- 3. In this case, ICU alleges that Braun's manufacture and sale of Braun's Ultrasite needless medical connectors infringes two patents owned by ICU: U.S. Patent No. 5,928,204 ("the '204 patent") and U.S. Patent No. 6,669,673 ("the '673 patent"). Braun denies infringement, and alleges the patents are invalid and/or unenforceable.
- 4. On March 14, 2005, this Court denied ICU's motion for summary judgment on Braun's affirmative defense of inequitable conduct, and scheduled a trial on the limited issue of Braun's inequitable conduct defense. (Ex. 19, 3/14/05 Order at 18-26.) The trial was conducted on ______, 2005. Based on the evidence presented at trial, this Court finds the '673 patent is unenforceable for inequitable conduct and enters judgment for Braun on ICU's claim of infringement based on that patent. The following are the Court's findings of fact and conclusions of law pursuant to Fed. R. Civ. P. 52(a) in support of the Court's determination.
- This patent infringement case is unusual in that the accused product, Braun's Ultrasite valve, was commercially available years before the ICU patents it is alleged to infringe issued.

1; (Ex. 501, '204 patent (issued July 27, 1999)); (Ex. 507, '673 patent (issued Dec. 30, 2003)). In fact, ICU's '673 patent was *filed* at the Patent Office ("PTO") almost one year *after* the parties were already in litigation over whether the Ultrasite valve infringed the '204 patent, and was added to this case by amendment after the '673 patent issued on December 30, 2003. (*See id.*); (*see also* Ex. 623, 12/30/03 ICU Mot. for Leave to File First Am. Compl.) ICU acknowledges that the reason the '673 patent was filed at the PTO during this litigation was to bring an additional patent infringement claim against Braun's Ultrasite valve. (*See, e.g.*, Ex. 702, 6/5/02 Attorney Declaration Supporting Petition To Make Special) (declaration by ICU's prosecution counsel, Steven Nataupsky, averring to patent examiner during '673 prosecution that the Braun Ultrasite "unquestionably infringe[s]" at least some of the '673 application's claims);(Nataupsky

¹ All emphases are added unless otherwise indicated.

REDACTED

6. Yet the PTO was *never* told about this on-going litigation, which ICU acknowledges is related to the '673 patent, during the prosecution of the '673 patent. (*E.g.*, Ex. 508, '673 file history) (containing no disclosure, by ICU or any other party, of ICU's pending litigation wherein ICU accused Braun's Ultrasite valve of infringing ICU's related '204 patent); (*see also* Ex. 623, 12/30/03 ICU Motion for Leave to File Amended Complaint, at 1) (requesting leave to add '673 patent to this case on the same day that patent issued and arguing "the '673 patent includes the same specification and inventor as the '204 patent and claims priority to the same line of applications as the '204 patent. Furthermore, ICU asserts that the accused device in this action, B. Braun Medical, Inc.'s ... UltraSite valve, infringes both the '204 and the '673 patent."); (Ex. 624, 12/30/03 ICU Notice of Related Cases) (asserting cases based on the '204 and the '673 patents "are related" under Local Rule 3-12 because "the patents at issue ... are related and have the same specification and inventors, and claim priority to the same line of patent applications"). It is the circumstances surrounding the prosecution of the '673 patent that are at issue in this trial.

A. The Parties Are Medical Valve Manufacturers.

- 7. ICU and Braun both manufacture and sell medical valves for use in IV sets. These medical valves are disposable components that allow a healthcare clinician to inject or withdraw fluids from an IV line without the use of a needle. They can be sold as stand alone products or part of a larger set that includes tubing or other IV components.
- 8. ICU sells a medical valve called the Clave. ICU has been selling the Clave valve since 1993. (*E.g.*, Ex. 1032, ICU 2000 10K, at 2.) ICU primarily sells its Clave valve through resellers, though it sells some Clave products directly to end user hospitals and other health care facilities. (*See*, *e.g.*, Ex. 1032, at 7.) For example, ICU sells the majority of its Clave valve and related products through a reseller arrangement with Hospira (formerly part of Abbott). (*Id.*)
- 9. Braun sells a medical valve called the Ultrasite. Braun has been selling the Ultrasite valve since 1996. The record is undisputed that ICU has been aware of the Ultrasite valve since

November 1996.

REDACTED

valves, most of Braun's sales of Ultrasite products are sold to end users through Braun's supply contracts with various hospital purchasing organizations. Braun does sell some of its Ultrasite valves through distributors and other resale arrangements.

B. The Parties Had A Contractual Relationship Prior To This Lawsuit.

10. For a period of time Braun sold both its proprietary Ultrasite valve and resold ICU's Clave valve to end users. In a January 1, 1998 Manufacture and Supply Agreement ("Clave Agreement"),

REDACTED

entered into the agreement after acquiring McGaw, Inc., which was already ICU's second largest reseller. (*E.g.*, ICU's 10/15/2002 Supplemental Response to Interrogatory No. 6.)

11. The Clave Agreement recognized that Braun was continuing to sell its own Ultrasite valve.

REDACTED

The Clave Agreement expired on

Unlike ICU's sales of Clave

December 31, 2002, subject to provisions for extending the term of the contract. (Id.)

12. Under the Clave Agreement, Braun was the second largest reseller of ICU's Clave valves after Abbott. (*E.g.*, Ex. 1031, 2001 10K, at ICU-BB 52528) ("Sales to B.Braun accounted for approximately 19%, 26% and 28% of our net sales in 2001, 2000 and 1999, respectively. The loss of Abbott or B.Braun as a customer could have a significant adverse effect on our business and operating results because they have full-line contracts with numerous healthcare providers"). While the

Clave Agreement was in force, Braun's resale of Clave products represented a significant portion of ICU's business. (E.g., id.)

- 13. On June 28, 2001, ICU sued Braun, alleging that it had failed to comply with the terms of the Clave Agreement. (Ex. 927, 6/28/01 ICU Complaint for Declaratory Relief in Superior Court of the State of California.) ICU alleged, "[u]pon information and belief," that Braun had violated the contract by marketing its Ultrasite valve to its customers of Clave valves. (*Id.* ¶ 14-15.) ICU sought a declaration that the Agreement was terminated. (*Id.* ¶ 33.) Braun denied any violation and countersued ICU for its own alleged breaches of the contract, including by permitting ICU resellers to market Clave connectors into its exclusive accounts and by reselling the Clave valve itself in competition with Braun under a different brand name—"Bravo-24." (*E.g.*, Ex. 928, 7/3/02 Braun's Amended Counterclaims ¶¶ 48-53.)
- 14. The parties' competing contract allegations were disputed and ultimately settled without admission by either party by terminating the Clave Agreement as of December 31, 2002. Which party was right and which was wrong is immaterial to the issue before the Court. What is relevant and abundantly supported by the record is that, notwithstanding the terms of the Clave Agreement, ICU—and in particular its CEO, Dr. Lopez—wanted Braun to stop selling Ultrasite valves, and resell only ICU's Clave valves. (E.g., Ex. 951, at BBM 031188, 6/26/01 e-mail from ICU's Costello, copied to ICU's CEO, George Lopez) (demanding of Braun that "[a]Il connector growth must be Clave").

C. Dr. Lopez and ICU's Patent Portfolio.

- 15. Dr. Lopez is the CEO of ICU Medical and (with his family) the largest single stockholder in the publicly traded company. (*E.g.*, Ex. 1131, ICU Schedule 14A) (showing "[s]ecurity ownership of certain beneficial owners," including Lopez). Dr. Lopez is actively involved in ICU's strategic decisions, and leads a quarterly conference call with ICU investors to discuss quarterly results and ICU's strategy. (*E.g.*, Exs. 730-742) (ICU inventor calls and meetings).
- 16. A significant part of ICU's business strategy is its patent portfolio. (See, e.g., Ex. 1031, ICU 2001 10K, at ICU-BB 52532) ("Our success may depend on our ability to obtain patent protection for our products and to operate without infringing the proprietary rights of third parties We also believe that ... patent protection on the CLAVE may be[] important in preventing others from

introducing competing products which are as effective as our products."). ICU has numerous patents, especially those related to its Clave valve. (*See, e.g.*, Ex. 275, attached Ex. A to 1/14/05 Rule 26(a) Expert Report of James T. Carmichael) (illustrating numerous of the Lopez/ICU patents in the "Clave Patent Tree").

- 17. ICU filed its first patent application related to its Clave valve in December 1991. After that initial filing, ICU filed scores of additional continuation applications, all sharing the same specification and all identifying the same inventor—Dr. Lopez. Numerous different patents have issued claiming priority to the original 1991 application, including both of the patents-in-suit. (*E.g.*, Ex. 275, attached Ex. A.) Moreover, ICU continues to have pending applications through the present day, all of which claim priority back to the 1991 application. (*Id.*) The expansive patent filings related to the Clave valve are aptly described as forming a patent tree, with various branches formed by different priority applications. (*See id.*) For example, the patents-in-suit in this case both claim priority to the same 1991 application, but each has been prosecuted and ultimately issued through a different line of priority applications, or branches, of the Clave patent tree. (*Id.*); (*see also* Ex. 501, '204 patent); (Ex. 507, '673 patent).
- 18. Dr. Lopez uses ICU's line of Clave patents and patent applications as a weapon against ICU's competitors. In fact, while the Clave valve itself made its commercial introduction in 1993, the first patent to issue from the line of applications claiming priority to the 1991 application did not issue until 1997, thus effectively extending the life of the patent. (*E.g.*, Ex. 275, 1/14/05 Carmichael Report at 11, 22) (explaining that "[r]ather than diligently seeking these ['673 patent] claims in 1991, or 1996, or 1997, or some other time, Lopez instead appears to have waited and filed related patent applications one at a time, in an effort to systematically extend a patent monopoly on medical valves and components").
- 19. In recent years, ICU has pursued an aggressive new patent strategy that involves adding claims to its pending patent applications that it contends cover its competitors products. (*E.g.*, Ex. 702, 6/5/02 Attorney's Declaration Supporting Petition To Make Special) (ICU prosecution counsel, averring to the PTO that Braun's Ultrasite valve infringed while ICU and Braun were already in litigation over same product, but not disclosing that litigation to examiner); (Ex. 705, 5/22/02)

Attorney's Declaration Supporting Petition To Make Special) (ICU prosecution counsel, averring to the PTO infringement by competitor Porex Corp.'s "NAC Adaptor" valve); (Ex. 709, 11/19/01, Attorney's Declaration Supporting Petition To Make Special) (ICU prosecution counsel, averring to the PTO infringement by competitor Alaris, Inc.'s "Smartsite" valve, which ICU later sued). These pending patent applications were prosecuted without the knowledge of the competitors. (*E.g.*, *id*.) When they issued, ICU sued the competitor with a tailor-made patent.

- 20. The primary architect of ICU's patent prosecution and enforcement strategy has been attorney Steven Nataupsky, Esq., at the law firm Knobbe Marten. ICU has no in-house counsel. Mr. Nataupsky has been Dr. Lopez's chief patent advisor since 1995, and Mr. Nataupsky has been representing ICU and Lopez since 1991. (Nataupsky Dep. at 15, 17.) Dr. Lopez relies on Mr. Nataupsky to develop his patent strategies for both prosecution and enforcement. Dr. Lopez, as CEO, is involved with and approves the strategies developed by Mr. Nataupsky.
- 21. Mr. Nataupsky has represented ICU and Dr. Lopez in both patent prosecution and litigation.

REDACTED

D. Dr. Lopez Works With Mr. Nataupsky On A Plan To Drive The Ultrasite From The Market And Braun Back To ICU.

22. With the Clave Agreement coming to the end of its term, Dr. Lopez implemented an aggressive campaign to cause Braun to switch 100% over to ICU's Clave valve. For example, Dr. Lopez instructed his Vice President of Sales, Richard Costello, and Vice President of Marketing, Allison Brummett, that they were free to allege infringement by Braun of unidentified ICU patents—even though no infringement analysis had been performed. (*E.g.*, Lopez Dep. (in Braun litigation) at

REDACTED

23. Mr. Nataupsky, working with Dr. Lopez and Mr. Fangrow, an ICU engineer, worked to find a patent that could be asserted against Braun. In the summer of 2001, Messrs. Nataupsky, Fangrow and Lopez determined that infringement allegations should be brought based on the '204 patent, as well as a new ICU patent that Mr. Nataupsky was prosecuting—U.S. Patent No., 6,245,048 ("the '048 patent"), which issued on June 12, 2001.

REDACTED

REDACTED

- 24. In June 2001, ICU brought its contract suit against Braun, its second largest customer. (Ex. 927, 6/28/01 ICU Complaint.) To raise the pressure, in August 2001, Dr. Lopez authorized filing a patent infringement lawsuit against Braun based on the '204 and '048 patent. The patent lawsuit was filed on August 21, 2001. (Ex. 500, 8/21/01 Complaint for Patent Infringement.)
- Dr. Lopez explained the two litigations against his second largest customer to his investors, saying Braun has a "product that they sell; it's called the Ultrasite, and that product, we didn't realize it until relatively recently, is infringing on two of our patents, two separate patents, both the CLC patent and the CLAVE patent." (Ex. 743, at ICU-BB 62670.) Lopez later clarified in his explanation that ICU has "two issues" with Braun—the contract "compliance" issue and the patent issues, and that "[t]he patent issues came about after the first [contract] issue came up." (*Id.* at ICU-BB 62674-675.) He asserted to his investors that Braun "clearly" is "infringing on multiple claims of both" the '204 and '048 patents (the latter of which ICU later dropped with prejudice at its own request). (*See id.* at ICU-BB 62670.)

E. ICU and Braun Litigate The '204 and '048 Patents.

- 26. ICU's complaint alleged that Braun's Ultrasite valve infringed the '204 and '048 patents. (E.g., Ex. 500.) The two patents-in-suit were directed to two entirely different ICU medical valve products.
- 27. The '204 patent is entitled "Medical Valve and Method of Use." (Ex. 501, '204 patent.) It is one of the Clave patents that claims priority to the 1991 specification and identifies Dr. Lopez as its sole inventor. (*Id.*) The '204 patent issued on July 27, 1999. (*Id.*) Mr. Nataupsky and his firm prosecuted the '204 patent. (*E.g.*, *id.*); (Ex. 502, '204 File History); (*see also* Nataupsky Dep. at 150-51, 168, 184).
- 28. The '204 patent is related to ICU's Clave valve, which uses a resilient rubber seal to open and close the valve over a spike that acts as a fluid conduit. (*See, e.g.*, Ex. 512, 2/5/02 ICU Initial Disclosure of Asserted Claims Under Patent LR 301, at 10-11) (identifying Clave as commercial

embodiment of the asserted '204 patent claims); (Ex. 1031, ICU 2001 10K, at ICU-BB 52525) (describing features of Clave connector).

29. The '048 patent is entitled "Medical Valve With Positive Flow Characteristics." (Ex. 504, '048 patent.) The '048 patent issued on June 12, 2001, shortly before this lawsuit was filed. (*Id.*) Mr. Nataupsky and his firm prosecuted the '048 patent, too.

REDACTED

30. The '048 patent is not directed to the Clave but instead to a different ICU medical valve, the CLC-2000. **REDACTED**

Unlike the Clave, the CLC-2000 uses a hard rubber piston or "poppet" that cannot bend to open and close the valve. (*E.g.*, 1031, ICU 2001 10K, at ICU-BB 52527) (describing CLC-2000, including its "poppet").

- 31. Braun's answer to the complaint denied infringement, and asserted invalidity and unenforceability. In particular, Braun alleged the '048 patent was unenforceable because the Ultrasite valve itself was prior art to the claims, and was never disclosed to the Patent Office despite the fact that ICU's own 510k filings with the Food & Drug Administration showed ICU's knowledge of the Braun product prior to the filing of the '048 patent. (*E.g.*, Ex. 503, 1/10/02 Braun's First Am. Answer & Counterclaims, ¶ 20.)
- 32. On January 22, 2002, ICU served its preliminary infringement contentions pursuant to the Local Rules. (Ex. 510, ICU's 1/22/02 Initial Disclosure of Asserted Claims Under Patent LR 3-1.) In its January 22, 2002 contentions, ICU asserted only infringement of the '204 patent, including claim 1. (Ex. 510, at 2-4.) Claim 1 of the patent covers a "seal" with a "resilient seal element" having a "wall" defined by a particular shape. (*E.g.*, Ex. 501, '204 patent, col. 15: 33-43.) ICU alleged in its infringement contentions that the blue piston component (or "sheath") of Braun's Ultrasite valve was the "resilient seal element." (*See* Ex. 510, at 2.)
- 33. On January 30, 2002, ICU served new preliminary infringement contentions, this time alleging infringement of both the '204 patent and the '048 patent claims. (Ex. 511, ICU's 1/30/02)

10

15 16

14

17 18

19

20

21 22

24

25

23

26

27 28

Initial Disclosure of Asserted Claims Under Patent LR 3-1, at 2-3.) In its new infringement contentions, ICU alleged that the Ultrasite valve infringed claims 1-4, 9, 10 and 12 of the '048 patent. (Ex. 511, at 3.) Claim 1 recites a "medical valve for controlling the flow of fluid between a first medical implement and a second medical implement, said valve comprising" "a body having a cavity in communication with a second medical implement and an opening adapted to receive a first medical implement" and a "rigid sealing element positioned within said body and movable between a first position in which said seal prevents flow through the body and a second position where fluid flow is permitted through said body." (Ex. 504, col. 26: 1-18.)

- 34. On February 5, 2002, ICU amended its initial disclosures for a third time. (Ex. 512, ICU's 2/5/02 Initial Disclosure of Asserted Claims Under Patent LR 3-1.) In these amended contentions, ICU now alleged that the piston assembly in the Ultrasite valve, including the elastomeric piston, rigid plug, and spring, formed the "rigid sealing element" recited in the asserted claims of the '048 patent. (Ex. 512, at 5, 7, 8, 9.) After Braun moved to compel complete infringement disclosures. ICU amended its disclosures for a fourth time, on May 17, 2002. (Ex. 513, ICU's 5/17/02 Amended Initial Disclosure of Asserted Claims Under Patent LR 3-1 And Preliminary Infringement Contentions.)
- 35. Meanwhile, after receiving some of ICU's infringement contentions identifying the asserted claims, Braun served its preliminary invalidity contentions on March 7, 2002. (Ex. 534, Defendant's Patent L.R. 3-3 Preliminary Invalidity Contentions.) These invalidity contentions identified several different references and included 75 pages of explanation detailing the bases for Braun's invalidity contentions with respect to the asserted claims. (Id.)
- 36. Pursuant to this Court's Patent Local Rules, the parties prepared a Joint Claim Construction Statement, and subsequent Revised Joint Claim Construction Statement for submission to the Court. (Exs. 540-541.) These statements provided proposed meanings for disputed terms and identified corresponding disclosure in the specification and prosecution history. (Id.) Among the disputed terms for construction were "seal," "resilient seal element" and "rigid sealing element" in the two patents-in-suit. (*Id.*)
- 37. On July 5, 2002, ICU served its opening claim construction brief on the meaning of disputed claim terms in '204 and '048 patents. (Ex. 542.) With its brief, ICU also served the

declarations of two of its expert witnesses, Mr. Fangrow and Mr. Prozeller. (*See* Ex. 543) (Fangrow Decl.); (Ex. 544) (Prozeller Decl.). Using strikingly similar language, these declarations opined that each of the disputed terms—including the "seal," "resilient seal element" and "rigid sealing element"—had a well-known, "ordinary" meaning in the field. (*E.g.*, Ex. 543, ¶¶ 13-14, 32); (Ex. 544, ¶¶ 14-15, 33.)

38. In a subsequent deposition, Mr. Fangrow opined that, in the view of one of ordinary skill in the art, the "resilient seal element" in the '204 patent could be a "rigid sealing element" within the meaning of the '048 patent.

REDACTED

39. On August 2, 2002, Braun served its answering brief on disputed claim terms. (Ex. 545.) The brief addressed ICU's inconsistent pleadings on "rigid sealing element" and "resilient sealing element." (*E.g.*, Ex. 545, at 13-14.) In addition, Braun moved for partial summary judgment on the date to which the asserted '048 patent claims were entitled to priority. (Ex. 550, 8/2/02 Braun's Motion for Summary Adjudication On The Priority Date Of The '048 Patent.) Because the claims of the '048 patent were not entitled to the priority date of an earlier filed patent application, the Ultrasite valve was prior art to the '048 patent. (*Id.* at 1-3.) As a result, ICU's infringement allegations invalidated its own patent. (*Id.*)

- 40. ICU did not respond to Braun's motion for partial summary judgment on the '048 patent. Instead, ICU moved to dismiss its '048 patent from the case. (Ex. 551, 8/12/02 ICU Notice And Memorandum Of Points And Authorities In Support Of Motion For Leave To Amend Complaint To Dismiss First Cause Of Action Without Prejudice.) Unknown to Braun and the Court, after reviewing Braun's motion, Mr. Nataupsky filed a reissue application for the '048 patent that contended that every single one of the asserted claims contained an "error" that left the patent wholly or partly inoperative or invalid. (*E.g.*, Ex. 505, File History for the '048 Reissue Application.)
- 41. After Mr. Nataupsky filed this '048 reissue application at the Patent Office, ICU requested that the Court dismiss the '048 patent from the case because of the reissue application, and allow ICU to prosecute new claims before the Patent Office *ex parte*. (*E.g.*, Ex. 552, 8/22/02 Transcript of Proceedings on ICU's Motion for Partial Dismissal or Stay of '048 Patent, at 4.) ICU explained to this Court that reissue applications have faster examination times than patents subject to a petition to make special—a statement that foreshadowed other activities already undertaken by Mr. Nataupsky, but not yet revealed in litigation. (*See, e.g.*, Ex. 702, 6/5/02 Attorney Declaration Supporting Petition To Make Special for '673 application). ICU acknowledged that (1) Mr. Nataupsky's reissue application was prompted by Braun's summary judgment motion; and (2) ICU wanted to write new claims that read on Braun's product and then add the reissue patent with new claims back into this suit. (*See, e.g.*, Ex. 551, at 3) ("ICU's currently proposed amendments would moot many of the issues raised in Braun's motion for summary adjudication," as it would allow ICU to address numerous errors with its '048 patent via a reissue application).
- 42. This Court denied ICU's request to dismiss without prejudice the '048 patent from the case, and ICU eventually dismissed the '048 patent claim with prejudice. (Ex. 615, 9/9/02 Order dismissing ICU's '048 patent from case with prejudice). This left ICU with only the '204 patent in the case—though unknown to Braun or the Court, Mr. Nataupsky and Dr. Lopez were already hard at work on a back-up plan.
- 43. The parties completed briefing on the disputed claims of the '204 patent, and a claim construction hearing was held before the Court on November 21, 2002. (E.g., Ex. 548, 11/21/02 Reporter's Transcript of Proceedings on Claim Construction for the '204 patent.) Before the Court,

ICU took the position that invalidity issues were not properly addressed in a claim construction hearing. (*E.g.*, Ex. 546, 10/15/02 ICU Reply Brief on Claim Construction, at 6, n.6) (stating ICU considers it "not appropriate" to address invalidity arguments during claim construction). Braun explained that if ICU's proposed constructions of the '204 patent were adopted, including the "seal" and "resilient seal element" limitations, the claims would be invalid over any number of prior art references, including those before the examiner. (*E.g.*, Ex. 545, 8/2/02 Braun's Answering Brief On Claim Construction, at 24-25.)

- 44. On November 27, 2002, this Court issued its Order on claim construction of the '204 patent. (Ex. 549.) The Order accepted ICU's constructions on "seal" and "resilient seal element." (Ex. 549, at 5-6.) On December 23, 2002, ICU served its final infringement contentions based on the '204 patent alone. (Ex. 530, 12/23/02 Plaintiff ICU Medical, Inc.'s Final Infringement Contentions.)
- 45. On January 21, 2003, Braun served its final invalidity contentions based on the Court's claim construction. (Ex. 535.) Braun identified over 35 references that rendered the claims invalid for anticipation or obviousness in light of ICU's accepted claim constructions. (*E.g.*, Ex. 535, at 3-5.) Braun's contentions included over 120 pages of explanation of its invalidity bases. (Ex. 535, at 24-145.)
- 46. On January 17, 2003, Braun moved for summary judgment of invalidity based on two references that were before the Patent Office, consistent with Braun's arguments during claim construction. (Ex. 570.) On January 31, 2003, ICU opposed summary judgment contending, *inter alia*, that the claims of the '204 patent required a "taper" that ICU alleged was not shown in the prior art references. (Ex. 571, 1/31/03 Plaintiff ICU Medical, Inc.'s Opposition to Braun's Motion for Summary Judgment of Invalidity of the '204 Patent, at 7) (arguing ICU's '204 patent claims are not anticipated by the prior-art Adams or Vailancourt references because "Adams and Vailancourt have non-tapered seal walls"); (id.) ("ICU's claims are distinct from Adams and Vailancourt ..., because ICU's seal wall tapers"); (id. at 11) ("Adams describes a non-tapered sheath that sticks in its retracted position after insertion of the needle contained within the sheath into another medical device, not a tapered seal element as claimed in the '204 patent.") (emphasis in original); (id. at 15) ("Without a taper, it cannot infringe").

- 47. Throughout the first part of 2003, the parties also filed cross motions for summary judgment for infringement (by ICU) and non-infringement by (Braun). (See Ex. 573, 1/31/03 Plaintiff ICU Medical, Inc.'s Notice of Motion and Motion For Summary Judgment Of Infringement And Memorandum Of Points And Authorities In Support Thereof); (Ex. 590, 4/25/03 Braun's Motion For And Memorandum In Support Of Summary Judgment Of Non-Infringement). In each of its motions and argument before the Court, ICU again alleged that the accused "taper" structure in the Ultrasite piston component was a key aspect of Braun's Ultrasite valve. (E.g., Ex. 573, at 14) ("The Ultrasite's seal has a tapered section in which arcuate segments form upon compression.") (id.) (containing "Illustration 4" of accused Ultrasite component with portions of the Ultrasite "taper" highlighted); (id. at 15) ("The tapering of the Ultrasite seal wall is shown clearly in Illustration 4"); (id.) ("Ultimately, Braun adopted a design having a tapered seal wall, like the seal wall in ICU's claims. This tapered seal wall").
- 48. In a March 12, 2003 Order and a June 4, 2003 Order, this Court denied the parties' respective summary judgment motions. (Ex. 580, 3/12/03 Memorandum And Order re: Summary Judgment of Invalidity and Infringement); (Ex. 596, 6/4/03 Order Denying Defendant's Motion for Summary Judgment of Non-Infringement.)
- 49. On July 11, 2003, Braun moved for leave to amend to add the defense of inequitable conduct against ICU's '204 patent. (Ex. 620, 7/11/03 Braun's Motion And Memorandum For Leave To File Its Second Amended Answer And First Amended Counterclaims.) In light of ICU's claim constructions of the '204 patent, Braun alleged that ICU failed to identify material prior art during the examination of the '204 patent. (Ex. 620.) ICU opposed the motion on the grounds that it was futile, citing again the alleged lack of "taper" in the withheld prior art reference. (E.g., Ex. 621, 8/1/03 Plaintiff ICU Medical, Inc.'s Opposition to Braun's Motion For Leave To File Second Amended Answer And First Amended Counterclaim, at 5 ("Braun repeatedly has attempted to ignore the *taper limitation*" in the '204 patent claims."); (id. at 5) (arguing ICU's own prior-art "Lopez" patent, U.S. Patent No. 4,782,841, does not disclose a "tapered" limitation; "the guard member disclosed in the [Lopez] patent is straight walled—not *tapered*—and therefore does not have 'differing maximum diameters' as claimed in the '204 patent"); (id. at 6) (asserting that the Court denied Braun's May 2003

1718

19 20

22

23

21

24

2526

2728

summary judgment motion of non-infringement because the prior-art references cited therein did not disclose the "tapered" limitation required by the '204 patent claims; "each of these references disclosed a straight-walled sheath or needle cover that was not tapered as claimed in ICU's asserted '204 patent") (emphases added).

- 50. In the same time frame, in July 2003, ICU sought the depositions of Braun witnesses for the first time in the then-two-year-old case, and in particular a Rule 30(b)(6) on the technical aspects of Braun's Ultrasite valve. (Ex. 642, 07/15/03 Notice of Deposition of B. Braun Medical Pursuant to Federal Rule of Civil Procedure 30(b)(6).) During this 30(b)(6) deposition, ICU spent the majority of its time trying to convince Braun's Rule 30(b)(6) witness, Peter Peppel, to accept ICU's characterizations of the Ultrasite valve as having a "housing" and "flexible element" and other precise terms not used in the claims of the '204 patent-in-suit. (*See, e.g.*, 9/24/03 Peppel Dep. at 33, 48-49, 85, 104, 137-38.)
- 51. At the same time, ICU stalled on presenting Dr. Lopez for deposition by Braun, repeatedly moving back his and other ICU witnesses' depositions throughout the fall of 2003. (E.g., Ex. 633, 08/07/03 M. Huser Letter to E. Donovan) ("ICU's witnesses are not available for deposition on the dates you propose."); (Ex. 635, 09/26/03 J. Koukios Letter to A. Taclas) ("[A]t ICU's request, Dr. Lopez's deposition will be postponed from the previously agreed upon date of October 8, 2001."); (Ex. 636, 10/01/03 A. Taclas Letter to J. Koukios) ("Given that the deposition of Dr. Lopez has been moved to October 21, 2003, we write to confirm that the deposition of [ICU's] Rich Costello will not be going forward as previously scheduled"); (Ex. 637, 10/01/03 J. Koukios Letter to A. Taclas) ("Braun did *not* agree to postpone the Costello deposition. To the contrary, when ICU requested that the Lopez deposition be postponed, Christopher Hockett confirmed to Dan Attridge that the Costello deposition would take place as scheduled.") (emphasis in original); (Ex. 638, 10/15/03 M. Huser Letter to E. Donovan) ("We would like to reschedule [Lopez's] deposition for November 21, 2003."); (Ex. 639, 11/03/03 A. Taclas Letter to J. Battaglia) ("We are checking on available dates for ICU's witnesses, which we will provide shortly."); (Ex. 640, 11/26/03 J. Battaglia Letter to Sue Vaughn) ("In addition, we are still waiting to receive deposition dates for ICU's noticed witnesses, including George

Lopez, Rich Costello, Francis O'Brien and Jim Pavese. Adrienne Taclas indicated more than three weeks ago that ICU would these deposition dates 'shortly.'").

- 52. On December 30, 2003, ICU revealed why it had been stalling on scheduling Dr. Lopez's deposition, and why it sought to have Braun witnesses agree to its characterizations of "housing," "flexible element," "diameter" and other claim terms not at issue. On December 30, 2003, the '673 patent issued—with claims directed to a "medical valve", a "housing" and a "flexible element" defined by "diameters." (*E.g.*, Ex. 507, '673 patent) (issued Dec. 30, 2003). ICU sued Braun the same day, and sought to add this new patent and lawsuit to the existing one because it was a related case. (Ex. 623, 12/30/03 Plaintiff ICU Medical, Inc.'s Notice Of Motion And Motion For Leave To File First Amended Complaint; Memorandum Of Points And Authorities); (Ex. 624) (ICU's 12/30/03 Notice Of Related Cases).
- 53. In ICU's words, the '673 patent should be added to ICU's pending '204 patent litigation against Braun because:

The '673 patent includes the same specification and inventor as the '204 patent and claims priority to the same line of applications as the '204 patent. Furthermore, ICU asserts that the accused device in this action, B. Braun Medical, Inc.'s ... UltraSite valve, infringes both the '204 and the '673 patent.

(Ex. 623, at 1) (emphases added); (accord id. at 5) ("Moreover, the '673 patent causes of action involve the same technology, witnesses and accused devices as the '204 patent causes of action. Therefore, discovery on the '673 patent causes of action will substantially overlap with discovery on the ['204 patent] claims already pending, and the amended complaint will require minimal additional discovery."); (Ex. 624, ICU's 12/30/03 Notice of Related Case, at 1) (asserting that ICU case filed separately for the '673 patent "is related" to the pending ICU case against Braun based on the '204 patent; "[i]n each action ICU alleges that Braun's UltraSite valve infringes ICU's patent. Furthermore, the patents at issue in the two cases are related and have the same specification and inventors, and claim priority to the same line of applications.").

54. As more fully explained below, neither Mr. Nataupsky, nor Dr. Lopez, nor anyone else ever disclosed to the examiner the existence of ICU's litigation against Braun based on the same Braun Ultrasite valve's alleged infringement of a '204 patent—a patent that ICU itself emphasized as being "related" to its '673 patent application. (See, e.g., id.)

F. Dr. Lopez and Mr. Nataupsky Simultaneously Prosecute The Related '673 Patent Application Tracking The Developments In The Litigation.

55. The '673 patent was filed with one purpose—to bring suit against Braun and its Ultrasite product. (*E.g.*, Ex. 702, 6/5/02 Attorney Declaration Supporting Petition To Make Special); (Nataupsky Dep. at 101-02) (admitting '673 patent application was prepared in anticipation of ICU's pending litigation against Braun). On June 5, 2002—almost a year after ICU filed this litigation based on Mr. Nataupsky's advice, and more than five-and-a-half years after ICU was aware of the Ultrasite valve—Mr. Nataupsky filed a new patent application claiming priority to the original 1991 application. (*E.g.*, Ex. 508, '673 file history);

REDACTED

The '673 application contained the same specification as the '204 patent, but issued from a different branch of the Clave family tree. (See, e.g., Ex. 275, attached Ex. A to 1/14/05 Rule 26(a) Expert Report of James T. Carmichael.)

56. The '673 patent application contained patent claims prepared by Mr. Nataupsky. (E.g., Ex. 508, '673 file history.) The claims were a hybrid between the claims of the '204 and '048 patent already in litigation. For example, the '673 patent application claims adopted the preamble and general valve structure language used in the asserted claims of the '048 patent: "A medical valve for controlling the flow of fluid between a first medical implement and a second medical implement, said valve comprising" (Ex. 507, '673 patent, claim 1); (compare Ex. 504, '048 patent, claim 1) (using identical language). On the other hand, the various elements of the recited medical valve in the '673 patent application claims closely tracked the '204 patent claims, including the requirement of a "seal" with a "wall" having a particular shape defined by "diameters." (Compare Ex. 508, '673 File History, at ICU-BB 54247) (reflecting original claims in the '673 application before ICU and counsel amended

them during prosecution) with (Ex. 501, '204 patent, claim 1) (requiring a "resilient seal element" with a "wall" having a particular shape).

- application to remove the '048 patent-in-suit. (Ex. 508, '673 File History, filed 6/5/02); (Ex. 505, File History for ICU's '048 Reissue Application, filed Aug. 9, 2002). Dr. Lopez and Mr. Nataupsky sought expedited treatment for the '673 patent application by filing a petition to make special, urging the Patent Office that expedited issuance was necessary because a company called "Braun" was selling a product called the "Ultrasite" that Mr. Nataupsky believed infringed the claims of the '673 patent application. (Ex. 508, '673 File History, at ICU-BB 54275-76) (Petition To Make Special as contained in '673 File History); (Ex. 702, Attorney's Declaration Supporting Petition To Make Special, signed by Steven J. Nataupsky.) Mr. Nataupsky filed the petition to make special with the June 5, 2002 application. (Id.) Mr. Nataupsky personally submitted a declaration attesting to this opinion. (Ex. 702); (Ex. 508, at ICU-BB 54278-79.) No sample or information relating the Ultrasite valve was submitted. (E.g., id.) No analysis of the infringement opinion—the claim construction or application of the properly construed claims—was submitted to the Patent Office. (Id.)
- 58. More importantly, neither the '673 patent application nor the petition to make special disclosed that that the assignee ICU was already in litigation over whether the same Ultrasite valve infringed a related patent, the '204 patent, and that the parties were presently briefing the ordinary meaning of the same claim language present in the '673 patent application. (Ex. 508, '673 File History, at ICU-BB 54275-76); (Ex. 702.)
- 59. With the '673 patent application, Mr. Nataupsky submitted a PTO-Form 1449 (Information Disclosure Statement, or "IDS"), which identified prior art to the Patent Office. The Form 1449 included different references, including—unbeknownst to the examiner—some of the prior art disclosed by Braun in this litigation via its invalidity contentions. (Ex. 508, '673 File History at ICU-BB 54281-89.) Mr. Nataupsky's Form 1449 did not include with these references, however, the extensive and detailed discussion of the relevance of those references in Braun's preliminary invalidity contentions. (See id.); (see also Ex. 534, Defendant's Patent L.R. 3-3 Preliminary Invalidity Contentions); (Ex. 535, 1/21/03 Defendant's Patent L.R. 3-6(b) Final Invalidity Contentions).

- 60. ICU's Form 1449 also identified numerous ICU Clave patents that share the same specification, including the ICU and Lopez '686 and '466 patents that issued in late 1997 from the original 1991 Lopez application. (See, e.g., Ex. 508, '673 File History at ICU-BB 54288.) Conspicuously absent from this ICU disclosure statement, however, was both the '204 and '048 patents that were presently in litigation. (Id., at ICU-BB 54281-89.)
- 61. The '673 patent application was assigned to a patent examiner, Examiner Thanh. Examiner Than had not examined either the '204 or '048 patents. (*E.g.*, Ex. 501, '204 patent); (Ex. 502, '204 File History); (Ex. 504, '048 patent). Ms. Thanh examined the application and on January 23, 2003, issued a restriction requirement requiring Dr. Lopez to elect between the '673 patent application's method claims and the apparatus claims directed to a valve. (Ex. 508, at ICU-BB 54295-98.) The examiner noted the apparatus claims could cover valves other than medical valves, such as fuel injection valves. (*Id.*, at ICU-BB 54295.)
- 62. Dr. Lopez responded through his attorney on February 26, 2003, electing to pursue the apparatus claims. (*See* Ex. 508, at ICU-BB 54300-02.) In addition, ICU and Lopez changed the claims in its application. (*Id.*, at ICU-BB 54301.) No longer did the claims recite a "seal" like the '204 patent. (*Id.*); (*see also* Ex. 501, '204 patent, claim 1.) Instead, they were amended to recite a "flexible element." (Ex. 508, at ICU-BB 54301.) Dr. Lopez also later removed the language that required that the "wall" of the "seal" flex "in an accordion-like manner." (Ex. 508, at ICU-BB 54318.) Dr. Lopez made a number of additional changes to his claims and added in new ones relating to a "single molding" and a "rigid member."
- 63. In making his February 26 submission to the PTO, at no time did Dr. Lopez or his representatives disclose this litigation to examiner Thanh. (See Ex. 508, at ICU-BB 54300-05.) For example, Examiner Thanh was not informed that the Court had issued a ruling as to the meaning of "seal" and other claim terms in the '204 patent, or that Braun had filed final invalidity contentions with respect to the '204 patent and a summary judgment motion for patent invalidity of the '204 patent. (Id.) Examiner Thanh also did not learn that Braun's opposition to ICU's summary judgment of infringement explained that the Ultrasite valve's piston component did not, as ICU alleged in its summary judgment motion, flex in an accordion-like manner. (See Ex. 574, attached 2/14/03)

Declaration of Dr. Vijay Kumar, ¶ 5) ("Buckling [of the accused Ultrasite piston] will not result in symmetric bellows or accordion-shape unless the cylinder is specifically modified to do so. The Ultrasite® piston has been modified to buckle into a symmetric bellows or accordion-shape."); (Ex. 575, 2/14/03 Declaration of Neil Sheehan, ¶ 9) ("Rather than forming a uniform accordion shape, the Ultrasite® piston buckles in an unpredictable and non-uniform manner."). Unbeknown to the '673 examiner, Dr. Lopez and Mr. Nataupsky would soon thereafter amend Lopez's secretly pending '673 application claims to account for this evidence presented to this Court.

- 64. On June 3, 2003, Examiner Thanh, unaware of this litigation, issued a notice of allowance, indicating that the '673 patent application was ready to be allowed subject to Dr. Lopez's payment of the requisite fees. (Ex. 508, at ICU-BB 54328.) In response, Dr. Lopez did not pay the fees. Instead, on June 17, 2003, Dr. Lopez, through his attorneys, submitted another amendment, this time adding to the independent claims a requirement that the "flexible element" have a "tapered portion." (*Id.*, at ICU-BB 54315, -318-19) ("Request For Continued Examination (RCE)" following examiner's 6/3/03 Notice of Allowance, which "Applicant acknowledges with appreciation"). ICU added this limitation without the Patent Office asking for it. (*Id.*) ICU did not explain why it did not want a patent without a "taper" limitation even though Examiner Thanh was willing to grant it. (*Id.*); (*see also id.*, at ICU-BB 54325-26) (issuing Notice of Allowability for amended claims incorporating ICU's newly added "tapered" limitation).
- 65. With his amendment, Dr. Lopez's attorney submitted another PTO-Form 1449 listing an additional 47 new prior art references. (Ex. 508, at ICU-BB 54321-323.) Included with this new PTO-1449 were the new prior art references that Braun had disclosed in this litigation relating to the '204 patent with its final invalidity contentions. (*Id.*) The 1449 did not provide the 195 pages of explanation with Braun's invalidity contentions (*see* Exhibits 534 & 535) (Braun's preliminary and final invalidity contentions), nor did it provide this Court's rulings on the validity of the related '204 patent (*see* Exhibit 549) (11/27/02 Claim Construction Order).
- 66. At no time did Dr. Lopez, Mr. Nataupsky (or anyone else) disclose to the patent examiner the existence of this litigation, or that the "taper" limitation had been the critical limitation on which ICU relied to distinguish Braun's invalidity summary judgment arguments. (See Ex. 508, '673

File History.) Nor did Examiner Thanh learn of the arguments ICU made in both seeking summary judgment of infringement and defending against Braun's summary judgment of non-infringement of the alleged importance of the "taper" in the piston of Braun's Ultrasite valve. (*Id.*)

- 67. On June 30, 2003, Examiner Thanh issued another notice of allowance. (Ex. 508, at ICU-BB 54325-328.) At that time, ICU knew that subject to payment of its fees, the claims of the '673 patent application would be allowed.
- 68. On July 9, 2003, Dr. Lopez, through his counsel, paid the issue fee. (Ex. 508.) While commenting that he wished to "clarify" the meaning of "taper" limitation, no disclosure of this litigation or its related materials was made to Examiner Thanh. (Ex. 508, at ICU-BB 54333-34.) Upon paying the issue fee, Dr. Lopez, and his assignee ICU, knew it was only a matter of time before the patent was printed and would issue. A few days later, ICU sought the above-mentioned 30(b)(6) deposition of Braun on the technical aspects of the Ultrasite valve. (Ex. 641, 7/15/03 C. Platt Letter to J. Battaglia re: Depositions); (Ex. 642, ICU's 07/15/03 Notice of Deposition of B. Braun Medical Pursuant to Federal Rule of Civil Procedure 30(b)(6).)
- 69. After completion of ICU's fact depositions, but before Dr. Lopez was deposed, the '673 patent issued on December 30, 2003. (Ex. 507, '673 patent.) At no time was this litigation disclosed to Examiner Thanh, at no time were the '204 or '048 patents disclosed to Examiner Thanh, and there is nothing in the record to indicate that Examiner Thanh knew of or considered this litigation, the patents-in-suit, or their prosecution histories. (*E.g.*, Ex. 508, '673 File History);

REDACTED

- G. The '673 Patent Issues And ICU Immediately Sues Braun, Seeks To Add The Patent To This Case As "Related Litigation" And Files For Summary Judgment Of Infringement.
- 70. On December 30, 2003—the same day the patent issued—ICU filed its complaint for patent infringement, and its motion to amend to add the '673 patent to the suit. (*E.g.*, Ex. 623, ICU Notice of Motion and Motion for Leave to File First Am. Complaint.)
- 71. Obviously, ICU's trial counsel worked with its prosecution counsel (Nataupsky and Knobbe Martens) to prepare its complaint to sue Braun, and prepared its motion to amend to add this

'673 patent to this case, before the '673 patent application (which ICU contended was "irrelevant" to this litigation) had issued.

REDACTED

(see also Ex. 565, 8/15/02 Plaintiff ICU

Medical, Inc.'s Opposition to Braun's Motion to Compel Production of Pending Patent Applications, at 1, 3, 5-7) (ICU brief in opposition to Braun's motion to compel, asserting repeatedly to the Court that pending patent applications, which included the '673 patent application, were not "relevant to this dispute"); (Ex. 563) (6/13/02 Letter from ICU counsel C. Platt to E. Donovan, arguing eight days after the filing of the '673 application and petition to make special that the "pending patent applications" Braun has been seeking in discovery since February 2002 "are irrelevant to the issue of whether Braun's UltraSite infringes the '048 or [related] '204 Patents").

72. The Court allowed the amendment adding the '673 patent claim to this case. Shortly thereafter, ICU moved for summary judgment of infringement of the '673 patent based on the deposition testimony taken of Braun's Rule 30(b)(6) witness prior to the '673 patent application being produced. ICU contended that no claim construction was necessary, relying on the "ordinary meaning" of the claim terms to one of ordinary skill in the art.

H. The Litigation Is Hidden From The Patent Office and The '673 Patent Application Is Hidden From Braun In The Litigation.

73. Braun did not learn of the '673 patent application during its prosecution, because ICU vociferously resisted any discovery on its pending patent applications in this matter. (*E.g.*, Exs. 560-63, 565.) From the outset of the litigation, ICU had a heightened sensitivity to producing any pending patent applications which might reveal its patent prosecution-litigation strategy.

- 74. In its document requests, Braun specifically sought patent applications, including pending patent applications, related to the patents-in-suit in its document requests and interrogatories. (*E.g.*, Ex. 560, 2/19/02 Plaintiff ICU Medical Inc.'s Objections And Responses To Braun's First Set Of Requests For The Production Of Documents And Things, at 4.) ICU refused to provide them, claiming that pending patents applications were irrelevant and Braun could not show any "potential relevance to this action" that outweighed the applications' confidentiality. (*Id.*) ICU's attorney instructed its witness not to answer on the subject matter of pending patent applications. (*E.g.*, Fangrow Dep. at 101, 102-03.)
- 75. On July 26, 2002, Braun moved to compel production of pending patent applications—approximately seven weeks after ICU and Mr. Nataupsky had filed the '673 patent application and petition to make special (and accompanying Nataupsky declaration) alleging that Braun's Ultrasite valve infringed the claims of the '673 patent. (See Ex. 564, 7/26/02 Braun's Motion And Memorandum Of Points And Authorities In Support To Compel The Production Of Certain Patent Applications And Prosecution Histories And Information Related Thereto.) The '673 patent application was among those applications ICU refused to produce. ICU refused to even identify how many pending applications it had.
- 76. On August 15, 2002, ICU filed its opposition to Braun's motion to compel the pending patent applications, just three days after ICU relied on Mr. Nataupsky's secretly filed reissue application in requesting the Court drop its '048 patent from the case without prejudice. (Ex. 565, 8/15/02 Plaintiff ICU Medical, Inc.'s Opposition to Braun's Motion to Compel Production of Pending Patent Applications.) In its opposition, ICU asserted no less than seven times that the pending patent applications were "irrelevant." (E.g., Ex. 565, at 1) (asserting "Braun cannot show that any of [ICU's] pending patent applications are relevant to this dispute"); (id. at 3) ("Braun Cannot Demonstrate that ICU's Pending Patent Applications are Relevant"); (id.) (stating "Braun contends that pending patent applications must be relevant. Braun is mistaken."); (id.) ("Pending Patent Applications are Irrelevant to Claim Construction"); (id. at 5) (pending applications not "relevant" to claim construction); (id. at 6) ("Pending Patent Applications Are Irrelevant to Double Patenting"); (id.) (pending patent applications "irrelevant"); (id. at 7) (arguing "ICU's pending applications are

15 16

17 18

19

20 21

22

23 24

25

26

27 28

irrelevant to any double-patenting arguments that Braun may assert"). Moreover, ICU alleged that producing the applications would endanger the "confidential" information they contained, even though the applications contained the identical subject matter to that in the patents-in-suit, except for the claims and prosecution documents. (*Id.*)

- 77. ICU alleged that the "attorneys' eyes only" protection under the protective order was insufficient to protect its interests, going so far as to argue that Braun's counsel in this case would violate the order if the pending patent applications were produced. (Ex. 565, at 7 & n.2) ("ICU became increasingly concerned about revealing pending patent applications to Braun's counsel").
- 78. On October 4, 2002, Judge James denied Braun's motion to compel, ruling that the heightened relevance standard had not been met. (Ex. 567, 10/4/02 Order Denying Defendant's Motion To Compel The Production Of Certain Patent Applications And Prosecution Histories, at 2.) As a result, Braun did not learn of the '673 patent application or ICU's petition to make special until the day it was sued on December 30, 2003.

I. The Law Of Inequitable Conduct.

79. A patentee commits inequitable conduct if, "during prosecution of the application, he makes an affirmative representation of material fact, fails to disclose material information, or submits false material information, and does so with intent to deceive." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1358 (Fed. Cir. 2003) (citation omitted). To find inequitable conduct. there must be clear and convincing evidence that both the materiality and intent prongs of the test are satisfied. See Bristol Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F. 3d 1226, 1233 (Fed. Cir. 2003).

1. Related Litigation Is Material Information That Must Be Disclosed.

80. A patent applicant's duty to disclose material information to the PTO arises under the general duty of candor, good faith, and honesty as set forth in 37 C.F.R. § 1.56(a), which states, in part:

Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.

37 C.F.R. § 1.56(a).

81. The PTO regards related litigation as material information that must be disclosed. The Manual of Patent Examining Procedure ("MPEP") specifically requires this disclosure:

Where the *subject matter* for which a patent is being sough is or has been involved in litigation, *the existence of such litigation and any other material information arising therefrom* must be brought to the attention of the U.S. Patent and Trademark Office. Examples of such material information include evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of "fraud," "inequitable conduct" and "violation of duty of disclosure." . . . Such information might arise during litigation in, for example, pleadings, admissions, discovery including interrogatories, depositions, and other documents, and testimony.

MPEP § 2001.06(c). Although MPEP § 2001.6(c) is not binding law, it sheds light on the PTO's official interpretation of 37 C.F.R.§ 1.56(a) regarding the materiality of related litigation.

- 82. In fact, related litigation is material per se. See MPEP § 2001.06(c) (stating that "the existence of such litigation and any other material arising therefrom" is material); see also DaimlerChrysler AG v. Fueling Advanced Techs., Inc., 276 F. Supp. 2d 1054, 1063 (S.D. Cal. 2003). Failure to disclose related litigation may lead to a finding of inequitable conduct. See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1255-59 (Fed. Cir. 1997); Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 68 F. Supp. 2d 508, 550-51 (D.N.J. 1999) (denying patentee's preliminary-injunction motion because accused infringer had substantial defense of inequitable conduct based on patentee's failure to disclose materials from a related litigation to the examiner).
- 83. Patent applicants must "continue to submit information for consideration by the Office in applications rather than making and relying on their own determination of materiality. An incentive remains to submit the information to the Office because it will result in a strengthened patent and will avoid later questions of materiality and intent to deceive." *Critikon*, 120 F.3d at 1257.
 - 2. A Section 290 Notice Cannot Discharge An Applicant's Duty To Disclose Related Litigation.
- 84. A district court's notice of litigation pursuant to 35 U.S.C. § 290 transmitted to the PTO upon the filing of a patent litigation cannot suffice to discharge the duty to disclose related litigation. If it could, there would be no reason to disclose related litigation because by definition, it would already be disclosed. As this Court explained in denying summary judgment, a

patent applicant has an independent duty to disclose the existence of related patent infringement litigation to the examiner. The duty of disclosure is particularly important in the context of patent prosecutions, which are conducted before an examiner in the

absence of any represented adversary. In *ex parte* prosecutions, PTO examiners rely on the patent applicants to make full disclosure of material information of which they are aware in each case.

(Ex. 19, 3/14/05 Order re: Motions for Summary Judgment & Scheduling Trial at 21) (citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 126 F. Supp. 2d 69, 147 (D. Mass 2001)). This Court noted that a contrary rule would eviscerate the duty of disclosure:

[A]n applicant cannot assume that an examiner, however diligent and well informed, will be aware of Section 290 notices in other patents. To do so would eviscerate the duty of disclosure regarding related litigation owed to each examiner.

(*Id.* at 22.) The PTO specifically advises that patent applicants "cannot assume that the examiner of a particular application is necessarily aware of other applications which are 'material to patentability' of the application in question, but must instead bring such other applications to the attention of the examiner." MPEP § 2001.6(b).

J. This Litigation Was Material Information That Should Have Been Disclosed But Was Not.

- the examination of the '673 patent. Related litigation is material *per se*, which must be disclosed. ICU admits that this litigation is related litigation—that is exactly what it represented to the Court when it sought to amend its complaint in this case to add the '673 patent infringement count. (Ex. 623, at 1) ("The '673 patent includes the same specification and inventor as the '204 patent and claims priority to the same line of applications as the '204 patent. Furthermore, ICU asserts that the accused device in this action, B. Braun Medical, Inc.'s ... UltraSite valve, infringes both the '204 and the '673 patent."); (Ex. 624, ICU's 12/30/03 Notice of Related Case, at 1) (representing that the '204 and '673 patents are related; "[i]n each action ICU alleges that Braun's UltraSite valve infringes ICU's patent. Furthermore, the patents at issue in the two cases are related and have the same specification and inventors, and claim priority to the same line of applications.").
- 86. Even if related litigation were not material *per se*, this litigation is highly material to the claims of the '673 patent. In fact, this litigation was the genesis of the '673 patent. ICU acknowledges that the patent was prepared and filed in anticipation of litigation with Braun on the exact same product

already in litigation.

REDACTED

ICU admits that the '673 patent shares the same specification and inventor as the '204 patent, already in litigation. (Ex. 624 ("Statement Of Related Cases").) The '673 patent claims have claim terms and language in common with both the '204 and '048 patents. No reasonable person could say this litigation was not material to the prosecution of the '673 patent.

- 87. Simply disclosing prior art from the litigation is not enough to satisfy the duty of disclosure. See Critikon, 120 F.3d at 1258 ("patent applicant's duty to disclose is not limited to disclosing prior art"). The PTO expects that "pleadings, admissions, discovery including interrogatories, depositions, and other documents, and testimony" from related litigations will be disclosed. MPEP § 2001.6(c). As the Federal Circuit has explained, "[p]atent disclosures are often very complicated, and different examiners with different technical backgrounds and levels of understanding may often differ when interpreting such documents." Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1368 (Fed. Cir. 2003). Thus, even though "examiners are not bound to follow other examiner's interpretations, knowledge of a potentially different interpretation is clearly information that an examiner could consider important when examining an application." Id. Here, ICU withheld all evidence of "potentially different interpretations" even while it changed the claims in light of them.
- 88. For example, the parties and Court engaged in months of briefing and argument about the meaning of the claim language in the '204 and '048 patent, including briefs, arguments, expert declarations, and expert depositions. (Exs. 540, 541, 542, 543, 544, 545, 546, 547, 548, 549, 630, 631). In those depositions, ICU's experts took the unlikely position that one of ordinary skill in the art would understand that a "resilient seal element" in the '204 patent claims—the same thing as the "flexible element" in the '673 patent claims—could be a "rigid sealing element:"

REDACTED

5

8

13

11

25

REDACTED

(Fangrow Dep. at 135) (testimony by ICU engineer and designated expert on claim construction).

That unusual interpretation was one never shared with Examiner Thanh, nor was Braun's alternative position.

- 89. Similarly, Examiner Thanh was never told that the '673 patent application amendments were caused by the developments in this litigation. Much of the prior art identified by Braun in its invalidity contentions was submitted to the Patent Office during the prosecution of the '673 patent but Examiner Thanh was inexplicably never provided Braun's detailed explanation of the relevance of that prior art. (Exs. 534, 535) Moreover, ICU deleted claim language from the application claims of the '673 patent (Ex. 508), for example, "in an accordion like manner" directly in response to evidence and arguments Braun made to distinguish the Ultrasite piston from the '204 patent claims (Ex. 574, 575). Examiner Thanh was never told why the claims were being changed and was never shown the briefs and argument that were the basis of this change. And ICU added claim limitations, including the "taper" limitation (Ex. 508), directly in response to the evidence and arguments presented in Braun's summary judgment motion for invalidity of the related '204 patent (Ex. 570, 571, 572, 577, 578, 579). Examiner Thanh was never shown any of the related materials from the litigation.
- 90. ICU cannot explain away its failure to disclose this information as somehow immaterial because the prior art itself was disclosed. If that were the case, there would never be any reason to disclose related litigation or other materials that contradict positions taken during prosecution. The PTO must be provided all evidence and all viewpoints to ensure issuance of valid patents as a result of the ex parte prosecution process. Thus, the Federal Circuit found inequitable conduct on appeal for failure to disclose related litigation, even where the district court found the patent-in-suit valid over the prior art. Critikon, 120 F.3d at 1256. In the Federal Circuit's view, the more important issue was the failure to disclose the related litigation. Id. at 1258-59 (concluding district court clearly erred in not finding inequitable conduct based on failure to disclose related litigation to the examiner; entering judgment of inequitable conduct based on that failure).
- 91. The litigation information was unquestionably material to the claims. For example, ICU voluntarily added the "taper" limitation to the '673 application claims in response to Braun's litigation

15 16 17

18

19 20

21

22

23

24 25

27

26

28

arguments in this case regarding patent invalidity without being asked by the Examiner to do so. Braun, however, never agreed that the "taper" limitation avoided invalidity of the '204 patent claims. or that ICU's interpretation of the prior art as not disclosing a "taper" was correct. (Exs. 572, 578) Examiner Thanh never had the opportunity to consider the evidence and make a decision for herself because ICU did not tell her.

92. ICU's own experience shows that the PTO cared about related litigation. Mr. Nataupsky's reissue application for the '048 patent was stayed when he disclosed this litigation, even when he requested that it not be stayed (in fact, the evidence shows the application remains stayed through the present day even though the '048 patent has been dismissed from the case with prejudice). (Ex. 505.)

K. Dr. Lopez and Mr. Nataupsky Intentionally Withheld The Litigation.

- 93. The evidence shows Mr. Nataupsky and Dr. Lopez knew of the co-pending related litigation, had a duty to disclose the litigation and related materials, and intentionally withheld them from the patent examiner.
- 94. Mr. Nataupsky was subject to the duty of candor and disclosure during the prosecution of the '673 patent application. Mr. Nataupsky was both directly involved in filing papers, including the original patent application and petition to make special, and indirectly involved as ICU's primary outside patent counsel overseeing the work of his subordinates.
- 95. Dr. Lopez was subject to the duty of candor and disclosure during the prosecution of the '673 patent application. Dr. Lopez is the named inventor of the '673 patent, and remained under a duty of candor and disclosure throughout its prosecution.
- 96. Mr. Nataupsky knew of the litigation, and that it was material information that should have been disclosed to the patent examiner. Mr. Nataupsky was involved in the prefiling investigation for this suit in 2001. (Lopez Dep. at 168, 203.) Mr. Nataupsky was actively involved behind the scenes in this litigation, including filing the reissue application for the '048 patent in response to Braun's summary judgment motion (Ex. 505, 551), and amending the claims and submitting prior art in response to Braun's non-infringement and invalidity positions in this case (Ex. 508). Mr. Nataupsky

97. Given the obvious relationship between the filing and prosecution of the '673 patent, and the filing and prosecution of this litigation, and Mr. Nataupsky's involvement in both, the Court finds that Mr. Nataupsky also knew this litigation was material to the examination of the '673 patent.

98. Dr. Lopez also knew of this litigation, and that it was material to the examination of the '673 patent application. In fact, as discussed above, Dr. Lopez intended that the '673 patent application be his next litigation weapon against Braun's Ultrasite. Dr. Lopez was involved in the decision to file this litigation and the decision to file the '673 patent application and petition to make special.

REDACTED

The record shows Dr. Lopez kept abreast of litigation developments as part of his business strategy for ICU. (See, e.g., Ex. 743, at ICU-BB 62670, -675) (describing ICU's contract and patent issues and related litigation against Braun); (see also Ex. 730-42) (additional conference calls between Lopez and inventors).

- 99. As explained throughout, the evidence clearly and convincingly shows Dr. Lopez and Mr. Nataupsky intentionally withheld the litigation from the PTO. No other credible explanation exists.
- 100. As a general principle, the requirements of materiality and intent are inversely proportional. *See Critikon*, 120 F.3d at 1257. "A lesser quantum of intent is necessary when the omission or misrepresentation is highly material, and vice versa." *DiamlerChrysler*, 276 F. Supp. 2d at 1065 (quoting *Amgen*, 314 F.3d at 1358).
- 101. Proof of intent to mislead may be shown by circumstantial evidence. *Paragon Podiatry Lab., Inc. v. KLM Lab., Inc.*, 984 F.2d 1182, 1189-90 (Fed. Cir. 1993) ("[S]moking gun' evidence is not required in order to establish an intent to deceive.... Rather, this element of inequitable conduct, must generally be inferred from the facts and circumstances surrounding the applicant's overall conduct.") (citation omitted). For example, an "intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information." *See Bruno*

Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F.3d 1348, 1354 (citing Paragon Podiatry, 984 F.2d at 1193). Where there is no "credible explanation for the nondisclosure, [an] inference of deceptive intent may fairly be drawn in the absence of such an explanation." Id.

102. Here, there is no other credible explanation for the nondisclosure except that the litigation was withheld to deceive the examiner. Mr. Nataupsky is an experienced patent prosecutor who is familiar with the Rules governing patent prosecution.

REDACTED

Mr.

Nataupsky was familiar with the law of inequitable conduct including that the duty of disclosure extends beyond prior art references. As ICU's counsel in its litigation with Medex shortly before this suit was filed, he was aware that ICU alleged that Medex committed inequitable conduct by failing to disclose co-pending patent applications and statements contradictory to positions taken during prosecution.

REDACTED

- patent, and in fact, changes were made by him or under his direction to the claims of the '673 patent application as a result of this litigation. Moreover, the record shows Mr. Nataupsky fully knew how to disclose litigation during prosecution. (*See, e.g.*, Ex. 505, File History for the '048 Reissue Application) (Nataupsky filings, showing he disclosed ICU's litigation against Braun in August 2002 and requested that the examination of the '048 reissue application proceed and "not [be] suspended in view of the litigation"); **REDACTED**
- 104. The evidence here shows that Mr. Nataupsky intentionally elected not to disclose the litigation. In fact, he intentionally chose not to even disclose the '204 or '048 patents to the examiner, even though he disclosed numerous other related ICU patents. The fact that the '204 and '048 patents are not prior art is not the point. The decision to omit disclosure of the two ICU patents he knew were

in litigation, while disclosing numerous other ICU patents not in litigation, is fully consistent with an intent to mislead the examiner.

105. Mr. Nataupsky cannot rely on the assertion that he understood that the litigation would be disclosed by the § 290 notice. As a practical matter, if that were the case, there would never be a need to disclose litigation since, by definition, the 290 notice would have already done so. Equally important though is the evidence that Mr. Nataupsky knew how to disclose litigation when he wanted to, for example the '048 reissue application, but elected not to do so in this case.

106. The Court finds Dr. Lopez equally culpable for intentional withholding of material information. Dr. Lopez cannot claim ignorance of the law. Dr. Lopez has acknowledged his familiarity with the need to disclose material information, both in his declaration to the Patent Office, and in his testimony when his company was alleging inequitable conduct:

REDACTED

And Dr. Lopez is no stranger to allegations of inequitable conduct against himself. (Exs. 720, 721) (denying ICU's summary judgment motion that Dr. Lopez had not committed inequitable conduct).

107. The evidence shows that Dr. Lopez had a powerful incentive to bring litigation quickly against Braun to force them back to ICU. The need to do so became particularly acute when the '048 patent was dropped from the case with prejudice. Knowing that time was of the essence, Dr. Lopez and Mr. Nataupsky elected not to do anything that might potentially slow, let alone endanger, the issuance of the '673 patent that could be used to sue Braun. The record shows Dr. Lopez was a knowing and willing participant in the strategy to file, prosecute, and add the '673 patent to this case as an additional litigation weapon, and the decision not to disclose the litigation to the patent examiner as part of that strategy.

108. The Court also finds ICU's refusal to provide the pending patent applications as indicative of ICU's intent to deceive. ICU's counsel must have been aware of the '673 patent application in making its representations that the application was irrelevant and contained confidential information of ICU. Plainly the '673 patent application, which already contained an allegation of infringement against Braun's Ultrasite valve, was not irrelevant. And equally plainly, the only

conceivable confidential subject matter in the pending '673 patent application was ICU's intention to sue Braun on the '673 patent application when it issued. The only credible explanation for ICU's actions is that ICU intended to hide the '673 patent application from Braun until after it issued. This evidence strongly supports the Court's finding of an intention to deceive.

109. Finally, the Court notes that neither Mr. Nataupsky nor Dr. Lopez can provide any alternative bases for their conduct. Mr. Nataupsky, an attorney, refused to answer questions about even the existence of communications with Dr. Lopez, his work on the '673 patent application, or any other issue related to his work for ICU because, in his view, they involved the attorney-client privilege or work product doctrine:

REDACTED

REDACTED Indeed, Mr. Nataupsky repeatedly refused to answer questions on privilege grounds, and 110. was instructed by ICU's counsel not to answer, even after being designated as ICU's corporate representative on the prosecution of the '204 and '673 patents. REDACTED Having elected to assert attorney-client privilege and work product over the subject matter of his work for ICU, Mr. Nataupsky cannot now offer an alternative explanation for his actions. Any other result would

impermissibly allow ICU to use the privilege as both a sword and shield. See, e.g., SNK Corp. of Am. v. Atlus Dream Enter. Co., Ltd., 188 F.R.D. 566, 571 (N.D. Cal. 1999) ("Fairness dictates that a party may not use the attorney-client privilege as both a sword and a shield. A party, therefore, may not selectively disclose privileged communications that it considers helpful while claiming privilege on damaging communications relating to the same subject.") (citations omitted).

111. Similarly, Dr. Lopez is precluded from offering any alternative explanations. At his deposition, despite being the sole named inventor and Rule 30(b)(6) designee of ICU on the conception of the patents-in-suit, Dr. Lopez could not recall any specific information about the '673 patent prosecution, but instead attempted to put it all off on his attorney Mr. Nataupsky:

REDACTED

112. After preventing discovery into the subject matter of the '637 patent prosecution, the Court will not hear alternative explanations from ICU now, particularly where ICU has relied on a broad assertion of privilege regarding these same events.

II. The '673 Patent Is Unenforceable

113. Inequitable conduct arises from the doctrine of unclean hands. *Dayco*, 329 F.3d at 1365 n.3. "Once thresholds of materiality and intent have been established, the court conducts a balancing

test and determines whether the scales tilt to a conclusion that 'inequitable conduct' occurred." *Critikon*, 120 F.3d at 1256. Inequitable conduct renders a patent unenforceable.

114. In this case, the Court find the balance tilt strongly towards inequitable conduct. The '673 patent was prepared, filed and prosecuted as a litigation weapon against Braun with patent claims tailor-made for ICU's infringement assertions against the Ultrasite valve. There is no credible reason why ICU did not disclose this clearly related litigation to Examiner Thanh. Instead, the evidence clearly and convincingly shows the '673 patent applicants intended to hide this litigation from Examiner Thanh to gain allowance of the patent to sue Braun. Consistent with the policies underlying the doctrine of inequitable conduct, this Court holds that the '673 patent is unenforceable for inequitable conduct.

Dated: March 24, 2005

Respectfully submitted,

<u>/s/</u>

Tony L. Richardson (SBN 126230) KIRKLAND & ELLIS LLP 777 South Figueroa Street Los Angeles, California 90017 Telephone: (213) 680-8400 Facsimile: (213) 680-8500

Daniel F. Attridge, P.C. Edward C. Donovan John T. Battaglia Gregory F. Corbett Justin P.D. Wilcox KIRKLAND & ELLIS LLP 655 15th Street, N.W. Washington, D.C. 20005 Telephone: (202) 879-5000 Facsimile: (202) 879-5200

Attorneys for Defendant B.Braun Medical Inc.