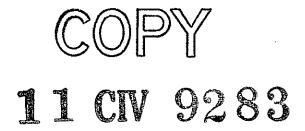
Alfred E. Yudes, Jr. (AY-4152) Jane Freeberg Sarma (JF-5473) Watson, Farley & Williams (New York) LLP 1133 Avenue of the Americas New York, NY 10036 Attorney for Plaintiff



UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

VYGON CORPORATION,

Plaintiff,

VS.

DOLPH SEMENZA and IVERA MEDICAL CORPORATION,

Defendant

Case No.: No.

VERIFIED COMPLAINT

S.D.C.

CASHIERS

N.Y.

### **VERIFIED COMPLAINT**

Plaintiff, Vygon Corporation by and through its attorneys Watson, Farley & Williams (New York) LLP, as and for its Verified Complaint against Dolph Semenza and Ivera Medical Corporation, respectfully alleges and pleads:

## **PARTIES**

- Plaintiff Vygon Corporation ("Vygon") is a Delaware corporation licensed to conduct business as a foreign corporation in the Commonwealth of Pennsylvania, with its principal place of business located at 103A Park Drive, Montgomeryville, PA 18936.
- 2. Upon information and belief, Defendant Dolph Semenza ("Semenza") is an individual domiciled in New York, residing at 49 Baxter Road, Pawling, NY 12564.

3. Upon information and belief, Defendant Ivera Medical Corporation ("Ivera") is a corporation organized and existing under the laws of California, with its principal place of business located at 25 Del Mar Heights Road, Suite 430, San Diego, CA 92130.

### **JURISDICTION AND VENUE**

- 4. This is an action for breach of a confidentiality, non-competition and non-solicitation agreement by Semenza, a former employee of Vygon and individual residing in the state of New York, and for intentional interference with such agreement by Ivera, a California corporation, and the amount in controversy exceeds \$75,000.
- 5. Venue is proper pursuant to 28 U.S.C. §1391 because defendant Semenza resides within this district, and a substantial part of the events giving rise to this claim occurred within this district.

### **BACKGROUND**

- 6. Vygon in the business of manufacturing and marketing medical devices.
- 7. On February 8, 2005, Vygon employed Semenza as a product salesman for the geographic area including portions of the State of New York and New York City.
- 8. On August 18, 2010, Vygon sent Semenza an offer of promotion (the "Offer of Promotion") to the position of Manager of Business Development, beginning on January 3, 2011. A copy of the Offer of Promotion is attached as Exhibit A hereto.
- 9. The terms of the Offer of Promotion required Semeza to execute a Confidentiality/Non-Compete/Non-Solicitation Agreement as a condition for the increase in salary and new title offered by Vygon, and the Offer of Promotion was consideration for the Confidentiality/Non-Compete/Non-Solicitation Agreement.

- Semenza accepted the terms of the Offer of Promotion, and signed it as "acknowledged" on August 20, 2010.
- 11. On August 20, 2010, as required by the Offer of Promotion, Vygon and Semenza entered into a Confidentiality/Non-Compete/Non-Solicitation Agreement (the "Agreement"). A copy of the Agreement is attached as Exhibit B hereto.
- 12. The Agreement is governed by Pennsylvania law.
- 13. Section B(3) of the Agreement requires that any Confidential Information (as such term is defined in the Agreement) disclosed to Semenza during the course of his employment by Vygon remain the exclusive property of Vygon, and any documents that embody Confidential Information must remain with Vygon following the termination of Semenza's employment.
- 14. Sections B(4) and B(6)(b) of the Agreement further require that, for a period of one year following the termination of Semenza's employment with Vygon, that Semenza not engage in any conduct for the purpose of selling or distributing any product that is the same, similar to or competitive with products manufactured and/or distributed by Vygon, or which are in the process of being developed for sale by Vygon.
- 15. On September 30, 2011, Semenza gave notice to Vygon that he was resigning from his employment with Vygon. On October 14, 2011, Semenza's employment with Vygon terminated.
- 16. At the time Semenza's employment with Vygon terminated, Vygon was in the process of developing for sale the Swab Cap product with one of its suppliers.
- 17. The Swab Cap product is used for protecting vascular access ports from potential infection by disinfecting the port with 70% isopropyl alcohol.

- 18. Semenza was aware, at the time his employment with Vygon terminated, that Vygon was in the process of developing for sale such Swab Cap product.
- 19. Upon information and belief, Defendant Ivera has employed Semenza as a salesman for its Curos Cap product, which performs the same function as the Swap Cap product being developed by Vygon, for the geographic area including the northeastern United States, in particular the State of New York.
- 20. Semenza has solicited the same hospitals and doctors' offices in the northeastern United States for sales of Ivera's Curos Cap product as he solicited for the sale of Vygon products while he was employed by Vygon.
- 21. Vygon is in the process of developing for sale the Swab Cap product, which is a similar product to the Ivera Curos Cap product.
- 22. Semenza's work for Ivera as a salesman of the Curos Cap product is in violation of the Agreement.
- 23. Vygon has lost business opportunities due to Semenza's conduct in working for Ivera as a salesman of the Curos Cap product.
- 24. Vygon has lost market advantage due to Semenza's conduct in working for Ivera as a salesman of the Curos Cap product.
- 25. Semenza has interfered with Vygon's customer relationships by soliciting such customers for Ivera as a salesman of the Curos Cap product.
- 26. Vygon has lost goodwill due to Semenza's conduct in working for Ivera as a salesman of the Curos Cap product.
- 27. Upon information and belief, Semenza has provided certain Confidential Information to Ivera, contrary to the terms of the Agreement.

- 28. Paragraph 6 of an affidavit by Bobby Rogers, Chief Executive Officer of Ivera, dated October 13, 2011, and filed with the United States District Court for the Southern District of California (the "Rogers Affidavit"), included a reference to certain internal Vygon email communications and attached copies of those email communications. A copy of the Rogers Affidavit is attached hereto as Exhibit C.
- 29. Upon information and belief, Semenza provided the email communications attached to the Rogers Affidavit to Ivera, in violation of the Agreement.
- 30. Upon information and belief, Ivera induced Semenza to provide the email communications attached to the Rogers Affidavit to Ivera.
- 31. Upon information and belief, in the course of his employment by Ivera, Semenza has used and will continue to use other Confidential Information provided by Vygon, contrary to the terms of the Agreement.
- 32. Vygon's confidential and trade secret information has been disclosed by Semenza.
- 33. Vygon has lost business opportunities due to Semenza's disclosure of Vygon's confidential and trade secret information.
- 34. Vygon has lost market advantage due to Semenza's disclosure of Vygon's confidential and trade secret information.
- 35. Semenza has interfered with Vygon's customer relationships by disclosing Vygon's confidential and trade secret information.
- 36. Vygon has lost goodwill due to Semenza's disclosure of Vygon's confidential and trade secret information.
- 37. On October 15, 2011, Vygon sent a letter to Semenza demanding that he comply with the terms of the Agreement, and offering to continue to pay Semenza's salary as additional

compensation, in addition to the consideration already received by Semenza pursuant to the Offer of Promotion.

# AS AND FOR A FIRST CAUSE OF ACTION FOR BREACH OF CONTRACT AGAINST SEMEZA

- 38. Vygon repeats and realleges the allegations contained in Paragraphs 1 37 as if set forth fully herein.
- 39. Semenza breached the Agreement by providing services to Ivera in connection with the sale of the Curos Cap product.
- 40. Vygon has suffered irreparable harm due to Semenza's breach of the Agreement.
- 41. Vygon has suffered damages in an amount to be determined at trial due to Semenza's breach of the Agreement.

# AS AND FOR A SECOND CAUSE OF ACTION FOR DISCLOSURE OF CONFIDENTIAL INFORMATION AGAINST SEMENZA

- 42. Vygon repeats and realleges the allegations contained in Paragraphs 1 41 as if set forth fully herein.
- 43. Semenza breached the Agreement by providing Vygon's confidential information to Ivera.
- 44. Vygon has suffered irreparable harm due to Semenza's breach of the Agreement.
- 45. Vygon has suffered damages in an amount to be determined at trial due to Semenza's breach of the Agreement.

# AS AND FOR A THIRD CAUSE OF ACTION FOR INDUCEMENT OF BREACH OF CONTRACT AGAINST IVERA

- 46. Vygon repeats and realleges the allegations contained in Paragraphs 1 45 as if set forth fully herein.
- 47. Ivera induced Semenza to breach the Agreement.

- 48. Ivera tortiously interfered with Semenza's performance of the Agreement.
- 49. Vygon has suffered irreparable harm due to Ivera's inducement of Semenza's breach of the Agreement and Ivera's tortious interference with Semenza's performance of the Agreement.
- 50. Vygon has suffered damages in an amount to be determined at trial.

## WHEREFORE, PREMISES CONSIDERED, Plaintiff Vygon respectfully requests:

- A. that process duly issue against Semenza and Ivera requiring them to appear and defend this action;
- B. that Vygon's prayer for relief be granted by this Court and judgment entered thereon in an amount to be determined at trial, plus interest and costs; and
- C. an Order for such other and further relief as the Court may in its discretion grant Semenza and Ivera, including but not limited to an award of punitive damages, attorney's fees and other costs incurred in this matter.

Dated this 194 day of December, 2011

Watson, Farley & Williams

(New York) LLP

1133 Avenue of the Americas

New York, NY 10036

Alfred E. Yudes, Jr. (AY-

4152)

Jane Freeberg Sarma (JF-

5473)

Of counsel: Philippe C.M.

Manteau

### **VERIFICATION**

- My name is Robert A. Combs. I am over the age of 21 and am competent to testify to the matters attested to herein.
- 2. I am employed as the President and Chief Executive Officer of Vygon.
- 3. I have read the foregoing Verified Complaint. Based upon my personal knowledge and upon documents and correspondence kept in the ordinary course of business, I verify that the contents of the foregoing Verified Complaint are true and correct to the best of my knowledge, information, and belief.
- 4. I DECLARE under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on this 4th day of December, 2011

At Montgomery ville, PA

Robert A. Combs

# Exhibit A



August 18, 2010

Mr. Dolph Semenza 48 Baxter Road Pawling, NY 12564

#### Dear DJ:

We are pleased to confirm our offer of promotion to you as a Manager of Business Development beginning on Monday, January 3, 2011 reporting to Robert Combs. Your base compensation will be \$168,000.00 per annum. Such "base" compensation may be adjusted by the Company in accordance with Company policy.

You will be eligible to receive a maximum individual merit bonus of \$7,000 per annum, or a portion thereof, depending on satisfying the bonus conditions set forth in the annual compensation program. Also, you will be eligible to receive a quarterly bonus for each quarter of Fiscal Year 2011. The Quarterly Bonus shall be paid quarterly by the Company and is set forth as follows:

- (a) \$3,000 if YTD Net Sales equal or exceed 100% of the OEM Revenue Budget
- (b) \$2,500 if YTD Net Sales equal 95% through 99.99% of the OEM Revenue Budget;
- (c) \$2,000 if YTD Net Sales equal 90% through 94.99% of the OEM Revenue Budget;
- (d) \$1,500 if YTD Net Sales equal 85% through 89.99% of the OEM Revenue Budget;
- (e) \$1,000 if YTD Net Sales equal 80% through 84.99% of the OEM Revenue Budget;
- (f) \$0 If YTD Net Sales equal less than 80% of the OEM Revenue Budget,

You will also be eligible for to receive an additional bonus for Fiscal Year 2011. The additional bonus is set forth as follows:

- (a) \$5,000 if Fiscal Year 2011 Net OEM Sales exceed the OEM Revenue Budget by 5% or more but less than 15%;
- (b) \$10,000 if Fiscal Year 2010 Net Sales exceed the OEM Revenue Budget by 15% or more but less than 25%;
- (c) \$15,000 if Fiscal Year 2010 Net Sales exceed the OEM Revenue Budget by 25% or more but less than 35%;
- (d) \$20,000 if Fiscal Year 2010 Net Sales exceed the OEM Revenue Budget by 35% or more but less than 50%; or
- (e) \$25,000 If Fiscal Year 2010 Net Sales exceed the OEM Revenue Budget by 50% or more.

In addition, you will be eligible to receive a car allowance of \$500.00 per month.

The Company is extending this offer contingent upon the understanding that: (1) you will execute the enclosed Confidentiality/Non-Compete/Non-Solicitation Agreement; (2) you will comply with all applicable Company policies and standards and shall perform your services in a manner consistent with the ethical and professional standards of the Company

Your employment is at will and is terminable at any time by the Company or you. This letter is not an employment contract.

Please confirm your acceptance of our offer by signing and returning this letter and the Confidentiality/Non-Compete/Non-Solicitation Agreement to me by Monday, August 23, 2010. This will serve as your official acceptance of our offer and confirm you have read, understood and will comply with the provisions of this letter in consideration of your employment and periodic performance and salary reviews. Please let me know if you have any questions or wish to discuss the Company's policy.

Sincerely,

Robert Combs Chief Executive Officer

Acknowledged:

h Semenza

Date

120/10

# Exhibit B



### CONFIDENTIALITY/NON-COMPETE/NON-SOLICITATION AGREEMENT

This Agreement is made on the date set forth above the signature lines on the final page of this Agreement between Vygon Corporation ("Vygon"), a corporation with its principal place of business at 103A Park Drive, Montgomeryville, PA 18936, and Dolph Semenza ("Employee").

### A. Definitions In this Confidentiality Agreement ("Agreement"):

- 1. <u>Vygon</u> means Vygon Corporation and any existing or future successors, affiliates, or subsidiaries, owned or controlled, directly or indirectly, by Vygon.
- 2. Confidential Information means information not generally known and proprietary to Vygon or to a third party who has furnished the information to Vygon, including trade secret information about Vygon's processes and products and information relating to research, development, manufacture, purchasing, accounting, engineering, marketing, merchandising, selling, distribution, finance and business systems and techniques. All information disclosed to you, or to which you obtain access, whether originated by you or others, during the period of your employment, and which you have a reasonable basis to believe is Confidential Information, or which is treated by Vygon as being Confidential Information, shall be presumed to be Confidential Information.
- 3. Conflicting Product means any product, process, system or service that is sold or distributed anywhere in the United States, of any person or organization other than Vygon, now in existence or under development, which is the same as or similar to or competes with, or has a usage allied to, a Vygon process, system or service, or a product that is manufactured or distributed by Vygon.
- 4. Conflicting Organization means any person or organization, wherever they may be located in the world, which is engaged in or about to become engaged in research on or development, production, marketing, leasing, selling or servicing of a Conflicting Product anywhere in the United States.

### B. Representations

I AM EMPLOYED OR DESIRE TO BE EMPLOYED BY VYGON IN A CAPACITY IN WHICH I MAY RECEIVE OR CONTRIBUTE TO CONFIDENTIAL INFORMATION. IN CONSIDERATION OF SUCH EMPLOYMENT OR CONTINUED EMPLOYMENT, AND THE WAGES OR SALARY AND OTHER EMPLOYEE BENEFITS OR COMPENSATION PAID TO ME FOR MY SERVICES, AND IN CONSIDERATION OF BEING GIVEN ACCESS TO CONFIDENTIAL INFORMATION, I AGREE THAT:

Vygon's ownership of confidential and proprietary information in its field is critical to its
continued growth. In addition, the Customer base and other purchasers of the products
that Vygon manufactures and distributes have been developed at substantial time, effort
and expense to the Company, and that Vygon's continued success depends to a

- significant degree on the Company's possession and protection of proprietary information that is not generally known to others, including its competitors.
- 2. Except as required in my duties to Vygon, I will never, either during my employment by Vygon or at any time thereafter, use or disclose any Confidential Information as defined in paragraph A.2. above.
- 3. I acknowledge and agree that all records and any compositions, articles, devices and other items which disclose or embody Confidential Information, whether prepared or made by me or others, are the exclusive property of Vygon and will be left with Vygon when my employment with Vygon terminates, regardless of the reason for termination.
- 4. I understand that many current and potential customers, including distributors, to which Vygon sells or supplies its products have been developed at substantial time, effort and expense to Vygon. As a consequence, I understand and agree that the names of and relationships with these customers and distributors are vitally important and of significant value to Vygon. Therefore, during my employment with Vygon, I agree to devote my best efforts and undivided loyalty to Vygon to develop Vygon's relationship with these customers and distributors. During the period of my employment and for a period of one (1) year thereafter, I agree that I will not, directly or indirectly, by any means whatsoever, for myself or on behalf of, or in conjunction with any person, partnership, corporation or other entity, engage in any conduct for the purpose or effect of designing, developing, soliciting, selling and/or distributing any product which is the same, similar to or competitive with the products manufactured and/or distributed by Vygon, or any such products which are in the process of being developed for sale to customers or distributors. Further, I agree that for one (1) year following termination of my employment, I will not recruit, assist in recruiting or cause any person to recruit any employee of Vygon to any said business or businesses.
- 5. I will promptly and fully communicate in writing to Vygon all ideas, discoveries, developments, methods, strategies, techniques, designs, processes, programs, inventions, improvements, know-how and data, whether or not patentable or registrable under copyright or similar laws, which were conceived, developed, learned or reduced to practice by me, either alone or jointly with others, during my employment with Vygon which relate in any manner to, or are useful in the business of Vygon, or are made using any Vygon equipment, facilities, materials, labor, money, time or other resources; or result from Employee's relationship with Vygon (collectively, "Business Ideas"). I further acknowledge that Vygon shall be the sole owner of all Business Ideas and all patents, copyrights, trademarks and other rights related thereto.
- 6. For a period of one (1) year after termination of my employment with Vygon:
  - a) I will inform any new employer, prior to accepting employment, of the existence of this Agreement and provide such employer with a copy thereof.
  - b) If I have been or am employed by Vygon in a sales capacity, I will not render services, directly or indirectly, to any Conflicting Organization in connection with any Conflicting Product.

- c) If I have been or am employed by Vygon in a non-sales capacity, I will not render to any Conflicting Organization services, directly or indirectly, in connection with a product which Vygon sells or distributes, except that I may accept employment with a large Conflicting Organization whose business is diversified (and which has separate and distinct divisions), and which as to part of its business is not a Conflicting Organization, provided that Vygon shall, prior to my accepting such employment, receive separate written assurances satisfactory to Vygon from such Conflicting Organization and from me, that I will not render services directly or indirectly in connection with any Conflicting Product.
- d) I acknowledge that the restrictions set forth above are reasonable in scope and essential to protect Vygon's legitimate business interests in maintaining its Confidential Information.
- e) I acknowledge that any breach of any of the covenants of this Section B(a) through (d) will result in irreparable injury to Vygon that could not be adequately compensated by money damages. In the event of any such breach, Vygon shall be entitled, in addition to all other rights and remedies which Vygon may have at law or in equity, to have an injunction issued by any competent court enjoining and restraining Employee and all other persons involved therein from continuing such breach. The existence of any claim or cause of action that Employee or any such other person may have against Vygon shall not constitute a defense or bar to the enforcement of any of the Covenants set forth in Section B (a) through (d). If Vygon must resort to litigation in order to enforce any of the Covenants which have a fixed term, then such term shall be extended for a period of time equal to the period during which a breach of such Covenant was occurring, beginning on the date of a final court order (without further right of appeal) holding that such a breach occurred or, if later, the last day of the original fixed term of such Covenant.
- 7. All of my obligations of this Agreement shall be binding upon my heirs, spouses, assigns, and legal representatives.
- 8. In the event that any portion of this Agreement is determined to be invalid or unenforceable for any reason, such determination shall in no way affect the enforceability of other portions of this Agreement, which shall remain in full force and effect. To the extent that a court or other body construing this Agreement can render it enforceable by modifying any clause, while continuing to preserve the intent of the parties to protect Vygon's legitimate business interests as set forth above, then the parties intend that the court or other body shall do so.
- This Agreement replaces and supersedes any existing Agreement entered into by me and Vygon relating generally to the same subject matter.
- 10. I acknowledge and agree that my employment with Vygon is on an at-will basis, meaning that either Vygon or myself may terminate my employment for any reason, with or without cause, and with or without notice. I agree that nothing contained in this Agreement shall be construed as giving me the right to be retained as an employee of Vygon for any period of time.

- 11. I represent that I am not a party to, or bound by, any confidentiality agreements, non-compete agreements, restrictive covenants, non-solicitation agreements, invention assignment agreements, or any other agreements or obligations to any former employer or other entity that will prevent me from performing, or impede me in performance of, services for Vygon. I also represent that I have disclosed to Vygon all contracts or agreements that could prevent me from carrying out my responsibilities to Vygon. I further acknowledge that I have not and will not take or remove from my prior employment the originals or copies of any documents maintained as confidential or proprietary information by my prior employer, and that I have not and will not disclose any confidential or proprietary information of my prior employer. I acknowledge that Vygon is relying on my representation in making its offer of employment, in employing me, or in continuing my employment with Vygon.
- 12. The Agreement and the rights and obligations of the parties shall be construed and determined in accordance with Pennsylvania law, irrespective of choice of law rules, and may not be amended except by writing signed by both Parties.

I hereby state that I have read this Agreement in its entirety, that I have been give an opportunity to consider this Agreement, and that I enter into this Agreement voluntarily and intending to be legally bound

For: Vygon Corporation

Date: 8-18-2010

3/20/10

Date

Dolph Seme

# **Exhibit C**

Case 3:11-cv-02185-H-JMA Document 13-1 Filed 10/14/11 Page 1 of 5 1 X-PATENTS, APC JONATHAN HANGARTNER, Cal. Bar No. 196268 5670 La Jolla Blvd. La Jolla, CA 92037 Telephone: 858-454-4313 Facsimile: 858-454-4314 ion@x-patents.com 5 Attorneys for Plaintiff Ivera Medical Corporation 7 UNITED STATES DISTRICT COURT 8 9 SOUTHERN DISTRICT OF CALIFORNIA 10 IVERA MEDICAL CORPORATION, Case No. 11-cv-2185 H (JMA) 11 SUPPLEMENTAL DECLARATION Plaintiff, 12 OF BOBBY ROGERS IN SUPPORT OF PLAINTIFF'S *EX PARTE* 13 v. APPLICATION FOR EXPEDITED DISCOVERY 14 **EXCELSIOR MEDICAL** CORPORATION. Hon. Marilyn L. Huff 15 Date: To be determined Defendant. 16 Time: To be determined Place: To be determined 17 Complaint Filed: September 19, 2011 18 19 20 I, Bobby Rogers, hereby declare as follows: 21 22 1. I am the founder and Chief Executive Officer of Ivera Medical Corporation 23 ("Ivera"). Except as otherwise indicated, I have personal knowledge of the matters set 24 forth herein and would testify truthfully hereto if so required. I am providing this 25 declaration in response to certain of the allegations made by Excelsior in its opposition 26 papers. 27 28

including those listed in ¶13 of my prior declaration have recently received

2.

23 · 24 ·

 MAUDE Report and raising false concerns about a link between the Curos® product and risk of infections including *candida* infections. In response to the declarations of Mr. Anderson and Mr. Sherman of Excelsior, I have learned additional details regarding these communications.

3. Specifically, I am informed that sometime prior to August 24, 2011, key officials involved in the evaluation of disinfecting caps at Kings County Medical Center in

communications from Excelsior's sales representatives and/or distributors regarding the

As I previously testified, I have been informed that potential customers

- officials involved in the evaluation of disinfecting caps at Kings County Medical Center in Brooklyn received an email communication from someone representing Excelsior that made specific statements about Ivera's Curos® disinfecting cap. I am informed that among these were false statements that: (1) the 70% isopropyl alcohol ("IPA") solution in the Curos product vents its alcohol, leaving behind moisture that allows bacteria to grow; and (2) that the organization JACHO frowns on the use of strips of caps, which is one very popular way that Ivera sells its caps to hospitals so that they can hang conveniently from an intravenous (IV) pole.
- 4. I am further informed that some time just prior to or on September 14, 2011, at least one official involved in infection control at Metropolitan Medical Center in Manhattan, New York, received an email from someone representing Excelsior that included an internet link to the MAUDE Report and stated that Curos can cause *candida* infections. I am also informed that an email with the same content was received at or about the same time by officials evaluating disinfecting caps at Kings County Medical Center. I am informed that the email received by the officials at Kings County Medical Center included a large number of email addresses, and thus appears to have been widely distributed.
- 5. I am informed that a committee responsible for evaluating disinfecting caps at Kings County Medical Center, which included officials who received the email on or

1

3

4 5

> 6 7

8

9

11

12

13

14 15

16

17

18 19

20

21

2223

24

25

26 27

28

of Curos was considered at that meeting and was not approved. It is my understanding that the issue of alleged *candida* infection risk was a significant concern.

6. I have also received a copy of two email messages dated September 14, 2011, sent by officials of a company called Vygon Corporation ("Vygon"). A true and correct copy of these emails is attached hereto as Exhibit C. In the first message – marked

high priority – a Vygon representative named Greg Palma sends Vygon vice president Ron

about September 14, 2011 referenced above, met on or about September 20, 2011. A trial

regarding Curos cap and adverse effect FDA Report A hospital has stopped using them

Metro an internet link to the MAUDE Report, and states: "Please see the above link

distribution of the link to the MAUDE report to potential customers, referred to in the

because of possible infections due to the cap drying out." The email then discusses

email as "clinicians." In the second email, Mr. Metro distributes Mr. Palma's message on to Vygon's "Sales Team" for use in "assisting in your account discovery." I understand

this to mean that it should be used to tell customers and potential customers (referred to as

"accounts") about alleged problems with Curos. While I do not have documents establishing further distribution of Mr. Palma's false statements about Curos to customers,

these emails are consistent with the information I have received about the emails that were

distributed to key hospital officials as discussed above.

7. The content of these emails is also consistent with the "talking points" developed by Excelsior to try to counter Ivera's success in the marketplace. See Anderson Decl. ¶10. As set forth by Mr. Anderson, these "facts" are themselves materially false and misleading. For example, by intentionally omitting facts known to Excelsior, talking point "iv." leads the reader to believe that the hospital removed Curos based on a causal connection between Curos and "an increase in *candida* related blood stream infections." Thus, the talking point intentionally misconstrues the MAUDE Report to lead customers and potential customers to a false conclusion. As described above, Excelsior's representatives and/or distributors then closed the loop completely, telling customers that

 there is a direct connection between Curos and risk of *candida* infections. Talking point "v" is an example of a misleading statement, which is being coupled in the field with statements that the Curos cap allows alcohol to evaporate and leave a most humid environment that could support bacterial and fungal growth. As Mr. Anderson should know, the isopropyl alcohol ("IPA") solution used by both Ivera and Excelsior as the disinfecting agent in their caps is also a drying agent. When mixed together isopropyl alcohol and water bind so that the evaporation rate of both materials becomes identical. Thus, as the IPA solution evaporates one of its principle and highly desirable characteristics is that it will not leave behind any water or by extension "humidity". Talking point (v) is direct evidence of a false and misleading statement.

- 8. There is no question that Ivera is being irreparably harmed by Excelsior's false statements. The MAUDE Report standing alone is not a problem, Ivera dealt with it directly by working with the hospital that filed it to confirm that Curos was *not* the source of their *candida* infections. The irreparable harm is being caused by Excelsior's false statements and its misleading use of the MAUDE Report to lend an air of credibility to its false statements.
- 9. Hospitals decide to use disinfecting caps and select the cap they will use by conducting "trials" of potential products. If your product is not in the trial, it will not even be considered for purchase by that hospital or hospital group. As described above, and in my prior declaration, Ivera has credible information establishing that potential customers have declined to include Curos even in their trials do to concerns about potential increase risk of *candida* infections concerns that were created and fueled by Excelsiors false and misleading statements.
- 10. Finally, while Excelsior's new allegations of false statements by Ivera in its brief and Mr. Anderson's declaration are completely irrelevant to the issues presented in this application for expedited discovery, I will briefly address one point. Mr. Anderson asserts that I have said "One mistake with [Excelsior's] product and a kid could choke and

Case 3:11-cv-02185-H-JMA Document 13-1 Filed 10/14/11 Page 5 of 5

die." This statement is presented as a direct quote by me, although the alleged time, place, or form of the quotation is not explained. I do not recall making such a statement. I have said that orange is a bad choice of color for a disinfecting cap used in intravenous access ports because feeding lines are typically orange. There are a multitude of products used in the neonatal intensive care unit (NICU) as well as pediatric intensive care units (PICU) used for feeding and their color is orange. Intravenous lines have no color coding. The misconnection of a feeding line to an intravenous line is a life threatening risk. I stand by this statement and firmly believe that there is inherent risk associated with Excelsior's color choice. I also have said that Excelsior's SwabCap can pop off the luer activated valve and I stand by this statement, as the SwabCap is a soft-bodied cap that can be relatively easily dislodged from a luer activated valve.

I declare under penalty of perjury under the laws of the United States of America that the foregoing statements are true and executed by me this 13th day of October, 2011.

Bolly E. Log

Bobby E. Rogers

Case 3:11-cv-02185-H-JMA Document 13-2 Filed 10/14/11 Page 1 of 3

# **EXHIBIT C**

Case 3:11-cv-02185-H-JMA Document 13-2 Filed 10/14/11 Page 2 of 3

---- Original Message -----

From: Ron Metro To: Sales Team

Cc: Ken Rafferty; Sharyn Flores; Cindy Varughese

Sent: Wed Sep 14 13:26:44 2011

Subject: FW: MAUDE Adverse Event Report

Sales Team-

Please review the email below from Greg Palma regarding the Adverse Event Report on the Curos alcohol swab cap. This is one report from one hospital. Please read it carefully. This is a For Your Information for assisting in your account discovery however should not be used to sell negatively. Thanks Greg.

Ron Metro Executive Vice President Vygon US 103a Park Drive Montgomeryville, PA 18936 (O) 800-473-5414 (C) 508-320-8595

----Original Message----

From: Greg Palma

Sent: Wednesday, September 14, 2011 8:37 AM

To: Ron Metro

Subject: MAUDE Adverse Event Report

Importance: High

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi\_\_i d=2163582

#### Ron

Please see the above link regarding Curos cap and adverse effect FDA Report A hospital has stopped using them because of possible infections due to the cap drying out.

The swab cap has a seal and the alcohol cannot dry out. The curos cap does not have a seal so the cap will dry over time allowing bacteria build up.

Please have the reps exercise caution when using this link. I would just show the

## Case 1:11-cv-09283-GBD Document 1 Filed 12/19/11 Page 25 of 62

Case 3:11-cv-02185-H-JMA Document 13-2 Filed 10/14/11 Page 3 of 3

clinician as an "FYI did you hear about this"

If anyone has any questions please feel free to reach out to me

Greg

Case 3:11-cv-02185-H-JMA Document 13-3 Filed 10/14/11 Page 1 of 2 1 X-PATENTS, APC JONATHAN HANGARTNER, Cal. Bar No. 196268 5670 La Jolla Blvd. La Jolla, CA 92037 Telephone: 858-454-4313 Facsimile: 858-454-4314 jon@x-patents.com 5 Attorneys for Plaintiff 6 Ivera Medical Corporation 7 UNITED STATES DISTRICT COURT 8 SOUTHERN DISTRICT OF CALIFORNIA 9 10 IVERA MEDICAL CORPORATION, Case No. 11-cv-2185 H (JMA) 11 SUPPLEMENTAL DECLARATION Plaintiff, 12 SUPPORT OF PLAINTIFF'S EX 13 v. PARTE APPLICATION FOR EXPEDITED DISCOVERY 14 EXCELSIOR MEDICAL CORPORATION, Hon. Marilyn L. Huff 15 Defendant. Date: To be determined 16 Time: To be determined Place: To be determined 17 Complaint Filed: September 19, 2011 18 19 20 I, Jonathan Hangartner, hereby declare as follows: 21 22 1. I am an attorney licensed to practice in the State of California and in the 23 United States District Court for the Southern District of California. I am counsel of record 24 for Plaintiff Ivera Medical Corporation ("Ivera") in the above-captioned action. If called 25 upon to do so, I could and would testify truthfully and competently as follows. 26 27 28 1

### Case 1:11-cv-09283-GBD Document 1 Filed 12/19/11 Page 27 of 62

Case 3:11-cv-02185-H-JMA Document 13-3 Filed 10/14/11 Page 2 of 2 2. A true and correct copy of a proposed amended Plaintiff's First Set of Expedited Requests for Production to Excelsior Medical Corporation is attached hereto as Exhibit C. 3. A true and correct copy of a proposed amended document subpoena to Vygon Corporation is attached hereto as Exhibit D. I declare under penalty of perjury under the laws of the United States of America that the foregoing statements are true and executed by me this 14th day of October, 2011. /s/Jonathan Hangartner Jonathan Hangartner 

Case 3:11-cv-02185-H-JMA Document 13-4 Filed 10/14/11 Page 1 of 5

# **EXHIBIT C**

	Case 3:11-cv-02185-H-JMA Document 13-	4 Filed 10/14/11 Page 2 of 5				
1 2 3 4 5 6 7	X-PATENTS, APC JONATHAN HANGARTNER, Cal. Bar No. 5670 La Jolla Blvd. La Jolla, CA 92037 Telephone: 858-454-4313 Facsimile: 858-454-4314 jon@x-patents.com  Attorneys for Plaintiff Ivera Medical Corporation	196268				
8	UNITED STATES DISTRICT COURT					
9	SOUTHERN DISTRICT OF CALIFORNIA					
10						
11	IVERA MEDICAL CORPORATION,	Case No. 11-cv-2185 H (JMA)				
12	Plaintiff,	PLAINTIFF'S FIRST SET OF				
13	v.	EXPEDITED REQUESTS FOR PRODUCTION TO EXCELSIOR				
14 15	EXCELSIOR MEDICAL CORPORATION,	MEDICAL CORPORATION				
16	Defendant.					
17	,					
18		,				
19	PROPOUNDING PARTY: Ivera Medic	cal Corporation				
20	RESPONDING PARTIES: Excelsion M	fedical Corporation				
21	SET NO.: One					
22						
23	Pursuant to Rule 34 of the Federal Rule	es of Civil Procedure, Ivera Medical				
24	Corporation ("Ivera") requests that Excelsior Medical Corporation ("Excelsior") produce					
25	the documents and things described below for inspection and copying on or before October					
26	21, at 10:00 a.m. at the offices of X-Patents, APC, 5670 La Jolla, Blvd., La Jolla, CA 92037.					
27						
28	1					

Case 3:11-cv-02185-H-JMA Document 13-4 Filed 10/14/11 Page 3 of 5

### DEFINITIONS AND GENERAL INSTRUCTIONS

- 1. As used in these requests for production, "YOU" or "YOUR" means and includes Excelsior Medical Corporation, any predecessors or successors in interest, any past and present officers and directors, employees, agents, independent contractors, sub-representatives, and representatives, any past and present attorneys and their agents and employees, any past and present accountants and their agents and employees, any past and present investigators and their agents and employees, and anyone else acting or who has ever acted on behalf of YOU. The use of the term "YOUR" shall relate to YOU.
- 2. As used in these requests for production, "Ivera" means and includes Ivera Medical Corporation, any predecessor or successor in interest, any past and present officers and directors, employees, agents, and representatives, any past and present attorneys and their agents and employees, any past and present accountants and their agents and employees, any past and present investigators and their agents and employees, and anyone else acting or who has ever acted on behalf of Ivera.
- 3. As used in these requests for production, "communication" includes any and all written communications, including without limitation, any electronic mail or other digital communications.
- 4. As used in these requests for production, the terms "RELATE TO" or "RELATING TO" mean, by way of example and without limitation, demonstrates, describes, memorializes, evidences, comprises, refers to, pertains to, supports, contradicts, affects, or concerns all or any portion of the matters, facts, and contentions specified in any Request.
- 5. As used in these requests for production "any" means and includes "all" and vice versa.
- 6. These requests for production cover all DOCUMENTS in YOUR possession, or subject to YOUR custody or control, whether such documents are held by YOU or by YOUR agents, employees, investigators, attorneys, or accountants, and whether such

Case 3:11-cv-02185-H-JMA Document 13-4 Filed 10/14/11 Page 4 of 5

divisional offices, or any other office or storage place maintained, utilized, operated, owned, or controlled by YOU.

documents are located in YOUR principal office, YOUR foreign, subsidiary, regional, or

- 7. For any DOCUMENT which YOU claim is protected against disclosure as "work product" or "privileged," please provide the following information:
  - A. A description of the DOCUMENT sufficiently particular to identify it and to enable the requesting party to identify it, and to disclose or produce it in response to an order of the above-entitled Court;
  - B. Its author or a list of all persons who participated in the preparation of the DOCUMENT;
  - C. Its date;
  - D. All addresses or recipients (including the identity of all persons who have received a copy);
  - E. The identity of all persons who now have or have ever had possession, custody or control of the original or any copy of such DOCUMENT, or to whom the contents of the DOCUMENT have been disclosed;
  - F. Its subject matter; and
  - G. The basis on which the privilege is claimed.
- 10. These requests for production are deemed to be continuing in nature, requiring supplemental responses if additional documents are located up to and including the time of trial.
- 12. As used herein, the "MAUDE Report" refers to the MAUDE Adverse Event Report referencing Ivera's Curos® disinfecting cap product, filed on or about July 11, 2011 with the U.S. Food and Drug Administration, a copy of which is attached hereto as Exhibit A.

Case 3:11-cv-02185-H-JMA Document 13-4 Filed 10/14/11 Page 5 of 5

## REQUESTS FOR PRODUCTION 1 2 **REQUEST NO. 1:** All communications between Excelsior and any third-party RELATING TO the 3 MAUDE Report since July 1, 2011. 4 5 **REQUEST NO. 2:** All communications between Excelsior and any third-party RELATING TO any 6 7 alleged risk of infection associated with use of Ivera's Curos® product since July 1, 2011. **REQUEST NO. 3:** 8 9 All communications between Excelsior and any third-party RELATING TO any alleged connection between Ivera's Curos® product and any incidence of candida 10 11 infections since July 1, 2011. 12 **REQUEST NO. 4:** All DOCUMENTS RELATING TO any alleged design flaw or deficiency in 13 Ivera's Curos® product that impacts the alleged risk of patient infection since July 1, 2011. 15 16 Dated: October 13, 2011 X-PATENTS, APC 17 18 By: /s/Jonathan Hangartner JONATHAN HANGARTNER 19 20 Attorneys for Plaintiff Ivera Medical Corporation 21 22 23 24 25 26 27 28

Case 3:11-cv-02185-H-JMA Document 13-5 Filed 10/14/11 Page 1 of 6

# **EXHIBIT D**

## C6256:3:11-tvc020203550MSNMAM(Doctorocente113-75-3 Fifeted 01/01/01/11 1 P8gag & 20fol 9

AO 88B (Rev. 06/09) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action

# UNITED STATES DISTRICT COURT

for the

Eastern District of Pennsylvania					
EXCELSIOR MED  Do  SUBPO  OF  To: VYGON CORPORA  Production: YO	AL CORPORATION  laintiff v.  DICAL CORPORATION  fendant  DENA TO PRODUCE DOCU  A TO PERMIT INSPECTION  ATION, 103A Park Drive, Monto of Stored information, or objects,  HMENT A	OF PRE	(If the action is pending in another Southern District of Co., INFORMATION, OR OF CMISES IN A CIVIL ACTION, PA 18936  The time, date, and place set for the set of the control of the cont	alifornia )  BJECTS  ION  orth below the following	
other property possessed	mises: YOU ARE COMMAN or controlled by you at the time rvey, photograph, test, or sample.	e, date, an	d location set forth below, se	o that the requesting party	
	FFed. R. Civ. P. 45(c), relating your duty to respond to this su				
	CLERK OF COURT  Signature of Clerk or Deputy	, Clerk		an Hangartner ney's signature	
The name, address, e-mai MEDICAL CORPORATIO Jonathan Hangartner, Es 5670 La Jolla Boulevard, Tel: (858) 454-4313	q., X-Patents, APC	attorney	• • • • • • • • • • • • • • • • • • • •	Plaintiff IVERA ests this subpoena, are:	

## Case 1:11-cv-09283-GBD Document 1 Filed 12/19/11 Page 35 of 62

## C6556:3:11-tvc02023560MSAMAMCDoDorocentett3-5-3 Fiffiled 0/0/4016/11 1 P85566 3 3 5 6 6 9

AO 88B (Rev. 06/09) Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action (Page 2)

Civil Action No. 11-CV-2185-DMS (WMC)

### PROOF OF SERVICE

(This see	ction should not be filed with the court	unless required by Fed. R. Civ. P.	45.)
This subpoena fo	T (name of individual and title, if any)		
as received by me on (d	ale)		····
☐ I served the su	ubpoena by delivering a copy to the nan	ned person as follows:	
		on (date)	; or
☐ I returned the	subpoena unexecuted because:		
tendered to the w	ena was issued on behalf of the United itness fees for one day's attendance, an		
fees are \$	for travel and \$	for services, for a total of	\$ 0.00
I declare under pe	enalty of perjury that this information is	s true.	
te:		Server's signature	
		Printed name and title	
	<del>4.1</del>	Server's address	

Additional information regarding attempted service, etc:

Case 1:11-cv-09283-GBD Document 1 Filed 12/19/11 Page 36 of 62

Case 3:11-cv-02185-H-JMA Document 13-5 Filed 10/14/11 Page 4 of 6

Attachment A

#### **DEFINITIONS**

- As used in these requests for production, "Vygon," "YOU" or "YOUR"
  means and includes Vygon Corporation, any predecessors or successors in interest, any
  past and present officers and directors, employees, agents, independent contractors,
  sub-representatives, and representatives.
- As used in these requests for production, "Ivera" means and includes Ivera
   Medical Corporation, any predecessor or successor in interest, any past and present
   officers and directors, employees, agents, and representatives.
- "DOCUMENT" or "DOCUMENTS" shall mean any handwritten, typed, printed, pictorial, or graphic matter, however produced or reproduced, of every kind and description, and any other tangible thing, including without limitation any "writings," "originals," and "duplicates," and any facsimiles, electronic records, film records, or productions. If a writing has been prepared in more than one copy and any copy was not - or is no longer - identical to the original (whether by reason of notations, revisions, versions, modifications, alterations, or marginal notes, including those made on "Post-Its" or their equivalent), each non-identical copy must be included. For the purposes of software and other electronic writings, revisions includes, without limitation, upgrades, enhancements, new versions, patches and fixes. For example, the term "DOCUMENT" includes, without limitation: records, correspondence, telegrams, notes, electronic mail, facsimiles, calendar pages, check lists, files, file folders, sound recordings, memoranda, reports, written analyses, contracts and their supplements, amendments, and modifications, licenses, agreements, illustrations, diagrams, instructions, photographs, films, videotapes, electronic or magnetic tapes, software, computer printouts, reports, books, job or transaction files, records of telephone conversations, meetings or minutes of any meetings, drafts of the foregoing or anything similar to any of the foregoing, however denominated by YOU. "DOCUMENT" includes without limitation any electronically stored documents such as electronic mail or other

Case 3:11-cv-02185-H-JMA Document 13-5 Filed 10/14/11 Page 5 of 6

Attachment A

documents stored on a computer system, backed-up voice-mail, any videotape, or audiotape. If any DOCUMENT exists only in electronic form, a printout or other output readable by sight, shown to reflect the data accurately, must be produced. Any and all attachments or enclosures which accompany requested DOCUMENTS shall be produced in response to these demands. Any DOCUMENT which related only in part to the DOCUMENT categories set forth below shall be produced.

In producing DOCUMENTS and other materials, YOU are requested to furnish all DOCUMENTS and materials in YOUR possession, custody or control, regardless of whether such DOCUMENTS or materials are possessed directly by YOU or by YOUR attorneys or their agents, employers, employees, representatives or investigators.

If a demand calls for the production of a DOCUMENT as to which YOU claim any privilege or any other ground for withholding or otherwise failing to produce the DOCUMENT, please provide at the time at which the other DOCUMENTS are produced a log that sets forth, separately for each DOCUMENT withheld: (a) the identify of the author; (b) his or her address; (c) any natural person who assisted in preparation of the DOCUMENT; (d) the title of the DOCUMENT or other identifying data sufficient to describe the DOCUMENT for purposes of a subpoena duces tecum; (e) the date of the DOCUMENT, or, if no date appears thereon, the approximate date it was created; (f) the identify of each person to whom the DOCUMENT, or any copy thereof, was transmitted, shown or disclosed by any person; (g) the identify and location of each person having or last having possession, care, custody or control of the original and each of any copies thereof; and (h) each and every fact or basis upon which YOU claim a privilege or the ground(s) for YOUR refusal to produce the DOCUMENT, in such detail as would be required for PLAINTIFF to test the claim of privilege or other grounds for refusal to produce in a motion to compel production of the DOCUMENT.

4. The terms "communication," "communications" or "communicated" as used herein means any contact between two or more persons or entitities and shall

Case 3:11-cv-02185-H-JMA Document 13-5 Filed 10/14/11 Page 6 of 6

Attachment A

include, without limitation, written contacts by such means as any DOCUMENT, or oral contact by such means as face-to-face or in-person meetings, telephone conversations, or any other form of electronic communication.

- 5. The terms "RELATING TO" or "RELATED TO" as used herein shall mean evidencing, memorializing, referring, refuting, constituting, containing, discussing, describing, embodying, reflecting, identifying, mentioning, stating, or otherwise relating to in any way, in whole or in part, the subject matter referred to in the request.
- 6. As used herein, the "MAUDE Report" refers to the MAUDE Adverse Event Report referencing Ivera's Curos® disinfecting cap product, filed on or about July 11, 2011 with the U.S. Food and Drug Administration, a copy of which is attached hereto.

#### REQUEST FOR PRODUCTION OF DOCUMENTS

## **REQUEST NO. 1:**

All communications between Vygon and any third-party RELATING TO the MAUDE Report since July 1, 2011.

#### **REQUEST NO. 2:**

All communications between Vygon and any third-party RELATING TO any alleged risk of infection associated with the use of Ivera's Curos product since July 1, 2011.

#### **REQUEST NO. 3:**

All communications between Vygon and any third-party RELATING TO any alleged connection between Ivera's Curos product and any incidence of *candida* infections since July 1, 2011.

#### **REQUEST NO. 4:**

All DOCUMENTS RELATING TO any alleged design flaw or deficiency in Ivera's Curos® product that impacts the alleged risk of patient infection since July 1, 2011.

	Case 3:11-cv-02185-DMS-WMC Document	10 Filed 10/12/11 Page 1 of 14	
1 2 3 4 5 6 7	mmurphy@sheppardmullin.com MATTHEW W. HOLDER, Cal. Bar No. 217619 mholder@sheppardmullin.com SHEPPARD, MULLIN, RICHTER & HAMPTON LLP A Limited Liability Partnership		
8	Attorneys for Defendant EXCELSIOR MEDICAL CORPORATION		
9			
10			
11	IVERA MEDICAL CORPORATION,	Case No. 3:11-cv-02185-DMS-WMC	
12	Plaintiff,	DEFENDANT EXCELSIOR MEDICAL	
13	v.	CORPORATION'S OPPOSITION TO PLAINTIFF'S EX PARTE	
14 15	EXCELSIOR MEDICAL CORPORATION,	APPLICATION FOR EXPEDITED DISCOVERY [DKT. NO. 7]	
16	Defendant.		
17			
18			
19			
20			
21	•		
22			
23		•	
24			
25			
26			
27			
28			
	W02-WEST:6MRM1W04040653.3	OPPOSITION TO EX PARTE APPLICATION	
		3:11-CV-02185-DMS-WMC	

Case 3:11-cv-02185-DMS-WMC Document 10 Filed 10/12/11 Page 2 of 14

Defendant Excelsior Medical Corporation ("Excelsior") opposes Plaintiff Ivera Medical Corporation's ("Ivera") ex parte application for expedited discovery. For the Court's information, there has been no ENE or Rule 26(f) conference in this case.

#### INTRODUCTION

In July of this year, Eden Valley Medical Center in Castro Valley, California ("Eden") filed four adverse event reports with the Food and Drug Administration ("FDA") regarding Ivera's Curos® Port Protector product ("Curos"). Those reports correlated the Curos product with four candida infections and indicated that the facility had discontinued use of the Curos product. The reports state that prior to the use of the Curos product, "line infections ha[d] been rare at [Eden's] facility". The reports also state that "[a]s a part of [Eden's] review, it was identified that use of the curos [sic] port protector caps on [Eden's] 12 lines were the only recent change." Finally, the reports state that "Per [Ivera], they do not 13 | have testing at this time that shows the efficacy of the curos [sic] port protector in regards to candida (as it is not required.)" These reports are publicly available on the FDA's MAUDE database. Hospitals and medical facilities use the MAUDE database as a means to consider the safety of medical products in patient treatment. As Ivera's CEO has stated, "[f]or a medical device designed to reduce the incidence of infection in a hospital, any perception that it may cause infections can be devastating, eliminating it from consideration for use by the hospital or hospital group." [Dkt. No. 7-4, ¶17.]

Rather than accept that its woes are the result of these publicly available adverse event reports submitted by Eden, Ivera has instead filed a false advertising suit against Excelsior<sup>2</sup>. Ivera's suit is baseless, and Ivera knows it. Despite its Fed. R. Civ. P. 11

3

4

5

6

7

8

10

11

17

18

19

20

22 l

23

24

See, e.g., http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\_\_id=2163582.

<sup>&</sup>lt;sup>2</sup> This is the second false advertising action filed by Plaintiff against Excelsior this year. The first action, <u>Ivera Medical Corporation v. Excelsior Medical Corporation</u>, Case No. 11CV 0426 (the "First Action") was also without merit. However, to avoid the unnecessary time and expense of defending against the merit less case, Excelsior settled prior to answering. The settlement agreement entered into in the First Action specifically stated that, "It is understood and expressly agreed by the Parties that this Agreement is a compromise of disputed claims and the consideration for this Agreement shall not be deemed or construed as an admission of any liability by any of the Parties." Despite this

responsibility, Ivera admits that it does "not have information establishing whether [any false] communications came directly from Excelsior or from its representatives and/or distributors." [Dkt. No. 7-4, ¶14.] Nevertheless, Ivera now seeks expedited discovery to support an anticipated motion for preliminary injunction – presumably with "facts" it should have and could have obtained before filing its lawsuit.

A review of the facts shows that Ivera's anticipated motion is fatally flawed, the discovery it requests will not cure these flaws, and provision of this discovery will prejudice Excelsior. No emergency necessitates the extraordinary relief Ivera requests. Ivera is unable to demonstrate that it has suffered irreparable harm. In fact, Ivera does not even allege that customers have ceased buying its products as a result of any alleged misconduct of Excelsior. Rather, Ivera merely asserts vague allegations regarding statements made to "potential" customers. Under the circumstances, Ivera has failed to demonstrate good cause exists to support its request. Accordingly, the Court should deny Ivera's motion in its entirety.

## II. BACKGROUND

Excelsior is a leading manufacturer and supplier of products used in the medical field. (See Declaration of William Anderson in Support of Defendant's Opposition to Plaintiff's Ex Parte Application for Expedited Discovery ("Anderson Decl.") ¶2.) One of these products is a luer access valve disinfection cap sold under the trademark SwabCap®. (Id.) The SwabCap helps hospitals to reduce the likelihood of nosocomial infections.

Nosocomial infections are infections acquired while in a hospital.<sup>3</sup>

language and the strictures of Federal Rule of Evidence 408, Plaintiff improperly refers to the First Action throughout its papers.

W02-WEST:6MRM1\404040653.3

-2.

The Centers for Disease Control and Prevention estimates that roughly 1.7 million hospital-associated infections cause or contribute to 99,000 deaths each year. Other estimates indicate that approximately 2 million hospital patients a year become infected, with the annual cost ranging from \$4.5 billion to \$11 billion. Needless to say, controlling nosocomial infections is something hospitals take very seriously.

Ivera sells a product called the Curos Port Protector. Ivera believes that the SwabCap and the Curos products directly compete with each other in the marketplace. (Id. ¶4.) Unable to compete with Excelsior in the marketplace, Ivera has launched a campaign of disinformation and litigation. In or about March 2011, Excelsior began to receive reports from customers that Ivera sales representatives were making false and misleading statements to Excelsior customers about the SwabCap product. These include e-mails attempting to link Excelsior's product with non-existent design flaws, and specific statements by Ivera's CEO, Bob Rogers, that Excelsior's SwabCap could kill a child and that the SwabCap does not lock onto an IV line and can be "popped off[.]"4 (See Anderson Dec., ¶¶5-8.)

Ivera's campaign of disinformation was apparently not enough, as on May 20, 2011, Ivera filed a suit for patent infringement against Excelsior, alleging that Excelsior's marketing and sales of the SwabCap product infringe two Ivera patents. [See Southern District Case No. 11cv1115 H-JMA, Dkt. No. 21. Excelsior denies that it infringes any of 15 | Ivera's patents and has filed its own counterclaim for declaratory judgment of 16 noninfringement and invalidity of the asserted patents. Realizing that its patent infringement suit was unlikely to go anywhere, on September 19, 2011, Ivera filed the current case alleging that Excelsior engages in false advertising when marketing its SwabCap product.

Despite the obvious relationship between these two actions, Ivera's counsel failed to file a notice of related case in violation of this Court's Civil Local Rule 40.1(e). 22 | Accordingly, Excelsior has filed the required notice and has requested that the patent infringement action and the false advertising action be transferred to the same District Court and Magistrate Judges. [See Southern District Case No. 11cv2185 DMS-WMC,

27 28

1

10

11

14

17

18

19

20

21

24

25

Compare Excelsior's specific and detailed evidence of misleading statements (e.g., Anderson Decl. ¶¶6-8) with Ivera's non-specific and speculative assumptions (e.g., Dkt. No. 7-4, ¶¶11,14 "I do not have information establishing whether these [allegedly false] communications came directly from Excelsior or from its representatives and/or distributors.").

Dkt. No. 8.] Upon transfer, Excelsior intends to request that the two actions be consolidated for all purposes. [See id.]

Ivera has decided to seek expedited discovery to support an anticipated motion for preliminary injunction. But the discovery Ivera seeks will not rescue its anticipated injunction application. On the contrary, it will merely cause Excelsior to spend needless and duplicative time and resources providing information that has no bearing on the purported "imminent and irreparable" harm Ivera claims it has suffered (without appropriate evidentiary support). Ivera's request is nothing more than a desperate fishing expedition and should be denied.

#### III. IVERA DOES NOT NEED EXPEDITED DISCOVERY FROM EXCELSIOR.

Except in actions for review of an administrative record, and unless the parties stipulate to a commencement of discovery or the court orders discovery to begin, Federal Rule of Civil Procedure 26(d) permits parties to seek discovery only after they have met 14 and conferred in compliance with Rule 26(f). When a party requests court-ordered 15 expedited discovery prior to the Rule 26(f) conference, this Court has applied a "good 16 | cause" standard. See Hansen Beverage Co. v. Innovation Ventures, LLC, 2008 WL 17 | 3992353 (S.D.Cal. August 28, 2008). "Good cause may be found where the need for 18 expedited discovery, in consideration of the administration of justice, outweighs the prejudice to the responding party." Id. Where the requested discovery is unnecessary, the good cause standard is not met. See id.

# Ivera's Desire for a Preliminary Injunction is Fatally Flawed and Cannot Support the Requested Emergency Discovery.

Ivera's stated need for expedited discovery is to bring a motion for a preliminary injunction to address alleged ongoing irreparable harm. [See Dkt. No. 7, p. 6.] However, expedited discovery is not automatically granted merely because a party seeks a preliminary injunction. American Legalnet, Inc. v. Davis, 673 F.Supp.2d 1063, 1066, 1071 (C.D. Cal. 2009). On the contrary, a request for expedited discovery to support a motion for preliminary injunction should be denied where a "plaintiff has not made an adequate

2

3

5

8

10

11

20

21

22

23

26

showing that it will be irreparably harmed by delaying the broad-based discovery requested until after the initial conference between the parties pursuant to Rule 26."). Id. at 1066-67 (quoting Dimension Data N. Am. v. NetStar-1, Inc., 226 F.R.D. 528, 532 (E.D.N.C. 2005).

Here, the alleged (and required) imminent and irreparable harm that Ivera claims to have suffered is never identified in Ivera's papers. According to Ivera, several potential customers have allegedly raised concerns regarding Ivera's Curos product. [See Dkt. No. 7-4, ¶13.] But Ivera does not describe what these concerns were, state how Ivera responded to these alleged concerns<sup>5</sup>, or explain whether these potential customers have decided not to use the Curos product (or the basis of such a rejection). Indeed, Ivera fails to identify a single customer or account that was allegedly lost (or will be lost) as a result of anything done by Excelsior.

Without any identification of its alleged irreparable harm, Ivera's anticipated preliminary injunction motion (the purported reason for expedited discovery) is fatally 15 | flawed. See Caribbean Mar. Serv. Co. v. Baldridge, 844 F.2d 668, 674 (9th Cir. 1988) (to 16 prevail on a motion for preliminary injunction "plaintiff must demonstrate immediate threatened injury as a prerequisite to preliminary injunctive relief." (emphasis in the 18 | original) see also, Oakland Tribune, Inc. v. Chronicle Pub. Co., 762 F.2d 1374, 1376 (9th 19 Cir. 1985). Thus, mere risk of irreparable harm in the indefinite future is insufficient; the 20 | harm must be imminent. Moreover, "[s]peculative injury does not constitute irreparable injury sufficient to warrant granting a preliminary injunction." Carribbean Mar. Serv., 844 F.2d at 674; see also Church v. Huntsville, 30 F.3d 1332, 1337 (11th Cir. 1994); Campbell Soup Co. v. ConAgra, Inc., 977 F.2d 86, 91 (3rd Cir. 1992); Goldie's Bookstore,

28

27

3

4

5

7

12

13

17

21

24

In fact, a review of Ivera's web site shows that Ivera has posted a letter in which it advises clients that the MAUDE Report was filed and further states that the Curos® product was cleared as a cause of the candida infections at Eden and that Eden has resumed using the product. No further remedial action is necessary.

Inc. v. Superior Court, 739 F.2d 466, 472 (9th Cir. 1984). Here, Ivera fails to provide even speculative alleged harm.

In addition to failing to demonstrate the existence of actual, imminent, and irreparable harm, Ivera has also utterly failed to link any such harm with any statement by Excelsior. On the contrary, Ivera admits that it does "not have information establishing whether [any allegedly false] communications came directly from Excelsior or from its representatives and/or distributors." [Id., ¶14.] Given this admission, it is hard to see how Ivera can even justify filing the current suit, let alone seek expedited discovery in support of a motion that has not even been filed.

Even if Ivera is presently suffering harm, such unidentified harm cannot be laid at the feet of Excelsior. Ivera admits that potential Ivera customers have good reason to raise concerns regarding the Curos product regardless of any purported actions by Excelsior. On July 11, 2011, four adverse event reports were placed on the FDA's MAUDE database. [See, e.g., Dkt. No. 7-5, p. 2.] These reports state that four patients were identified with candida infections. They state that prior to use of Curos product "line infections have been rare at our facility." [Id.] They state that Ivera did "not have testing at this time that shows the efficacy of the curos port protector in regards to candida[.]" [Id.] And they state that use of the Curos product was pulled. [Id.]

If Ivera does have a problem, it is not Excelsior, but the existence of these MAUDE reports. Ivera admits that "any perception that [the Curos product] may cause infections can be devastating, eliminating [the Curos product] even from consideration for use by the hospital or hospital group." [Dkt. No. 7, p. 6 ll. 17-20.] However, rather than accept that

28

27

3

7

10

16

17

18

19

20

21

22

23

·24

- 6 -

<sup>&</sup>lt;sup>6</sup> See also Ortho Biotech Products, L.P. v. Amgen Inc., No. 05-4850, 2006 WL 3392939, at \*9 (D.N.J. Nov. 21, 2006) (finding no irreparable harm where all of plaintiff's injuries flowed from alleged decrease in profits and "any loss in profits, as well as any harm collaterally flowing from these loss of profits, can be remedied by monetary damages at the end of a trial on the merits ... If the simple recitation of potential economic injuries like loss of sales, market share and profits could signify irreparable harm, it would require a finding of irreparable harm to every manufacturer/patentee, regardless of circumstances." (quoting Sunrise Med. Hhg. v. Airsep Corp., 95 F. Supp., 2d 348, 462 (W.D. Pa. 2000)).

medical institutions would research the public safety record of a medical device before choosing to use that device, Ivera lays all the blame for its predicament on Excelsior. Ivera's position lacks merit. The point of a MAUDE report is to publicly document potential safety issues, so that medical institutions may take into account any correlation between specific products and reported adverse events when treating patients. Given the existence of the MAUDE reports, Ivera's inability to identify any lost customers, and the admitted lack of any evidence linking Excelsior to any false statements, Ivera's proposed motion for preliminary injunction is dead on arrival. Thus, its request for expedited discovery to support this fatally flawed motion is nothing more than a fishing expedition to shore up a baseless action that should never have been brought in the first case. Accordingly, the Court should deny Ivera's application in its entirety.

#### Ivera's Requested Discovery Is Unnecessary to Its Purported Motion В.

In a desperate attempt to lay the blame on Excelsior, Ivera identifies several medical facilities on the East Coast that have purportedly expressed concern regarding the Curos product, and requests an emergency deposition of Excelsior employee Roger Sherman. 16 || However, such a deposition is unnecessary. In connection with this opposition brief, Mr. Sherman provides sworn declaration confirming that he "had no communication whatsoever with any representative [from four of these facilities] regarding the fact that a 19 | MAUDE report, relating to the Curos product, had been filed or the fact that, for a period of time, the Eden Medical Center ceased using the Curos product." (See Declaration of Roger Sherman in Support of Defendant's Opposition to Plaintiff's Ex Parte Application for Expedited Discovery ("Sherman Decl."), ¶4.) Although Mr. Sherman did inform a representative of Metropolitan Medical Center that a MAUDE report had been filed, he merely "informed the representative that the MAUDE Report could be viewed at the

25

21

3

5

10

11

12

13

14

26 27

Case 3:11-cv-02185-DMS-WMC Document 10 Filed 10/12/11 Page 9 of 14

FDA's web site." (See Sherman Decl., ¶6.) Given his declaration, an expedited deposition of Mr. Sherman is unnecessary and will only be a waste of time and expense.

Ivera also requests information regarding whatever talking points Excelsior may have related to Ivera's Curos product. To the extent such information is necessary for Ivera's purported motion, that information is adequately supplied by the sworn declaration of Mr. Anderson. Mr. Anderson's declaration sets forth Ivera's disinformation, and Excelsior's talking points to counter this disinformation. (See Anderson Decl. ¶ 6-10.)

Moreover, given that Ivera's alleged harm is that "several potential customers [] have serious concerns about Ivera's Curos® product relating to its clinical performance, and in particular due to concerns regarding potential candida infections," Ivera should not be demanding discovery from Excelsior, but rather from those third parties to determine the basis for their concerns. Ivera's utter failure to explain or reasonably determine why potential customers may be concerned about its Curos product (as if the publicly available 14 | MAUDE reports were not enough) is fatal to its motion for preliminary injunction, and its 15 requested expedited discovery will not cure this flaw. Thus, Ivera has not shown good cause to waive the standard discovery procedures required by Rule 26. Accordingly, Ivera's request should be denied.

#### IV. **EXCELSIOR WILL SUFFER SIGNIFICANT PREJUDICE FROM IVERA'S** REQUESTED EMERGENCY DISCOVERY.

A court generally has the discretion, in the interests of justice, to prevent excessive or burdensome discovery. Fed.R.Civ.P. 26(b) (2). Here, Ivera's requested expedited discovery is overly prejudicial and unduly burdensome to Excelsior. Ivera seeks the deposition of Roger Sherman, several document requests from Excelsior, and third-party discovery.

25 26

27 28

3

5

6

7

8

9

18

19

20

21

To the extent the Court permits Ivera to depose Mr. Sherman on an expedited basis, the deposition should be limited to any communications he had with the five facilities cited in Ivera's moving papers regarding the Curos product, and should not become an openended fishing expedition.

case 3:11-cv-02185-DMS-WMC Document 10 Filed 10/12/11 Page 10 of 14

Ivera's proposed discovery is neither sufficiently tailored nor focused to permit expedited discovery. Although all the document requests are limited in time, the proposed discovery seeks a wide range of documents and information that will likely require collection, review, and production of both paper documents and electronically stored information (ESI), specifically requested to be produced in "native format." For example, several of the requests seek information that may be contained in a proprietary database that tracks customer information and contacts. This database was not designed for litigation purposes and contain many different fields of data which, depending on the nature of the information sought, may or may not be relevant, and may be trade secrets or protected by state privacy laws.

Based on the research that Excelsior and its counsel have conducted to date, it appears that much of the information being sought is not contained within a single database, nor is it contained within the program run against these databases. As a result, to extract data responsive to the requests may require programming by individuals with expertise in that system, or the retention of a third party vendor specializing in the 16 extraction of data from such systems. This is unduly burdensome and oppressive for Excelsior to undergo now, especially since Excelsior has not even had time to respond to the Complaint.

The complexity of these systems, the compressed response period demanded by Ivera, the nature of the requests, and the complexity of the document and data sources involved would potentially result in precisely the sort of error-prone and incomplete discovery of ESI that the amended Federal Rules were designed to avoid. Thus, expedited discovery in this case is a lose-lose proposition. It could only be accomplished in an incomplete and non-standardized manner, using procedures susceptible to missing documents and requested information; expedited discovery would not permit a thoughtful and deliberate approach. At the end of Ivera's proposed fire drill, considerable time and financial resources will have been expended, only to face (no doubt) the all-too common criticisms regarding partial ESI responses, incomplete custodian lists, inadequate search

1

3

10

11

12

17

18

19

22

ase 3:11-cv-02185-DMS-WMC Document 10 Filed 10/12/11 Page 11 of 14

methodologies, etc. To ensure that discovery in this case proceeds in an orderly and appropriate fashion, with litigation limited to the merits rather than to satellite disputes over ESI concerning baseless claims, the Court should refuse Ivera's request for expedited discovery.

In addition, many of the requests are overbroad and seek irrelevant documents. Proposed Requests Nos. 1 and 2 seek all documents relating to any communications with or within Excelsior (apparently, including any third party anywhere in the world) relating to the MAUDE report. This is wholly unjustified, based upon the lack of evidentiary showing made to date by Ivera. Similarly, Proposed Requests Nos. 3 through 7 seek all documents relating to any communications or relating to any undefined documents (see 11 No. 7) with or within Excelsior (apparently, including any third party anywhere in the 12 world) relating to any alleged risk of infection or any incidence of *candida* infection 13 associated with the use of an Ivera product. This case is NOT about any statements about 14 | any Ivera product to anyone anywhere in the world, but rather the Curos product, and the 15 alleged statements that were purported to take place in one limited region in the U.S., in 16 association with one salesperson. Again, Ivera is on a fishing expedition for possible conduct that it cannot support and has not supported with any appropriate evidentiary basis. Proposed Request No. 8 seeks to demand documents be produced by Excelsior, 19 concerning any Ivera product, that relate to any alleged design flaws or deficiencies, "including without limitation" design features that "impacts the alleged risk of patient infection." Ivera has alleged public misrepresentations about alleged facts concerning its products, and requests any internal documents questioning or proving that Ivera's Curos product (and any other Ivera products) has design flaws. Just because Ivera's product may or does have design flaws, as may be demonstrated in Excelsior's confidential internal laboratory and/or research documents, has nothing to do with whether Excelsior has made public statements about such flaws to any third person.

If all of this fishing expedition is not enough, Ivera seeks document discovery on an expedited basis from a third party, Vygon Corporation. [See Dkt. No. 7, p. 8.] As a matter

3

4

5

171

of due process, it is unclear if Vygon has been served with a copy of Ivera's moving papers or an appropriate subpoena. Moreover, Vygon is a Delaware corporation with its principal place of business in Pennsylvania and Ivera has failed to set forth any basis for this Court to extend its jurisdiction to cover Vygon if the thought of plaintiff is to join that company as a defendant. Aside from these procedural failings, Ivera's request with respect to Vygon lacks any evidentiary substance. Ivera accuses Vygon of failing to preserve evidence but provides no factual basis for these unsubstantiated accusations. [See Dkt No. 7-4, ¶15.] Thus, Ivera asks the Court to issue an order permitting discovery over a third party outside of the Court's jurisdiction, which has not been served with Ivera's moving papers - and therefore is unable to appear to defend itself - on unsubstantiated rumors from unidentified sources. Ivera's request should be summarily denied.

Finally, there is a significant risk that Ivera's expedited discovery in this case is nothing more than a "jump" on what should be regularly scheduled discovery in the related patent case between the parties. The similarities and overlap (and thus need to minimize duplicative discovery and the burden on the parties and the Court) are explained in the Notice of Related case filed by Excelsior on Friday, October 7.

### DISCOVERY IS INAPPROPRIATE PRIOR TO THE COURT'S RULING V. ON EXCELSIOR'S RESPONSE TO THE COMPLAINT.

Excelsior is considering filing a motion for judgment on the pleadings seeking 20 dismissal of Ivera's false advertising complaint pursuant to Rule 12(c), on grounds that 21 || Excelsior has failed to state a claim for its false advertising and Section 17200 causes of 22 action.

Ivera is attempting to preempt the Court's ruling on any motion attacking its pleadings. If the Court grants Excelsior's motion, Ivera's claims will be significantly affected and the scope of discovery will likely be significantly diminished. Accordingly, 26 || the Court should deny Ivera's request for any discovery (whether expedited or not) until after Excelsior has attacked the Complaint, and after the claims have been sufficiently pled, properly putting in issue the matters as to which Ivera seeks discovery.

1

3

6

7

8

9

10

11

12

13

16 I

17

18

19

ase 3:11-cv-02185-DMS-WMC Document 10 Filed 10/12/11 Page 13 of 14

VI. **CONCLUSION** 

Ivera's problems lie not with Excelsior, but with Eden Valley Medical Center, the MAUDE reports, and the reasonable concerns of its customers in light of those reports. Ivera's requested discovery does nothing to address these issues and cannot save its anticipated preliminary injunction motion. Furthermore, to the extent that any discovery from Excelsior, as opposed to Ivera's unidentified lost customers, is relevant, Ivera has provided that information in the sworn declarations of Roger Sherman and William Anderson. Accordingly, the requested discovery is unnecessary at this time. Thus, there is no good cause to grant Ivera's request.

Moreover, Ivera's requested document discovery would only lead to satellite litigation regarding production of ESI at this early stage of the case. Similarly, Ivera';s requested third-party discovery will merely result in litigation in a different district that 13 | will not be resolved until well after Ivera brings its purported motion for preliminary 14 | injunction - assuming the injunction motion is more than a stalking horse. Under the 15 circumstances, Excelsior respectfully requests that the Court deny Ivera's ex parte 16 application.

17 18

19

20

21

22

23

I

2

3

5

6

7

8

9

10

11

Dated: October 12, 2011

Respectfully submitted,

SHEPPARD, MULLIN, RICHTER & HAMPTON LLP

By:

s/ Robert S. Gerber

ROBERT S. GERBER MICHAEL MURPHY MATTHEW W. HOLDER Attorneys for Defendant

**EXCELSIOR MEDICAL CORPORATION** E-mail: rgerber@sheppardmullin.com

24

25

26 27

28

W02-WEST:6MRM1\404040653.3

OPPOSITION TO EX PARTE APPLICATION 3:11-CV-02185-DMS-WMC

ase 3:11-cv-02185-DMS-WMC Document 10 Filed 10/12/11 Page 14 of 14 **CERTIFICATE OF SERVICE** The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on October 12, 2011 to all counsel who are deemed to have consented to electronic service via the Court's CM/ECF system per Civil Local Rule 5.4. Any other counsel of record will be served by electronic mail, facsimile and/or overnight delivery. s/ Robert S. Gerber ROBERT S. GERBER (SBN 137961) E-mail: rgerber@sheppardmullin.com - 13 -

W02-WEST:6MRM1V404040653.3

OPPOSITION TO EX PARTE APPLICATION 3:11-CV-02185-DMS-WMC

## Case 3:11-cv-02185-DMS-WMC Document 10-1 Filed 10/12/11 Page 1 of 4

1 2 3 4 5	MICHAEL MURPHY, Cal. Bar No. 234695 mmurphy@sheppardmullin.com MATTHEW W. HOLDER, Cal. Bar No. 217619 mholder@sheppardmullin.com SHEPPARD, MULLIN, RICHTER & HAMPTON LLP A Limited Liability Partnership Including Professional Corporations 12275 El Camino Real, Suite 200 San Diego, California 92130-2006		
7	Attorneys for Defendant		
8	EXCELSIOR MEDICAL CORPORATION		
9	UNITED STATES DISTRICT COURT		
10	SOUTHERN DISTRICT OF CALIFORNIA		
1.1	. ·		
12	IVERA MEDICAL CORPORATION,	CASE NO. 3:11-cv-02185-DMS-WMC	
13	Plaintiff,	DECLARATION OF WILLIAM	
14		ANDERSON IN SUPPORT OF	
15	٧,	DEFENDANT EXCELSIOR MEDICAL CORPORATION'S	
16		OPPOSITION TO PLAINTIFF EX	
17	EXCELSIOR MEDICAL	PARTE APPLICATION FOR EXPEDITED DISCOVERY	
18	CORPORATION,	EM EDITED DISCOVERY	
19	District of		
1	Defendant.	Date: To be determined	
20		Time: To be determined	
21		Place: To be determined	
22			
23		-	
24		٠.	
25			
26			
27	•		
28		Case No. 3:11-cv-02185-DMS-WMC	

Case No. 3:11-cv-02185-DMS-WMC ANDERSON DECLARATION ISO OPPOSITION TO PLAINTIFF'S FX PARTE APPLICATION

- I, William Anderson, hereby declare as follows:
- 1. I am the Vice President of Business Development and Strategic Marketing for Defendant, Excelsior Medical Corporation, ("Excelsior").
- Excelsior is a leading manufacturer and supplier of products used in the medical field, including a luer access valve disinfection cap sold under the trademark SwabCap.
- 3. Plaintiff, Ivera Medical Corporation, ("Ivera") alleges that it manufactures, markets, and sells Curos<sup>®</sup> Port Protector, a device that Ivera alleges disinfects and protects the entry port on certain types of valves used with intravenous lines to help reduce bloodstream infections in hospital patients.
- SwabCap and Curos products compete directly with each other in the market place.
- 5. In or about March 2011, Excelsior began to receive reports from its customers that Ivera's sales representatives were making false and misleading statements to Excelsior's customers about the SwabCap.
- 6. These false and damaging statements included statements that the color of the SwabCap caused it to be confused with feeding tubes in neonatal intensive care units, which could cause children to be inadvertently given enteral nutrition intravenously; and, that the SwabCap is not a luer lock design but is a "pop-on" device allowing it to "pop off" of intravenous lines and become a potential choking hazard. Attached hereto as Exhibit A is an e-mail from Lonnie Zofchak, Ivera's representative, to an Excelsior customer dated April 28, 2011, containing certain of the false and misleading statements that Ivera continues to propagate.
- 7. Ivera's misconduct is not limited to its salespeople. Rather, it appears that Ivera's salespeople are engaged in a concerted course of misinformation orchestrated and approved at the very top of Ivera's corporate structure. Excelsior has been informed by one of its independent distributors that Ivera's founder and

1.5 

## Case 3:11-cv-02185-DMS-WMC Document 10-1 Filed 10/12/11 Page 3 of 4

Chief Executive Officer, Bobby E. Rogers has been stating "Ours is green and not orange [like the SwabCap] because there is a product used in the NICU that is orange and used for feeding. One mistake with [Excelsior's] product and a kid could choke and die. [Excelsior's] product can be popped off, ours locks onto the connector."

8. Indeed, Excelsior has been advised that Ivera's representatives are going so far to mislead potential clients that they are actually using obsolete earlier

- 8. Indeed, Excelsior has been advised that Ivera's representatives are going so far to mislead potential clients that they are actually using obsolete earlier versions of the SwabCap, which Excelsior no longer manufactures, in presentations to Excelsior's customers, in order to mislead them into believing that the currently manufactured iteration of the SwabCap could "pop off".
- 9. As Excelsior continued to receive reports of Ivera's representatives' false and misleading comments, it was determined that Excelsior's sales force should be provided with a set of talking points in order truthfully to defend the SwabCap against Ivera's lies regarding the SwabCap.
- 10. Accordingly, it was determined that when confronted by a customer who had been misinformed by an Ivera representative, Excelsior's sales force would state that, "Curos reps may have misled you on a couple of things, let me clarify" and counter with the following facts:
  - i. There is no color standard for luer access valves and, in fact, color coding is discouraged by industry groups generally;
  - The SwabCap does not "pop-off" and, in fact, is an ISO standard luer lock design compatible with INS standards;
  - iii. Excelsior has sold tens of millions of the SwabCaps to several hundred customers and has never received an adverse

. 9

### Case 3:11-cv-02185-DMS-WMC Document 10-1 Filed 10/12/11 Page 4 of 4

Ĺ events report to the FDA Medwatch (a "MAUDE Report"); 2 3 iv. A check of the Curos port protector on the MAUDE 4 database reveals that the Curos product had been removed from 5 a hospital due to an increase in candida related blood stream 6 infections; 7 8 Excelsior uses a thread cover seal which keeps alcohol in 9 and contamination out. Excelsior uses an alcohol retention seal 10 in its design because it did not want the alcohol to evaporate and 11 leave a moist humid environment that could support fungal 12 growth; and 13 vi. 14 Excelsior spent six months testing various foams. 15 Polyurethane foams did not meet Excelsior's tests for degradation, particulate generation, tearing and toxicity. 16 17 18 11. Each of the above stated facts is true and accurate. 19 20 I certify that the foregoing statements made by me are true. I am aware that if 21 any of the foregoing statements are willfully false, I am subject to punishment. 22 23 Dated: October 12, 2011 24 25 26 27 28

> Case No. 3:11-cv-02185-DMS-WMC ANDERSON DECLARATION ISO OPPOSITION TO PLAINTIFF'S RX PARTE APPLICATION

#### **EXHIBIT A**

Case 3:11-ev-02185-DMS-WMC\_\_Document 10-2 Filed 10/12/11

From: Lonnie [mailto:lonniez@earthlink.net] Sent: Thursday, April 28, 2011 5:23 PM To: Hohenfeld, Debra Subject: Curos Port Protector

#### Helio Debra.

I am the local rep for the Curos Port Protector. We are one of the other disinfecting caps that is available on the market. I heard that you are trialing another disinfection cap and I think it is great that you see the value in keeping your valves clean and govered. Would you be willing to take a look at our cap before you make a final decision on product? We offer some advantages over your current product that I have defineated below. Thank you so much for your consideration and I wish you the best of tuck during your trial.

1-Secure luer lock design that meets INS standard 28.3 regarding add-on devices

2-Bright green skip in sudifing and is not confused with other routes of administration. (Orange is designated for "Enter's Only" for NICU and PICU—could lead to sentine event misconnection errors)

3-Minimal packaging waste

4-We offer "the strip" which aids in compliance and reduces product waste. I have attached a schematic of the strip which has just become available.

#### Warmest regards,

Lonnie Zofchak, RN Clinical Technology, inc 330-472-4841 LonnleZ@earthlink.net



PM - 100 - 100 - 10 F

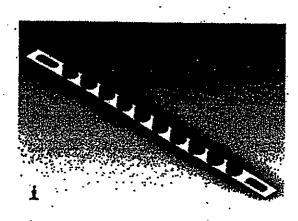
Southwest General - HEALTH is our passion, QUALITY is our focus, COMPASSION is our way 18697 Bagley Road | Middleburg Heights, Ohio | 44130-3497 | Tel: 440-816-8000 | www.swgeneral.com

Follow us on Facebook at www.facebook.com/SWGeneral

The enclosed information is STRICTLY CONFIDENTIAL and is intended only for use by the person(s) to whom it is addressed. Southwest General and its affiliates disclosing any responsibility for unauthorized disclosure of this information by persons receiving this information. If you receive this information in error, please notify the sender immediately by reply e-mail or notify Southwest General's Privacy Officer at 440-816-4719. Also, if you are not the inference excition, any dissemination, distribution or duplication of this transmission is strictly prohibited and please delate or destroy all copies of file message.

If this e-mail contains any patient medical information, please note that federal and Ohio law protect patient medical information, including psychiatric diagricular, (HIV) test results, AlDs-related conditions, alcohol and/or drug dependence or situse. Unless otherwise permitted by specific law, you are prohibited from disclosing this information to anyone else without the specific written consent of the person to whom it pertains.

Please consider the environment before printing this e-mail





# Case 3:11-cv-02185-DMS-WMC Document 10-3 Filed 10/12/11 Page 1 of 3

1 2 3 4 5 6	MICHAEL MURPHY, Cal. Bar No. 234695 mmurphy@sheppardmullin.com MATTHEW W. HOLDER, Cal. Bar No. 217619 mholder@sheppardmullin.com SHEPPARD, MULLIN, RICHTER & HAMPTON LLP A Limited Liability Partnership Including Professional Corporations 12275 El Camino Real, Suite 200 San Diego, California 92130-2006 Telephone: (858) 720-8900/Facsimile: (858) 509-3691		
8	Attorneys for Defendant EXCELSIOR MEDICAL CORPORATION		
. 9	UNITED STATES DISTRICT COURT		
· 10	SOUTHERN DISTRICT OF CALIFORNIA		
12	IVERA MEDICAL CORPORATION,	CASE NO. 3:11-02185 DMS WMC	
13	Plaintiff,	DECLARATION OF ROGER	
14	v.	SHERMAN IN SUPPORT OF	
15	EXCELSIOR MEDICAL CORPORATION,	DEFENDANT EXCELSIOR MEDICAL CORPORATION'S	
16	Defendant.	OPPOSITION TO PLAINTIFF	
17		IVERA MEDICAL CORPORATION'S EX PARTE	
18		APPLICATION FOR EXPEDITED	
19		DISCOVERY	
20			
21	•	Date: To be determined	
22		Time: To be determined Place: To be determined	
23		Ji idoo, To be determined	
24			
25			
26	. ,		
27			
28	,		

3

4 5

7 8

6

9 10

11 12

13

14 15

16 17

18 19

20 21

22 23

24

25

26 27

I, Roger J. Sherman, hereby declare as follows:

- I am the Territory Manager for the Greater New York Area for 1. Defendant, Excelsior Medical Corporation, ("Excelsior").
- 2. I have been informed that the Plaintiff in this action, Ivera Medical Corporation, ("Ivera") is seeking to take my deposition on an expedited basis alleging that I have made false and/or misleading statements to representatives of the following hospitals regarding the filing of a MAUDE Adverse Event Report involving Ivera's Curos product (the "MAUDE Report"): Kings County Medical Center, Metropolitan Medical Center, Northern Westchester Hospital, Wyckoff Medical Center and Memorial Sloan Kettering Medical Center.
- Each of the above listed hospitals is either a potential customer or one 3. of my current customers, some of which have been my customers for years.
- I have had no communication whatsoever with any representative of 4. Kings County Medical Center, Northern Westchester Hospital, Wyckoff Medical Center or Memorial Sloan Kettering Medical Center regarding the fact that a MAUDE report, relating to the Curos product, had been filed or the fact that, for a period of time, the Eden Medical Center ceased using the Curos product.
- 5. However, it does not surprise me that these hospitals would raise concerns with Ivera about the Curos product and potential candida infections. There is a publicly filed MAUDE report on the Food and Drug Administration's ("FDA") web site relating to the issue which states that Ivera, "do[es] not have testing at this time that shows the efficacy of the curos [sic] port protector in regards to candida". Exhibit A to the Declaration of Bobby Rogers in Support of Plaintiff's Ex Parte Application for Expedited Discovery. [Docket 7-4]
- I did have a conversation with a representative of Metropolitan Medical 6. Center in which I stated that a MAUDE report had been filed relating to the use of the Curos product and informed the representative that the MAUDE Report could be 28 viewed at the FDA's web site. These statements are true. In fact, as set forth above,

# Oct 12 20ase 3:153evi-02186-DM85V4V46-Document 10-3 Filed+10212/4d10Fage 3 of 3 p.2 OCT. 12. 2011 10:55AM MCCARTER&ENGLISH NO. 2819 P. 4

1	a copy of the MAUDE Report, is available on the FDA's website. Indeed, a copy of		
2	that report is attached as Exhibit A to the Declaration of Ivera's founder and Chief		
3	Executive Officer, Bobby Rogers, in Support of Plaintiff's Ex Parte Application for		
4	Expedited Discovery. Id.		
5	I certify that the foregoing statements made by me are true. I am aware that if		
6	<u>'</u>		
7	any of the foregoing statements are willfully false, I am subject to punishment.		
8.			
9	Dated: October 12, 2011		
10	les Isa		
11	Roger J. Sherman		
12			
13			
14			
15 16			
17	1		
18	1		
19			
20	1		
21			
22			
23			
24			
25			
26			
. 27			
28	CHERMAN DECLARATION ISO OPPOSITION TO		
•	PLAINTIFF'S EX PARTE APPLICATION		



Dāwna Rae Jones Manager Equipment Center Distribution Center 3959 Broadway New York, NY 10032

TEL 212 342 8480 VOKT MAN 212 342 1676 16X 212 342 8482 djones@rtyp.org