringed, an identification of any direct infringement and a description of the acts of the alleged indirect infringer that contribute to or are inducing that direct infringement. Insofar as alleged direct infringement is based on joint acts of

multiple parties, the role of each such party in the direct infringement must be described;

(e) Whether each limitation of each asserted claim is alleged to be present in the Accused Instrumentality literally or under the doctrine of equivalents;

(f) For any patent that claims priority to an earlier application, the priority date to which each asserted claim is alleged to be entitled; and

(g) If Plaintiff(s) wish(es) to preserve the right to rely, for any purpose, on the assertion that its(their) own or its(their) licensee's apparatus, product, device, process, method, act, or other instrumentality practices the claimed invention, Plaintiff(s) shall identify, separately for each asserted claim, each such apparatus, product, device, process, method, act, or other instrumentality that incorporates or reflects that particular claim ("Embodying Instrumentality").

10. Document Production Accompanying Infringement Contentions.

Plaintiff(s) shall produce with the Infringement Contentions or make available for inspection and copying:

(a) Documents (e.g., contracts, purchase orders, invoices, advertisements, marketing materials, offer letters, beta site testing agreements, and third party or joint development agreements) sufficient to

evidence each discussion with, disclosure to, or other manner of providing to a third party, or each sale of or offer to sell, or any public use of, the claimed invention prior to the date of application for the asserted patent(s);

(b) All documents evidencing the conception, reduction to practice, design, and development of each claimed invention, that were created on or before the date of application for the asserted patent(s) or the priority date(s) identified pursuant to paragraph 9(f) of this Order, whichever is earlier; and

(c) If Plaintiff(s) identifies(y) instrumentalities pursuant to paragraph 9(g) of this Order, documents sufficient to show the operation of any aspects or elements of such instrumentalities the patent claimant relies upon as embodying any asserted claims.

Plaintiff(s) shall separately identify by production number the documents that correspond to each category set forth in this paragraph. The production of a document as required by this paragraph shall not constitute an admission that such document evidences or is prior art under 35 U.S.C. § 102.

11. Addition or Substitution of Asserted Claims or Prior Art and Amendment of Contentions. The addition or substitution of asserted claims or prior art and the amendment of the Noninfringement Contentions, Invalidity Contentions, Infringement Contentions, Preliminary Disclosure of Asserted Claims, and Preliminary Disclosure of Asserted Prior Art may be made only by

order of the Court upon a timely showing of good cause. A request to add an asserted claim will likely only be granted if Plaintiff(s) drop(s) a claim or claims previously asserted. A request to add an asserted prior art reference will likely only be granted if Defendant(s) drop(s) a prior art reference or references previously asserted. The duty to supplement discovery responses does not excuse the need to obtain leave of the Court to add or substitute asserted claims or prior art or to amend contentions.

12. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before _____.

13. Discovery.

(a) Discovery Cut Off. All discovery in this case shall be initiated so that it will be completed on or before _____.

(b) Document Production. Document production shall be completed on or before _____.

(c) Requests for Admission. A maximum of __ requests for admission is permitted for each side.

(d) Interrogatories. A maximum of __ interrogatories, including contention interrogatories, is permitted for each side.

(e) Depositions.

(1) Limitation on Hours for Deposition Discovery. Each side is limited to a total of ___ hours of taking testimony by deposition upon oral examination.

(2) Location of Depositions. Any party or representative (officer, director, or managing agent) of a party filing a civil action in this District Court must ordinarily be required, upon request, to submit to a deposition at a place designated within this District. Exceptions to this general rule may be made by order of the Court or by agreement of the parties. A Defendant who becomes a counterclaimant, cross-claimant, or third-party plaintiff shall be considered as having filed an action in this Court for the purpose of this provision.

14. Pinpoint Citations. Pinpoint citations are required in all briefing, letters, and concise statements of facts. The Court will ignore any assertions of controverted facts and controverted legal principles not supported by a pinpoint citation to, as applicable: the record, an attachment or exhibit, and/or case law or appropriate legal authority. *See United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991) (“Judges are not like pigs, hunting for truffles buried in briefs.”).

15. Application to Court for Protective Order. Should counsel find it will be necessary to apply to the Court for a protective order specifying terms and conditions for the disclosure of confidential information, counsel should confer and attempt to reach an agreement on a proposed form of order and submit it to the Court within ten days from the date of this Order.

Any proposed protective order must include the following paragraph:

Other Proceedings. By entering this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that the information may be relevant and subject to disclosure in another case. Any person or party subject to this Order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this Order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

16. Disputes Relating to Discovery Matters and Protective Orders. Should counsel find that they are unable to resolve a dispute relating to a discovery matter or protective order, the parties shall contact the Court's Case Manager to schedule an in-person conference/argument.

(a) Unless otherwise ordered, by no later than 72 hours prior to the conference/argument, the party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and the

party's position on those issues. The party shall submit as attachments to its letter (1) an averment of counsel that the parties made a reasonable effort to resolve the dispute and that such effort included oral communication that involved Delaware counsel for the parties and (2) a draft order for the Court's signature that identifies with specificity the relief sought by the party. The party shall file concurrently with its letter a motion that in no more than one paragraph sets forth the relief sought.

(b) By no later than 48 hours prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's reasons for its opposition.

(c) Two hard copies of the parties' letters and attachments must be provided to the Court within one hour of e-filing the document(s). The hard copies shall comply with paragraphs 14 and 18 of this Order.

(d) If a motion concerning a discovery matter or protective order is filed without leave of the Court and does not comport with the procedures set forth in this paragraph, the motion will be denied without prejudice to the moving party's right to bring the dispute to the Court through the procedures set forth in this paragraph.

17. Papers Filed Under Seal. When filing papers under seal, counsel shall deliver to the Clerk an original and two copies of the papers. A redacted version of

any sealed document shall be filed electronically within seven days of the filing of the sealed document.

18. Hard Copies. The parties shall provide to the Court two hard copies of all letters filed pursuant to paragraph 16 of this Order, all briefs, and any other documents filed in support of any such letters and briefs. This provision also applies to papers filed under seal.

a. Exhibits and Attachments. **Each exhibit and attachment to a letter, brief, or pretrial order shall be separated by a tab.** (Accordingly, each brief filed in connection with a motion *in limine* in a pretrial order must be separated by a tab.) Each exhibit and attachment shall have page numbers of some sort such that a particular page of an exhibit or attachment can be identified by a page number. The parties shall take all practical measures to avoid filing multiple copies of the same exhibit or attachment. The parties should highlight the text of exhibits and attachments they wish the Court to read. The parties are encouraged to include in an exhibit or attachment only the pages of the document in question that (1) identify the document (e.g., the first page of a deposition transcript or the cover page of a request for discovery) and (2) are relevant to the issue(s) before the Court.

b. Colors of Front Covers. The covers of briefs filed in connection with all motions except for motions *in limine* included in a pretrial order shall be as follows:

- i. Opening brief – Blue
- ii. Answering brief – Red
- iii. Reply brief – Gray

19. Claim Construction Issue Identification. On or before _____, the parties shall exchange a list of those claim term(s)/phrase(s) that they believe need construction and their proposed claim construction(s) of those term(s)/phrase(s). This document will not be filed with the Court. Subsequent to exchanging that list, the parties will meet and confer to prepare a Joint Claim Construction Chart to be filed no later than _____. The Joint Claim Construction Chart, in Word format, shall be e-mailed simultaneously with filing to cfc_civil@ded.uscourts.gov. The text for the Joint Claim Construction Chart shall be 14-point and in Times New Roman or a similar typeface. The parties' Joint Claim Construction Chart should identify for the Court the term(s)/phrase(s) of the claim(s) in issue and should include each party's proposed construction(s) of the disputed claim language with citation(s) only to the intrinsic evidence in support of their respective proposed constructions. A separate text-searchable PDF of each of the patent(s) in issue shall be submitted with this Joint

Claim Construction Chart. In this joint submission, the parties shall not provide argument. Each party shall file concurrently with the Joint Claim Construction Chart a “Motion for Claim Construction” that requests the Court to adopt the claim construction position(s) of that party set forth in the Joint Claim Construction Chart. The motion shall not contain any argument and shall simply state that the party “requests that the Court adopt the claim construction position[s] of [the party] set forth in the Joint Claim Construction Chart (D.I. []).”

20. Claim Construction Briefing. The Plaintiff(s) shall serve, but not file, its(their) opening brief, not to exceed 5,500 words, on _____. The Defendant(s) shall serve, but not file, its(their) answering brief, not to exceed 8,250 words, on _____. The Plaintiff(s) shall serve, but not file, its(their) reply brief, not to exceed 5,500 words, on _____. The Defendant(s) shall serve, but not file, its(their) sur-reply brief, not to exceed 2,750 words, on _____. The text for each brief shall be 14-point and in Times New Roman or a similar typeface. Each brief must include a certification by counsel that the brief complies with the type and number limitations set forth above. The person who prepares the certification may rely on the word count of the word-processing system used to prepare the brief.

No later than _____, the parties shall file a Joint Claim Construction Brief. (Should the parties later stipulate or otherwise request to have

this deadline extended, the parties will presumptively lose their claim construction hearing date upon the Court’s granting the extension.) The parties shall copy and paste their untitled briefs into one brief, with their positions on each claim term in sequential order, in substantially the form below.

JOINT CLAIM CONSTRUCTION BRIEF

- I. Agreed-upon Constructions
- II. Disputed Constructions
 - A. [TERM 1]
 - 1. Opening Position of Plaintiff(s)
 - 2. Answering Position of Defendant(s)
 - 3. Reply Position of Plaintiff(s)
 - 4. Sur-Reply Position of Defendant(s)
 - B. [TERM 2]
 - 1. Opening Position of Plaintiff(s)
 - 2. Answering Position of Defendant(s)
 - 3. Reply Position of Plaintiff(s)
 - 4. Sur-Reply Position of Defendant(s)

Etc. The parties need not include any general summaries of the law relating to claim construction. If there are any materials that would be submitted in an appendix, the parties shall submit them in a Joint Appendix. Citations to intrinsic evidence shall be set forth in the Joint Claim Construction Brief. Citations to expert declarations and other extrinsic evidence may be made in the Joint Claim Construction Brief as the parties deem necessary, but the Court will review such

extrinsic evidence only if the Court is unable to construe the disputed claim terms based on the intrinsic evidence. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 (Fed. Cir. 1996). Declarations shall not contain legal argument or be used to circumvent the briefing word limitations imposed by this paragraph. The Joint Claim Construction Brief and Joint Appendix shall comply with paragraphs 14 and 18 of this Order.

21. Meet and Confer Confirmation and Amended Claim Chart. On or before _____ [no earlier than three weeks before the claim construction hearing and no later than two weeks before the claim construction hearing], Delaware and lead counsel for the parties shall meet and confer and thereafter file an Amended Joint Claim Construction Chart that sets forth the terms that remain in dispute. During the meet and confer, the parties shall attempt to reach agreement on any disputed terms where possible and to narrow the issues related to the remaining disputed terms. The parties shall file with the Amended Joint Claim Construction Chart a letter that identifies by name each individual who participated in the meet and confer, when and how (i.e., by telephone or in person) the meet and confer occurred, and how long it lasted. If no agreements on constructions have been reached or if no dispute has been narrowed as a result of the meet and confer, the letter shall so state, and the parties need not file an Amended Joint Claim Construction Chart.

22. Hearing on Claim Construction. Beginning at _____ .m. on _____, the Court will hear argument on claim construction. Absent prior approval of the Court (which, if it is sought, must be done by joint letter submission no later than the date on which answering claim construction briefs are due to be served), the parties shall not present testimony at the argument, and the argument shall not exceed a total of three hours.

23. Narrowing of Asserted Prior Art and Claims. Unless otherwise agreed to by the parties, no later than 28 days after the Court issues a claim construction order, Defendant(s) shall serve on Plaintiff(s) a “Final Election of Asserted Prior Art” that reduces the number of prior art references that Defendant(s) allege(s) anticipates each asserted claim or renders the claim obvious. Defendant(s) shall identify in the Final Election of Asserted Prior Art no more than six prior art references for any one patent from among the 12 prior art references identified for that patent in the Preliminary Disclosure of Asserted Prior Art and shall identify no more than a total of 20 references from among the references identified in the Preliminary Disclosure of Asserted Prior Art. No later than 14 days after service of the Final Election of Asserted Prior Art, Plaintiff(s) shall serve on Defendant(s) a “Final Election of Asserted Claims” that shall identify for any one patent no more than five asserted claims from among the 10 claims identified for that patent in the Preliminary Disclosure of Asserted Claims and

shall identify no more than a total of 16 claims from among the claims identified in the Preliminary Disclosure of Asserted Claims.

24. Disclosure of Expert Testimony.

(a) Expert Reports. For the party with the initial burden of proof on the subject matter, the initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before _____. The supplemental disclosure to contradict or rebut evidence on the same matter identified by another party is due on or before _____. Reply expert reports from the party with the initial burden of proof are due on or before _____. No other expert reports will be permitted without either the consent of all parties or leave of the Court. Along with the submissions of the expert reports, the parties shall provide the dates and times of their experts' availability for deposition. Depositions of experts shall be completed on or before _____.

(b) Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later than [].

25. Case Dispositive Motions. The Court will not entertain summary judgment motions.

26. Daubert Motions. A party that files more than one *Daubert* motion shall number each motion to make clear the order in which the party wishes the Court to consider the motions in question. The first motion the party wishes the Court to consider shall be designated #1, the second motion shall be designated #2, and so on. The Court will review the party's *Daubert* motions in the order designated by the party. If the Court decides to deny a motion filed by the party, barring exceptional reasons determined sua sponte by the Court, the Court will not review any further *Daubert* motions filed by the party. If the Court denies a *Daubert* motion and the party that brought the motion does not cross examine the expert witness at trial about the matters raised in the *Daubert* motion, the Court will reduce by an appropriate amount the time allotted to that party at trial.

27. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

28. Pretrial Conference. On _____, the Court will hold a Rule 16(e) final pretrial conference in court with counsel beginning at _____ .m. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5:00 p.m. on _____ [21 days before the pretrial conference]. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the

preparation of the proposed joint final pretrial order. The joint pretrial order shall comply with paragraphs 14 and 18 of this Order.

29. Motions in Limine. Motions *in limine* shall not be separately filed. All *in limine* requests and responses thereto shall be set forth in the proposed pretrial order. Each party shall be limited to three *in limine* requests, unless otherwise permitted by the Court. Each *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and the party making the *in limine* request may add a maximum of one additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three-page submission (and, if the moving parties, a single one-page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court. Motions *in limine* shall comply with paragraphs 14 and 18 of this Order.

30. Compendium of Cases. A party may submit with any briefing two courtesy copies of a compendium of the selected authorities on which the party would like the Court to focus. The parties should not include in the compendium authorities for general principles or uncontested points of law (e.g., the standards for claim construction). An authority that is cited only once by a party generally

should not be included in the compendium. An authority already provided to the Court by another party should not be included in the compendium. Compendiums of cases shall not be filed electronically with the Court, but a notice of service of a compendium of cases shall be filed electronically with the Court. Compendiums shall comply with paragraph 18 of this Order.

31. Trial. This matter is scheduled for a ___-day bench trial beginning at 8:30 a.m. on _____, with the subsequent trial days beginning at 8:30 a.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases. The Court will limit the number of claims and prior art references asserted at trial. Absent a showing of good cause, no claim may be asserted at trial that was not identified in the Final Election of Asserted Claims, and no prior art reference may be asserted at trial that was not identified in the Final Election of Asserted Prior Art.

32. Requests to Modify the Limits on Asserted Claims and Prior Art References. Any request to increase the limits on asserted claims and prior art references imposed by this Order must demonstrate with specificity why the inclusion of additional asserted claims or prior art references is warranted. *See In*

re Katz Interactive Call Processing Pat. Litig., 639 F.3d 1303, 1312 (Fed. Cir. 2011).

The Honorable Colm F. Connolly
United States District Court Judge

