IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

Calmedica LLC, Paintiff/Counterdefendant, v. Novoste Corporation, Defendant/Counterclaimant.	CIVIL FILE NO. 1:04-CV-2646-RWS JUDGE RICHARD W. STORY

DECLARATION OF ROBERT E. FISCHELL

I, Robert E. Fischell, declare as follows:

1. I have been retained by Novoste Corporation in connection with the pending litigation. I have been asked to discuss my understanding and views on some of the claim construction issues before the Court. The views that I express in this Declaration are based on my personal knowledge unless I state otherwise.

2. I have considerable experience in the field of art to which the '168 patent is directed. I am a named inventor on over 150 U.S. patents. More than 40 of those patents are in the field of devices to treat stenosed arteries which field is directly related to the subject matter of the Hess '168 patent. Johnson & Johnson and IsoStent Inc. are licensees of my patents in this field. The devices for which I hold patents in this field have been used to treat more than one million patients. I

invented radioactive tips on quidewires to treat dilated stenoses to prevent restenosis. This invention is described in US Patent No. 5,059,166 that was filed approximately 21 months prior to the filing by Hess of his '168 patent. I also hold many patents to improvements in stent design and the use of stents. I was a founder, Chairman and President of the company "IsoStent , Inc." whose goal was to prevent arterial restenosis by the application of a radioactive stent placed at the site where a stenosis was dilated by angioplasty. I was a co-inventor of several patents that utilized radiation within a dilated stenosis to prevent restenosis.

3. While I am not a patent attorney, I have prosecuted over 130 of my patents in the Patent Office. I prosecute my own patents because I have found over the years that patent lawyers often fail to write in a way that skilled art workers readily understand. When I write a patent, I try to write simply, using language familiar to my audience which is those persons who are of ordinary skill in the art described in that patent. I approached my review of the '168 patent in the same way – asking myself how a skilled art worker, such as myself, would understand the language of the claims in the '168 patent.

4. My curriculum vitae is attached to this Declaration as Exhibit A.

5. The general subject matter of the '168 patent is in the field of devices for opening stenosed blood vessels, and more specifically the opening of arterial

stenoses. A person of ordinary skill in this field is someone who designs or uses devices to apply radiation to reduce restenosis of arteries that have been dilatated by a procedure such as angioplasty. That person likely would have at least an undergraduate degree in science or engineering, some training in radiation physics, and some experience in the field of interventional cardiology.

6. I am a person of at least ordinary skill in the art to which the '168 patent is directed because of my years of experience and inventions in this specific field.

7. I have reviewed the '168 patent, including the claims and specification, the '168 file history, and portions of the file histories for the '466 and Re '466 patents.

8. As a person of at least ordinary skill in the art, I read the '168 patent as being directed to a method for reducing restenosis by using radioactive material attached to the distal end of a catheter or guidewire. With the method of the '168 patent, radioactive material is advanced to, and removed from, the treatment site by moving a catheter shaft or guidewire forward or backward in the artery. Nothing in the patent or file histories suggests to me that the patent is broader in scope than that.

"POSITIONING MEANS"

9. I have been asked for my opinion on the meaning of the phrase "positioning means" as used in the claims of the '168 patent. Nothing in the claims of the '168 patent tells me what the structure is for positioning the radioactive material in the artery. Based on my reading of the patent, the function of the "positioning means" is to position the "radioactive dose means" within the stenosed region of an artery that has been opened by a procedure such as angioplasty. I have studied the specification of the '168 patent to determine what structures are identified as performing the function of positioning the "radioactive dose means" in the artery.

10. The only structures identified in the patent as "positioning means" are either a catheter shaft or a motion wire to which radioactive material is attached at its distal end. I found two references to "positioning means" in the specification: (1) "A radioactive dose means 30 is moveable by advancing or retracting catheter shaft 26 which may be referred to as a positioning means." 3:33-35; and (2) "Device 48 includes positioning means 52 which is a motion wire providing slideable motion of the radioactive dose means 54 within the sheath." 4:17-20.

11. Calmedica contends that "positioning means" can include a liquid or gas that transports the radioactive source to the treatment site. The sole support it

offers for this argument is the following sentence in the specification: "These materials [referring to radioactive materials] may be incorporated into or delivered in a solid, liquid, or gaseous form, and the delivery of such forms is considered to be within the scope of the subject invention." 4: 8-12. That sentence is extracted from a discussion of the types of radioactive material -- it does not purport to describe the different ways in which the radioactive material can be delivered to the treatment site. It says simply that the form of the radioactive material that is the source of the radiation can be solid, liquid, or gas. To confirm the fact that Hess never suggested in the '168 specification that he envisioned delivering the radioactive source to the site of the stenosis by means of a liquid one need only look at the radioisotopes that are listed in the preceding sentence in that same paragraph. Hess lists several isotopes of which the first (Radon 222) is a gas, the fifth (Iodine 125), being readily soluble, is often thought of as a liquid, and the other three are all solids. Hence his next sentence states that "[t]hese materials [specifically those that he just listed] may be…delivered in a solid, liquid or gaseous form…." The form that he is describing is, of course, the form of the different radioactive materials which, at body temperature, are either gas, liquid or solid. Hess shows a cylindrical container (element 30 in Fig. 1 and element 54 in Fig. 5) which could be hermetically sealed to contain a gas or liquid as well as a

solid "radioactive dose means", the container "delivered" to the site of the stenosis by the "positioning means". For Hess to maintain that this sentence has any connection with delivering solid radioactive pellets by means of a non-radioactive liquid is truly ludicrous and without any foundation in fact. There is absolutely no discussion anywhere in the '168 patent's drawings or specification that teaches, describes in any way, or even suggests how to use a non-radioactive liquid to deliver radioactive material to the site of a reduced stenosis. Still further, the use of a gas to deliver anything into a patient's arterial system is certainly avoided because of the potential danger of gas leakage. If a liquid is inadvertently delivered into a patient's vascular system, there is no harm done. However, using gas to deliver anything into the vascular system is certainly avoided because any escaping gas can cause the patient's death. A person of at least ordinary skill in this art, would have known that and would never have read the '168 patent to suggest the use of a gas to deliver the "radioactive dose means" into a patient's vascular system.

12. I conclude that a person of at least ordinary skill in the art would not read the language relied on by Calmedica as providing support for its interpretation of the phrase "positioning means." I do not read the specification to disclose, or even suggest, the delivery of a radioactive material to the treatment site by any

means other than a motion wire or catheter shaft. Nowhere in the patent does Hess tell the reader how to deliver radioactive material to the treatment site without the use of a catheter shaft or motion wire (guidewire). Nowhere in the patent's specification and drawings does Hess teach or even suggest how to use a liquid as a positioning means.

13. Because the purpose of the '168 patent is to reduce restenosis, I also would expect the claims to contain structure or means that would control the exact amount of radiation released at the treatment site. It is well known in this art that the exact radiation dose must be carefully controlled to eliminate the possibilities of either too much or too little radiation exposure at the site of the reduced stenosis. In other words, the purpose of the claims is accomplished only if there is structure to control the release of radiation so that it is administered in a precise therapeutic amount. That additional structure to control the radiation to which the site is subjected must reside in either the "positioning means," the "radioactive dose means," or the "operative" connection. However, it is unclear from the patent which, if any, of these phrases include within their scope structure for controlling the release of radiation.

14. At first I thought it would make sense to include this structure in the "radioactive dose means," however, after I studied portions of the '168 patent, the

'466 continuation patent, and their file histories, it became clear that the means to control the radiation dose resides in the "positioning means." In the application that issued as the '168 patent, Hess discussed additional structure to accomplish the stated purpose of the invention. In claim 10 of that application, Hess defines the phrase "positioning means" to include "a retractable sheath which may be removably positioned over said radioactive dose means." Issued claim 1 of the '466 patent states that the "positioning means" includes "an angioplasty balloon." 5:20-22. Issued claim 3 of the '466 patent states that the "positioning means" includes "a retractable sheath which may be removably positioned over said radioactive dose means and the dose means being located in a housing having a cut-out in a sidewall thereof, the dose means being exposed to the stenosed region by moving the sheath from a first position wherein the cut-out is covered by the sheath to a second position wherein the cut-out is not covered by the sheath." 6: 3 - 13. Issued claim 5 states that the "positioning means" includes "a retractable remotely activated cover which may be removably positioned over said radioactive dose means and the dose means being located in a housing having an opening therein, the dose means being exposed to the stenosed region by moving the remotely activated cover from a first position wherein the opening is covered

by the remotely activated cover to a second position wherein the opening is not covered by the remotely activated cover." 6: 25-35.

15. Based on this written record, I conclude, as I think other persons of ordinary skill in the art would conclude, that "positioning means" must include either a retractable sheath or a retractable remotely actuated cover, both of which serve to properly position the radioactive material in relation to the arterial wall. Alternatively, if a balloon catheter is used, the "positioning means" would include the balloon.

"RADIOACTIVE DOSE MEANS"

16. The claims of the '168 patent also require an understanding of the term "radioactive dose means." That phrase does not have an ordinary meaning to those who work in the field to which the '168 patent is directed. It is not a term of art.

17. Calmedica contends that "radioactive dose means" should be construed as a "radioactive source." Based on my review of the file histories, I disagree. During prosecution of the reissue application to the '466 patent, Hess used the phrase "radioactive dose means" in claims 1 through 9, but used the phrase "radioactive source" starting with claim 10. To me, that suggests that the two phrases have different meanings. Otherwise, he would have continued to use

the phrase "radioactive dose means" in the claims or he would have defined the term "radioactive dose means" as a "radioactive source" in the specification.

18. The phrase "radioactive dose means" does not tell the structure or form of the "means." I can't tell from the phrase whether the "means" are solid, liquid, or gas. I can't tell what kind of radioactive material is used. Nor can I tell its shape.

19. Based on my review of the '168 patent, it is my opinion that the function of the "radioactive dose means" is to administer a dose of radiation to the treatment site. Claim 1 speaks in terms of "applying a radioactive dose to the area of reduced stenosis by exposing the area of reduced stenosis to the radioactive dose means . . . ." The claim itself defines the function of the "radioactive dose means."

20. When I read the specification of the '168 patent to look for structure that performs the stated function, I see only two configurations: (1) a solid piece of radioactive material; and (2) radioactive material, whether solid, liquid, or gas, that is confined by a single, inflexible housing or canister.

"OPERATIVELY CONNECTED"

21. The claims of the '168 patent also use the phrase "operatively connected." This phrase does not have an ordinary meaning to those who work in the field to which the patent is directed. It is not a term of art. I have seen the

phrase used in patents in the following way: if two structures are "operatively connected," then when one of those structures is moved, the other structure also moves. As that phrase is used in the '168 patent, when the "positioning means" is moved, the "radioactive dose means" moves with it. More specifically, when the catheter shaft or guidewire is moved in the artery, the radioactive material on its tip (distal end) moves with it because the radioactive material is physically attached to the shaft or guidewire. That is precisely what the Hess '168 patent teaches.

22. I find nothing "ordinary" about the definition of "operatively connected" offered by Calmedica. As construed by Calmedica, the phrase includes virtually any association between two structures. Specifically, Calmedica would say that two structures can be "operatively connected," even if one of the structures does not move when the other structure does move. In other words, Calmedica contends that its claims cover the use of a device where the radioactive material need not move in the artery even when the catheter shaft or guidewire is moved. I do not find anything in the patent or file histories that would support Calmedica's construction.

"CONTAINING . . . BEFORE AND AFTER EXPOSURE"

23. Claim 6 of the '168 patent contains the phrase "containing . . . before and after exposure . . . ." The language of claim 6 specifically omits containment

during exposure. In everyday language, the term "containing" typically refers to holding. However, it is clear from the claim itself that the intended meaning of "containing" is not its everyday meaning. If it meant "to hold," then the claim would make no sense. All of the containers described in the patent "hold" the radioactive material before, during, and after exposure. A claim that specifies containment only before and after exposure implies that there is no containment during exposure. Yet we know that nothing in the specification of the patent suggests that kind of container. Similarly, claim 6 is described as a step – i.e., some activity or change over time. A claim that is read to apply to a container that simply continues to hold the radioactive material before, during, and after exposure, does not involve any activity or change. There is no step. Calmedica's construction of "containing" does not make sense in the context of the claim.

24. The claim makes more sense if "containing" is construed to refer to having or not having radioactive shielding. All of the embodiments in the '168 patent that make use of a catheter shaft or guidewire employ radioactive shielding. In all of the embodiments in the patent showing containment, Hess has shielded the radioactive source from the body both while advancing the source to the treatment site and, after treatment, when removing the source from the body. Containment except during the time of treatment at the area of reduced stenosis is used to protect

the body from the hazards of radiation exposure during the time it takes to advance the radioactive source to the treatment area and to remove the source from the treatment area. In other words, the body is shielded from radiation, i.e., there is containment of the radiation "before and after exposure . . . ."

25. My construction of "containing" not only makes sense, it is supported by language in the specification of the '168 patent. Fig. 1 depicts "a radioactive element contained within a wire wound housing for radioactive containment, the housing having a window cut-out." 2:46-48 (emphasis added). The purpose of the sheath/housing combination in Fig. 1 is to shield the body from radiation except with the sheath 24 is drawn back, that is, going into or out of the body there is containment of the radiation. With respect to the embodiment of Fig. 5, "sheath 50 of said device is preferably made from a helically wire wound member to provide a measure of shielding for the radioactive dose means." 4:15-17 (emphasis added). The purpose of the sheath/remotely actuated window of Fig. 5 is to shield the body from radiation except when the sheath 50 and remotely actuated window are withdrawn. The purpose of the canister depicted in Fig. 6 is to shield the body from radiation except when the remotely actuated window is withdrawn. With respect to the embodiment of Fig. 6, "this canister 64 has a remotely actuated window 66 which can be actuated through port 68 to expose the radioactive dose

means to the lesion 70." 4:30-33 (emphasis added). Therefore the step of claim 6 is the act of placing the containment shield over the radiation dose means during the advancement through the body and the removal from the body which are the actions that do occur "…before and after exposure to said area of reduced stenosis." No other interpretation of claim 6 is possible in light of the teachings of the '168 patent.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

February 7, 2006

Robert E. Fischell