

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

MEDINOL LTD.,

Plaintiff,

-against-

BOSTON SCIENTIFIC CORPORATION,
PETER M. NICHOLAS, MICHAEL BERMAN,
LAWRENCE C. BEST, JAMES M. CORBETT,
JANET M. KELLY, PAUL A. LAVIOLETTE,
STEPHEN R. PAIDOSH, ARTHUR L. ROSENTHAL
and PAUL W. SANDMAN,

Defendants.

01 Civ. _____

COMPLAINT

PLAINTIFF DEMANDS
TRIAL BY JURY FOR ALL
ISSUES SO TRIABLE

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April 5, 2001

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Plaintiff Medinol Ltd. (“Medinol”), by and through its undersigned attorneys, for its Complaint against Boston Scientific Corporation (“BSC”), Peter M. Nicholas, Michael Berman, Lawrence C. Best, James M. Corbett, Janet M. Kelly, Paul A. LaViolette, Stephen R. Paidosh, Arthur L. Rosenthal and Paul W. Sandman, avers:

NATURE OF THE ACTION

1. This action seeks redress for an unprecedented fraudulent scheme by BSC--one of America’s largest companies--and certain of its top executives (including its chairman), to steal Medinol’s intellectual property, misappropriate opportunities belonging to Medinol, improperly cause BSC to breach its contracts with Medinol, and injure Medinol in its property and business.

2. On April 21, 2000, after Defendants had been engaged in their massive fraud for over three years, BSC’s new Chief Executive Officer (“CEO”), James R. Tobin, disclosed--partly--Defendants’ illegal activities to Medinol. BSC made this disclosure because public disclosure of a key element of the fraud had become inevitable; BSC’s outside auditors told BSC that it had to correct false financial statements. Indeed, a BSC executive later confirmed that his idea--conceived no later than December 1999--to make an earlier disclosure of the fraud had been overruled.

3. In this April 21, 2000 meeting, Tobin, referring to BSC and its management, stated that he had not known that he was involved with “such crooks” and that he was “ashamed to represent such a dishonest company”. Tobin gave Medinol a damning written chronology of some of the events that occurred in connection with this massive fraud, showing that the fraud started as early as March 1997. (See Exh. 1.)

4. This chronology is a devastating indictment of the “crooks” and the “dishonest company”. It reveals a scheme called BBD, which stands for “Bringing a Better Deal”, a “Better Deal” than BSC had struck with Medinol. (The scheme is also called “Project Independence”.) The chronology is devastating even though it contains a

bogus explanation for the fraud and omits many crucial facts. For example, this chronology omits the role of the Executive Committee (which included most of the defendants) in approving the fraud, even though Tobin himself said that an executive of Boston Scientific Ireland Ltd. (“BSIL”) stated that senior management of BSC had directed that the fraud be undertaken. Although inadequate, this chronology is one of the most shocking and extraordinary documents that any CEO of a major U.S. company has had to divulge.

5. To show that we are not making up this extraordinary web of deceit by Defendants, we submit an Appendix that contains documents that BSC has provided to Medinol pursuant to a commitment by Tobin--not fully honored--of “Open Door/Open Files”. We quote from these documents throughout the Complaint. Although the extent of the fraud can begin to be divined from some of these documents, we do not yet know its full scope.

6. About a month after Tobin’s partial disclosure of the fraud, Tobin proposed three options for Medinol in the face of the fraudulent and illegal conduct: (1) try to make the Medinol/BSC venture work; (2) try to negotiate a deal whereby BSC acquired Medinol; or (3) have a “divorce”, i.e., dissolve the venture. Since then, Medinol has tried its best to make the venture succeed, but the “crooks” have successfully obstructed that goal. Concurrently, Medinol has negotiated in good faith with BSC and endeavored to come to a deal, but the “crooks” have blocked that, too. Medinol is now left with no other option but Tobin’s third choice, a “divorce”. This lawsuit seeks that “divorce” plus damages.

7. In 1995, Medinol, today a world leader in stent design and manufacture and then a new startup, and BSC, a medical device company, entered into a venture for the purpose of supplying various generations of Medinol’s NIR® stents to the worldwide market. Under the venture, Medinol develops, manufactures and supplies stents, while

BSC is responsible for making the balloon delivery systems used for the insertion of these stents into the human body and for bringing these stents to market.

8. Defendant Nicholas, in BSC's announcement of the venture with Medinol in November 1995, stated that the "partnership . . . shares common objectives".

9. Medinol held these "common objectives", but, unbeknownst to Medinol, Defendants did not, in fact, share these "common objectives".

10. Soon after Medinol contributed its valuable intellectual property and trade secrets, Defendants, including Nicholas, began a scheme, conspiracy and course of conduct directed against Medinol and involving a pattern of racketeering activity, fraud, bad faith, breach of contract, breach of fiduciary duty and other tortious conduct, which became known to Medinol only years later. Far from promoting the "common objectives", Defendants stole Medinol's property, denied Medinol its rights, froze Medinol out of the venture and promoted their own "objectives" to the detriment of the "common objectives".

11. Although the venture was supposed to involve a cooperative effort to make stent systems, with Medinol supplying the stents and BSC supplying the delivery systems and doing the marketing, Defendants initiated their scheme secretly to misappropriate Medinol's NIR® stent intellectual property and machinery in order to obtain for themselves the capability to manufacture NIR® stents independent of Medinol.

12. Defendants' scheme included incorporating a "shel[l] company" for developing a "secret capacity" to manufacture stents using Medinol's intellectual property. They called this company "BBD", signifying their goal of "Bringing a Better Deal" to BSC than the deal to which BSC had agreed in entering into the venture with Medinol. Defendants also referred to "BBD" as "Project Independence" to signify that their goal was to secure BSC's "independence" from Medinol.

13. The heart of the BBD deceit, which was directed by BSC's highest officers and endorsed by BSC's Executive Committee, involved the theft of Medinol's technology and trade secrets for the purpose of building a "secret capacity" for manufacturing NIR® stents and obtaining a fraudulent approval from the Food and Drug Administration ("FDA"), which would enable BSC to sell stents--based on intellectual property owned by Medinol-- "independently" of Medinol and the Medinol/BSC venture, thereby "Bringing a Better Deal" to BSC.

14. As set out in Defendants' own words in their documents, Defendants, beginning no later than March 1997:

(a) created a "shel[l] company" named Forwich, Ltd. that did business under the name "BBD";

(b) established a "ghost office" for BBD with "no traceable links" to BSC in order to "shield Boston Scientific from being associated with" BBD;

(c) insisted upon the maintenance of "[t]otal secrecy from Medinol and minimal awareness of BSC personnel", as Medinol's discovery of BBD would have a "catastrophic impact on [BSC's] relationship with Medinol" and alert the FDA to the fraud;

(d) instructed those involved with BBD to "not discuss [it] with ANYONE", "to make everything look legitimate (as much as possible)", to tell "lies about this activity to our people to keep them in the dark" and to use "roundabout method[s] of keeping vendors in the dark";

(e) stole Medinol's stent designs, "duplicate[d]" Medinol's stent manufacturing machinery, "emulate[d]" Medinol's inspection routine, "false sign[ed] . . . prints" of stolen drawings of Medinol's stents using an "alias", and gave misleading titles to drawings stolen from Medinol, calling drawings of stents,

which are medical devices to be placed in the human body, drawings of “heat exchangers”, which are not medical devices;

(f) instituted what they called “functionally equivalent” processes that could produce and “supply ‘Knock off’ style stents to” BSC;

(g) because they needed regulatory approval from the FDA to market the BBD stents in the United States, falsely characterized Medinol as a supplier/vendor even though the contract between BSC and Medinol states that Medinol should be presented to the FDA in the original pre-market approval (“PMA”) as an additional manufacturer, and even though BSC did not treat Medinol as a supplier/vendor under BSC’s own internal policies and procedures governing relationships with supplier/vendors (which BSC listed in the PMA that was submitted to the FDA); and

(h) to seek regulatory approval from the FDA to market the BBD stents, fraudulently hid the relationship between BSC and BBD by, among other things, using “psuedo name[s]” so that they could characterize BBD as a supplier/vendor in order to defraud the FDA and make BBD appear independent from BSC, as BSC’s own definition of a vendor required. Defendants specifically ensured that the FDA regulatory filings were “carefully drafted to maintain secrecy from Medinol and allowing us to use BBD as an alternative vendor”, i.e., to deceive the FDA into believing BBD was independent from BSC and was an equivalent alternative to Medinol.

15. Defendants made false representations to the FDA to invoke the FDA approval process for replacing an approved independent supplier/vendor with another independent supplier/vendor, rather than the more cumbersome process of replacing the manufacturer with another manufacturer. Thus, Defendants sought to deceive the FDA into viewing Medinol as a supplier/vendor so that BSC could more easily substitute

“equivalent” stents made by another supplier/vendor for those made by Medinol. In addition, Defendants had to deceive the FDA into believing that BBD was independent of BSC, because it could not substitute BBD as an independent supplier/vendor if the FDA knew that BBD was a subsidiary of BSC. In Defendants’ euphemism, the FDA filing had to be “carefully drafted . . . to use BBD as an alternative vendor”. Defendants thus repeatedly and unilaterally made “carefully drafted” regulatory filings with the FDA, without Medinol’s consent and in violation of Medinol’s right to review and approve all such filings related to the NIR® stent.

16. BBD was approved and promoted by the BSC Executive Committee, a group of top BSC executives, including Defendants Nicholas, Berman, Best, Corbett, Rosenthal and Sandman, as early as July 1997. Indeed, as noted in a July 15, 1997 memorandum, the Executive Committee even weighed-in on the name of the fraud--it did not like the name “BBD” because it thought “BBD” was too revealing--and changed the name to “Project Independence”. (Exh. 9.)

17. BSC failed to discharge its responsibilities to Medinol because, at Defendants’ direction, it made its “secret capacity”, stolen from Medinol, its number-one priority. For example, an October 27, 1998 Project Prioritization listed this secret capacity as the “priority #1 project”. (Exh. 33.) BSC continued to make this theft the “priority #1 project”, even though the reference to it was “cross[ed] off” the “new stent project priority list” because it “is a very sensitive subject and should not be discussed openly”. (Id.)

18. Making BBD the “priority #1 project” resulted in BSC delaying by many years, and in some cases forever, the introduction into the markets of Medinol’s stents. BSC’s delay was particularly severe with respect to Medinol’s new generation of stents when BBD did not have the capability to copy these stents.

19. Even after the partial disclosure of BBD, Defendants continued to divert priorities to their own objectives, including the cover-up of their misconduct. This has caused BSC to continue to fail to discharge its responsibilities to Medinol. For example, the diversion of priorities from the “common objectives” continues to cause substantial delays in getting new products to market, resulting in enormous, continuing economic loss to Medinol.

20. Many of those responsible for designing and managing the fraudulent and illegal scheme are still employed by BSC in spite of Tobin recognizing that they lied to him. These crooks continue to be employed by BSC even though, in a March 20, 2001 meeting, nearly a year after partially disclosing the fraud, Tobin said that he knew BBD was wrong when he revealed it to Medinol and, despite the efforts of BSC’s lawyers and management over the ensuing year to persuade him that BBD was not wrong, he still knew that BBD was wrong.

21. The “crooks” within BSC have fought to cover up their misconduct. Indeed, after Tobin’s partial disclosure of BBD to Medinol, James H. Taylor, Jr., BSC’s new senior vice-president of Corporate Operations, asked for Medinol’s help to clean up BSC’s problems by assisting Taylor in his battle for Tobin’s “ear”, a battle that he stated was being waged against other BSC employees who had played a key role in the fraud and were trying to prevent its full disclosure and correction, including Defendant Best.

22. The “crooks” have won the battle inside BSC.

23. Defendants have not stopped their illegal activity, and have actually engaged in a cover up. Thus, as set forth below (e.g., ¶¶ 167-185):

(a) Defendants have continued to fail to deliver new products to market, and falsely blamed Medinol for BSC’s problems in an attempt to shift blame and harm Medinol’s reputation;

(b) Defendants have continued to make false representations to the FDA in support of their previous fraudulent representations;

(c) Defendants have stopped development and market launch of Medinol's stent systems and have developed their own stent, the Express stent, without Medinol's knowledge, as a potential competitor to Medinol's stents, so that BSC would be able to buy Medinol cheaply;

(d) Despite Tobin's claim that BBD would stop, Defendants have not stopped BBD but, instead, tried to "consolidate" BBD's activities with legitimate activities to make BBD look legitimate; and

(e) Defendants have not honored Tobin's Open Door/Open Files commitment;

24. The BBD deceit was part of a wider pattern of misconduct by the "crooks" pursuing their own crooked objectives rather than the "common objectives". Thus,

(a) Defendants sought to undermine the symmetry of the venture. For example, although the contract between BSC and Medinol requires BSC to name Medinol as an additional manufacturer and to add it as an additional distributor of the stent, Defendants deliberately failed to honor this commitment. This failure was an integral part of the BBD deceit, because, if BSC had honored this commitment, Medinol would have been able to market its own stents in the United States in compliance with FDA rules in the event of a breach of the Supply Agreement between Medinol and BSC, dated October 25, 1995 (the "Supply Agreement"). Any such Medinol ability was obviously contrary to Defendants' plan to steal Medinol's property. Similarly, although the contract requires sharing stent-related developments, Defendants have not done so. Instead, Defendants

have misused Medinol's stent-related intellectual property, even outside BBD. (See, e.g., ¶¶ 187-197);

(b) Defendants delayed development of the delivery systems necessary to sell and gain regulatory approvals for Medinol's stents because of their diversion of priorities to other stents. (See, e.g., ¶¶ 198-203);

(c) Defendants have pursued another way to "Bring a Better Deal" to BSC by wrongfully obtaining an "insurance policy" against the failure of their scheme against Medinol: the "Express" stent. On February 6, 2001, BSC claimed that its May 17, 2000 agreement with Guidant gave it the right to develop the Express stent. The agreement with Guidant, made at the time that BSC was aware of the inevitable public disclosure of BBD, involved a breach of the Supply Agreement. In other words, Defendants pursued their own "objectives"--BSC breached the Settlement Agreement in order to obtain Guidant's technology to develop the Express stent, to which BSC has devoted substantial time over the past months. As Defendant Best stated on February 6, developing this stent was "an insurance policy" in case BSC could not achieve its objectives with respect to Medinol. Moreover, BSC's efforts on the Express stent breached BSC's obligation to concentrate its stent business on Medinol's stents and use all commercially reasonable efforts to promote and market Medinol's stents (Supply Agreement §§ 2.11, 3.02(b)). Indeed, in a March 20, 2001 meeting, Tobin stated that BSC was now fully committed to the Express stent and it simply had "no more resources" to commit to the NIRFLEX™, Medinol's next generation stent. (See, e.g., ¶¶ 204-206);

(d) Defendants stole Medinol's confidential intravascular ultrasound technology. Medinol disclosed this technology in a series of meetings in which BSC pretended to be interested in cooperating with Medinol on the use of this

technology. Defendants then stole this technology from Medinol. Tobin has admitted this, and the Defendants reassigned the stolen patents to Medinol after they were caught. (See, e.g., ¶¶ 207-220);

(e) Defendants repeatedly failed to make, or unreasonably delayed in making, payments owed to Medinol. (See, e.g., ¶¶ 221-222); and

(f) BSC interfered with Medinol's plans for an initial public offering of Medinol's stock, perhaps because Defendants wanted to maintain the option for BSC to purchase Medinol at a discount, or perhaps because this would interfere with their plan to steal Medinol's property. In 1997, Defendants proposed to purchase Medinol and pursued substantive negotiations over such a sale. Defendants then withdrew their offer, after Defendants Nicholas and Best had signed a detailed letter of agreement to buy Medinol. (See, e.g., ¶¶ 223-229).

25. Defendants' conduct constitutes a violation of the federal Racketeer Influenced and Corrupt Organizations ("RICO") statute, 18 U.S.C. § 1962(c) and (d). In addition, the conduct complained of constitutes breach of contract, tortious interference with contract, breach of fiduciary duties, aiding and abetting a breach of fiduciary duties, fraud, fraudulent concealment, negligent misrepresentation, misappropriation of trade secrets, conspiracy, defamation and unjust enrichment.

26. Medinol is entitled to equitable relief that includes:

(a) An order requiring BSC to add Medinol's name as an additional manufacturer of NIR® stents for purposes of the relevant FDA regulatory submissions; supplement all relevant PMA's that have been filed with the FDA to state that Medinol is an additional manufacturer; supplement all relevant PMA's that have been filed with the FDA to state that Medinol is an additional distributor of NIR® stent systems; take all necessary actions to make such amendments and

supplements to the FDA on a timely basis; and take all actions necessary to make such amendments and supplements possible on a timely basis;

(b) A declaration by this Court that BSC no longer has the right under Section 2.01 of the Supply Agreement to use, market, distribute and sell Medinol's stents and Medinol's technology;

(c) A declaration by this Court that Medinol may sell its stents and technology independent of BSC. In order to allow Medinol to make, use, market, distribute and sell its stents independently of BSC, the Court should order BSC to: (i) grant Medinol a life-time royalty-free license to make, use, market, distribute and sell stent-delivery balloon catheters; (ii) share with Medinol BSC's technology required to manufacture such stent-delivery balloon catheters; and (iii) sell such balloon catheters to Medinol (at the price at which they were previously sold to Medinol, or five-percent of the end-user price) for the interim period while Medinol establishes this manufacturing capability;

(d) To prevent any further misappropriation and improper use by BSC of Medinol's stents and technology, this Court should issue an injunction barring BSC from selling any of Medinol's stents or any stents using Medinol's technology and intellectual property;

(e) To prevent any further benefit to BSC from its use of intellectual property wrongfully-obtained in a settlement of a lawsuit with Guidant in exchange for a covenant not to sue--given over Medinol's written objection and in breach of the Supply Agreement--this Court should issue an injunction barring BSC from selling, marketing, using and distributing any Express stents;

(f) To prevent BSC from further encumbering Medinol's rights to protect its patents and intellectual property, this Court should issue an injunction barring BSC

from making any covenants not to sue, or settling any cases, that affect Medinol's patents and/or intellectual property; and

(g) To prevent BSC from any further misappropriation and improper use of Medinol's confidential intellectual property and technology, this Court should order BSC to return all material systems and items built, designed or manufactured based on the intellectual property and confidential information of Medinol.

27. In addition, Medinol is entitled to monetary damages in an amount to be determined at trial.

JURISDICTION AND VENUE

28. The Court has subject-matter jurisdiction over Medinol's claims pursuant to:

(a) 28 U.S.C. §§ 1331 and 1367, because certain of Medinol's claims arise under the laws of the United States and Medinol's other claims form part of the same case or controversy under Article III of the United States Constitution; and

(b) 28 U.S.C. § 1332, because the amount in controversy exceeds \$75,000, exclusive of interest and costs, and the controversy is between citizens of a State and of a foreign state.

29. Venue is proper in this district under 18 U.S.C. § 1965.

30. Pursuant to Section 12.08 of the Supply Agreement between Medinol and BSC, BSC has consented to the exclusive jurisdiction of the United States District Court for the Southern District of New York for the purpose of all actions arising out of or relating to the Supply Agreement. Likewise, pursuant to Section 9.08(a) of the Transaction Agreement between Medinol and BSC (the "Transaction Agreement"), and Section 6.07(a) of the Stockholder Agreement between the two companies (the "Stockholder Agreement"), both dated October 25, 1995, BSC has consented to the exclusive jurisdiction of the United States District Court for the Southern District of New

York for the purpose of any action of proceeding arising out of or relating to either the Transaction Agreement or the Stockholder Agreement.

31. This action arises out of and/or relates to the Supply Agreement, the Transaction Agreement and/or the Stockholder Agreement.

32. Section 12.12 of the Supply Agreement, Section 9.12 of the Transaction Agreement and Section 6.10 of the Stockholder Agreement provide that, with respect to one another, Medinol and BSC have each waived the right to a trial by jury in any action, proceeding or counterclaim (whether based on contract, tort or otherwise) arising out of or relating to any of the three aforementioned agreements.

THE PARTIES

33. Plaintiff Medinol Ltd. is a corporation organized under the laws of Israel, with its principal place of business in Israel.

34. Defendant Boston Scientific Corporation is a corporation organized under the laws of the State of Delaware, with its principal place of business in Natick, Massachusetts. BSC owns shares of Medinol.

35. Defendants Nicholas, Berman, Best, Corbett, Rosenthal and Sandman were, in 1997, members of the BSC Executive Committee, a committee organized and headed by Nicholas and comprising top executives who make key strategic, financial and organizational decisions for BSC. The Executive Committee approved the BBD deceit as early as July 1997. Indeed, a July 15, 1997 memorandum notes how the Executive Committee considered the name of the scheme, “BBD” (i.e., “Bringing a Better Deal”), and, after making the decision that the name “BBD” was unpalatable, changed the name of the scheme to “Project Independence”. (Exh. 9.)

36. Defendant Peter M. Nicholas is a co-founder of BSC and is its largest shareholder. He is chairman of the BSC Board of Directors and was BSC’s CEO and president from 1979 until 1999. Nicholas was head of the BSC Executive Committee at

the time it approved the BBD scheme. Nicholas approved the funding of BBD and signed the Capital Expenditure Request & Authorizations (“CERAs”) that gave BBD its initial funding. Nicholas signed the Supply Agreement in New York. Nicholas is a citizen of the United States.

37. Defendant Nicholas, at all relevant times up to today, controls BSC. Nicholas controls BSC’s Board and ensures that only management views are presented to the Board.

38. Defendant Michael Berman was a senior vice-president of BSC and a former president of BSC’s cardiology business, Scimed. Berman was a member of the Executive Committee when it approved the BBD fraud. Berman is a citizen of the United States.

39. Defendant Lawrence C. Best is a senior vice-president and chief financial officer of BSC. Best was a member of the Executive Committee when it approved the BBD fraud. Best approved the funding of BBD and signed the CERAs that gave BBD its initial funding. Best is a citizen of the United States.

40. Defendant James M. Corbett was a vice-president of BSC and the president of Boston Scientific International (“BS International”), a division of BSC. According to BSC’s chronology of BBD, Corbett initiated and directed “Project Independence” until he resigned from BSC on or before October 28, 1998. Corbett is a citizen of the United States.

41. Defendant Janet M. Kelly is a vice-president and was the corporate comptroller of BSC. Along with Nicholas and Best, Kelly approved the funding of BBD and signed the CERAs that gave BBD its initial funding. Tobin has stated that when he first confronted Kelly with BBD, she denied knowledge, but she returned half-an-hour later to say that she had not told the truth. Kelly is a citizen of the United States.

42. Defendant Paul A. LaViolette is president of BS International Corporation and a senior vice-president of BSC. LaViolette replaced Corbett as president of BS International on or about October 28, 1998 and he knew about, pursued and facilitated the goals of BBD. LaViolette is a member of BSC's Executive Committee. LaViolette is a citizen of the United States.

43. Defendant Stephen R. Paidosh was an employee of BSIL, a wholly-owned subsidiary of BSC, until 1999. According to the chronology of BBD given to Medinol by Tobin, Paidosh was enlisted to head BBD under the direction of Corbett and others in BSC. Paidosh is a citizen of the United States.

44. Defendant Arthur L. Rosenthal is a senior vice-president and chief scientific officer of BSC. Rosenthal was a member of the Executive Committee when it approved the BBD fraud. Rosenthal was in charge of BSC's regulatory filings, including the false FDA filings, and personally stole trade secrets from Medinol. Rosenthal is a citizen of the United States.

45. Defendant Paul W. Sandman is a senior vice-president and general counsel of BSC. Sandman was a member of the Executive Committee when it approved the BBD fraud. According to BSC, Sandman approved the legal status of BBD. Sandman is a citizen of the United States.

ALLEGATIONS OF FACT

A. The Medinol/BSC Venture

46. Medinol is a world leader in the design and manufacture of medical stents. Medinol developed, and currently manufactures, the NIR® family of stents, including the NIR®, the NIROYAL®, the NIR Conformer™, the NIRenal™, the NIR® Peripheral and the NIR® Biliary. Medinol has also finished the development of additional products, including the NIR PRINCE™ (for small vessels), the NIRSIDE™ for

bifurcations, the NIRFLEX™, a new generation of stents for all applications, and the NIRovascular™. Medinol is the owner of patents covering the NIR® family of stents and Medinol's unique method of manufacturing.

47. A stent is a small metallic medical device that is placed into an artery in the human body, usually during angioplasty, in order to support the walls of the artery against reclosure after a constricted section of a vessel is propped open by a balloon catheter. The placement of a balloon-expandable stent in a human body is accomplished by using a stent premounted on a balloon catheter and inserting it through the arterial system to the location of the constriction. When the stent mounted on the balloon is in the proper location, the balloon is inflated, the constriction is opened and the stent expands to press against the expanded inner walls of the artery. Then, the balloon is deflated and removed, while the stent remains in place permanently, holding the artery open and resisting its tendency to recoil or reclose.

48. In the method for manufacturing stents used by most companies, the stent is cut by a laser beam out of a tube of metal and then electropolished. In the patented method invented, developed and used by Medinol, multiple stents are simultaneously photochemically etched on a flat metal sheet. Individual stents are then cut out of the panel, folded into cylinders, welded and electropolished. Medinol's method of manufacturing is substantially more cost-efficient in producing a high-quality stent than that of its competitors.

49. Medinol does not manufacture the balloon delivery systems used for the insertion of the NIR® stents into the human body.

50. In the mid-1990's, Medinol sought a co-venturer with experience and presence in the cardiovascular device field that could reliably and efficiently cooperate with Medinol to bring Medinol's innovative stent products to market by developing delivery catheters for Medinol's stents and selling the stents.

51. More than a year after BSC initiated the discussions with Medinol, BSC came back and persuaded Medinol to choose BSC to provide the balloon delivery systems for Medinol's NIR® stents, to help Medinol obtain regulatory approval of its stents in the United States (and elsewhere) and to market Medinol's stents.

52. On October 18, 1995, Medinol and BSC entered into a Confidentiality and Non-Disclosure Agreement (the "Confidentiality Agreement"). Paragraph 2 of the Confidentiality Agreement provides that the party receiving the other party's confidential information:

"will retain the confidential information in the strictest confidence, will not disclose the confidential information to any party whatsoever, except to those of its employees having a need to know, will use the confidential information only for the purpose(s) of equity investment, exclusive distribution and/or acquisition or other business relationships between the parties and for no other purpose whatsoever and will use at least the same measures to protect the confidential information that it uses to protect its own confidential information."

Confidential information is defined as "information concerning the disclosing party's past, present and future research development and business activities and the results therefrom, including but not limited to the NIR stent". (Confidentiality Agreement ¶1.)

53. On October 25, 1995, Medinol and BSC executed the Supply Agreement and the Transaction Agreement. On that same day, Medinol, BSC and Medinol's principals, Dr. Judith Richter and Dr. Jacob ("Kobi") Richter, executed the Stockholder Agreement.

54. Section 10.01 of the Supply Agreement imposes a duty on BSC not to disclose Medinol's confidential information, intellectual property and trade secrets to third parties. Specifically, Section 10.01 of the Supply Agreement provides: "Each party agrees to take all reasonable steps to prevent disclosure of Confidential Information". In addition, Section 5.03 of the Transaction Agreement commits BSC and Medinol, and their representatives, to comply with "all of their respective obligations under the Confidentiality Agreement".

55. Pursuant to the Supply Agreement, Medinol agreed to design and manufacture stents and sell these stents exclusively to BSC (Supply Agreement § 2.01) and BSC promised to “use all commercially reasonable efforts to promote and market Stents developed by or for Medinol in all significant markets” in all of the countries of the world (Supply Agreement § 2.11). BSC promised “to concentrate its Stent business on the development, marketing, distribution and sale of NIR Stents and other Stents developed by or for Medinol under this Agreement”, with the exception of BSC’s Symphony stent when it was used as a minimally invasive bypass stent. (Supply Agreement § 3.02(b).) If BSC sells any non-Medinol stents anywhere that Medinol stents “could have been sold”, BSC is required to pay Medinol a royalty equal to twenty percent of the average sales price less the burdened costs that Medinol would have incurred had it manufactured such stents. (Supply Agreement § 3.02(b).)

56. Section 2.07 of the Supply Agreement requires Medinol and BSC “to promptly report and disclose to each other all” inventions, ideas and improvements, relating to stents, developed or conceived during the term of the Supply Agreement.

57. Section 3.01(a) of the Supply Agreement provides that BSC “shall deliver monthly to Medinol a twelve month Forecast of Stents to be purchased by BSC”. Under Section 3.01(b), BSC may supplement the forecast from time to time. Medinol is required to fill these supplemented orders to the extent they occur in the fourth, fifth or sixth months of the current forecast and are between 80% and 125% of the forecasted amounts.

58. In order to satisfy BSC’s orders for stents, Medinol agreed to establish in Israel two commercial volume production lines for the manufacture of NIR® stents. (Supply Agreement § 2.02(a).)

59. At BSC’s request, Medinol agreed to establish in a BSC facility a back-up automated commercial volume production line for the manufacture of stents (the

“Alternative Line”). (Supply Agreement § 2.02(a).) This Alternative Line was to be used by BSC only in the event Medinol failed to meet BSC’s demand for stents as reflected in a twelve month forecast provided to Medinol. (Supply Agreement § 2.02(c).) Absent such a failure by Medinol, BSC was not permitted to use the Alternative Line to manufacture more than a nominal number of stents to keep the equipment in good condition. (Id.) Specifically, Section 2.02(c) of the Supply Agreement provides:

“BSC agrees that it will not manufacture Stents on the Alternative Line unless and until such time as Medinol has failed to satisfy BSC’s requirements for Stents as described in Section 3.03; provided that BSC may, prior to such time, manufacture on the Alternative Line such nominal number of Stents (currently estimated at no more than 500 a month) necessary to maintain the Alternative Line in good operating condition.”

60. Section 3.03 of the Supply Agreement sets forth the conditions under which Medinol will be deemed to have failed to satisfy BSC’s requirements. It provides:

“Certain Failure to Supply. In the event that Medinol does not satisfy BSC’s requirements for Stents for two months out of any four month period, and the purchase orders of BSC do not exceed 125% of the Forecast for such periods as permitted by Section 3.01(a), BSC will have the right to operate the Alternative Line to the extent of Medinol’s failure to supply (plus 25%) until such time as Medinol provides reasonable assurances to BSC that Medinol has and can maintain for the foreseeable future capacity sufficient to satisfy Medinol’s production and delivery obligations pursuant to Sections 3.01(a) and (b); provided that in no event shall BSC be obligated to cease manufacturing Stents under this Section 3.03 within two months of the initial failure of supply hereunder.”

61. Medinol has never failed to supply BSC with stents in accordance with Medinol’s obligations under the Supply Agreement. BSC has never claimed to Medinol that Medinol failed to supply stents. Indeed, BSC’s CEO Jim Tobin publicly conceded in a Web-cast conference call on October 17, 2000, that Medinol has never failed to meet BSC’s stent requirements.

62. Under the Supply Agreement, Medinol retained its proprietary rights and patent rights over its NIR® stent design and manufacturing technology, subject only to BSC’s exclusive license to use, market, sell and distribute (but not manufacture) Medinol’s stents for medical applications and BSC’s co-exclusive license (with Medinol)

to manufacture stents solely on the Alternative Line in accordance with the restrictions of the Supply Agreement.

63. The Supply Agreement protects Medinol's trademarks. Although BSC received an exclusive license to use the specified "Company Trademarks", including, among others, "NIR" and "NIR on", "on and with respect to the stents and in connection with the marketing, sale and advertisement of the Stents in the Territory, and any and all written materials hereto", BSC has "no right, title or interest in Company Trademarks". (Supply Agreement § 9.05.) The Supply Agreement provides further that "BSC agrees to use Medinol Trademark 'NIR' in connection with NIR Stents" (id.) and makes provisions for protection of Medinol's rights in product labeling, requiring the use of the applicable trademark notice to the right of Medinol's trademarks (i.e., "®" if registered and "™" if not registered) and language indicating whether the mark was either a "registered trademark of Medinol" or a "trademark of Medinol". (Supply Agreement § 9.06(a).) These provisions require such trademark notification on the "Stents, packaging, or labeling of same, when Company Trademarks first appear in text, or whenever Company Trademarks are used by BSC". (Id.)

64. The Supply Agreement sets forth procedures to obtain FDA approval to market Medinol's stents in the United States. Section 4.02 of the Supply Agreement provides that "Medinol and BSC agree to cooperate with each other to obtain all FDA approvals necessary for the manufacture, marketing, distribution and sale of the Stents to be sold hereunder in the United States". Medinol and BSC agreed to submit to the FDA an application in BSC's name for a PMA under the Federal Food, Drug, and Cosmetic Act, in respect to the stents to be sold in the United States pursuant to the Supply Agreement.

65. Medinol is the independent manufacturer of the NIR® stent. The Supply Agreement states that "BSC desires to market, distribute and sell Stents

developed by or for Medinol throughout the territory”. Medinol develops and manufactures the stent according to its own design and specifications, and is the only entity that controls the quality of the manufacturing process of the stent, including compliance of the process with FDA regulatory rules such as Good Manufacturing Practices (“GMP”). Medinol also performed and owns the Investigational Device Exemption (“IDE”) of the NIR® stent, mounted on three different balloons.

66. Under Section 4.02 of the Supply Agreement, BSC was required to designate Medinol in the PMA “as an additional manufacturer for purposes of the PMA”. In addition, at an appropriate time, BSC and Medinol were to submit a PMA supplement listing Medinol “as an additional distributor of Stents in the United States”. (Id.) Section 4.02 of the Supply Agreement also provided that if BSC retained no license from Medinol following termination of the Supply Agreement, then BSC would assign the PMA to Medinol.

67. Defendants knew full well that BSC had an obligation not to communicate with the FDA on the NIR® stent without cooperation with Medinol. For example, in an April 24, 1998 facsimile sent via the wires from Natick, Massachusetts to Tel Aviv, Israel, Nicholas reiterated that “no substantive contact with FDA on any NIR™ related matters will be originated or conducted without thorough discussion and agreement with Medinol”. Nicholas repeated this commitment to “consult with Medinol on all FDA communication issues” in a letter faxed to Medinol on July 19, 1999. (Exh. 48.) Indeed, in documents that lay out the BBD fraud in graphic detail, including the fraud on the FDA, Defendants showed that they were fully aware of Medinol’s rights. Thus, in a February 1999 “visit to Scimed . . . to discuss and define parameters associated

with the submission to the FDA of the BSC NIR Stent”, the “[c]orporate concerns” were said to be:

“The submission to the FDA was an area of concern for regulatory with regards to the identification of the new panel vendor. It was felt that the submission should include the details of the new vendor as this would be a critical process to identify to the FDA.

Corporate concerns with this disclosure centred on Medinol's reaction to the submission as they have the right to review all details associated with a submission to the FDA including the NIR stent.” (Exh. 37.) (Emphasis added.)

68. The Supply Agreement provides that, among other things, Medinol and BSC will:

- (a) jointly participate in a development program for the future generation of pre-mounted stents;
- (b) discuss marketing, distribution and sale of stents;
- (c) consult each other in connection with the retention or termination of key employees primarily engaged in the stent business;
- (d) promptly disclose to each other all inventions, ideas and improvements relating to stents or conceived during the term of the Supply Agreement and make all such inventions, ideas and improvements available for incorporation into the stent specifications; and
- (e) together make all submissions to the FDA for all approvals necessary for the manufacture, marketing, distribution and sale of stents to be sold in the United States, and agree on the content of all submissions (or note where the two companies diverge).

69. Under the Supply Agreement, Medinol and BSC combined their property, skill and knowledge in numerous ways. For example:

- (a) Medinol and BSC exchanged development and manufacturing equipment;

(b) Medinol shared its intellectual property with BSC and Medinol and BSC shared access to one another's offices;

(c) Medinol prepared presentation and promotional materials and trained BSC sales and marketing executives, describing how to sell NIR® stent products;

(d) From at least August 1997 until March 1999, Medinol and BSC participated in a joint Steering Committee to direct the business of the venture;

(e) Medinol made presentations at conventions and participated in meetings between BSC and its financial analysts in presenting the stent product line and its potential, and helped BSC to forecast market dynamics;

(f) Medinol, at the request of BSC, met with "preferred customers" to help sell the products;

(g) BSC employees, including about twenty quality control personnel from Ireland, came to work or to be trained at the Medinol facilities for various lengths of time as Medinol employees in order to create a common knowledge base and promote quality control;

(h) Medinol trained BSC manufacturing personnel for the Alternative Line;

(i) Executives from Medinol and BSC frequently met to discuss business models and the world market in order to determine a joint business plan;

(j) In 1998, at BSC's request, Dr. Kobi Richter helped to evaluate failures in the balloon components of the delivery systems following a specific personal request from Defendant Nicholas for Dr. Richter's assistance and expertise;

(k) Medinol and BSC contributed assets to the Medinol/BSC venture. For example, Medinol contributed intellectual property and its expertise relating to the development and manufacturing of NIR® stents. BSC contributed to the development and manufacturing of delivery systems for placement of the NIR® stents in the human body;

(l) Medinol and BSC mutually profited from the venture's commercial sales of NIR® stents and stent delivery systems under a fixed formula set forth in the Supply Agreement. Medinol and BSC share expenses, including development costs and legal expenses relating to patent rights;

(m) Medinol and BSC held meetings to keep BSC updated about Medinol's quality control systems and specifications for BSIL criteria for incoming stent inspection; and

(n) Dr. Kobi Richter of Medinol invented and contributed to the development of a balloon component of a stent delivery system that was evaluated by a BSC subsidiary.

70. BSC and its officers have described the venture as follows:

(a) Nicholas stated in a "Letter to Shareholders" contained in BSC's 1995 Annual Report: "First, . . . I would like to single out the BSC investment in and partnership with Medinol and its principals, Kobi and Judith Richter. . . . We consider this to be a significant new product opportunity and look forward to a long-term, mutually rewarding partnership with our Israeli colleagues at Medinol."

(b) In a November 13, 1995 press release announcing BSC's venture with Medinol, BSC stated: "The agreement between Boston Scientific and Medinol represents a partnership that shares common objectives."

(c) In a letter dated March 21, 1997 (the very month BBD began), Nicholas stated: "[W]e have agreed philosophically that we are committed to act as one company and one team We have developed between us, I believe, a remarkable kinship, partnership and a mutual vision of the future."

(d) In a November 26, 1997 letter, Nicholas stated "be assured that I value your partnership and your friendship as always".

(e) In a letter on January 28, 1998, Nicholas noted that: “Too much time has passed since we sat talking about partnership and growth”; “I realize the last couple of months have been difficult for both sides as we attempted to deal with our long-term partnership objectives. . . . We have together given birth to a brilliant child; while very special is also very demanding”; and “I value greatly our partnership and I want us both to fully realize the promises made to each other, our teammates, our customers and their patients.”

(f) In a March 18, 1998 letter, Nicholas stated: “Partnering together creates great opportunities for us both, but it also implies a willingness to appreciate, undertake and share risks equally. We have done this in the past, and I expect we will do this in the future.”

(g) In an April 24, 1998 facsimile sent via the wires from Natick, Massachusetts to Tel Aviv, Israel, Nicholas declared: “I of course remain highly enthusiastic about the eventual launch of the NIR® stent system in the United States and have every confidence that the BSC/Medinol partnership is and will continue to be a winning one.” In this letter, Nicholas stated (falsely) that he “do[es] not believe BSC has undertaken consciously any efforts to undermine Medinol’s important contribution to the field of medical stents and I find it inconceivable . . . that you honestly believe . . . that BSC is acting in bad faith to undermine, understate, misrepresent or otherwise wrong or harm Medinol”.

(h) In a June 15, 1999 Master Validation Plan by BSC prepared for submission to the FDA, BSC refers to the “Medinol/BSC partnership”. (Exh. 45.)

(i) On April 17, 2000, just two days prior to the originally scheduled date for partial disclosure of the BBD deceit to Medinol, Rosenthal hand-delivered a letter from Nicholas, in which Nicholas stated that “[m]uch has happened during the past twelve months to reshape our relationship and move us ahead as trusting

partners” and expressed a desire to “keep [the] organizations in operational alignment and harmony”. He stated that “[t]he relationship with Medinol is fundamental to us and, as you . . . know, near and dear to me personally”.

(j) In an October 17, 2000 Web-cast conference call with market analysts on BSC’s third quarter results, Best declared: “The Medinol agreement and our partnership requires Boston Scientific to concentrate on the NIR platform as our primary platform”.

B. BBD: Defendants Steal From Medinol and Defraud the FDA

1. Defendants Approve the Theft of Medinol’s Property

71. At least as early as March 1997, according to the incomplete and inaccurate BBD chronology provided by BSC’s Tobin, Paidosh proposed to Corbett (then a vice-president of BSC and president of Boston Scientific International) the scheme that would become known first as “BBD” (“Bringing a Better Deal” to BSC), then as “Project Independence”. Later, “Project Harmony” was an outgrowth of “Project Independence”. (Exh. 1.)

72. Paidosh and Corbett knew that BBD was unlawful and agreed to facilitate its aims.

73. No later than July 1997, the members of the Executive Committee of BSC, which included Defendants Nicholas, Berman, Best, Corbett, Rosenthal and Sandman, approved BBD’s goals. At least as of July 15, 1997, the Executive Committee approved BBD. (See Exh. 9.)

74. The members of the Executive Committee knew that BBD was unlawful and agreed to facilitate its aims.

75. According to BSC’s chronology, the first name selected for the scheme was “BBD” to signify the Defendants’ goal of “Bringing a Better Deal” to BSC, *i.e.*, a deal financially superior to BSC than the deal entered into with Medinol.

76. According to BSC, the Executive Committee later changed the project name from BBD to Project Independence, (Exh. 9), to signify the goal of securing BSC's "independence" from Medinol. Further, according to a February 1, 1999 BSC memorandum, Project Independence was later renamed "for legal reasons". (Exh. 36.)

77. Paul Redmond (of BSIL) and Paidosh were assigned to manage BBD in May of 1997. (See Exh. 7.) BSC's partial list, provided to Medinol after BSC disclosed BBD, identifies more than two dozen personnel involved with BBD. (See Exh. 2.) Many more were actually involved. These personnel conspired with Defendants to facilitate BBD's goals through wrongful means.

78. BSC provided the funding for BBD as a wholly-owned subsidiary, while presenting BBD as an independent entity to the outside world, including to regulatory authorities and tax authorities.

79. On September 15, 1997, Paidosh and others prepared various drafts of a CERA seeking funding for BBD from BSC. One of these drafts set forth the following justification for BBD:

"The Purpose of this CERA is to justify and receive approval for \$955,185.00 for the procurement of capital equipment required to meet the objectives of Project Independence.

* * *

The objective of Project Independence is to establish contingency capacity for the manufacturing of coronary and peripheral stainless steel stents within Ireland. The project goals include:

- 1.) Establish the ability to manufacture 6,000* coronary stents per week on a 2 shift operation by December 1, 1997.
- 2.) Establish and certify a second photo-chemical etching vendor outside of Israel by December 1, 1997.
- 3.) Establish the ability to manufacture 7,965* coronary and peripheral stents per week on a 2 shift operation by March 1, 1998.

* * *

7.) Ensure that the coronary and peripheral stents manufactured by BBD. (Forwich Ltd.) have equivalent performance to stents of the same design manufactured in Israel by January 15, 1998.

Note* The contingency capacities outlined above were established from current weekly purchase rates from Israel, current inventory status within BSIL and future sales forecasts.

* * *

Functional testing must be done to ensure the stents made at BBD. are equivalent to the stents made in Israel. Where possible we will use the functional stent testing equipment within SciMed to save money and time however, there will be a need to duplicate some functional testing equipment to maintain project confidentiality and for life cycle testing. After this project is completed this equipment can be utilized by the R&D Department at BSIL as more stent development projects are initiated.” (Exh. 16.)

80. Another draft of the September 15, 1997 CERA added:

“This capital justification was reviewed by BSIL Operations (Stephen Paidosh and Eric Stenzel) and BSIL R&D (Aiden Flanagan and Paul Redmond). We feel this is the minimum capital required to successfully complete Project Independence objectives and protect an ever increasing portion of BSC revenue. We recommend that senior BSC management approve this capital in order for the project team to meet the established project objectives and deadlines.” (Exh. 17.) (Emphasis added.)

81. “Senior BSC management” did approve the funding of BBD.

82. In order to avoid company requirements for the approval of amounts in excess of \$500,000, Defendants deliberately broke up their funding request into two separate CERAs, each for less than \$500,000. Bernard Collins, a vice-president of BSC and the president of BSIL, nevertheless required that the CERAs obtain the highest level authorization (from Nicholas, Best and Kelly). Collins required that Nicholas, Best and Kelly approve the CERAs because he knew that BBD was unlawful.

83. In the fourth quarter of 1997, Nicholas, Best and Kelly approved the CERAs for the funding of BBD. (See Exhs. 17 and 18.)

84. Nicholas, Best and Kelly knew that BBD was unlawful and agreed with the other Defendants to facilitate its aims.

85. Redmond was instructed by Collins in a July 15, 1997 memorandum to provide bi-weekly status reports on BBD to Corbett and to provide Collins with a copy of

these reports. (See Exh. 9.) In July 1997, Redmond began to issue monthly BBD status reports to Corbett and others. (See, e.g., Exh. 11.)

86. On or about October 28, 1998, Corbett resigned and was replaced by LaViolette. LaViolette knew that BBD was unlawful and agreed to facilitate its aims.

87. On December 23, 1998, Paidosh and Stenzel approved a CERA, seeking funding of Phase II of the project:

“The purpose of this CERA is to justify and procure approval for Phase II funding of \$366,900.00 to complete Project Independence objectives.

* * *

Phase II objectives is [sic] to implement the capability of manufacturing 40,000 Nir stents per month in BSIL to support our customers The final objective is to implement a new electropolishing and passivation process to our ability to process Nir stents more compatible with BSC balloon catheters.” (Exh. 35.)

88. On and around June 29, 1999, BSC’s top management, including Nicholas, LaViolette and BSC’s new CEO, Jim Tobin, visited BSIL’s facilities in Ireland. The agenda included a tour of “Independence” and an update on BBD’s status. In connection with the visit, Paidosh put together a presentation that included, among other things, a review of BBD’s manufacturing capabilities, a review of the efforts to obtain FDA approval for BBD’s stents and a discussion of whether BBD’s objectives were “still appropriate for today’s Medinol/BSC relationship”. (Exh. 47.) This top management team allowed the continued operation of BBD.

89. The conspirators sought additional funding in September 1999. In a September 1, 1999 CERA, Stenzel wrote:

“The purpose of this CERA is to seek funding totaling \$134,800 USD to bring project Harmony to a stage where a subsequent successful validation of chemically etched NIR Stent panels from an alternative vendor can be achieved in an expedient manner.

* * *

Project Harmony is a continuation of Project Independence

As the main objectives of Project Independence were achieved, Project Harmony was initiated to address the continued development of the chemical etching process

used by our selected subcontractors to provide an alternative supply of the standard NIR Stent panel.

* * *

Upon completion of Project Harmony, management will have available a viable second supply source for the standard Chemically Etched NIR Stent panel ready to initiate validation procedures.

* * *

Should circumstances arise that require back up, emergency, or other production requirements, Project Harmony can be combined with the Project Independence results to begin validation of a full standard NIR Stent manufacturing line.” (Exh. 49.)

90. In another CERA dated September 2, 1999, Stenzel wrote:

“The primary objective of this CERA is to provide sufficient gold plating equipment to meet current R & D capacity and new project requirements. The secondary objective of this CERA is to have available extra production capacity when peak demands present themselves.

* * *

Upon completion of this project, an additional gold plating line will be installed and ready to commence the validation process. If immediate authorisation is received, the validation may be able to be conducted in conjunction with the Hot Gold project of which this is associated.” (Exh. 50.)

91. Even after BBD was disclosed to Medinol and commitments were made to Medinol to stop BBD, BBD did not stop. The activity in support of BBD in the spring of 2000 included a June 30, 2000 directive--that was part of Defendants’ cover-up--in which Collins was told by senior BSC management to “continue with the establishment and validation of the alternate line for stent manufacture in Ireland” and that “[a]ll stent producing equipment should be consolidated into one line known as the alternative line”. (Exh. 62.) Taylor gave the “authoriz[ation] to begin spending the U.S. \$177,740 required for the completion of Phase One” of this effort to continue with their illegitimate manufacturing of stents and their cover-up by trying to make their fraudulent conduct look legitimate through “consolidat[ing]” the two stent-manufacturing lines (the illegitimate and the legitimate “alternative line”) into one line. Defendants were trying to remove evidence of their wrong-doing.

92. The goal of BBD was to freeze Medinol out of the venture by, among other things, stealing Medinol's NIR® stent technology and manufacturing technology, using that technology to manufacture an "equivalent" stent, and fraudulently obtaining FDA approval to market the "equivalent" stent in the United States, all without Medinol's knowledge and while misleading Medinol, and without the FDA's knowledge.

93. BBD involved stealing Medinol's confidential technology and trade secrets. Defendants' scheme involved obtaining that technology for purported use on a contractually legitimate Alternative Line, while actually using the information to copy, build and operate an illegal Secret Line.

94. BSC had a right under the Supply Agreement to establish an Alternative Line designed and erected by Medinol in a facility designated by BSC to manufacture stents with Medinol's technology in the event that Medinol failed to meet its supply obligations under the Supply Agreement. Absent such a failure by Medinol, BSC was not permitted to use the Alternative Line to manufacture more than a nominal number of stents (estimated to be no more than 500 per month) necessary to maintain the Alternative Line in good condition. BSC was obligated to use panels supplied by Medinol (or a Medinol-approved vendor) in connection with any manufacture of stents on the Alternative Line.

95. In 1997, BSC stated that it was invoking its right under the Supply Agreement to establish the Alternative Line and sought Medinol's assistance in establishing the Alternative Line. BSC told Medinol that the Alternative Line would be located in BSIL's Galway, Ireland facilities. BSC represented to Medinol that Medinol's assistance in setting up an automated commercial volume production line for the manufacture of stents in BSIL's Ireland facilities would be used solely for the purpose of establishing the Alternative Line authorized by the Supply Agreement, under the restrictions contained therein. Each of these statements by BSC was false.

96. Medinol never failed under the Supply Agreement to meet BSC's stent supply requests. Therefore, BSC never had any right to manufacture more than a nominal number of stents on the Alternative Line.

97. BSC never even operated the Alternative Line.

98. Instead, without Medinol's knowledge, Defendants, pretending to establish the Alternative Line, stole Medinol's technology and trade secrets to create the Secret Line.

2. Defendants Set Up the Secret Shell Company

99. Defendants created a shell company to hide their unlawful activity. In order to "shield Boston Scientific from being associated with" the Secret Line, in June 1997, Defendants retained Richard Gahan and Mr. Mulligan (a friend of Bernard Collins and an outside consultant) to set up a "shel[l] company" in Ireland. This company was incorporated as a wholly owned subsidiary of BSIL named Forwich Ltd. ("Forwich"). On July 21, 1997, Sandman approved Forwich's legal status. (Chronology) (Exh. 1.) To provide "another level of protection" and further obscure Forwich's ties to Defendants, Forwich did business under the name "BBD". (*Id.*) On or around July 25, 1997, Defendants rented manufacturing facilities for BBD in Dublin, Ireland and set up a "ghost office" with a phone receptionist. (Exh. 30.)

100. Defendants decided in May 1997 that the manufacturing facility of BBD was to be established as "a separate entity to BSIL with no traceable links" (Exh. 7), in order to conceal it from Medinol and to gain FDA approval through a simplified and abbreviated process, by replacing Medinol, falsely characterized as a vendor rather than the manufacturer, with BBD, also falsely characterized as a vendor rather than an affiliate.

101. From the start, Defendants decided that this untraceable secret facility would manufacture a large number of stents. Thus, a May 20, 1997 memorandum

provides an early outline, with an initial goal to establish a stent manufacturing facility with the capacity to produce 1,500 NIR® stents per week by mid-November 1997. (Exh. 7.) Similarly, a 1997 memorandum by Stenzel entitled “Project Independence Objectives” described the Defendants’ goals as follows: “Develop an internal ability to manufacture 6000 balloon expandable stents (all 8 models) per week by Dec. 19, [19]97”. (Exh. 3.) And, by September 1997, BBD’s stent production goal had risen to approximately 8,000 stents per week.

102. The Secret Line involved “the secret capacity”, according to an October 19, 1999 e-mail from Stenzel. (Exh. 52.)

103. The Supply Agreement did not permit Defendants to establish the Secret Line, to manufacture any NIR® stents on the Secret Line or to hide it from Medinol, which has the right under the Supply Agreement to perform a quality systems inspection on NIR® stent manufacturing, to assure itself of the quality of its NIR® stents.

104. Maintaining BBD’s secrecy was important to the Defendants because the scheme’s central elements were the stealing of Medinol’s technology and confidential trade secrets, and deceiving the FDA. All this secrecy was to keep the BBD scheme secret from Medinol and the FDA.

105. Therefore, Defendants did not inform Medinol of their plans to establish the Secret Line or of the existence of the Secret Line. A constant theme of the internal communications relates to the need for secrecy, to avoid discovery by Medinol and the FDA. For example:

(a) In an October 28, 1997 e-mail, Kelly set out Corbett’s direction “not [to] discuss Forwich with ANYONE”. (Exh. 22.)

(b) In an e-mail, Paidosh stated that BBD needed to maintain “[t]otal secrecy from Medinol and minimal awareness of BSC personnel”. (Exh. 5.) Paidosh cautioned: “PMA amendment needs to be carefully drafted to maintain

secrecy from Medinol and allowing us to use BBD as an alternative vendor”. In addition to the listed “Con[]” of “High awareness of BSIL personnel of alternative vendor to Medinol and additional capacity”, another “Con[]” was that “FDA reactions and risks are great”. (Id.)

(c) In February 1999, when a BSIL employee who was not part of the conspiracy was accidentally copied on an e-mail about BBD, Paidosh e-mailed the following warning to his co-conspirators:

“Many people in BSIL are not aware of project Independence but are receiving e-mails from folks in SciMed on this topic. Eric [Stenzel] and I spend an increasing amount of time telling white lies about this activity to our people to keep them in the dark. The problem is they will buy it once but they continue to get e-mails that reference BBD or alternative panels, etc. Pete Nicholas hasn’t decided how far he wants to take this so it would be a shame for Medinol to learn of the initiative. The people copied on this e-mail know about this and have a responsibility to maintain control. Please talk to anybody you have told other than on this list and stop the flow of info.” (Exh. 38.)

(d) In October 1999, BBD employee Denise Heneghan arranged for Eric Stenzel and other BBD employees to give to “Peter Cohen, a consultant working for Jim Tobin”, a presentation of “the project history” which “was followed by a visit to BBD where the secret capacity was demonstrated”. (Exh. 52.) When David Toohey learned of this, he sent a return e-mail on October 20, 1999 declaring the disclosure to Cohen was “not authorised and was a serious mistake” and requesting another employee “talk to Peter Cohen immediately to redress this error”. (Id.) Toohey further noted: “Given that this project has always been on a ‘need to know’ basis and has a potentially catastrophic impact on our relationship with Medinol it is absolutely essential that we treat it as such.” (Id.) Denise Heneghan, the organizer of the meeting with Cohen, apologized to her co-conspirators but stated that she had checked “whether or not it was appropriate to be completely frank with Peter Colen [sic]”, who was sent at Tobin’s direction,

and she “understood that it was”. (Id.) She repeated that Tobin knew about BBD and requested that his consultant be told about it “frank[ly]”. The conspirators were still quite concerned, however, with “whether it is appropriate to share this project with Jim Taylor or not” and the final word from Phillip Champaud was “make sure that Peter [Cohen] only feedbacks what he learned about Harmony to Jim Tobin only until we get more info re. Jim Taylor”. (Id.)

(e) In a December 14, 1999 e-mail sent to Redmond, Toohey and others, Stenzel described a “[d]isturbing phone call” that he received on the BBD telephone line “probing the function, product line, and ownership of BBD”. Stenzel described how he deceived the caller:

“I was first alerted when he mentioned that they were interested in supplying their steel to other stent manufacturers like ourselves to which I replied that we don’t make [s]tents, we make heat exchangers with that material.

The next questions was [sic] ‘Are you affiliated with Boston Scientific’ to which I replied no.

* * *

As this is a sensitive issue, I wanted to pass this on. The caller had an English accent and was definitely trying to find out who BBD is and what we do. (Perhaps it was one of our chemical etchers trying to find out who we are.)” (Exh. 54.)

106. Defendants needed BBD to be located outside of BSIL headquarters until the summer of 1998 when the site audit of BSIL by the FDA inspector was completed. Although Defendants still sought to keep BBD secret from Medinol after the FDA site audit, Defendants decided to move BBD to BSIL’s Galway site because they could do so without fear of discovery by the FDA inspector.

107. Stenzel and Paidosh discussed plans to maintain the secrecy of the project in the event of such a move. Defendants devised the following plan in June 1998: keep some accounts open in the name of BBD; transfer BBD’s operating address to the “ghost office” in Dublin so that deliveries would arrive there; have the “ghost office”

repack such deliveries and courier them to an address in Galway; and maintain Dublin telephone and fax numbers and have calls transferred to numbers in Galway. (Exh. 30.) Paidosh warned that “[i]t has been agreed that we want to maintain optimal secrecy around on the BBD Project” and that certain equipment should be installed in BSIL’s facilities only “as long as we feel that we can achieve this without breaching the secrecy issue of the project”. (Exh. 31.)

108. Paidosh described the following three “Options”:

(a) “BBD set up as offsite vendor of stent panels and unfinished stents”;

(b) “BBD set up as offsite vendor of stent panels with its capability to supply unfinished stents located within BSIL”; and

(c) “BBD set up as offsite vendor of stent panels (BBD laser welding capability integrated into BSIL)”. (Exh. 5.)

For each “Option”, Paidosh analyzed the impact on “secrecy from Medinol” and analyzed the “FDA reactions and risks”. (*Id.*) And for each “Option”, Paidosh provided the “Caution[.]” that: “PMA amendment needs to be carefully drafted to maintain secrecy from Medinol and allowing us to use BBD as an alternative vendor”. (*Id.*)

109. Defendants portrayed BBD as one of BSIL’s outside vendors, a misrepresentation that was also vital to achieving a fast approval track with the FDA.

Stenzel explained the plan to his co-conspirators in an April 12, 1999 e-mail:

“As discussed previously, we are adding BBD to the BSIL approved vendor list. Last week, I received a request from BSIL purchasing to complete a supplier survey.

To make everything look legitimate (as much as possible) I began drafting a quality manual based on the ISO 9001 standard. I did not want it be [sic] highly visible to an auditor (internal or external) that we started buying key items from a “cowboy” vendor. The inclusion of official quality procedures with the survey should assist in this.” (Exh. 42.)

110. In an October 28, 1999 e-mail, Stenzel described his concerns over the merging of BBD’s capacity with that of BSIL:

“With regards to your plans to wrap up Forwich (T/A BBD), there are a few issues that will need to be continued to keep in line with the secrecy aspects and project continuation issues.

We would need to maintain the Dublin ghost office, re-directed telephone & fax lines, vendor accounts, and the Forwich current accounts. This would be the minimum in order to keep the project running.” (Exh. 53.)

3. Defendants Actually Steal From Medinol

111. Under the BBD scheme, Defendants stole Medinol’s confidential technology and trade secrets, both with respect to the panel design, involving the manufacture of the panels, and the manufacturing design, including the folder-welder, for creating finished stents from panels.

112. In July 1997, Defendants hired Eric Stenzel to run the day-to-day operations of BBD. (Chronology) (See Exh. 1.) Stenzel’s presence needed to be explained to the BSIL employees who were not involved in the fraud. In an April 16, 1998 e-mail, Paidosh told BSC employees:

“On Monday the 20th a new contract engineering employee will be starting at BSIL. His name is Eric Stenzel and his primary focus will be to support the Nir manufacturing cell in Metals from a manufacturing engineering function. . . . Eric will report directly to me during this contract period.” (Exh. 27.)

113. Stenzel set out a timetable for BBD to steal the tools and materials necessary to manufacture the “secret capacity”. For example, BBD was to: “[p]rocur[e] and certify 2 sources of photo-chemically etched panels by Nov. 1, [19]97”; “[d]esign and build final manual tooling for laser welding, rolling and trimming operations by Nov. 15, [19]97”; and “[m]anage offsite development of the Lumonics semi-automated laser system for delivery and implementation by Feb. 28, [19]98”. (Exh. 3.) Stenzel also noted the need to “[p]rove BBD stent manufacturing processes produce stents functionally equivalent to current market product by Jan. 15, [19]98”. (*Id.*) (As explained below, proof of equivalence was an essential component of Defendants’ plan to obtain FDA

approval of the BBD stents.) To that end, he suggested that BBD “[l]earn functional testing requirements from John Sherry [of Scimed]”. (Id.)

114. Stenzel expanded BBD to include vendors that would assist Forwich/BBD with the theft of Medinol’s technology and trade secrets. Stenzel thus brought Lumonics Ltd. (“Lumonics”), Micro Metallic Ltd. (“Micro Metallic”) and Microponents Ltd. (“Microponents”) into the BBD enterprise:

(a) On July 18, 1997, Micro Metallic signed a confidentiality agreement relating to “the Project” of “manufacturing photochemically etched stent components”. (Exh. 10.) At all relevant times, Micro Metallic was aware of the purpose to which the photochemically etched stent panels would be put, and of the project’s secret nature as manifested by the title “Heat Exchanger” on the drawings it knew were for stents.

(b) In July 1997, Microponents signed a confidentiality agreement relating to “the Project” of “manufacturing photochemically etched stent components”. At all relevant times, Microponents was aware of the purpose to which the photochemically etched stent panels would be put, and that the “Project” was secret in nature since it knew it was making stents from drawings falsely labeled “Heat Exchanger”.

(c) On September 6, 1997, Stenzel and Lumonics discussed “the overall scheme of BBD’s long term plan of operations”. (Exh. 14.) On September 10, 1997, Lumonics acknowledged BBD’s purchase order for a fully integrated laser system, a machine needed to manufacture NIR® stents. (See Exh. 15.) At all relevant times, Lumonics was aware of the purpose to which the laser would be put.

115. Defendants stole Medinol’s confidential technology and trade secrets, including its manufacturing and panel technology in a number of different ways. For

example, Defendants sent BSC employees to visit the facilities of Medinol and its panel supplier, under the guise of the venture's "common objectives", but, in reality, to steal information from Medinol. Similarly, Defendants obtained a folder-welder machine from Medinol under the guise of the "common objectives", but, in reality, to steal the design. Indeed, BSC redirected to the "ghost office" in Dublin the machine that Medinol sent to Galway in order that it could be copied by Lumonics for BBD.

116. Defendants sent BSC employees to Medinol and requested information from Medinol under the pretense that they were working to promote the Medinol/BSC venture's objectives, whereas, in fact, they were stealing from Medinol. For example:

(a) Defendants misused confidential information and trade secrets gathered by a BSC employee during a visit to Medinol in Israel for three weeks, during which time he was updated on the definition of defects based on Failure Mode Analysis ("FEMA") performed by Medinol. BSC had falsely represented to Medinol that such information, which was the basis for the inspection criteria for stents, would only be used as the incoming inspection criteria for Medinol-supplied stents.

(b) In a July 3, 1997 memorandum, Flanagan repeated to Paidosh that he had learned the "inspection routine used here at Medinol and will be able to emulate it". (Exh. 8.). Flanagan came to Medinol pursuant to an invitation to be trained in operating the folder-welder system Medinol supplied to BSIL.

(c) BSC ascertained the identity of Medinol's U.S. steel supplier and the technical specifications for the product after requesting details from Medinol purportedly for the purpose of the submission to the regulatory bodies. (See Exh. 21.) BBD used this information to order the correct steel for BBD. On November 26, 1997, BBD received enough steel to manufacture approximately one million stents, according to its own estimate.

(d) To further the establishment of the Secret Line and the copying of the folder-welder machine for BBD, Paidosh faxed a letter from Galway, Ireland to Medinol in Israel, dated August 8, 1997, requesting assistance in helping with the machine and arranging a meeting at Medinol for Paidosh to obtain more of Medinol's confidential intellectual property and trade secrets and learn more of Medinol's manufacturing processes, all under the guise of perfecting the Alternative Line. Paidosh faxed another draft of this letter to Medinol on August 11, 1997. (Exh. 12.)

117. Medinol shipped the folder-welder machine to BSC on July 20, 1997. Defendants stole the Medinol manufacturing technology and trade secrets embodied in the folder-welder machine. After Medinol sent the folder-welder machine to BSC, Defendants diverted it to Dublin.

118. BSC contracted with Lumonics to steal Medinol's design. A July 21, 1997 e-mail from Redmond to Corbett states that the Defendants planned to divert the folder-welder machine to Lumonics, which would "prepare duplicate prints of machine on arrival in Ireland prior to delivery to BSIL", and would then "duplicate" the machine for BBD. (Exh. 11.) BBD's "primary goal [wa]s now to duplicate this machine at [its] premises in Dublin". (Id.) Defendants disseminated Medinol's stent technology trade secrets to Lumonics without authorization.

119. Lumonics reverse engineered the machine and reduced it to drawings. Using those drawings, Lumonics manufactured a folder-welder machine for BBD. Lumonics delivered a completed folder-welder machine to the Dublin facility on April 22, 1998. Lumonics knew that the folder-welder machine was, and is, owned by Medinol and that BSC requested an illegal copying of the system. On July 8, 1998, this stolen folder-welding system was commissioned and debugged in BBD's secret facilities in Dublin.

120. Defendants stole Medinol's etching technology and trade secrets. To produce stents equivalent to Medinol's on the Secret Line, Defendants needed to obtain steel panels chemically etched with Medinol's NIR® stent design. The panels are manufactured for Medinol by Suron, an outside chemical etch vendor in Israel. Medinol's drawings of its panels are Medinol's confidential intellectual property and trade secrets. Under the guise of furthering the Alternative Line and using the information for regulatory submissions, Defendants obtained from Medinol drawings of the panels.

121. In 1997, Defendant Rosenthal was given the assignment to "get the complete set of up-to-date prints out of our supplier". (Exh. 9.) BBD was instructed to "reverse engineer" whatever drawings Rosenthal could not obtain from Medinol. (Id.) In a series of communications using the mails and wires, including a letter faxed by Paidosh on September 14, 1997, Defendants falsely represented to Medinol that BSC was requesting the drawings for legitimate purposes.

122. In 1997, Paidosh made a visit to Medinol's panel vendor for the purposes of obtaining panels for Stenzel to compare to the panels provided by the third-party vendors and auditing the facilities in connection with Defendants' plan to defraud the FDA and steal Medinol's confidential intellectual property and trade secrets. (See Exh. 21.) In a series of communications using the mails and wires, Defendants falsely represented to Medinol, which had arranged the visit, that the purpose of the visit was to obtain a general understanding of the technology as related to the operation of the legitimate Alternative Line. Defendants made these representations in, among others, a September 14, 1997 letter faxed from Paidosh; an October 13, 1997 letter faxed from Paidosh; an October 14, 1997 letter faxed from Paidosh; and an October 15, 1997 letter faxed from Collins to Kobi Richter. Those representations were false.

123. In anticipation of Paidosh's trip to Israel, in a September 26, 1997 memorandum, Heneghan set forth a list of issues:

“Some questions we need answers for to develop the project

Who are we selling the product to?

SciMed? If yes – shall we be dispatching the stents in Bulk packaging ...

If NO we need boxes, packaging DFU's etc [sic] as I presume we wont [sic] be marketing BSIL stents as “Medinol” product. . . .

Can you ask Medinol for Drawing P50049 which is referenced on all panel drawings?

Can you have the Medinol M/C specs as requested on e-mail before E. Hawkins leaves next Friday, or is that impractical?” (Exh. 19.)

124. In fact, Defendants intended to and did change these drawings. Medinol did not give permission to BSC to change the drawings. And Defendants used the drawings outside of BSIL. Defendants disclosed and disseminated the drawings to Micro Metallic, Microponents and various other vendors. Medinol did not give BSC permission to disclose the drawings to Micro Metallic or Microponents, or to sub-license any Medinol technology to a third party.

125. On October 3, 1997, Paidosh informed Stenzel that Paidosh had received additional Medinol drawings. He noted that “[t]he 7 cell parts need to be modified and the 9 cell parts need to be re sized. This will be completed next week and sent to you for review before ordering”. (Exh. 20.)

126. After Defendants copied Medinol's drawings, Paidosh in a November 24, 1997 fax, used the wires falsely to represent to Medinol that BSIL's “identical drawings” would be used in connection with NIR® stents built on the Alternative Line “within BSIL” and would “only be updated or changed” if Medinol sent revised drawings. (Emphasis added.) (Exh. 23.) These representations were false.

127. BSC contacted at least nine different chemical etch vendors in addition to Micro Metallic and Microponents, in an attempt to locate a supplier of panels to use on the Secret Line. BSC sent its copies of Medinol's drawings to each of these third-party vendors. The copies of the drawings sent to the third-party vendors had been modified by Defendants. Defendants had changed the logos on the drawings from "Medinol" to "BBD" and had changed the titles of the drawings from "NIR stent" to "Heat Exchanger". For example, on December 9, 1997, Stenzel mailed copies of confidential Medinol drawings to a third-party chemical etch vendor, Etchform BV. The drawings were falsely labeled "Property of BBD Confidential".

128. Stenzel, in a February 25, 1999 e-mail to Paidosh, explained a method of funneling money from BSC to BBD's accounts, as a "roundabout method of keeping vendors in the dark to BSIL's involvement with BBD". (Exh. 39.)

129. In order to keep some "vendors in the dark to BSIL's involvement with BBD" (Exh. 39) and to avoid responsibility if caught, the Defendants and others signed the counterfeit drawings using "pseudo name[s]". (Exh. 25.) Thus, Paidosh wrote in a February 9, 1998 e-mail:

"Guys, I think we should false sign these prints. Eric you should sign your name but we should use alias for the rest of us. Can you send new copies and everyone pick a new name to sign them with." (Exh. 26.)

Heneghan responded on February 11, 1998:

"Eric,

We reviewed the drawings . . . [I]f we are to get set up for the minimum amount of hassle, and the maximum amount of efficiency, BBD would want to use the same panel inspection/washing fixtures as us For maximum efficiency, tooling and fixtures, and indeed everything else, should be - ultimately - interchangeable between the two lines (BSIL and BBD).

In terms of signatures, rather than get ourselves into an awkward situation when it comes to detailing who the DONOR and RECEIVING teams are, I've suggested to Steve, who is amenable, that you 'check' the drawings, and sign them, and that they should be 'approved' and countersigned by Richard, in his capacity of M.D. (Two signatures should be enough, but from a practical point of view, it would be

appropriate for Aiden and self, at least, to review any changes first, but not sign on.)” (Exh. 26.)

130. In January 2000, Stenzel visited Micro Metallic and Microponents to discuss issues relating to those companies continued development of chemically etched panels. Stenzel’s visit to these vendors was described in an e-mail from Howard to various conspirators:

“On Friday 28 January, I accompanied Eric Stenzel on a visit to two proposed etching vendors, Micro-Metallic and Microponents, with a view to having an introduction to the process so that I could prepare for a quality systems audit at a later stage. This would be to assess whether they would be suitable for submitting to the FDA as alternative etching vendors for project Harmony.” (Exh. 60.)

131. In his January 31, 2000 trip report to Champaud, Stenzel listed the measurements being produced by Micro Metallic, indicating BBD’s theft of Medinol’s NIR Conformer™ stent specifications. (See Exh. 55.)

132. BBD placed orders for panels from Microponents. (See, e.g., Exh. 63.)

4. Defendants Defraud the FDA In Order to Steal From Medinol

133. Defendants’ scheme to steal Medinol’s confidential stent technology and trade secrets involved making false regulatory submissions to the FDA in order to obtain the FDA’s approval to market BBD’s stents in the United States.

134. Defendants’ plan was falsely to represent to the FDA that Medinol was a component supplier/vendor rather than a co-manufacturer of the NIR® stent system. Thereafter, Defendants intended to invoke a relatively simple regulatory procedure to replace Medinol with BBD as an alternative supplier/vendor. To achieve this fraudulent goal, Defendants, in addition to mischaracterizing Medinol’s role, had to succeed in hiding from the FDA that BBD was a subsidiary of BSC and not an independent vendor.

135. By mischaracterizing Medinol as a component supplier and BSC as the sole manufacturer, BSC sought to take advantage of differences between the FDA rules governing manufacturers and those governing component suppliers/vendors. For

example, a company may replace one supplier/vendor for another simply by demonstrating “equivalence” of the “component” and sending a 30-day notification to the FDA.

136. A May 15, 1998 e-mail from Heneghan details Defendants’ efforts to validate the BBD stents by this “equivalence” tactic:

“Kevin,

We are finally approaching the completion of the process validations for the BSC NIR stent. I hope I’m not being too optimistic, but expect to be closing out the PQ [Product Qualification] - workwise - this month . . .

In your opinion, is a product performance qualification required for this ‘design transfer’[?] . . . We have done extensive testing [on corrosion, balloon bursting, etc.] . . . “ (Exh. 29.)

Ballinger responded:

“Denise,

I’m glad to hear of the progress being made on the BSC NIR stent.

Ensuring that this stent functions as well as, or better than, the existing NIR is a BIG deal. If there is any possibility that we may someday sell this stent, it is critical that it is properly qualified. As such, I think that it would be wise to gather group [sic] of the right people to discuss the plans for this stent.

I see two stages to the product qualification; stent integrity testing (bare stents) and delivery system testing (pre-mounted stents).

Stent Integrity:

Because long-term patient outcomes will be directly affected, we need to prove equivalence to the current NIR.” (Exh. 29.)

137. The Defendants’ scheme is further set forth in a memorandum entitled “BBD / BSC NIR Stent Project Status”. (Exh. 4.) That memorandum, which explains that “the projects associated with BBD and the BSC NIR Stent are closely related and dependent on each other”, sets out the “FDA Submission Strategy”: BSC would make a submission under the FDA’s pilot program for approval of a second manufacturing site (Medinol being the first). “This method of submission allows for a 30 day submission time based on equivalence between the Medinol process and the BSIL process”. (Id.)

After the FDA approval, BSC would “submit second panel vendor (BBD) for FDA approval”. (Id.)

138. Paidosh listed three options of how to get FDA approval of “BBD as an alternative vendor”, noting that some of the “Cons” to these options included “FDA reactions and risks” being “great”. Principally, Paidosh noted that the “PMA amendment needs to be carefully drafted to maintain secrecy from Medinol and allowing us to use BBD as an alternative vendor.” (Exh. 5.)

139. Defendants proceeded in 1999 with plans for submission to the FDA. Stenzel, Heneghan and Denise Howard visited Scimed in February 1999:

“The purpose of this visit to Scimed was to discuss and define parameters associated with the submission to the FDA of the BSC NIR Stent. . . .

* * *

Project Name

A discussion ensued with reference to the name for this project and ramifications with combining two or more activities into one project.

To provide clarity in this issue, The name of this project will be Harmony. The scope of project Harmony is to gather data for an FDA submission as a second manufacturing site and the inclusion of a new etched panel vendor.

* * *

Submission Strategy

The submission to the FDA was an area of concern for regulatory with regards to the identification of the new panel vendor. It was felt that the submission should include the details of the new vendor as this would be a critical process to identify to the FDA.

Corporate concerns with this disclosure centered on Medinols [sic] reaction to the submission as they have the right to review all details associated with a submission to the FDA including the NIR stent.

The decision of the meeting was to proceed with the gathering of all validation test data for both the Medinol panels and the new panels. When it comes time to submit to the FDA, there are three options available:

- Submit for a second manufacturing site with Medinol panels only. Medinol copied with submission.

- Submit for a second manufacturing site with both panel vendors. Medinol copied with the submission.
- Submit for a second manufacturing site with both panel vendors. Medinol not copied of the submission.

Validations will be completed using both panels and corporate management will decide on the inclusion of the new panel vendor at the time of submission. Submission to the FDA for an alternate manufacturing site is scheduled for mid July, 1999.” (Exh. 37.)

140. Defendants prepared a June 15, 1999 Master Validation Plan (“MVP”) for submission to the FDA, listing as its purpose: “to re-validate the BSC Nir stent production line using stent panels which are being acquired from an alternative vendor to Medinol. At the outset, it is not known whether the BSC Nir stent line will continue to use Medinol sourced panels and thus it was decided to generate a separate MVP to keep the validation requirements of the two panel sets separate”. (Exh. 45.)

141. An e-mail from Stenzel on June 16, 1999 stated:

“As of yesterday, we are planning to continue the validations of the BSC NIR line to submit to the FDA before Christmas. If possible, we will be using the Suron panels Alternate timeliness will be generated for the use of my panels.

The conference call included Angie Rhaun, Tim Ley, & Brian Brown from Scimed & Stephen, Helen and I from this end.

There were some disturbing comments that were made that will need to be discussed with Charles [Piggot, BSIL head of quality] that I am not comfortable with. First, Stephen wants to submit without pinhole/Balloon compatibility testing. The reasoning he is using is that we are trying to show equivalence to the Medinol stent only, not necessarily a stent we could use. Scimed actively supported this.

This sounds rather ‘Cowboyish’ to me, we will be asking the FDA to approve a line making product that has not been proven to work. Also, we have highlighted a pinhole issue with the FDA due to the recall and I think that this makes it a key test issue.

The next point is that Stephen wants to submit without any fatigue testing. Again this seems funny.

* * *

There were comments that maybe we should form two teams to conduct this submission project, one here and one in Scimed which I objected to. There were also comments as to who will complete the testing and if other tests could be ignored.

In short, it seems like the speed requested to get the line submitted to FDA takes precedence over doing a through [sic] job.

* * *

If worse comes to worse and the FDA changes it to a 180 day submission due to a lack of data, we can at least adopt the position that we submitted all the data to Scimed yet they failed to include it in the submission. (a ‘watch your back’ approach seems prudent)” (Exh. 46.)

142. A March 1999 Validation Protocol for Product Performance

Qualification of BSC NIR® stents, i.e., BBD, states: “a newly acquired panel vendor - BBD . . . will be placed on the SAP system as an alternative vendor for stent panels and BBD manufactured panels will be received in under the same part number as regular Medinol panels.” (Exh. 41.)

143. A June 7, 2000 Validation Protocol Operational Qualification (“OQ”)

was prepared in order to receive FDA approval of the “BSC Nir stent Electropolishing/Passivation unit”. This FDA submission described the Project Independence plan: “Stents made from panels from each of two sources will be processed for this OQ; namely, stents from the original Medinol (Israel) panel vendor . . . , and a newly acquired panel vendor - BBD. . . . This validation will be deemed to have passed for the BSC Nir stents if the results from the testing performed on the Medinol sourced population meet all acceptance criteria This validation should also begin the process of validating the processing of the alternatively sourced panels which are processed under identical conditions as the Medinol panels.” (Exh. 64.)

144. Defendants knew that it was false to characterize Medinol as a

component supplier/vendor, rather than as a co-manufacturer of the NIR® stent system. For example, BSIL specifies quality rules applicable for all vendors in a quality manual that BSC submitted to the FDA as part of the PMA. None of those rules was ever applied to Medinol. Medinol is simply not a vendor. Moreover, in communications with Medinol, Defendants told Medinol to expect a GMP site audit by the FDA. (The FDA

conducts GMP site audits of manufacturers, but not of suppliers/vendors.) Medinol accepted BSC's proposal for Medinol to engage a BSC employee as a Medinol employee, to advise Medinol on how it would prepare for such an audit. However, as a result of Defendants' false characterization of Medinol as a vendor in the PMA, the FDA never performed a site audit of Medinol. Rather, Defendants presented a BSC internal report generated by those BSC employees as an "audit" to the FDA during the FDA's site audit of BSIL. Similarly, in support of its efforts to mischaracterize Medinol as a supplier/vendor, BSC claimed to be responsible for qualifying and auditing Medinol, as the FDA does not itself audit the site of a supplier/vendor. Accordingly, in connection with BSC's late-1997 visit to Israel, Defendants purported to audit the facilities of Medinol and Suron without telling Medinol the purpose of its visit.

145. Even after Tobin revealed the BBD fraud, Defendants still sought to maintain this "audit" pretense. On July 6-7, 2000, Dennis Ocwieja of BSC visited Medinol's facilities in Israel. In several meetings in Natick, Massachusetts in January 2000 and in Ireland and Israel in February 2000, Ocwieja recognized and represented to Medinol that the characterizations of Medinol on the PMA by Defendants were incorrect and inconsistent with the Supply Agreement, and that they should be corrected to name Medinol as a manufacturer and add Medinol as an additional distributor. On June 28, 2000, prior to his visit to Israel, Ocwieja met with Dr. Kobi Richter in New York and signed an agreement indicating that the purpose of his visit to Israel was only to read Medinol's files and to use the information gathered "in good faith" and "only for the potential correction of BSC's mistake in an open way with the FDA". Following Ocwieja's return to the United States, however, Sandman caused Ocwieja to sign a letter (and caused the letter to be faxed to Medinol on July 25, 2000) retracting the commitments and representations made by Ocwieja in Israel and New York, as part of the

continuing scheme to make BSC's past regulatory behavior comport with BSC's defense of Defendants' alleged conduct.

146. Defendants' fraudulent portrayal of BBD as a vendor raised some questions at BSIL. On March 1, 1999, a BSIL employee who was not part of the conspiracy inquired about BBD from her boss Joe Bree (who was part of the conspiracy):

"Joe,

With regards the above vendor [BBD Limited] can you complete the attached form and have it signed off by the relevant areas. . . .

To be honest I got a shock this morning to see a vendor up on out [sic] AVL [Approved Vendor List] and nothing ringing a bell with me - I would die if an auditor was to print off AVL and to pull on that one and me not having a clue about the vendor.

* * *

Can you please ensure that you leave the putting of a vendor up on the system to John or myself in the future as it causes a lot of confusion when the access is giving around the plant as you can imagine." (Exh. 40.)

Bree, who was part of the conspiracy, responded that he would deal with that vendor.

147. Defendants deliberately filed a false PMA.

148. As required by the Supply Agreement, Medinol was given the opportunity to review the PMA before its submission to the FDA. In January 1998, Defendant Rosenthal mailed to Medinol a draft of parts of the PMA for the NIR ON RANGER™ Premounted Stent System that related to Medinol. This draft incorrectly described BSIL as manufacturing panels and stents. Medinol commented that BSIL merely performed incoming inspection on finished stents received from Medinol and intended for the U.S., and did not manufacture the stents. BSC told Medinol that it would correct the characterization of BSIL, and in fact removed from the section reviewed by Medinol the description of BSIL as manufacturer. However, Defendants included the false and misleading description of BSIL as manufacturing stents and the plan to validate the BBD manufacturing in another section of the PMA, which described BSIL manufacturing and which was not sent to Medinol for review.

149. Defendants thereafter caused to be mailed to the FDA a PMA application, dated January 27, 1998, signed by Rosenthal, that portrayed BSIL as a stent manufacturer and Medinol as a supplier/vendor. The same PMA application also included a detailed description of arrangements that BSIL had with vendors including commitments and an audit, entered into by all BSIL's vendors. Medinol was never subject to such arrangements.

150. Defendants also made false statements to the FDA about Medinol's tests. On April 2, 1998, BSC's Bruce Beauchemin sent a fax to a Boston FDA inspector stating that the NIRVANA IDE Clinical Trial (the "Trial") "was conducted as a cooperative effort between several different organizations" under BSC responsibility. In fact, the Trial was conducted, managed and fully funded by Medinol and the results were owned by Medinol. When Medinol learned of the fax, it urged BSC to correct the misleading statements and honor the Supply Agreement. After repeated pleas by Medinol, BSC mailed a corrective letter to the FDA clarifying that the NIRVANA Trial was conducted and managed by Medinol. Defendant Rosenthal faxed a copy of this to Medinol via wire from Natick, Massachusetts to Tel Aviv, Israel on May 18, 1998. This letter falsely represents that there were "no hidden agendas". In fact, Defendants' effort to take ownership of the clinical study and results were part of their regulatory fraud.

151. On April 22, 1998, Rosenthal used the wires and sent a facsimile to Medinol, from the U.S. to Israel, attempting to downplay the importance of the PMA application for NIR on RANGER™ Premounted Stent System that misrepresented Medinol's role. Rosenthal urged Medinol not to contact the FDA directly, falsely claiming BSC was correcting it and that it wanted to avoid having "FDA (central)" involved. (Exh. 28.)

5. BBD Diverts BSC From Its “Primary Platform”

152. Defendants’ involvement in BBD diverted BSC’s attention from its obligations under the Supply Agreement to concentrate on the NIR® as its “primary platform”. In Section 2.11 of the Supply Agreement, BSC promised to “use all commercially reasonable efforts to promote and market Stents developed by or for Medinol in all significant markets”. Further, Section 3.02(b) of the Supply Agreement requires BSC to “concentrate its Stent business on the development, marketing, distribution and sale of NIR Stents and other Stents developed by or for Medinol under this Agreement”.

153. BSC correctly recognized that this created an obligation “to concentrate on the NIR platform as [its] primary platform”. These are the words of Defendant Best on October 17, 2000. Defendants, including Best, ensured that BSC did not comply with that obligation.

154. First, BSC’s intentional diversion of its plans and priorities from the “common objectives” to focus on BBD resulted in various delays in BSC’s fulfillment of its obligations to Medinol.

155. On July 9, 1996, Berman sent Medinol a letter listing the personnel who would focus their efforts on the work of the Medinol/BSC venture. (See Exh. 6.) Many of these individuals subsequently focused their efforts on BBD.

156. BSC failed to discharge its responsibilities to Medinol because it made its “secret capacity” the number one priority. Indeed, an October 27, 1998 Project Prioritization listed this capacity as the “priority #1 project”. (Exh. 33.) BSC continued to make BBD the “priority #1 project”, even though the reference to BBD was “cross[ed] off” the “new stent project priority list” because it “is a very sensitive subject and should

not be discussed openly”. (Id.) Similarly, in an October 14, 1998 e-mail to Paidosh, Dan Adams wrote:

“As you know in dealings with Medinol it is vary [sic] difficult to get much attention as we have no credible alternative to the NIR stent. It seems the highest priority that we get full capability to make the NIR. As I understand it from Chuck Euteneuer the issue is a qualified etcher. Where are w[e] at? How can we get this going fast and good? What help can I give to this effort? If we can get this process qualified we can deal with issues from a strength standpoint.” (Exh. 32.) (Emphasis added.)

157. Adams replacement, Fred Colen, took over this scheme to implement the “highest priority”--BBD--and to make BSC independently capable of manufacturing the NIR® stent.

158. BSC realized that its diversion of resources would damage Medinol. Therefore, it was BSC’s plan, if BBD failed, to achieve the same result (i.e., independence from Medinol) by acquiring Medinol at a discount. The alternative plans were discussed in a September 8, 1999 e-mail sent by Toohey:

“Perhaps with Jim Tobin’s intent to buy Medinol [Project Independence] may not be seen as a priority but, on the other hand, it seems to me like the right contingency plan to have in place in case anything goes wrong.” (Exh. 51.)

159. The diversion of priorities has caused substantial delays, resulting in enormous economic loss to Medinol. BSC delayed development of the delivery systems necessary to sell and gain regulatory approvals for Medinol’s stents. These delays were caused by, among other things, BSC’s diversion of priorities and plans from the venture to BBD (and to BSC’s other stents, discussed below). A substantial portion of Medinol’s damages was caused by BSC’s delays in introducing products to the marketplace, which caused loss of market share for various Medinol NIR® stents, lost profits and harm to Medinol’s reputation as a leading innovator.

160. BSC's delays resulting from its diversion of priorities to BBD (and to BSC's own stents) manifested themselves in at least the following ways:

(a) In 1996, BSC caused delay in the introduction of the premounted stent system, the NIR PRIMO™, in Europe. Premounted stent systems at that time accounted for eighty to eighty-five percent of the stents sold in Europe. BSC failed to develop a delivery system for the NIR PRIMO™ in a timely manner, thereby delaying its introduction in Europe by almost one year and resulting in a significant loss of market share. This failure also prevented the presentation of the premounted NIR® system at the Thorax Center Conference in Rotterdam in December 1996 and ETC Conference in Toulouse in May 1997.

(b) Despite Medinol's repeated requests for the delivery system, Medinol's advance warning in September 1996 and BSC's knowledge of Medinol's intent to launch its US IDE Trial, NIRVANA, for the NIR® stent, BSC did not develop the system in time for this trial and the trial was performed late and on a European delivery system (NIR PRIMO™, which BSC did not have the right to use in the U.S. at the time). This led to the need for two more trials to approve the U.S. delivery systems (NIR ON™ Ranger™ and NIR ON™ Ranger with SOX™). BSC's failures led to a year-long delay in the NIR®'s introduction in the United States, resulting in great financial loss, loss of market share and damage to Medinol's reputation.

(c) BSC failed until 2000 to develop a delivery system for Medinol's large vessel stent to be used also for Saphenus Vein Graft ("SVG"), which was already developed and available in 1996 and approved for use in the IDE Trials in 1996. BSC tried to sell its own Radius stent in Europe under the name "Makros" for that application, claiming there was no NIR® system for this application. During the time of BSC's failure to develop a balloon system for the venture, Medinol's large

vessel and SVG stent was the only known system that could go up to the five-millimeter diameter range and the only stent for large vessels approved for trials in the U.S. by the FDA. Hence, the venture could have captured a large share of the SVG stents sold were it not for BSC's decision to undertake BBD and to develop and market its competing stents instead of fulfilling its obligations for the venture.

(d) Medinol was prepared to sell its NIROYAL® gold-plated Radiopaque stent in Europe in February 1997, and had presented this stent to an eager audience in Rotterdam in December 1996 at the most important worldwide stent conference. However, BSC again delayed in developing a delivery system for this unique stent, designed to be visible under x-rays, a critical requirement of cardiologists.

Because of BSC's delays, the NIROYAL® was first marketed more than a year late in May 1998, and ineffectively as a bare stent that addressed, at that time, less than five percent of the market. BSC first marketed the pre-mounted NIROYAL®, which captured more than fifty percent of NIR® sales rapidly after its introduction, in 1999 in Europe and in 2000 in the United States, more than two and three years, respectively, after it was completed and presented in conferences by Medinol.

(e) BSC has failed to develop a delivery system for Medinol's 5-Cell Stent optimized for small vessels (the "NIR® PRINCE"), presented at Rotterdam in 1996, and tested in a pilot trial in human patients in the first half of 1997.

Medinol, by manufacturing this stent designed for small vessels, was two years ahead of the competition in its recognition and development of a stent for this application. Now, four years later and after competitors have already introduced such stents into the market, BSC still has not launched a system for small vessel stents.

(f) BSC has failed to develop a competitive delivery system for Medinol's NIREnal® Stent, which was tested very successfully in pilot studies in human patients as early as 1998. BSC has delayed its qualification and market release.

(g) BSC has failed to develop a delivery system for the NIR Conformer™ stent. The NIR Conformer™, Medinol's new generation, improved stent, was designed to conform with the contours of the blood vessel more closely than Medinol's former stents. Medinol intended this innovative product to represent its "next generation" stent for sale in Europe and the U.S. Medinol first manufactured the NIR Conformer™ stent in early 1997. In recognition of the strategic importance of this stent, the BSC/Medinol Steering Committee agreed on September 30, 1997 that "Medinol will transition all production to Conformer on October 5, 1997". Despite this agreement on the importance of the NIR Conformer™, the shipment by Medinol of more than 100,000 such commercial stents to BSC in 1997 and repeated pleas by Medinol to BSC to develop the balloon system, BSC failed to deliver on its obligation, delaying the introduction of the NIR Conformer™ stent by as much as three years. Moreover, BSC had refused Medinol's request to market a NIROYAL® Conformer™ stent, insisting on a focus, instead, on a NIROYAL® regular stent. BBD was not, at the time, capable of manufacturing Conformer stents.

(h) BSC and Medinol planned to launch its NIR ON™ Ranger™ system, a pre-mounted stent system, in the United States in the second-half of 1997. Medinol discussed this launch with BSC as early as May 1996 and, during a September 30, 1997 Steering Committee meeting, BSC committed to provide NIR ON™ Ranger™ systems beginning in October of 1997. BSC failed to supply U.S. systems for the IDE; then delayed the supply of NIR PRIMO™ systems by using 1,435 of the IDE stents for marketing in Europe; and for more than a year, delayed

the development of NIR ON™ Ranger™ systems. All these failures resulted in the launch of the NIR® in the United States about a year later than the original plan (from 1997 to August 1998).

(i) Medinol proposed to BSC the concept of using SOX™ for the NIR® stent in February 1996. However, BSC failed even to begin developing the system until more than a year after this February 1996 meeting. Then, BSC delayed the delivery date three separate times from June 1997 and delayed submission of the PMA so that the product was not introduced until August 1998, after which BSC's quality problems led to a recall of the system.

(j) The introduction of Medinol's 9-millimeter length stents in the United States was delayed by more than a year due to BSC's failing to develop a delivery system on time. This crucial delay prevented the Medinol/BSC venture from participating in the short stent segment, which represented about 17-20 percent of the market.

(k) BSC has had, from Medinol, the regular NIROYAL® stent since 1997, and the Conformer NIROYAL® stent since 1998. However, BSC delayed filing for FDA approval in the U.S. until April 2000 because it had failed to complete development and validation of delivery systems. Even that April request for approval only covered three lengths of this stent because BSC has failed to develop delivery systems for the three additional lengths. When the FDA approved these three lengths in August 2000, BSC was, again, not ready to launch the product. BSC has only recently announced, on February 6, 2001, that it will now begin to launch this product. These delays have caused a drastic decline in market share for the venture.

(l) BSC delayed (and delays to the present time) in developing a delivery system for Medinol's new and inventive NIRFLEX™ stent, a fourth generation

stent. Medinol had this revolutionary stent at the beginning of 2000, with a joint plan to complete the delivery system and make it ready to be launched in Europe in the third quarter of 2000 and in the United States in the first half of 2001. Medinol completed delivery of the NIRFLEX™ and up to May 2000 sent to BSC more than 2,000 stents. When BBD was revealed, BSC refused to commit to regulatory cooperation. The launch of this stent has been delayed indefinitely by BSC, as part of its attempt to put pressure on Medinol to sell its assets to BSC at a discounted price.

161. Second, BSC's recall of the NIR ON™ Ranger™ with SOX™ resulted from BSC's diversion of priorities and attention from the NIR® stent.

(a) BSC received FDA approval to market the NIR ON™ Ranger™ with SOX™ stent in the United States in August 1998.

(b) On October 5, 1998, BSC announced that the NIR ON™ Ranger™ with SOX™ stent was being voluntarily recalled. The recall resulted from reports of balloon leakage at a pressure lower than the Rated Burst Pressure ("RBP"), a product specification which the FDA requires to be placed on the package which indicates a pressure level under which the manufacturer assures the user that the system will not fail.

(c) The leaks resulted from the formation of pinholes in the balloon caused by changes in the manufacturing processes in BSC, specifically those of balloon manufacturing and stent crimping process. Indeed, BSC reported this to the FDA in connection with a PMA supplement requesting the approval of re-launching the NIR ON™ Ranger™ with SOX™.

(d) Mounting the stent on the delivery system was BSC's obligation. BSC's failure to have ready at that time an appropriate mounting system caused the balloon leakage.

(e) BSC's bad-faith refusal to accept responsibility delayed the re-launch of NIR ON™ Ranger™ with SOX™ by more than a year.

162. Third, Defendants' operation of BBD affected the manner in which BSC carried out its obligations to make periodic forecasts of the number of stents to be ordered and to purchase stents according to those forecasts.

163. Defendants in 1997-1998 used fake forecasts because of BBD. Thus:

(a) Defendants provided Medinol with forecasts for stents based on estimates of the size of the worldwide stent market and of the venture's share of that market that were significantly lower than the estimates of others in the industry. BBD was the reason. In fact, Defendants had more accurate forecasts that were used internally but concealed from Medinol. The cumulative shortfall in BSC's forecasts was equivalent to the monthly amount of stents (approximately 45,000) that Defendants expected to manufacture in BBD. Defendants, in forecasts to Medinol and others not in on the fraud, omitted part of the forecast to be supplied by BBD.

(b) During 1997-1998, Nicholas and Berman represented to Medinol by mail that BSC's forecasts represented BSC's honest assessment of market conditions. These representations were false.

164. Defendants' involvement in BBD affected the purchase orders for stents that BSC sent to Medinol. For instance:

(a) In a meeting at BSC on September 8, 1997, Corbett made a false presentation to Medinol that BSC had as a "Key Objective" to "[d]evelop sales and marketing strategy" for the NIR Conformer™ and NIR ROYALE Conformer™ stents and that BSC sought to "[g]et Conformer to market", when BSC really had no interest in marketing NIR Conformer™ stents.

(b) Although BSC had been ordering Medinol's regular stents since the onset of the venture, on October 20, 1997, BSC's purchase order changed dramatically from requesting regular stents to ordering Medinol's new NIR Conformer™ stents. In fact, BSC's purchase order to Medinol for October, November and December 1997 stated that it was "assumed that all future deliveries are of [Medinol's newly developed] Conformer Stent type".

(c) Medinol advised BSC against ordering only new NIR Conformer™ stents, given that BSC did not appear to be ready to deploy a NIR Conformer™ delivery system and that it would be costly and complicated to revert back to the production of regular stents.

(d) In a series of communications using the mail and wires, Defendants misled Medinol. In a letter from Corbett to Medinol faxed on September 24, 1997, BSC confirmed that it would "convert all production of coronary NIR® stents to 'CONFORMER'® design". In a letter faxed by Collins on October 15, 1997, Defendants falsely represented to Medinol that BSC was requesting the NIR Conformer™ stents for the purpose of marketing them in the ordinary course of business pursuant to the Supply Agreement. Medinol therefore began to ship the NIR Conformer™ stent to BSC on November 13, 1997.

(e) In fact, BSC requested the NIR Conformer™ stents in an attempt to cause Medinol to fall short of its obligations under the Supply Agreement and improperly give itself the excuse to manufacture stents. BSC also wanted to stockpile NIR Conformer™ stents, so that it could sell them along with the BBD stents after achieving independence from Medinol, until such time that it would be able to copy Medinol's NIR Conformer™ stents at BBD. BSC's intent to cause Medinol to fall short on the NIR Conformer™ stents is made clear by the fact that it did not sell, until May 2000, most of those stents ordered beginning in 1997.

(f) On December 22, 1997, BSC changed course again. It asked Medinol to ship 45,000 regular stents, rather than the NIR Conformer™ stents that it had been ordering. Defendants had failed to get the BBD manufacturing ready to supply regular NIR® stents in time. At great burden and expense, Medinol reverted back to the production of regular stents, not knowing that this burden was created by Defendants' theft of Medinol's property.

165. Fourth, Defendants used the Secret Line improperly to supply BSC with stents. For example:

(a) R&D stents. Defendants began using the Secret Line to develop stents to be used for Research and Development ("R&D") at Scimed. BSC would achieve cost savings by using BBD stents for R&D instead of Medinol stents, which sold for \$75 per stent. Stenzel proposed such a use to Paidosh in an April 19, 1999 e-mail:

"It came to mind during the meeting today organized by Matt that BBD could play a part in supplying R&D with stents used for trials. Matt mentioned later that their lasers are making about 300 - 400/week for Scimed but that laser cut ones are not representative of etched and Welded.

We are close to finalizing the standard NIR now

Would you like me to start drafting up some of the other parts such as NIR SIDE, renal 5 cell, conformer, etc. . . ." (Exh. 42.)

Hackett of Scimed also asked Paidosh about R&D stents on November 4, 1998:

"I also am curious to hear your thoughts on building some R&D stents for us and targeting a range of cross section dimensions. These stents would be necessary for us to verify/correct our calculations and improve upon system performance. . . . This work will also be done with Kobi eventually, but I fear it will not start for some time and turnaround times will be long." (Exh. 34.)

Paidosh responded that he "would be happy to try making some stents for" Scimed. (Exh. 34.) Stenzel told Paidosh "that BBD could play a part in supplying R&D with stents used for trials". He noted in an April 19, 1999 e-mail that BBD was

close to finalizing the standard NIR® stent “as we have had 9 cell acceptable from Micrometallic and the 7 cell acceptable from Microponents”. (Exh. 42.)

(b) Pretending BBD was an independent vendor. On April 28, 1999, Stenzel provided Fred Colen of Scimed with samples of NIR® stents manufactured by BBD “as discussed” during Colen’s visit. Stenzel’s transmittal letter indicated that Stenzel worked for “BSIL / BBD” and identified the enclosed samples as including items from Medinol and BBD. (Exh. 44.) Obviously he was told that he did the wrong thing. On April 30, 1999, Stenzel sent Colen a revised transmittal letter deleting all references to Medinol, NIR®, BSC, BSIL and BBD. (See Exh. 44.) Stenzel pretends in this April 30, 1999 letter to Fred Colen that there was no meeting and no relationship between BBD and BSC:

“Thank you so much for contacting us regarding the range of mesh patterns we manufacture. From our conversations over the last few days, I am confident that our manufacturing capabilities and products can meet your requirements.

To highlight our manufacture capabilities, I enclose a few samples of mesh patterns we have manufactured in the past with various stages of processing. The samples we enclose were selected because they appear to be similar to the mesh design you described.

These samples have been manufactured using a special grade of 316 stainless steel that has been ultra purified by subjecting the standard 316 L grade to a laser remelting process in a vacuum which drives unwanted impurities from the material.

To highlight the range of capabilities we currently offer our customers, the samples enclosed indicate various processing capabilities such as photochemical etching, folding, welding, electropolishing, and gold plating to name a few.

We look forward to receiving a copy of one of your drawings in order to allow our offering a quotation for your review. I am confident that you will be more than satisfied with the price, delivery, and quality that we will offer.

Should you have any questions or comments, please do not hesitate to contact us for any assistance or service we can offer.”

(c) “Knock off” stents. In March 2000, Scimed asked Stenzel whether BBD could use the Secret Line to manufacture “Knock off” stents for Scimed’s research and development purposes. Stenzel forwarded the request to Champaud. He noted:

“In summary, I would like to mention the following:

BSC NIR stent production line - Discuss potential savings in using these stents instead of the \$75 Medinol stent where possible.

Flex/Conformer stent - Discuss the benefit of BSIL getting chemically etched panels from Medinol.

Harmony - Discuss the benefit of pursuing the flex, S\$, and Conformer stent designs.

Stent Development - Discuss the benefit of our sharing stent development projects to increase efficiency.” (Exh. 56.)

The “flex” stent discussed in this e-mail is the NIRFLEX™, Medinol’s newest stent. This shows how the plans to steal Medinol’s property was a continuous one, targeting even Medinol’s last-generation design.

(d) Proposal for using BBD stents in BSC. On April 6, 2000, Stenzel sent Champaud a proposal for R&D stent supply. Stenzel suggested that the conspirators “begin investigation into the use of the BSC stent manufacturing line [i.e., the Secret Line] as a means of supplying the R&D \$75 stent to the company”. (Exh. 57.) He then noted that during the period in which BSC was seeking Medinol’s support for using the Alternative Line to make R&D stents, “the BSC NIR line [i.e., the Secret Line] can be used in conjunction with Scimed’s laser line to supply ‘Knock off’ style stents to [BSC]”. (Id.)

(e) Use in animal studies. On April 24, 2000, after BBD was revealed to Medinol, Scimed contacted BSIL via e-mail:

“Marlene Schwarz needs to do some in vivo release studies, however there are some delays in getting the next batch of stents from Medinol. We were

wondering if the quality of the stents that BSIL produced would be adequate for this animal work. . . .

I'm guessing they will be ok. The laser cut NIR stents produced at Scimed were equivalent to Medinol NIR's when evaluated in swine coronary." (Exh. 59.)

The names used in this message are unknown to Medinol and appear to be pseudonyms.

166. Fifth, the BBD scheme kept BSC from honoring other aspects of the venture. For example, despite a detailed agreement by the technical personnel of BSC and Medinol that BSC would implement a sampling mode of testing--an agreement that contained detailed procedures (developed at great expense to Medinol) for inspecting each manufactured lot--BSC never implemented the sampling mode. Instead, BSC continued to perform inspection on 100% of incoming stents while telling Medinol it would implement sampling mode inspection. This decision was part of BSC's fraudulent plan to present Medinol as a supplier/vendor in direct violation of the agreement between the companies and their quality managers.

C. BBD: Defendants Cover Up Their Theft and Fraud (Even After Outside Auditors Insisted on Disclosure)

167. In December 1999, Jim Taylor requested Dr. Kobi Richter's cooperation in solving manufacturing problems and asked him to come to Galway, Ireland for three days in February to tour the facilities. On January 26, 2000, at a meeting in Natick, Massachusetts, Taylor told Dr. Richter that, although he was still invited to come, Taylor would be so busy in Ireland that he could only devote a half-day (not the three days originally planned) to meet with Dr. Richter. Dr. Richter went to Ireland anyway and briefly met with Taylor on February 14, 2000 in Ireland. Taylor, after Tobin's partial disclosure of BBD in April 2000, revealed to Medinol that he had intended to show BBD to Medinol in the February 2000 visit, but that he had been directed not to make this disclosure.

168. After Tobin's partial disclosure, Taylor also asked Medinol's help to clean up BSC's problems by assisting Taylor in his battle for Tobin's "ear", a battle that he stated was being waged against other BSC employees, including Best, who had played a key role in the fraud.

169. Defendants' fraud was also detected by Ernst & Young, BSC's outside auditors. BBD had been filing false financial statements that failed to reveal its ties to BSC. An e-mail exchange between two auditors at Ernst & Young demonstrates the problems facing Defendants in April 2000. One auditor wrote:

"Forwich Limited is a 100% subsidiary of Boston Scientific Limited. 100 Shares are in issue which are held in Trust by two individuals on behalf of Boston Scientific Limited, the beneficial owner. These individuals are the current Directors of the company. The clients rationale in relation to same was to break the relationship between both companies.

We have issue draft accounts and noted in the Parent Undertaking note that the company is a 100% subsidiary of Boston Scientific Limited The [sic] client has now asked us to reconsider this disclosure.

Is there ant [sic] way we can avoid the disclosure in our Audit Report if the client insists on the removal of the note from the Accounts." (Exh. 58.)

The other Ernst & Young auditor responded:

"There is no way that disclosure can be avoided in the financial statements." (Id.)

Accordingly, Ernst & Young required BBD to restate its financial statements so that BBD's ties to BSC and BSIL would be disclosed. In April 2000, BBD issued restated financial statements for 1998 and 1999.

170. When BSC saw that public disclosure of BBD was inevitable, it decided to disclose, in part, the existence of BBD to Medinol.

171. On April 21, 2000, Tobin told Medinol about BBD and disclosed--partly--Defendants' illegal activities. Tobin committed to a policy of Open Door/Open Files and to stop the unlawful activity. Tobin stated, referring to BSC's management and

employees, that he had not known that he was involved with “such crooks” and that he was “ashamed to represent such a dishonest company”.

172. Tobin told Medinol that, upon learning that Medinol had been told about BBD, Best said: “We scr**** up. What do we do now to make it go away?” Tobin also stated that when he had discussed the disclosure of BBD with Nicholas, “Pete acted as if he had amnesia, selective amnesia”.

173. On or around May 26, 2000, pursuant to Tobin’s commitment of Open Door/Open Files, Art Gates and another BSC representative met with Medinol and disclosed the findings of an alleged internal investigation. Gates falsely represented that BSC had made a complete disclosure of all details about BBD and falsely represented that BSC intended to give Medinol all documentation concerning this investigation.

174. BSC has not, in fact, honored Tobin’s commitments in at least five respects.

175. First, BSC did not stop BBD. Contrary to Tobin’s representation, BSC continued with its plan to manufacture Medinol’s NIR® stents on the unauthorized BBD line.

176. Second, BSC has not fully honored the Open Door/Open Files commitment. BSC has not provided all BBD documents wherever they are located. Moreover, BSC concedes that it has withheld documents on claims of privilege. But BSC is not entitled to make any such claim of privilege because of the crime/fraud exception and because of its waiver of the attorney-client privilege by virtue of a May 26, 2000 meeting that Gates had with Medinol.

177. Third, Defendants have continued to make false representations to the FDA.

178. Despite Nicholas’s commitments on April 24, 1998 and July 19, 1999, BSC made submissions to the FDA without discussion with, and agreement of, Medinol.

179. Throughout 2000, Medinol repeatedly asked BSC to stop making these submissions. BSC has not stopped this conduct.

180. In a meeting on November 12, 2000, Tobin told Dr. Judith Richter and Dr. Kobi Richter that the content of the regulatory submissions was being determined on the advice of BSC's attorneys in connection with an effort to ensure that BSC's regulatory behavior comported with BSC's prior actions, i.e., a cover-up. In a subsequent meeting on March 20, 2001, Tobin said that Dennis Ocwieja (BSC's vice-president of regulatory affairs) is very frustrated and unhappy to have to work under the instructions of lawyers rather than according to the accepted professional standards.

181. On November 12, 2000, Tobin promised Medinol that cooperation on regulatory matters would return to the manner envisioned in the Supply Agreement. This included permitting Medinol to comment on all FDA submissions, ensuring that Medinol and BSC jointly agreed to what would be sent (and if there was no agreement, to inform the FDA of Medinol's contrary opinion), and to restore the PMA cover-letters to their pre-January 2000 form with language indicating proper ownership and responsibility of Medinol. A November 21, 2000 letter sent by e-mail from BSC's Dennis Ocwieja refers to "Jim Tobin's commitment" and requests Medinol's review and comment on upcoming FDA submissions. BSC has not honored that commitment. Instead, BSC merely changed a recently-submitted PMA cover letter to make it appear as if they were cooperating as they ought and that Medinol had approved the content of the PMA. But, BSC was not acting in accord with Tobin's promise and it did not change the content of the PMA.

182. After April 2000--while Medinol was still waiting for BSC to commit to proper regulatory cooperation--BSC's improper FDA communications included the following:

(a) On July 12, 2000, BSC filed two PMA supplements without Medinol's authorization. The supplements do not accurately reflect Medinol tests or Medinol's manufacturing, ownership and participation.

(b) On July 13, 2000, BSC submitted an unauthorized 510(k) filing for Medinol's NIR® Biliary stents.

(c) On July 29, 2000, BSC conducted a conference call with the FDA with respect to restenotic lesions without Medinol's approval or knowledge. After that call, Medinol learned that BSC changed the labeling of the NIROYAL® Elite that removed the indication for restenotic lesions. Due to BSC's conduct, Medinol lost valuable market opportunities for the NIROYAL® Elite stent, a move that could have been prevented had BSC kept its obligation to have Medinol personnel, who were knowledgeable about the stent, participate in the call.

(d) On August 2, 2000, BSC sent a submission to the FDA for the NIR® Elite Monorail.

(e) On October 12, 2000, BSC mailed an Amendment to the FDA without making corrections.

(f) BSC made three submissions in December without including most of Medinol's comments: a December 19, 2000 submission to the FDA of an Amendment for the NIROYAL® Elite Monorail's additional sizes; a December 19, 2000 Amendment to the NIR® Elite; and a December 20, 2000 NIROYAL® Biliary Premounted Stent System.

183. Fourth, Defendants are trying to kill the Medinol/BSC venture in order to buy Medinol cheaply. BSC has stopped moving forward with its development of

products for the venture. (See, e.g., ¶¶ 152-160, supra.) BSC has taken these steps to injure Medinol so that it can purchase Medinol at an artificially depressed price.

184. Fifth, Defendants have falsely blamed Medinol for BSC's problems of failing to get products to market. Just as Defendants' continued false regulatory submissions have been motivated by a desire to cover up their wrongdoing, so too have Defendants' false statements to the media. Medinol has always fulfilled its obligations, as Medinol has always worked towards the venture's "common objectives". Following the disclosure of the BBD deceit, however, and in an attempt to shift the blame away from their own wrongdoing, Defendants have engaged in a pattern of making false statements to the media suggesting that Medinol is responsible for BSC's failure to fulfill its obligations.

185. BSC has falsely told the media that BSC's problems are due to a problem of "relationship" with Medinol. This effort by BSC to smear Medinol--in addition to shifting blame from BSC's own wrongdoing--promotes Defendants' goal of acquiring Medinol cheaply.

D. Defendants' Other Promotion of Their Own "Objectives" at Medinol's Expense and Without Medinol's Knowledge

186. The BBD deceit was part of a wider pattern of misconduct by the Defendants to further their own "objectives". Thus, while Medinol was promoting the "common objectives" of the venture, Defendants pursued their own "objectives". Most of this conduct was directed at, and succeeded in, BSC's destruction of Medinol's rights.

1. Destruction of the Symmetry of the Medinol/BSC Venture

187. Medinol and BSC set up their venture so that each would be protected, and would be able to continue to reap the benefits of the Medinol/BSC venture. For example, as described above, BSC was given the right to have an Alternative Line established and to run that Alternative Line in the event that Medinol failed to meet specified supply obligations; BSC, in its application for a PMA for the NIR® stents, was required to designate Medinol as an additional manufacturer for purposes of the PMA and to submit a PMA supplement to list Medinol as an additional distributor of NIR® stents in the United States; and, if, following the termination of the Medinol/BSC venture, BSC retained no license from Medinol under the Supply Agreement, BSC has to assign the PMA to Medinol. Similarly, the Supply Agreement obligated both Medinol and BSC to disclose to each other all inventions, ideas and improvements relating to stents. Under the Supply Agreement, BSC had an obligation “to promptly report and disclose” to Medinol “all inventions, ideas and improvements relating to stent development”. Indeed, BSC has a contractual obligation to sue to enforce Medinol’s intellectual property rights or “fully cooperate” in any lawsuit instituted by Medinol. (Supply Agreement § 9.04.)

188. BBD is the most obvious example of BSC destroying the symmetry between it and Medinol. However, it is only one example. BSC’s pattern of cheating Medinol, misappropriating for its own benefit assets and opportunities of Medinol and the Medinol/BSC venture, limiting Medinol’s ability to make use of these assets and opportunities in case of BSC’s failure, carelessness with Medinol’s property and rights, and other symmetry-destroying behavior is also evident in the following four examples:

189. First, Defendants have simply ignored their reciprocal obligations. This was an integral part of the BBD deceit. Defendants’ failure to name Medinol as an additional manufacturer and additional distributor in connection with the PMA

undermined Medinol's ability independently to market its stents in the United States upon learning of Defendants' misconduct.

190. Indeed, it was only once they knew BBD would be revealed that Defendants offered to begin taking the contractually-required steps to give Medinol independence, namely designating Medinol as an additional manufacturer. On April 10, 2000, just before the disclosure of BBD to Medinol, BSC's assistant general counsel, Lawrence Knopf, faxed a letter to Medinol (which included a draft of a letter from Tobin to Medinol) falsely representing that BSC "is committed to designating Medinol as an additional manufacturer for purposes of the NIR® coronary stent system PMA". BSC knew that it was not committed to so designating Medinol and made this representation only because it knew that it was about to disclose partially the BBD deceit to Medinol. In fact, however, more than eleven months later, BSC has still not so designated Medinol or acted to enable such designation.

191. Moreover, BSC continues to make false representations to Medinol that it understands its clear obligations and that it intends to honor them. For instance, in a June 5, 2000 letter, Tobin falsely assured Medinol of his intention to supplement the PMA's to "enable BSC and Medinol to become, after a transitional supply period, independent manufacturers and distributors of stent systems". (Exh. 61.)

192. Second, BSC failed to report and disclose its applications for a number of patents, including the application that resulted in U.S. Patent No. 6,042,597; U.S. Patent Application No. 09/111,531 (published in the Patent Cooperation Treaty ("PCT") as Application PCT/US99/15122); and U.S. Patent Application No. 09/151,053 (disclosed in the PCT publication as PCT/US99/20383). In connection with each of the patent applications, BSC misused its knowledge of Medinol's intellectual property, which Medinol has disclosed to BSC in connection with the Medinol/BSC venture. Moreover, BSC never disclosed to Medinol the stent intellectual property it claims to have received

from Guidant from which BSC has developed its Express stent. This failure to “promptly report and disclose . . . Stent developments” to Medinol is a breach of Section 2.07 of the Supply Agreement. (Supply Agreement § 2.07.)

193. Third, BSC chose to work out a deal to its own benefit in a lawsuit that implicated Medinol’s contractual and patent rights. In working out this deal for itself in a lawsuit with Guidant, a competitor of the Medinol/BSC venture, BSC, despite Medinol’s written objection, covenanted not to sue Guidant for patent infringement in breach of Section 9.04 of the Supply Agreement.

194. In exchange for this unauthorized purported waiver of Medinol’s contractual rights, BSC claimed to have received from Guidant a license to stent intellectual property. BSC has announced in a February 6, 2001 Web-cast conference call with the investment community that, from this wrongfully-obtained technology, BSC has developed its own stent, the Express stent, to which it has devoted substantial time over the past months. As Defendant Best declared in this call, developing this stent was “an insurance policy” in case BSC’s plans with respect to Medinol failed. This “insurance policy” was initiated at the time when BSC knew that it would soon have to disclose BBD.

195. Fourth, BSC has been improperly indifferent to protecting Medinol’s confidential intellectual property and trade secrets against theft even by persons other than the Defendants.

196. For instance, BSC failed to take adequate steps to prevent its former employees from making improper use of Medinol’s confidential intellectual property and trade secrets. Thus, two BSC employees, including the head of stent marketing in Europe, who received Medinol’s confidential intellectual property and trade secrets left BSC in 1996 and started a competing company using Medinol’s proprietary information and trade secrets, to manufacture a NIR knock-off, thereby damaging Medinol.

197. Similarly, in the summer of 1996, Defendants began to alter the packaging of the stent systems marketed by BSC on behalf of the venture by, for example, no longer referring to Medinol as a manufacturer. In communications sent by facsimile, including a May 14, 1996 letter from BSC's Stacy Exing Seng to Dr. Judith Richter and a June 13, 1996 letter from BSC's John Sherry to Medinol, BSC falsely told Medinol that this was being done for regulatory reasons.

2. Promotion of BSC's Own Inferior Stents While Delaying Market Introduction of Medinol's Stents

198. In addition to diverting priorities and efforts to BBD, Defendants also wrongfully diverted priorities and efforts to the development and marketing of a competing and inferior stent--the Radius stent manufactured by Scimed--and other inferior stents, such as BSC's newly announced Express stent. BSC has wrongfully diverted its research and development and marketing efforts from NIR® stents to BSC's own stents.

199. Motivated by a desire to complete the Radius IDE before the NIR® IDE, BSC intentionally or recklessly handled NIR® data as a means of sabotaging the 1997-98 IDE trial for the NIR® stent, which was necessary for FDA approval to market the NIR® stent in the United States. BSC then submitted the Radius PMA to the FDA prior to the NIR® PMA. Later, when the FDA asked BSC which of the two PMAs should be considered for a more expedited approval, BSC refused to choose either of the PMAs, thus further delaying entry of the NIR® stent to the U.S. market. BSC wanted to have the Radius approved before the NIR® so that the Radius could be sold in a market in which the NIR® was not approved, thereby allowing BSC to take the erroneous position that it did not owe Medinol a twenty percent royalty as mandated under the Supply Agreement.

200. Medinol has repeatedly objected to BSC's efforts to market Radius in conjunction with Medinol's stents. Radius has an inferior design. Promoting this stent erodes public and professional confidence in BSC's and Medinol's commitment to quality stents. Moreover, having two competing programs at Scimed creates an "our stent, their stent philosophy" that conflicts with fundamental goals of the venture. Similarly, giving attention to Radius diverts research and resources away from BSC's efforts to fulfill its obligations to get NIR® products to market and results in a loss of NIR® market share.

201. In a December 16, 1997 letter sent via fax and federal express from Natick, Massachusetts to Medinol in Tel Aviv, Israel, Nicholas falsely told Medinol that BSC would focus on the products of the Medinol/BSC venture and that progress on the FDA approval of NIR® would be "unimpeded by the Radius co-pending PMA". (Exh. 24.) In fact, because of BSC's efforts on the Radius stent, BSC failed to perform a required site-audit for the NIR® stent, and because of its efforts to develop a Radius stent system for large vessels, BSC failed to develop a delivery system for large-vessel NIR® stents. BSC also failed to identify for the FDA the NIR® PMA as a priority project and told the FDA that it required the promotion of the NIR® PMA and the Radius PMA in parallel. This resulted in the FDA devoting the same resources to two PMA's instead of the NIR® only, which resulted in a considerable delay in the approval of the NIR® PMA. BSC knew at the time that the NIR® had a much greater potential than the Radius, but preferred its own stent so as to gain more power relative to Medinol.

202. In the Spring of 1998, BSC planned to present the Radius in conjunction with the NIR® at a marketing meeting in Florida. When Medinol learned of this effort, it reiterated its previously expressed concerns and BSC changed the Florida meeting to a Radius-only event.

203. BSC repeatedly misrepresented to Medinol its plans and intent for the Radius stent:

(a) In May 1998, Nicholas falsely told Medinol that BSC would not move forward on Radius without agreement by Medinol. Nicholas knew at the time that BSC had other plans, and, in a late May or June 1998 Steering Committee meeting, BSC announced, without seeking Medinol's opinion, much less its agreement, that BSC was moving forward with the introduction of the Radius in the United States.

(b) At a later 1998 Steering Committee meeting, Nicholas falsely assured Medinol that, according to the agreement with Medinol, the Radius would only be offered for sale at the forty sites in the United States previously used for Radius IDE trials, sites that were already familiar with the stent, to prevent diversion of marketing efforts from the NIR® stents. But BSC actually offered Radius stents for sale in 100 sites in the United States, at Nicholas's instruction, without Medinol's knowledge. When confronted with this fact, Nicholas asked Medinol to grant him the favor of permitting Radius to continue to be distributed at these 100 sites, so that he would not have to reverse his personal orders, because this did not require additional marketing efforts. Medinol consented to these sales, after the fact, on the condition that the Radius would not be released anywhere else in the world without a written approval from Medinol, a condition that Nicholas accepted. Nicholas falsely represented to Medinol that BSC would not increase the number of United States sites, nor would it introduce the Radius stents into any other territory without Medinol's written consent. But in September 1998, Medinol learned that BSC planned to start selling the Radius stents in Europe without seeking Medinol's consent.

(c) On May 11, 1999, Nicholas wrote to Medinol to inform it that BSC had "elected to move ahead with a full scale worldwide launch of Radius". This was

also done without seeking Medinol's consent and was in violation of BSC's commitment not to introduce the Radius further without Medinol's written consent--a commitment that was given when Nicholas increased the number of sites from 40 to 100.

3. BSC's Express Stent: A Wrongful "Insurance Policy"

204. BSC announced in a February 6, 2001 Web-cast conference call with the investment community that it has devoted substantial time to developing an "insurance policy", the Express stent.

205. BSC's actions in regard to the Express stent breach the Supply Agreement in at least the following ways:

(a) In its settlement with Guidant, in order to obtain the license for the Express intellectual property, BSC covenanted not to sue Guidant for patent infringement despite the fact that BSC has a contractual obligation to sue to enforce Medinol's intellectual property rights or "fully cooperate" in any lawsuit instituted by Medinol. (Supply Agreement § 9.04.) BSC's covenant not to sue, given without Medinol's consent, is a breach of Section 9.04 of the Supply Agreement;

(b) BSC has failed to disclose to Medinol the stent intellectual property that it claims to have obtained from Guidant in breach of Section 2.07 of the Supply Agreement. BSC has a contractual obligation to "promptly report and disclose . . . Stent developments" to Medinol. (Supply Agreement § 2.07.); and

(c) BSC's attention to the Express stent has diverted its attention from its "primary platform", the NIR® stent. In Section 2.11 of the Supply Agreement, BSC promised to "use all commercially reasonable efforts to promote and market Stents developed by or for Medinol in all significant markets". Further, Section 3.02(b) of the Supply Agreement requires BSC to "concentrate its Stent business

on the development, marketing, distribution and sale of NIR Stents and other Stents developed by or for Medinol under this Agreement”. Devoting at least the past seven months to the Express stent is a breach of the Supply Agreement’s requirements that BSC concentrate on the NIR®.

206. BSC has now made its “insurance policy” its top priority, despite its contractual obligations. In a March 20, 2001 meeting with Dr. Judith Richter and Dr. Kobi Richter, Tobin stated that BSC was now fully committed to the Express stent and had no resources to commit to the NIRFLEX™, Medinol’s next generation stent. This is a material breach of Sections 2.11 and 3.02(b) of the Supply Agreement.

4. Theft of IVUS Technology

207. BSC stole some of Medinol’s non-stent intellectual property relating to Medinol’s intravascular ultrasound (“IVUS”) technology.

208. Prior to entering into the venture with BSC, Medinol began researching and developing a program for the enhancement of IVUS signal and image processing to provide better images to physicians performing vascular procedures by catheter.

209. Medinol submitted a patent application for Medinol’s unique methods of performing motion detection and image stabilization. Medinol’s IVUS imaging patent application was filed with the U.S. Patent and Trademark Office on June 18, 1997. (U.S. Patent App. Ser. No. 08/879,125.)

210. In 1994, Medinol entered into discussions with Cardiovascular Imaging Systems, Inc. (“CVIS”), of Sunnyvale, California, to develop enhancements to the CVIS systems. Medinol proposed developing signal processing software to improve the intravascular images generated by CVIS’s product. In connection with these discussions, Medinol shared certain of its confidential intellectual property and trade secrets with CVIS, subject to a confidentiality agreement.

211. On March 9, 1995, shortly after Medinol's disclosure of its intellectual property and trade secrets to CVIS, CVIS was acquired by BSC. Following this acquisition, Medinol and BSC signed Confidentiality and Non-Disclosure Agreements governing their exchange of proprietary information on IVUS research and development.

212. Over the next two years, Medinol shared its confidential intellectual property and trade secrets pursuant to the Confidentiality and Non-Disclosure Agreements and further oral and written assurances of confidentiality made by the parties, including by defendant Rosenthal, which were designed to protect the information and forbid its use in any manner except to explore mutual business relationships.

213. Medinol shared its research and confidential information and trade secrets including, among other things: a project plan for IVUS image processing delineating its proposal to solve certain image stabilization problems; Medinol's Progress Reports; and demonstration tapes of Medinol's IVUS research, which included films and images of Medinol's specific image stabilization by polar coordinates.

214. Medinol met several times with BSC staff to explain its research and development and made several confidential disclosures. Medinol also responded to specific inquiries and letters by BSC researchers regarding stabilization using different types of coordinate systems. An April 11, 1997 memorandum entitled "Summary of disclosure between Tat-Jin Teo and Medinol's Ehud Nachtomy", confirms Medinol's demonstration to BSC personnel on April 10 and 11, 1997 and details the disclosure of Medinol's proprietary and confidential work. This memo also mentioned Medinol's prior presentation to BSC staff on October 28, 1996 of similar information.

215. After BBD got under way, BSC decided to use Medinol's confidential intellectual property and trade secrets to begin development of its own improved IVUS system.

216. Rosenthal represented to Medinol that BSC was not interested in the technology. This representation was false.

217. On November 7, 1997, without Medinol's knowledge, BSC filed its application for a patent on IVUS imaging enhancement which listed as "inventors" Tat-Jin Teo and J. Steve Reynolds, the BSC employees to whom Medinol had disclosed so much of its research.

218. BSC's patent application resulted in the issuance to BSC on March 23, 1999 of U.S. Patent No. 5,885,218, which claims as a BSC innovation the procedures of performing motion detection and stabilization. These concepts are identical to those found in Medinol's patent application (submitted prior to BSC's) and those introduced and demonstrated to BSC through Medinol's aforementioned presentations and disclosures.

219. BSC has since assigned this patent to Medinol, only after a complaint was drafted and presented to BSC before filing.

220. Tobin has admitted that BSC stole Medinol's IVUS technology.

5. Failure to Meet Payment Obligations

221. BSC repeatedly failed to make or unreasonably delayed in making payments owed to Medinol, including, among other items:

(a) payments for thousands of stents delivered by Medinol and accepted by BSC in 1997 for sale in the European market;

(b) payments arising out of BSC's improper sale of 1,435 U.S. IDE stents in the European market;

(c) underpayments based on BSC's manipulation of transfer price calculations;

(d) royalties arising out of BSC's sales of some of its own stents, for example, Symphony stents not used for minimally invasive bypass procedures; and

(e) BSC's share of litigation expenses.

222. BSC also manipulated sales data within its control in order to deceive Medinol into believing that the net sales price of stents was lower than the actual price. Thus, BSC presented free promotional stent packages to Medinol as if they were a part of regular sales, resulting in improperly low payments to Medinol by BSC.

6. Interference with Medinol's IPO

223. BSC interfered with Medinol's plan to proceed with an initial public offering of its stock (the "IPO").

224. After learning of Medinol's plans for an IPO in 1997, BSC proposed that it purchase Medinol, leading to negotiations between Medinol and BSC regarding such a sale. This had the effect of preventing Medinol from completing an IPO. Defendants needed to cause the IPO to be abandoned because BSC wanted to maintain an option to acquire Medinol cheaply, certainly did not wish Medinol to have the independence required by a public company and knew that a Medinol IPO would result in the disclosure (which BSC did not want) of commercially sensitive price information on the relationship between BSC and Medinol.

225. Using the mails and wires, Nicholas, Best and Rosenthal made false representations to Medinol concerning BSC's intention to purchase Medinol should Medinol abandon its plan for an IPO. Nicholas also falsely represented to Medinol, in a March 21, 1997 letter to Judith Richter and Kobi Richter sent via mail to Israel from Massachusetts, that BSC opposed Medinol's IPO because BSC feared it would interfere with the Medinol/BSC venture.

226. Nicholas and Best, in several face-to-face meetings with Dr. Judith Richter, Dr. Kobi Richter and Medinol's bankers and lawyers, between August and December of 1997, told Medinol that BSC was interested in purchasing Medinol. Nicholas sent a fax to Medinol using the wires from Massachusetts to Israel on

August 23, 1997 stating that “acquisition [of Medinol by BSC] may remain the best option for both companies” and that “an IPO” is not Medinol’s best option since their “valuation expectation is unsupportable in today’s market”. (Exh. 13.) On November 23, 1997, Nicholas and Best signed a letter of agreement to purchase Medinol.

227. BSC and Nicholas did not (at that time) have any intention to go through with a purchase of Medinol. Apparently, at that time, BSC was making plans to purchase another cardiovascular company. In fact, BSC announced the completion of this other deal in February 1998.

228. BSC intended to interfere with and prevent Medinol’s IPO, so that Defendants’ scheme to steal from Medinol would not be disrupted.

229. Medinol devoted time and resources to plans for a sale to BSC in reliance on BSC’s representations concerning its intent to negotiate a purchase of Medinol in good faith.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF **(Breach of Contract--Supply Agreement)** **(Against BSC)**

230. Paragraphs 1 through 229 are incorporated herein by reference.

231. BSC and Medinol are parties to the Supply Agreement.

232. The Supply Agreement is a valid and binding contract.

233. BSC materially breached both the express terms of this agreement and its implied obligation of good faith and fair dealing, as expressed by the reciprocal nature of BSC’s and Medinol’s obligations in the contract. For example:

(a) BSC’s unauthorized manufacture of NIR® stents in a manufacturing facility in Ireland constitutes a material breach of Sections 2.01 and 2.02 of the Supply Agreement.

(b) BSC's disclosure and dissemination of Medinol's confidential intellectual property and trade secrets to third parties, including, but not limited to, Lumonics and at least eleven photo-etching vendors, constitutes a material breach of Sections 2.02, 9.01, 9.02 and 10.01 of the Supply Agreement.

(c) BSC's wrongful conversion of such confidential intellectual property and trade secrets for its own purposes constitutes a material breach of Section 9.01 of the Supply Agreement.

(d) BSC's failure to promote and market Medinol's stents in all significant markets and to concentrate its stent business on the development, marketing, distribution and sale of Medinol stents, in favor of its effort toward developing its own stents, constitutes a material breach of Sections 2.11 and 3.02(b).

(e) BSC's failure to deliver accurate and timely monthly forecasts to Medinol, constitutes a material breach of Section 3.01(a) of the Supply Agreement.

(f) BSC's pattern of diverting its research and development efforts and resources toward manufacturing and developing its own, unapproved stents and toward its unauthorized production in the Ireland manufacturing facility, constitutes a material breach of Sections 2.11 and 3.02(b) of the Supply Agreement.

(g) BSC's failure to pay Medinol the royalties it was contractually obligated to pay constitutes a material breach of Section 3.02(b) of the Supply Agreement.

(h) BSC's characterization of Medinol as a "vendor" in submissions to the FDA, rather than an "additional manufacturer", constitutes a material breach of Section 4.02 of the Supply Agreement.

(i) BSC's failure to cooperate with Medinol in the filing of regulatory submissions and failure to comply with Section 4.02, constitutes a material breach of Section 4.01 of the Supply Agreement.

(j) BSC's failure promptly to report and disclose BBD's activities to Medinol constitutes a material breach of Section 2.07 of the Supply Agreement.

(k) BSC's failure to report and disclose BSC's activities related to U.S. Patent No. 6,042,597; U.S. Patent Application No. 09/111,531; and U.S. Patent Application No. 09/151,053 constitutes a material breach of Section 2.07 of the Supply Agreement.

(l) BSC's unauthorized covenant not to sue for patent infringement in exchange for a benefit that accrued only to BSC in the settlement of a lawsuit with Guidant, was a material breach of BSC's contractual obligation to sue to enforce Medinol's intellectual property rights or "fully cooperate" in any lawsuit instituted by Medinol pursuant to Section 9.04 of the Supply Agreement.

(m) BSC's failure to disclose to Medinol the stent intellectual property that it claims to have obtained from Guidant is a breach of Section 2.07 of the Supply Agreement.

(n) BSC's focus, for a substantial period of time over the past months, on the Express stent has diverted its attention from its "primary platform", the NIR® stent, and is a material breach of Sections 2.11 and 3.02(b) of the Supply Agreement.

234. Medinol has performed under the Supply Agreement.

235. Medinol has suffered and will continue to suffer substantial and foreseeable damages as a result of these breaches of contract by BSC.

SECOND CLAIM FOR RELIEF
(Breach of Contract--Confidentiality Agreement)
(Against BSC)

236. Paragraphs 1 through 235 are incorporated herein by reference.

237. BSC and Medinol are parties to the Confidentiality Agreement.

238. The Confidentiality Agreement is a valid and binding contract.

239. BSC materially breached both the express terms of this agreement and its implied obligation of good faith and fair dealing.

240. For example, BSC's disclosure and dissemination of Medinol's confidential intellectual property and trade secrets to third parties, including, but not limited to, BBD, Lumonics and at least eleven photo-etching vendors, constitutes a material breach of the Confidentiality Agreement.

241. Medinol has performed under the Confidentiality Agreement.

242. Medinol has suffered and will continue to suffer substantial and foreseeable damages as a result of these breaches of contract by BSC.

THIRD CLAIM FOR RELIEF
(Breach of Contract--Transaction Agreement)
(Against BSC)

243. Paragraphs 1 through 242 are incorporated herein by reference.

244. BSC and Medinol are parties to the Transaction Agreement.

245. The Transaction Agreement is a valid and binding agreement.

246. BSC materially breached both the express terms of this agreement and its implied obligation of good faith and fair dealing.

247. The Transaction Agreement requires that the parties comply with their obligations under the Confidentiality Agreement.

248. For example, BSC's disclosure and dissemination of Medinol's confidential intellectual property and trade secrets to third parties, including, but not limited to, BBD, Lumonics and at least eleven photo-etching vendors, constitutes a material breach of the Confidentiality Agreement.

249. BSC's breach of the Confidentiality Agreement constitutes a material breach of the Transaction Agreement.

250. Medinol has performed under the Transaction Agreement.

251. Medinol has suffered and will continue to suffer substantial and foreseeable damages as a result of this breach of contract by BSC.

FOURTH CLAIM FOR RELIEF
(Breach of Contract--IVUS Confidentiality and Non-Disclosure Agreement)
(Against BSC)

252. Paragraphs 1 through 251 are incorporated herein by reference.

253. BSC and Medinol are parties to the IVUS Confidentiality and Non-Disclosure Agreements.

254. BSC materially breached both the express terms of these agreements and their implied obligation of good faith and fair dealing.

255. For example, BSC's misappropriation of Medinol's confidential IVUS technology and its wrongful use of that confidential technology to obtain for itself a patent thereon constitutes a material breach of the IVUS Confidentiality and Non-Disclosure Agreements.

256. Medinol has performed under the IVUS Confidentiality and Non-Disclosure Agreements.

257. Medinol has suffered and will continue to suffer substantial and foreseeable damages as a result of these breaches of contract by BSC.

FIFTH CLAIM FOR RELIEF
(Tortious Interference with a Contract)
(Against Nicholas, Berman, Best, Corbett, Kelly, LaViolette, Paidosh, Rosenthal and Sandman)

258. Paragraphs 1 through 257 are incorporated herein by reference.

259. The Supply Agreement and the Transaction Agreement between BSC and Medinol are valid contracts.

260. Nicholas, Berman, Best, Corbett, Kelly, Paidosh, Rosenthal and Sandman knew that BSC and Medinol had entered into the Supply Agreement and the Transaction Agreement and were familiar with the content of those agreements. Since

joining BSC, LaViolette has been aware of and familiar with the content of the Supply Agreement and the Transaction Agreement.

261. The Confidentiality and Non-Disclosure Agreement between BSC and Medinol is a valid contract.

262. Nicholas, Berman, Best, Corbett, Kelly, Paidosh, Rosenthal and Sandman knew that BSC and Medinol had entered into the Confidentiality and Non-Disclosure Agreement and were familiar with the content of the Confidentiality and Non-Disclosure Agreement. Since joining BSC, LaViolette has been aware of and familiar with the content of the Confidentiality and Non-Disclosure Agreement.

263. Nicholas, Berman, Best, Corbett, Kelly, LaViolette, Paidosh, Rosenthal and Sandman intentionally caused BSC to breach the Supply Agreement and Confidentiality and Non-Disclosure Agreement by and through the commission of the separate torts alleged herein, with actual malice and without a proper corporate purpose.

264. Medinol has suffered and will continue to suffer substantial damages due to these Defendants' actions.

SIXTH CLAIM FOR RELIEF
(Breach of Fiduciary Duty)
(Against BSC)

265. Paragraphs 1 through 264 are incorporated herein by reference.

266. BSC owed fiduciary duties to Medinol because BSC and Medinol engaged in a joint venture, doing business in a manner in which Medinol reposed trust and confidence in BSC and BSC gained a resulting superiority over the business of Medinol. BSC was aware of this obligation, as the repeated reference by its executives to the "partnership" between BSC and Medinol indicate. (See ¶¶ 46-70, supra.)

267. BSC's fiduciary duties to Medinol included the duties of utmost care, good faith, fairness, loyalty, honesty and full disclosure. BSC breached these fiduciary duties.

268. For example, in the fast-paced stent market, even cutting-edge products have the potential to become rapidly out-dated. Consistent and constant innovation and delivery of new products to the market is vital to survival in the stent industry. Medinol, from the beginning of the venture to the present, has continuously developed new and better stents. Medinol endeavored to enhance the reputation, market share and success of the Medinol/BSC venture by continuously creating revolutionary new stents.

269. BSC had a fiduciary obligation to use its best efforts to contribute to research and development of delivery systems for Medinol's stents for the benefit of the Medinol/BSC venture. The Supply Agreement specifies that "BSC shall use all commercially reasonable efforts to promote and market Stents developed by or for Medinol in all significant markets". (Supply Agreement § 2.11.) Further, Section 3.02(b) of the Supply Agreement requires BSC to "concentrate its Stent business on the development, marketing, distribution and sale of NIR Stents and other Stents developed by or for Medinol under this Agreement".

270. Because BSC's efforts were focused on BBD (and on its own stents), and because BSC wanted to damage Medinol and cheapen its market price so that it could maintain the option to purchase Medinol at a deflated price, BSC failed to make the efforts required of it. For example:

(a) BSC breached its fiduciary duties to Medinol through its participation in the scheme to freeze Medinol out of the Medinol/BSC venture and misappropriate for BSC opportunities belonging to Medinol and the venture. As described above, specific efforts to oust Medinol from the venture included: the misappropriation of Medinol's confidential intellectual property and trade secrets; the secret development by BBD of an "equivalent" stent that would be used by BBD as a substitute for Medinol's stents; the false characterization of Medinol as a

supplier/vendor in BSC's regulatory filings with the FDA; and the improper exclusion of Medinol from the FDA submission process.

(b) BSC breached its fiduciary duties to Medinol by stealing Medinol's NIR® stent technology, disclosing that technology to BBD and various chemical etch vendors and using that technology to manufacture an "equivalent" stent.

(c) BSC breached its fiduciary duties by diverting its resources from the Medinol/BSC venture to BBD, and by focusing on, and diverting resources to, the development of its own stents. BSC's continued diversion of resources to these other activities caused BSC to delay the development and production of delivery systems necessary to sell and gain regulatory approval for Medinol's stents, and resulted in the recall of the NIR on RANGER with SOX™ stent in the United States.

(d) BSC breached its fiduciary duties by attempting to "patent around" the NIR® patents belonging to Medinol, thereby trying to gain partial ownership in the technology Medinol disclosed to it under the venture. Such behavior includes several patents and patent applications by Scimed engineers, for example: U.S. Patent 6,042,597; U.S. Application 09/111,531, published in the Patent Cooperation Treaty ("PCT") as Application PCT/US99/15122; and the U.S. Application 09/151,053 disclosed in the PCT publication as PCT/US99/20383.

(e) BSC breached its fiduciary duties to Medinol by, without Medinol's approval or consent, settling a lawsuit against Guidant. In this settlement, BSC claims that, in order to obtain a license from Guidant of stent intellectual property, BSC covenanted not to sue Guidant for patent infringement despite the fact that BSC has a contractual obligation to sue to enforce Medinol's intellectual property rights or "fully cooperate" in any lawsuit instituted by Medinol. (Supply Agreement § 9.04.) From this wrongfully-obtained technology, BSC has

developed its own stent, the Express stent, to which it has devoted substantial time over the past months. BSC breached its fiduciary duties by: giving this covenant not to sue given over Medinol's written objection; focusing on the development of the Express stent; and developing this stent as a potential competitor to Medinol's stents.

271. Medinol has suffered and will continue to suffer substantial damages as a result of BSC's breaches of its fiduciary duties.

SEVENTH CLAIM FOR RELIEF
(Aiding and Abetting Breach of Fiduciary Duty)
(Against Nicholas, Berman, Best, Corbett, Kelly, LaViolette, Paidosh, Rosenthal and Sandman)

272. Paragraphs 1 through 271 are incorporated herein by reference.

273. As alleged above, BSC owed Medinol the fiduciary duties of utmost care, good faith, fairness, loyalty, honesty and full disclosure.

274. Nicholas, Berman, Best, Corbett, Kelly, LaViolette, Paidosh, Rosenthal and Sandman knew that BSC owed Medinol the fiduciary duties of utmost care, good faith, fairness, loyalty, honesty and full disclosure. These Defendants all aided and abetted BSC in breaching its fiduciary duties to Medinol.

275. For example, Nicholas, Berman, Best, Corbett, Kelly, LaViolette, Paidosh, Rosenthal and Sandman knew that BSC misappropriated Medinol's confidential intellectual property and trade secrets and confidential NIR® stent technology, disclosed that confidential technology to others, secretly developed an equivalent stent that would be used by BBD as a substitute for Medinol's stents, falsely characterized Medinol as a supplier/vendor in BSC's regulatory filings with the FDA, and improperly excluded Medinol from the FDA submission process.

276. Nicholas, Berman, Best, Corbett, Kelly, LaViolette, Paidosh, Rosenthal and Sandman knowingly participated in and substantially assisted the aforementioned acts.

277. Medinol has suffered and will continue to suffer substantial damages as a result of the acts of Nicholas, Berman, Best, Corbett, Kelly, LaViolette, Paidosh, Rosenthal and Sandman.

EIGHTH CLAIM FOR RELIEF
(Fraud)
(Against BSC)

278. Paragraphs 1 through 277 are incorporated herein by reference.

279. BSC made material fraudulent representations to Medinol with the intent to defraud Medinol and upon which Medinol relied to its detriment. These material fraudulent representations, as described above, include, inter alia: falsely representing to Medinol that BSC was acting in the interests of the Medinol/BSC venture when it was, in fact, acting in its own interest; falsely representing to Medinol that Medinol's confidential intellectual property and trade secrets would be used in connection with the development of the Alternative Line, when in fact, it was used in connection with the creation of the Secret Line; falsely representing to Medinol an intent to purchase Medinol so that Medinol would abandon its plans for an IPO; falsely representing the scope of BSC's marketing efforts for the Radius stent and BSC's revenues from the sale of the Radius stents; falsely representing to Medinol the content of BSC's regulatory filings (January 1998); and a visit by BSIL employee, Aiden Flanagan, to inspect Medinol under the guise of learning Medinol's confidential intellectual property and trade secrets for the legitimate alternative line, when really seeking the information for establishing the Secret line.

280. The representations made by BSC were false. The representations were known by BSC to be false at the time they were made and/or BSC made the

representation recklessly and without regard to its truth or falsity. BSC intended to defraud Medinol by making these material fraudulent representations.

281. Medinol reasonably relied on these material fraudulent representations and was deceived by them. Medinol reasonably relied on the representations made to it by BSC, which owed Medinol a fiduciary duty of utmost good faith, fairness, loyalty, honesty and full disclosure, and BSC knew that Medinol would rely on these representations. Medinol relied on BSC's representations to its detriment and these false representations caused injury to Medinol. Medinol, in reliance upon these fraudulent representations, entrusted to BSC and Defendants its intellectual property, invested substantial resources in the Medinol/BSC venture and its products, and abstained from pursuing its rights and remedies under the contracts and common and statutory law.

282. Medinol has suffered and will continue to suffer substantial and special damages as a result of BSC's fraud.

NINTH CLAIM FOR RELIEF
(Fraudulent Concealment)
(Against BSC)

283. Paragraphs 1 through 282 are incorporated herein by reference.

284. As alleged above, BSC made fraudulent misrepresentations to Medinol which Medinol relied upon to its detriment.

285. BSC had a fiduciary duty to Medinol.

286. BSC possessed knowledge of Project Independence and BBD and provided funding to operate BBD. BSC intentionally kept information about Project Independence and BBD hidden from Medinol with the intent to defraud Medinol. BSC had a duty to disclose this information to Medinol.

287. BSC knew that Medinol acted without knowledge of the Project Independence and BBD.

288. Medinol has suffered and will continue to suffer damages as a result of BSC's fraudulent concealment of Project Independence and BBD.

TENTH CLAIM FOR RELIEF

(Fraud)

**(Against Nicholas, Berman, Best, Corbett, LaViolette, Paidosh,
Rosenthal and Sandman)**

289. Paragraphs 1 through 288 are incorporated herein by reference.

290. Nicholas, with knowledge of the falsity of the representations and with intent to deceive, made material fraudulent representations to Medinol upon which Medinol reasonably relied to its detriment. These fraudulent representations include a March 21, 1997 letter to Medinol stating that BSC opposed Medinol's plans for an IPO because an IPO would interfere with the goals of the Medinol/BSC venture; numerous face-to-face representations between August and December 1997 that BSC was interested in purchasing Medinol; a series of letters between 1995 and 1998 in which Nicholas declares his commitment to the venture and its goals; a December 16, 1997 letter to Medinol stating that the NIR® PMA would be unimpeded by BSC's co-pending Radius PMA; and an April 24, 1998 letter to Medinol stating that BSC was not acting in bad faith to undermine, understate, misrepresent, or otherwise wrong or harm Medinol. Medinol, in reliance upon these fraudulent representations, among other things: entrusted to BSC and Defendants its confidential intellectual property and core trade secrets; invested substantial resources in the Medinol/BSC venture; invested enormous resources over many years in developing the stent design and fabrication technology that were among the trade secrets shared with and entrusted to BSC; and abstained from pursuing its rights and remedies under the contract and common and statutory law.

291. Berman, with knowledge of the falsity of the representations and with intent to deceive, made material fraudulent representations to Medinol upon which Medinol reasonably relied to its detriment. These fraudulent representations include a

November 4, 1998 facsimile assuring Medinol that every effort was being taken to reintroduce NIR ON™ Ranger™ with SOX™ after BSC's recall and to focus on the balloon and crimping process when their real focus was to blame Medinol for the product failure and to concentrate on BSC's own products; and a May 21, 1998 letter promising Medinol that BSC/Scimed was committed to NIR® products and to taking the "NIR Stent to a dominant #1 status in the US" when Scimed was really focusing on the Radius stent, BBD and BSC's own products. Medinol, in reliance upon these fraudulent representations, among other things: entrusted to BSC and Defendants' its confidential intellectual property and core trade secrets; invested substantial resources in the Medinol/BSC venture; invested enormous resources over many years in developing the stent design and fabrication technology that were among the trade secrets shared with and entrusted to BSC; and abstained from pursuing its rights and remedies under the contract and common and statutory law.

292. Best, with knowledge of the falsity of the representations and with intent to deceive, made material fraudulent representations to Medinol upon which Medinol reasonably relied to its detriment. These fraudulent representations include numerous face-to-face representations between August and December 1997 that BSC was interested in purchasing Medinol; and a face-to-face representation to Medinol in Paris in 1998 that BSC was fully committed to the goals of the Medinol/BSC venture. Medinol, in reliance upon these fraudulent representations, among other things: entrusted to BSC and Defendants its confidential intellectual property and core trade secrets; invested substantial resources in the Medinol/BSC venture; invested enormous resources over many years in developing the stent design and fabrication technology that were among the trade secrets shared with and entrusted to BSC; and abstained from pursuing its rights and remedies under the contract and common and statutory law.

293. Corbett, with knowledge of the falsity of the representations and with intent to deceive, made material fraudulent representations to Medinol upon which Medinol reasonably relied to its detriment. These fraudulent representations include a face-to-face representation at a meeting on September 8, 1997, at BSC where Corbett told Dr. Judith Richter and Dr. Kobi Richter that BSC wanted to market and sell NIR Conformer™ stents, when in fact, BSC wished to stockpile NIR Conformer™ stents and was attempting to cause Medinol to breach its contractual obligations. Medinol, in reliance upon these fraudulent representations, among other things: entrusted to BSC and Defendants its confidential intellectual property and core trade secrets; invested substantial resources in the Medinol/BSC venture; invested enormous resources over many years in developing the stent design and fabrication technology that were among the trade secrets shared with and entrusted to BSC; and abstained from pursuing its rights and remedies under the contract and common and statutory law.

294. LaViolette, with knowledge of the falsity of the representations and with intent to deceive, made material fraudulent representations to Medinol upon which Medinol reasonably relied to its detriment. These fraudulent representations include face-to-face representations to Medinol in Natick, Massachusetts, Paris and Israel in 1998 and 1999 that BSC was working to repair the companies' damaged relationship, when in fact, BSC was continuing to operate BBD. Medinol, in reliance upon these fraudulent representations, among other things: entrusted to BSC and Defendants its confidential intellectual property and core trade secrets; invested substantial resources in the Medinol/BSC venture; invested enormous resources over many years in developing the stent design and fabrication technology that were among the trade secrets shared with and entrusted to BSC; and abstained from pursuing its rights and remedies under the contract and common and statutory law.

295. Paidosh, with knowledge of the falsity of the representations and with intent to deceive, made material fraudulent representations to Medinol upon which Medinol reasonably relied to its detriment. These fraudulent representations include falsely representing to Medinol that Medinol's confidential and proprietary information and trade secrets would be used in connection with the development of the Alternative Line, when, in fact, it was used in connection with the creation of the Secret Line. Medinol, in reliance upon these fraudulent representations, among other things: entrusted to BSC and Defendants its confidential intellectual property and core trade secrets; invested substantial resources in the Medinol/BSC venture; invested enormous resources over many years in developing the stent design and fabrication technology that were among the trade secrets shared with and entrusted to BSC; and abstained from pursuing its rights and remedies under the contract and common and statutory law.

296. Rosenthal, with knowledge of the falsity of the representations and with intent to deceive, made material fraudulent representations to Medinol upon which Medinol reasonably relied to its detriment. These fraudulent representations include a May 18, 1998 representation to Medinol that "[t]here are no hidden agendas"; a July 16, 1997 representation to Medinol that its "suspicion[] that somehow BSC has conspired against Medinol is far from the truth"; representations in 1998 concerning the manner in which BSC was presenting Medinol in the PMA application for the NIR ON™ Ranger™ Premounted Stent System; and a face-to-face representation to Medinol in Paris in 1998, that BSC was fully committed to the goals of the Medinol/BSC venture. Medinol, in reliance upon these fraudulent representations, among other things: entrusted to BSC and Defendants its confidential intellectual property and core trade secrets; invested substantial resources in the Medinol/BSC venture; invested enormous resources over many years in developing the stent design and fabrication technology that were among the

trade secrets shared with and entrusted to BSC; and abstained from pursuing its rights and remedies under the contract and common and statutory law.

297. Sandman, with knowledge of the falsity of the representations and with intent to deceive, made material fraudulent representations to Medinol upon which Medinol reasonably relied to its detriment. These fraudulent representations include a July 25, 2000 letter from Ocwieja to Medinol, which Sandman caused Ocwieja to sign and caused to be faxed to Medinol, falsely representing that BSC's regulatory behavior was proper. Medinol, in reliance upon these fraudulent representations, among other things: entrusted to BSC and Defendants its confidential intellectual property and core trade secrets; invested substantial resources in the Medinol/BSC venture; invested enormous resources over many years in developing the stent design and fabrication technology that were among the trade secrets shared with and entrusted to BSC; and abstained from pursuing its rights and remedies under the contract and common and statutory law.

298. Medinol justifiably relied on these material fraudulent representations to its detriment by, among other things, delaying its plans for IPO, turning over its confidential intellectual property and trade secrets to BSC, failing to take measures to protect its rights under the Medinol/BSC venture and failing to take measures to protect its intellectual property rights.

299. Medinol has suffered and will continue to suffer substantial and special damages as a result of Defendants' fraud.

ELEVENTH CLAIM FOR RELIEF
(Aiding and Abetting Fraud)
(Against All Defendants)

300. Paragraphs 1 through 299 are incorporated herein by reference.

301. As alleged above, Defendants made fraudulent misrepresentations to Medinol upon which Medinol relied to its detriment.

302. Each of the Defendants knew of the fraudulent activities of the other Defendants and substantially assisted one another in committing the fraud by telling Medinol that BSC was committed to and acting in the best interest of the Medinol/BSC venture; approving and agreeing to fund Project Independence; participating in managing Project Independence; causing fraudulent submissions to be sent to the FDA; misrepresenting to Medinol the contents of the submissions to the FDA; and failing to inform Medinol about Project Independence.

303. Medinol has suffered and will continue to suffer substantial damages as a result of Defendants' fraud.

TWELFTH CLAIM FOR RELIEF
(Negligent Misrepresentation)
(Against BSC, Nicholas, Berman, Best, Corbett, LaViolette, Paidosh, Rosenthal and Sandman)

304. Paragraphs 1 through 303 are incorporated herein by reference.

305. As alleged above, Defendants made misrepresentations to Medinol upon which Medinol justifiably and reasonably relied to its detriment. Medinol, in reliance upon these fraudulent representations, entrusted to BSC and Defendants its intellectual property, invested substantial resources in the Medinol/BSC venture and its products, and abstained from pursuing its rights and remedies under the contract and common and statutory law.

306. Defendants made these representations in the course of business and supplied the information for the guidance of Medinol in its business transactions.

307. Defendants failed to exercise reasonable care and competence in obtaining and communicating the information.

308. Medinol has suffered and will continue to suffer substantial damages as a result of Defendants' negligent misrepresentations.

THIRTEENTH CLAIM FOR RELIEF
(Misappropriation of Trade Secrets)
(Against All Defendants)

309. Paragraphs 1 through 308 are incorporated herein by reference.

310. Medinol possesses confidential trade secrets and intellectual property relating to stents. For example, one of these trade secrets is Medinol's sketches of photo-etched NIR® stent panels which are included in the PMA. Another is Medinol's unique folding and welding system used to manufacture stents.

311. Defendants misappropriated Medinol's confidential trade secrets and intellectual property relating to stents and BSC used these confidential trade secrets in breach of the Supply Agreement, the Confidentiality and Non-Disclosure Agreement and its fiduciary duties to Medinol. For example, Defendants obtained confidential drawings of the panels used to manufacture Medinol's NIR® stents and disclosed those drawings to BBD. BBD changed the logo on those drawings from "Medinol" to "BBD"; changed the title of the drawings from "NIR stent" to "heat exchanger" and disseminated Medinol's stent technology trade secrets by sending these designs and drawings to eleven photo-etching vendors in violation of the confidentiality provisions of the Supply Agreement, the Transaction Agreement and the October 18, 1995 Confidentiality and Non-Disclosure Agreement. Also Defendants, for example, disseminated Medinol's stent technology and trade secrets by sending the drawing of the folder/welder machine and its components to at least two vendors. BSC allowed at least one of these vendors to examine the laser-welding machine and to make copy drawings.

312. Defendants misappropriated Medinol's confidential intellectual property and trade secrets and put Medinol's trade secrets to commercial use by manufacturing NIR® stents.

313. BSC also misappropriated Medinol's confidential IVUS technology trade secrets and proprietary information, which BSC obtained pursuant to

Confidentiality and Non-Disclosure Agreements with Medinol, and converted such secrets to its own use for a patent application.

314. BSC used Medinol's confidential IVUS technology trade secrets and intellectual property in breach of the Confidentiality and Non-Disclosure Agreement.

315. BSC patented around Medinol's NIR® patents to try and steal Medinol's proprietary rights for the stent, copying design concepts and stent designs disclosed to BSC under confidence for the purpose of fulfilling its role in the Medinol/BSC venture.

316. Defendants' disclosure of Medinol's confidential intellectual property and trade secrets was unauthorized.

317. Medinol has suffered and will continue to suffer substantial damages as a result of BSC's misappropriation of Medinol's trade secrets.

318. Accordingly, Medinol is entitled to recover all its actual and compensatory damages from Defendants' misappropriation of Medinol's confidential trade secrets and intellectual property, its disclosure of Medinol's trade secrets and its wilful acts of fraud and bad faith in obtaining these trade secrets for improper purposes including disclosure to third parties.

FOURTEENTH CLAIM FOR RELIEF
(Conspiracy)
(Against All Defendants)

319. Paragraphs 1 through 318 are incorporated herein by reference.

320. Each Defendant, by words and/or conduct, knowingly agreed and conspired to participate in a common plan to defraud Medinol, and each engaged in overt acts in furtherance thereof.

321. Medinol has suffered and will continue to suffer substantial damages as a result of Defendants' conspiracy.

FIFTEENTH CLAIM FOR RELIEF
(Defamation)
(Against All Defendants)

322. Paragraphs 1 through 321 are incorporated herein by reference.

323. Defendants made false, misleading and defamatory statements regarding Medinol's business, products and its relations with Medinol to the FDA, third parties and the public in general.

324. As a result of Defendants' false, fraudulent and defamatory statements, Medinol has suffered damages and loss of money and property, including lost profits, lost sales and harm to its business and reputation.

325. Accordingly, Medinol is entitled to recover all its actual and compensatory damages, including recovery for lost profits and harm to its business and reputation as a result of Defendants' fraudulent and defamatory statements.

SIXTEENTH CLAIM FOR RELIEF
(Unjust Enrichment)
(Against BSC)

326. Paragraphs 1 through 325 are incorporated herein by reference.

327. BSC knowingly received benefits from Medinol, including, among other things, Medinol's confidential NIR® stent technology, Medinol's confidential IVUS technology and Medinol's assistance in obtaining the PMA and related regulatory approvals for the marketing of NIR® stent technology in the United States.

328. Medinol has not received payment for the value of its technology and assistance.

329. BSC wrongfully used Medinol's technology and assistance for its own advantage and at Medinol's expense.

330. Under the circumstances alleged above, BSC's receipt of Medinol's technology and assistance and the fruits thereof constitutes unjust enrichment. It would

be inequitable for BSC to retain these benefits without payment of their fair and reasonable value to Medinol.

SEVENTEENTH CLAIM FOR RELIEF
(RICO – 18 U.S.C. § 1962(c))
(Against All Defendants)

331. Paragraphs 1 through 330 are incorporated herein by reference.

332. Since at least 1997, and continuously thereafter up to the present, Forwich Ltd., Lumonics Ltd., Micrometallics and Microponents have associated-in-fact as an enterprise (the “BBD Enterprise”) set up to freeze Medinol out of the Medinol/BSC venture and misappropriate for BSC opportunities belonging to Medinol and the venture. As an entity through which Defendants and others conducted their unlawful activities, the BBD Enterprise is an “enterprise” as defined in 18 U.S.C. §§ 1961(4) and 1962(c), the activities of which affected interstate commerce during the relevant times.

333. Since at least 1997, and continuously thereafter up to the present, Medinol has been an enterprise (the “Medinol Enterprise”) used by Defendants fraudulently to misappropriate intellectual property and to deceive the FDA. As an entity through which Defendants and others conducted their unlawful activities, the Medinol Enterprise is an “enterprise” as defined in 18 U.S.C. §§ 1961(4) and 1962(c), the activities of which affected interstate commerce during the relevant times.

334. Since at least 1997, and continuously thereafter up to the present, BSC and Medinol have associated-in-fact as an enterprise (the “BSC/Medinol Enterprise”) used by Defendants fraudulently to misappropriate intellectual property and to deceive the FDA. As an entity through which Defendants and others conducted their unlawful activities, the BSC/Medinol Enterprise is an “enterprise” as defined in 18 U.S.C. §§ 1961(4) and 1962(c), the activities of which affected interstate commerce during the relevant times.

335. BSC, Nicholas, Berman, Best, Corbett, Kelly, LaViolette, Paidosh, Rosenthal and Sandman are each a “person” within the meaning of 18 U.S.C. §§ 1961(3) and 1964(c).

336. BSC, Nicholas, Berman, Best, Corbett, Kelly, LaViolette, Paidosh, Rosenthal and Sandman were each employed by or associated with an enterprise, that is, the BBD Enterprise, the Medinol Enterprise and/or the BSC/Medinol Enterprise, and did conduct, participate in, operate and manage, directly or indirectly, the affairs of the BBD Enterprise, the Medinol Enterprise and/or the BSC/Medinol Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1)(B) and 1961(E) and 1961(5) and 1962(c), to wit:

(a) Defendants knowingly participated in a scheme or artifice to defraud Medinol and to obtain and disseminate to certain third parties Medinol’s stent technology trade secrets and other intellectual property and the intangible property rights of the Medinol/BSC venture by means of false or fraudulent pretenses, representations, or promises as set forth above, and used the United States mails or private or commercial interstate carriers in furtherance of the scheme or artifice to defraud, in violation of 18 U.S.C. § 1341, and aided and abetted the same.

(b) Defendants knowingly participated in a scheme or artifice to defraud Medinol and to obtain Medinol’s intellectual property and the intangible property rights of the Medinol/BSC venture by means of false or fraudulent pretenses, representations, or promises as set forth above, and used the interstate or international wires in furtherance of the scheme or artifice to defraud, in violation of 18 U.S.C. § 1341, and aided and abetted the same.

337. Specified uses of the United States mails or private or commercial interstate carriers and of interstate or international wires by BSC, Nicholas, Berman, Corbett, Paidosh and Rosenthal are set forth above.

338. Best, Kelly, LaViolette and Sandman aided and abetted the acts of mail and wire fraud described above.

339. Medinol was deceived by Defendants' scheme and in reliance thereon, Medinol postponed its plans for IPO, turned over its confidential intellectual property and trade secrets to BSC, failed to take measures to protect its rights under the Medinol/BSC venture and failed to take measures to protect its intellectual property rights and its confidential trade secrets.

340. As a result of Defendants' violations of 18 U.S.C. § 1962(c), Medinol has been injured and has suffered damage to its business and property, in at least the following ways:

(a) Medinol has suffered lost profits and revenues from Defendants' diversion of Medinol's and the venture's assets.

(b) Medinol has suffered injury to its value, business and professional reputation through BSC's commission of the above listed predicate acts.

(c) Medinol has suffered injury to its proprietary stent technology trade secrets through Defendants' predicate acts defrauding Medinol of those secrets and improperly, and without authorization, disseminating them to certain third parties.

341. As alleged herein, the Defendants have committed, among other things, mail and wire fraud in violation of 18 U.S.C. § 1341 and § 1343. Any communications relating to BBD or Project Independence were in furtherance of the mail and wire fraud. Accordingly, BSC is not entitled to maintain a privilege with respect to any such communication.

342. Pursuant to 18 U.S.C. § 1964(c), Medinol is entitled to treble its general and special compensatory damages, plus interest, costs and attorneys' fees by reason of Defendants' violations of 18 U.S.C. § 1962(c). Moreover, Medinol is entitled

to equitable relief against Defendants in the form of such injunctive and related relief as might be appropriate in accordance with 18 U.S.C. § 1964(a) including:

(a) Reasonable restrictions on the future activities of Defendants.

(b) An equitable accounting for all benefits, consideration and profits received directly or indirectly by Defendants as a result of their misconduct, including but not limited to, the imposition of a constructive trust with tracing.

(c) Any restrictions which may be appropriate on future conduct or activities.

(d) For such other damages, relief and pre- and post-judgment interest as the Court may deem just and proper.

EIGHTEENTH CLAIM FOR RELIEF
(RICO Conspiracy – 18 U.S.C. § 1962(d))
(Against All Defendants)

343. Paragraphs 1 through 342 are incorporated herein by reference.

344. Beginning in at least March 1997, and continuously thereafter up to and including the present, Defendants conspired with one another and others to violate the provisions of 18 U.S.C. § 1962(c), as described above.

345. During the relevant times, each Defendant, by words and conduct, knowingly agreed to commit the aforementioned acts in violation of the 18 U.S.C. § 1962(c) and in furtherance of the common purposes of the BBD Enterprise, the Medinol Enterprise and the BSC/Medinol Enterprise, and each engaged in overt acts in connection therewith.

346. Each Defendant knowingly agreed to facilitate the predicate acts set forth above, with knowledge that such acts were in furtherance of their pattern of racketeering activity.

347. As a result of Defendants' conspiracy to violate 18 U.S.C. § 1962(c), Medinol has suffered damage to its business and property, as set forth above.

348. Pursuant to 18 U.S.C. § 1964(c), Medinol is entitled to treble its general and special compensatory damages, plus interest, costs and attorneys' fees, by reason of Defendants' violation of 18 U.S.C. § 1962(d).

Prayer for Relief

WHEREFORE, Medinol respectfully requests the following relief:

I. Medinol be awarded equitable relief that includes:

(a) An order requiring BSC to add Medinol's name as an additional manufacturer of NIR® stents for purposes of the relevant FDA regulatory submissions; supplement all relevant PMA's that have been filed with the FDA to state that Medinol is an additional manufacturer; supplement all relevant PMA's that have been filed with the FDA to state that Medinol is an additional distributor of NIR® stent systems; take all necessary actions to make such amendments and supplements to the FDA on a timely basis; and take all actions necessary to make such amendments and supplements possible on a timely basis;

(b) A declaration by this Court that BSC no longer has the right under Section 2.01 of the Supply Agreement to use, market, distribute and sell Medinol's stents and Medinol's technology;

(c) A declaration by this Court that Medinol may sell its stents and technology independent of BSC. In order to allow Medinol to make, use, market, distribute and sell its stents independently of BSC, the Court should: (i) grant Medinol a life-time royalty-free license to make, use, market, distribute and sell stent-delivery balloon catheters; (ii) share with Medinol BSC's technology required to manufacture such stent-delivery balloon catheters; and (iii) sell such balloon catheters to Medinol (at the price at which they were previously sold to Medinol, or five-percent of the end-user price) for the interim period while Medinol establishes this manufacturing capability;

(d) To prevent any further misappropriation and improper use by BSC of Medinol's stents and technology, this Court should issue an injunction barring BSC from selling any of Medinol's stents or any stents using Medinol's technology and intellectual property;

(e) To prevent any further benefit to BSC from its use of intellectual property wrongfully-obtained in a settlement of a lawsuit with Guidant in exchange for a covenant not to sue--given over Medinol's written objection and in breach of the Supply Agreement--this Court should issue an injunction barring BSC from selling, marketing, using and distributing any Express stents;

(f) To prevent BSC from further encumbering Medinol's rights to protect its patents and intellectual property, this Court should issue an injunction barring BSC from making any covenants not to sue, or settling any cases, that affect Medinol's patents and/or intellectual property; and

(g) To prevent BSC from any further misappropriation and improper use of Medinol's confidential intellectual property and technology, this Court should order BSC to return all material systems and items built, designed or manufactured based on the intellectual property and confidential information of Medinol.

II. That Medinol be awarded its actual damages in an amount to be proved at trial, trebled pursuant to 18 U.S.C. § 1964(c), as well as reasonable attorneys' fees and costs pursuant to 18 U.S.C. § 1964(c).

III. Because Defendants have engaged in gross, wanton and willful fraud; dishonesty and malicious wrongdoing involving a high degree of moral culpability; a course of conduct with willful, wanton and reckless disregard for Medinol's rights and the public interest; and a fraud on the United States government, the FDA and Medinol, thereby seriously compromising the integrity of a critical regulatory process and causing risk to human life, Medinol be awarded punitive damages.

IV. That Medinol be awarded all its actual and compensatory damages from Defendants' misappropriation of Medinol's confidential trade secrets and intellectual property, its disclosure of Medinol's trade secrets and its wilful acts of fraud and bad faith in obtaining these trade secrets for improper purposes including disclosure to third parties, and that Medinol be awarded reasonable attorneys' fees.

V. That Medinol be awarded its reasonable attorneys' fees and costs incurred in maintaining this action.

VII. That the Court award such further and other relief as it deems just and proper.

April 5, 2001

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