UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA

WORLD WIDE MEDICAL TECHNOLOGIES, LLC; ADVANCED CARE MEDICAL, INC.; and BRACHYSCIENCES, INC.

Plaintiffs

v.

CORE ONCOLOGY, INC.; COLOPLAST CORPORATION; JOHNSON & JOHNSON, as successor in interest to Mentor Corporation; ONCURA, INC.; C.R. BARD, INC.; BEST MEDICAL INTERNATIONAL, INC.; THERAGENICS CORPORATION; and ISORAY MEDICAL, INC.

Defendants.
_____/

CIVIL ACTION NO. _____

December 6, 2011

JURY TRIAL REQUESTED

COMPLAINT FOR DAMAGES

Plaintiffs, WORLD WIDE MEDICAL TECHNOLOGIES, LLC; ADVANCED CARE MEDICAL, INC.; and BRACHYSCIENCES, INC. file this Complaint against the Defendants CORE ONCOLOGY, INC.; COLOPLAST CORP.; JOHNSON & JOHNSON, as successor in interest to Mentor Corporation; ONCURA, INC.; C.R. BARD, INC.; BEST MEDICAL INTERNATIONAL, INC.; THERAGENICS CORPORATION; and ISORAY MEDICAL, INC. and respectfully allege as follows:

1. This is an action for damages flowing from the misappropriation of intellectual property interests in certain medical device inventions of the Plaintiffs utilized principally in brachytherapy treatments of cancer. Brachytherapy is the

implantation of therapeutic elements or sealed radioactive sources into the body in or next to the tumor site requiring treatment. The key invention is the needle assembly utilized for these brachytherapy implants and for which Plaintiffs held patent interests during the relevant time period pursuant to U.S. Patent No. 6,554,760 ("the '760 Patent"), filed October 24, 2001 and issued on April 29, 2003. **Exhibit A**. Plaintiff's '760 Patent specifically encompasses the invention of a pre-plugged and pre-loaded needle assembly to a patient's prescription, packaged and delivered sterile to the hospital or clinic for the implantation of the therapeutic elements[1] into the body for the treatment of cancer.

2. Beginning as early as August 2002, Defendants knowingly misappropriated the technology encompassed by the '760 Patent for their own economic gain without consideration for and in violation of Plaintiffs intellectual property rights. As a result, Plaintiffs suffered significant injury in lost business and lost customers and the loss of tens of millions of dollars in revenue.

PARTIES

3. Plaintiff WORLD WIDE MEDICAL TECHNOLOGIES, LLC ("World Wide") is a Connecticut Limited Liability Company with a principal place of

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[1] Although the principal application has been low dose rate radioactive seed elements for prostate brachytherapy, the '760 Patent encompasses any variety of "therapeutic elements" such as bio-absorbable or biodegradable elements containing vaccines and drugs that need to be delivered to a localized site within the body for treatment, as well as fiducial and localization markers which aid in treatment of cancer. The '760 Patent represents a breakthrough affording convenient and safe handling of the therapeutic elements and the precise delivery to the treatment site to maximize the effectiveness. The '760 Patent is in many respects an advance equivalent to that of smart bombs over their predecessors.

business located at 115 Hurley Road, Building 3, Oxford, Connecticut 06478. Plaintiff World Wide is the assignee and owner of the '760 Patent

4. Plaintiff ADVANCED CARE MEDICAL, INC. ("Advanced Care") is a Connecticut corporation with a principal place of business located at 115 Hurley Road, Building 3, Oxford, Connecticut 06478. ADVANCED CARE MEDICAL, INC. is successor in interests to Advanced Care Pharmacy, LLC, formerly a Connecticut limited liability company and Advanced Care Pharmacy, Inc., formerly a Massachusetts corporation.

5. Plaintiff BRACHYSCIENCES, INC. ("BrachySciences") is a Connecticut corporation with a principal place of business located at 115 Hurley Road, Building 3, Oxford, Connecticut 06478. BRACHYSCIENCES, INC. is successor in interests to Advanced Care Technology, Inc.

6. Plaintiffs World Wide, Advanced Care, and BrachySciences (hereinafter collectively "World Wide Plaintiffs") are affiliated through the common, one hundred percent (100%) ownership, of Gary Lamoureux, a resident of the State of Connecticut.

7. Defendant JOHNSON & JOHNSON ("J&J") is a corporation organized and existing under the law of the State of New Jersey with a principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. With respect to the matters complained of herein, Defendant J&J is a successor in interest to Mentor Corporation ("Mentor") from the acquisition consummated on or about January 23, 2009. Mentor marketed and sold products in violation of Plaintiff's intellectual property rights from as early as August 2002

through June 2, 2006 when Mentor's brachytherapy division was sold to Coloplast Corp. During the period relevant to this action Defendant J&J sold infringing product into the Northern District of Florida.

8. Defendant COLOPLAST CORP., ("Coloplast") is a corporation organized and existing under the law of the State of Delaware with a principal place of business located at 1601 West River Road, Minneapolis, MN 55411. Coloplast is the domestic subsidiary of Coloplast A/S, Humlebæk, Denmark which manufactures and markets ostomy devices, urology products, continence care devices, wound care and skin care products. With respect to the matters complained of herein, Coloplast marketed and sold brachytherapy products in violation of Plaintiff's intellectual property rights from June 3, 2006 until June 8, 2007 when Core Oncology closed on the purchase of Coloplast's brachytherapy division. During the period relevant to this action Defendant Coloplast sold infringing product into the Northern District of Florida.

9. Defendant CORE ONCOLOGY, INC. ("Core") is a corporation organized and existing under the law of the State of Washington with principal places of business as follows: (Legal and Finance) 7525 SE 24th Street, Suite 450, Mercer Island, WA 98040; (Corporate and Sales) 3916 State Street, Suite 110, Santa Barbara, CA 93105; and (Manufacturing) 120 NE 26th Street, Oklahoma City, OK 73105. Core was organized and incorporated on September 18, 2006 for the express purpose of acquiring the brachytherapy business of Coloplast. With respect to the matters complained of herein, Core knowingly marketed and sold brachytherapy products in violation of Plaintiff's intellectual property rights

beginning on June 8, 2007 when Coloplast closed on the sale of its brachytherapy division to Core Oncology. During the period relevant to this action Defendant Core sold infringing product into the Northern District of Florida.

10. Defendant ONCURA, INC. ("Oncura") is a corporation organized and existing under the laws of Delaware with principal offices located 3350 North Ridge Avenue, Arlington Heights, IL 60004. Defendant Oncura is the brachytherapy business unit of GE HEALHCARE, INC ("GE Healthcare") a Delaware corporation with offices located at 101 Carnegie Center, Princeton, NJ 08540. Defendant Oncura and its predecessors are original low dose radiation ("LDR") manufacturers of Iodine (I-125) seeds and became both a legitimate customer of Plaintiff Advanced Care's pre-plugged and pre-loaded needle technology and, as complained of herein, a non-customer infringer of the very same protected intellectual property. During the period relevant to this action Defendant Oncura sold infringing product into the Northern District of Florida.

11. Defendant C. R. BARD, INC. ("Bard") is a corporation organized under the laws of the State of New Jersey with principal offices located at 730 Central Avenue, Murray Hill, New Jersey 07974. Defendant Bard's Medical Division manufactures and/or distributes both Iodine (I-125) and Palladium (Pd-103) seeds, implant and applicator needles, seed and linked-seed delivery systems and brachytherapy equipment. Defendant Bard's manufacturers radioactive sources through a wholly owned subsidiary, Bard Brachytherapy, Inc., a corporation organized under the law of Delaware with offices located at 295 East

Lies Road, Carol Stream, Illinois. During the period relevant to this action Defendant Bard sold infringing product into the Northern District of Florida.

12. Defendant BEST MEDICAL INTERNATIONAL, INC. ("Best") is a corporation organized and existing under the laws of Delaware with principal offices located 7643 Fullerton Road, Springfield, Virginia 22153. Defendant Best has been manufacturing and/or distributing low dose radioactive sources, , both Iodine (I-125) and Palladium (Pd-103) seeds, together with pre-plugged and pre-loaded needle assemblies since before 2005. In May 2009 Defendant Best acquired out of bankruptcy the brachytherapy production assets and equipment of North American Scientific, Inc. ("NASI") and through a wholly owned subsidiary Brachytherapy Services, Inc. has continued production and distribution of the a SurTrak clone pre-plugged and pre-loaded needle assembly previously sold by NASI in violation of the '760 Patent. During the period relevant to this action Defendant Best sold infringing product into the Northern District of Florida.

13. Defendant THERAGENICS CORPORATION ("Theragenics") is a corporation organized and existing under the law of Delaware with principal offices located at 5203 Bristol Industrial Way, Buford, Georgia 30518. Defendant Theragenics is an original LDR manufacturer and distributor of Palladium (Pd-103) seeds and more recently Iodine (I-125) seeds. Defendant Theragenics employs internal manufacturing and distribution of its LDR seeds in pre-plugged, pre-loaded needle assemblies. During the period relevant to this action Defendant Theragenics sold infringing product into the Northern District of Florida.

14. Defendant ISORAY MEDICAL, INC. ("IsoRay") is a corporation organized and existing under the law of Delaware with principal offices located at 350 Hills St., Suite 106, Richland, Washington 99354. Defendant IsoRay manufactures and distributes Cesium (Cs-131) seeds in pre-plugged, pre-loaded needle assemblies. During the period relevant to this action Defendant IsoRay sold infringing product into the Northern District of Florida.

NATURE OF THE ACTION, JURISDICTION, AND VENUE

15. This is an action for misappropriation of intellectual property rights and specifically: (a) for patent infringement, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and in particular arising under 35 U.S.C. § 271; and (b) for recovery of damages for lost profits and such other relief as may be warranted but in no event less than recovery of a reasonable royalty in connection with patent rights, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and in particular arising under 35 U.S.C. § 154(d).

16. The events giving rise to this cause of action occurred in the Northern District of Florida; and jurisdiction is proper in this Court.

17. Venue is proper in this court.

18. All conditions precedent to bringing this suit have been performed or have been waived.

GENERAL ALLEGATIONS

A. The Invention Of The '760 Patent

19. United States Patent No. 6,554,760, entitled "*Pre-Loaded Needle Assembly*," was duly filed on October 24, 2001 and was legally issued by the

United States Patent and Trademark Office on April 29, 2003, naming as inventors plaintiffs Gary A. Lamoureux and Richard A. Terwilliger. A Certificate of Correction to the '760 Patent was later issued by the U.S. Patent and Trademark Office on November 25, 2003, to correct errors which arose in the printing of the '760 Patent. A true copy of the '760 Patent, as printed and originally issued by the United States Patent and Trademark Office on April 29, 2003, together with the November 25, 2003 Certificate of Correction, is attached as **Exhibit A** to this Complaint and incorporated by reference. The '760 Patent currently is, and at all relevant times in the past has been, in full force and effect.

20. The '760 Patent rights were originally jointly owned by the co-inventors, Gary Lamoureux and Richard Terwilliger. At the time of invention and the filing of the patent in 2001, Mr. Terwilliger was an employee of Plaintiffs World Wide and Advanced Care which were owned by Mr. Lamoureux. All right, title, and interest in the '760 Patent have been assigned to Plaintiff World Wide.

21. Although other applications are envisioned and under development, the '760 patent has been and is principally directed to a "brachytherapy" needle assembly containing radioactive elements ("seeds") and a method for manufacturing such a needle assembly for treating cancer. Brachytherapy is a method of cancer treatment whereby a pattern of radioactive seeds is implanted in the vicinity of a cancerous tumor to destroy cancer cells with low-dose radiation. Optimal treatment of the patient depends on the proper spacing and precise location of the radioactive seeds in the patient's body relative to the tumor.

22. The principal application of brachytherapy is in the treatment of prostate cancer, although it has also been applied to other types including cervical, breast, lung, and skin cancers. In brachytherapy techniques for treating prostate cancer, the fundamental procedure is for seeds of radioactive material, including as Iodine l25, Palladium 103, and Cesium 131 isotopes to be implanted in three (3) dimension grid fashion within the prostate gland in a specified number and at specified locations so as to surround the tumor site. The grid array of implanted seeds around the cancerous tumor is predetermined by a radiation oncologist based upon ultrasound mapping of the prostate gland and tumor.

23. The preferred delivery method for radioactive seeds uses multiple hollow needles, each comprising a cannula that acts as a holder and carrier of the seeds. For implantation, seeds are loaded into the bore of a suitably sized needle cannula, and are spaced apart from each other (or others) within the needle bore using biocompatible spacer material so that, when deposited in body of a cancer patient, the seeds will be in the desired spaced array. A solid wire stylet is typically introduced into the rear end of the cannula behind the stack of seeds and spacers. The loaded cannula is inserted into the body to the proper depth and position. Once in position, the stylet is held firmly in place and the cannula is pulled back, depositing the radioactive seeds and spacers into the patient in the desired array. In a typical prostate brachytherapy procedure, anywhere from 50 to 150 seeds need to be deposited in the prostate in particular locations and a specific array around the tumor, using as many as 10 to 30 needles, each loaded with from 1 to

10 radioactive seeds. The number of seeds and spacers may vary for other types of cancer treatment.

Prior Art

24. Before the breakthrough improvement represented by the '760 Patent, the loading of the brachytherapy needles with seeds and spacers was performed on site at the hospital or clinic by a radiation oncologist or medical physicist. Traditionally, the oncologist or physicist had to pre-load radioactive seeds into needles immediately prior to the procedure—a process which was time-consuming, inconvenient, yielded inconsistent results, and risked repeated exposure to radiation.

25. In loading these brachytherapy needles, it is necessary to plug the exit end of the needle with some material so that the seeds and spacers will not fall out (and also to prevent body fluids from entering the needle bore when it is inserted into the prostate). Historically, the oncologists or physicists employed a "bone wax"[2] or similar material, and would either dip the needle exit (distal) end into the bone wax or employ other means to force it up into the exit end of the bore of the needle. Once plugged in this manner, the needle bore would be loaded with the desired number of seeds and spacers from the rear (promixal) end of the needle. When inserted to the desired depth within the prostate, the seeds and spacers are urged out by placing a stylet or mandrel against the back (promixal)

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[2] "Bone wax" is made of beeswax containing a softening agent such as paraffin. True "bone wax" formulations have been largely unchanged since being developed by Horsely in 1886. "Bone wax" is used to mechanically stop bone bleeding during surgical procedures.

end of the line of seeds and spacers and pulling the needle back over the stylet held in a fixed position pushing the needle contents through the sticky "bone wax" plugging material and into the patient.

26. This prior process for needle preparation and seed loading had many drawbacks, including the vast amount of hospital and physician time required, especially when up to 60 loaded needles per patient procedure might need to be prepared. Another serious problem with this on-site loading process relates to the plugging of the needle exit end with "bone wax." Due to the nature of the plugging materials employed, and especially the manner of plugging, the distance to which the plugging material extends up into the needle bore exit end is quite variable. Given that the seeds must be implanted at precise locations in the prostate in the desired array to achieve optimal results, the variability of the depth of plugging material at the needle tip in turn yields an inconsistent and imprecise the seed load and eventually an inconsistent and imprecise seed array deposited in the prostate—all posing a significant impediment to the intended effectiveness of the treatment.

'760 Patent

27. The needle assembly covered by the '760 patent comprises a needle that is "*pre-plugged*" and thus may be "*pre-loaded*" with radioactive seeds and spacers on the specific order or treatment plan of the physician. Once loaded, the needle can be *sterilized, packaged, and shipped* to the facility where the brachytherapy treatment will take place. The '760 patent addresses the drawbacks associated with loading brachytherapy needles at the treatment site or actually in

the operating room immediately prior to the procedure, drawbacks which include time consumption, inconvenience, inconsistency, and potentially excessive radiation exposure.

28. In the invention of the '760 Patent, there is described a "pre-plugged" needle for use in implanting therapeutic elements. More particularly, the invention provides a needle in which the exit end bore contains within it a "plug," of any suitable biocompatible material, which is placed at a predetermined distance from the needle exit end. The needle may then be loaded with radioactive seeds and spacers, or with stranded, linked or otherwise connected spaced seeds, and used for implantation, during which the plug is urged out of the needle cannula along with the seeds and spacers.

29. An important aspect of the '760 patent needle assembly is the ability to use an end plug that precisely locates the first seed a known and repeatable distance from the distal end of the cannula, thus improving the accuracy with which the radioactive seeds are placed in the body, which is important to the efficacy of the cancer treatment. The end plug is preferably frictionally held within the cannula in a manner to position the first seed of a needle a precise *"predetermined distance from the distal end"* or sharp end of the needle cannula.

30. The advantages of the invention of the '760 Patent over the prior art needle loading methods employed by hospital personnel are many. Principally, the use of a plug which is placed at a *defined, predetermined* distance within the needle bore end—in contrast to the prior art practice of plugging the needle end in a manner which results in a *varied* and *uncontrolled depth* of plugging material

within the needle bore tip area—means that the desired predetermined placement of seeds and spacers within the needle to produce a specific implantation array and seed pattern in the patient can be achieved with precision rather than the imprecision occasioned by the prior art. Still further, by providing a "pre-plugged" needle, the invention enables completely different approaches to loaded needle preparation. For example, in situations in which a hospital physicist or oncologist is still to be employed to load the seeds and spacers (or stranded, linked or otherwise connected spaced seeds) into the needle, the provision of the pre-plugged needle relieves such person of the time and effort involved in plugging the needle (which, as earlier noted, was fraught with imprecision).

31. Still more fundamentally, the ability to provide a pre-plugged needle enables the needle loading to be taken out of the hospital's hand altogether, at great savings of time, money, and effort. In particular, it is now possible to prepare for hospitals and doctors *fully loaded* needles. The doctors can provide to a medical device manufacturer the requisite information regarding the number of seeds required and the specific seed array pattern sought for implantation in the particular patient in question. Based on this information, the required numbers of loaded and pre-plugged needles can be prepared for delivery to the hospital, with all the correct number and placement of seeds, and *in sterile form*, such that the physician can conduct the implantation without any need for hospital staff to prepare the loaded needles, handle radioactive seeds, sterilize the individual components and attempt to assemble them while maintaining sterility of the complete assembly.

32. As reflected in the patent filings, the acceptance in the marketplace displacing the prior art, and in the claim construction rulings of the Connecticut District Court pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed.Cir. 1995), aff'd, 517 U.S. 370 (1996), the '760 Patent constitutes a significant advance in the efficacy, convenience, and efficiency of brachytherapy treatment.

B. **AnazaoHealth Corporation Infringing Activity**

33. The advantages of the invention that is set forth in the '760 Patent were immediately recognized by the industry upon WWMT's announcement in late October 2000 of its "Readi-Load" pre-plugged needle system embodying the invention.

34. To assist in the rapid adoption of the pre-plugged and pre-loaded brachytherapy needle system embodied by the '760 Patent, beginning in September 2001 Plaintiff World Wide entered into an arrangement with AnazaoHealth Corporation ("Anazao") (f/k/a as Genesis Pharmacy Services, Inc. d/b/a Custom Care Pharmacy) whereby Anazao (i) purchased "Readi-Load™" pre-plugged needles (later called "Seed-Lock™" pre-plugged needles for the "Readi-Load™" System); (ii) acquired radioactive seeds from seed manufacturers, including the Defendants in this case (based on information and arrangements made with such seed manufacturers by Plaintiff World Wide); (iii) prepared on behalf of seed manufacturers sterilized, pre-plugged and pre-loaded needles with seeds and spacers and kits containing multiple such pre-loaded needles all loaded with the prescribed number of seeds, spacing of said seeds, and number of pre-loaded needles per the patient's treatment plan as ordered from the hospital,

clinic, or doctor; and (iv) delivered to the hospital, clinic, or doctor customers of the seed manufacturers the pre-plugged and pre-loaded needles and kits, packaged and sterilized ready for implantation per patient order. This loading and assembly operation was an entirely new business for Anazao—introduced by, arranged by, and facilitated by Plaintiff World Wide for Anazao's benefit.

35. The arrangement Plaintiff World Wide enabled for Anazao called for Anazao to pay World Wide for the SeedLock™ pre-plugged needles as a "cost of sales," **plus** a ten percent (10%) royalty fee under the '760 Patent computed based upon the total final hospital/clinic price of the full kit delivered by Anazao's seed manufacturing company customer to their end user hospital or doctor customer. The radioactive seeds were an essential component of the final delivered product, and the seed manfacturers' were participants in the royalty pricing to Plaintiff World Wide. The end user hospitals, clinics, and doctors were the customers of the seed manufactures. The seed manufacturers were charged by Anazao for the royalty fee that Anazao collected from the seed manufacturers and was in turn obligated to remit to Plaintiff World Wide.

36. The arrangement between Plaintiff World Wide and Anazao terminated because of discrepancies with Anazao's accounting for the quantity of delivered SeedLock™ pre-plugged needles and the amount of royalty payments due. As of September 2002, Anazao ceased operating under the loading and assembly service agreement with Plaintiff World Wide.

37. In actual fact, Anazao initiated a plan to circumvent Plaintiff World Wide in direct competition with the SeedLock™ pre-plugged and pre-loaded

needles and kits. Without authorization or license from World Wide, Anazao has continued loading seeds and spacers, or stranded, linked or otherwise connected spaced seeds into pre-plugged needles either manufactured by Anazao or obtained from others (not including World Wide), manufacturing and assembling pre-plugged and pre-loaded needles and kits, and offering for sale, selling, and distributing such kits to hospital, clinic, and doctor customers of the seed manufacturers. This action by Anazao was and continues to be a direct infringement of the '760 Patent, a violation of United States patent law, 35 U.S.C. §§ 1 *et seq.*, and the source of the Plaintiff World Wide's claims in the ongoing Anazao Action in U.S. District Court of Connecticut.

Non-Party Infringment Claim

38. On or about August 11, 2003, Plaintiff World Wide and '760 Patent inventors Gary Lamoureux and Richard Terwilliger instituted a lawsuit against Genesis Pharmacy Services, Inc. (n/k/a Anazao) for patent infringement and other claims (D.CT Case No. 3:03cv01382(WIG)) ("Anazao Action"). This litigation has been ongoing since. On information and belief Defendants have been on actual and constructive notice of the potential for infringement claims against them under the '760 Patent.

39. On or about November 11, 2009 the U.S. District Court for the District of Connecticut issued the Claim Construction Opinion for the '760 Patent and on January 22, 2010 followed with the Ruling On Plaintiffs' Motion For Reconsideration which describe the '760 Patent claims as encompassing "a pre-plugged and pre-loaded needle assembly for the implantation of therapeutic

elements into the body for the treatment of cancer." **Exhibit B and C.** The District Court ruling on the '760 fully describes the infringing product offerings of the Defendants in this action which have been marketed, sold, and distributed for the brachytherapy treatment of cancer.

C. **Low Dose Radioactive Seed Manufacturer Activity**

40. As noted, the advantages of the pre-plugged, pre-loaded needle assembly under the '760 Patent were immediately recognized by the industry. Beginning from zero in 2002, within as little as five (5) years, fully 50-60% of the entire brachytherapy market, with as much as $150 million in annual revenue, employed a pre-plugged, pre-loaded needle assembly manufactured and distributed from either World Wide's affiliate, Advanced Care, or from others in violation of the '760 Patent. The Defendant seed manufacturers were knowing culprits in this infringing activity. The problem is that World Wide is a small company and depended on the same seed manufacturers, who were also customers, for survival.

Coloplast Corporation, Core Oncology, Inc., and Johnson & Johnson, as Successors to Mentor Corporation

41. Anazao ceased operating under agreement with Plaintiff World Wide on or about September 2002. Not coincidentally, as early as August 2002 Anazao's initial customer, Mentor Corporation, was marketing and selling mainly two (2) types of brachytherapy seeds (Iodine 125 and Palladium 103) for the treatment of prostate cancer, together with the associated supplies and delivery systems that included pre-plugged, pre-loaded needles and kits.

42. Since that time Mentor and its successors have dealt with Anazao or on their own account avoiding the royalty fee to Plaintiff World Wide.

43. Mentor's brachytherapy division was sold to Coloplast on or about June 2, 2006, but there was no interruption or change in the method of delivery of the brachytherapy service or the use of infringing pre-plugged, pre-loaded needles and kits.

44. Coloplast sold the brachytherapy business on or about June 8, 2007 to Core—again without interruption or change in the method of delivery of the brachytherapy service or the use of infringing pre-plugged, pre-loaded needles and kits.

45. On or about January 23, 2009, Defendant J&J acquired Mentor Corporation in a stock purchase. As a result, Defendant J&J, as successor to Mentor, marketed and sold pre-plugged, pre-loaded needle assemblies in violation of the '760 Patent from as early as August 2002 through June 2, 2006.

Oncura, Inc.

46. Defendant Oncura originated the I-125 isotope seed for brachytherapy and was and is an early and an important customer of Plaintiff Advanced Care. However, Defendant Oncura places only a small portion of its business with Plaintiff Advanced Care. Defendant Oncura's seeds are pre-loaded in a pre-plugged needle assembly as a loose seed and spacer configuration and in a stranded configuration (RAPID Strand Rx Brachytherapy Kit).

47. Defendant Oncura, operating as Amersham, Inc. until its acquisition by GE Healthcare in 2004 and since then, has been a dominant seed manufacturer

in the brachytherapy marketplace. Defendant Oncura distributes its brachytherapy products world wide. Defendant Oncura markets both I-125 and Pd-103 isotope seeds. Annual revenue in infringing product of pre-plugged, pre-loaded needle assemblies since 2005 is estimated to be well in excess of $10.0 million per year.

C.R. Bard, Inc.

48. Defendant Bard has been manufacturing and selling I-125 isotope seeds since at least 2003. Bard is one of the largest manufactures of I-125 seeds from its Carol Stream, IL facility under the name of "Brachysource" and pre-loaded in the "BrachyStar FastFill" needle assembly in direct violation of the '760 Patent. Defendant Bard also distributes the Pd-103 isotope seed manufactured by Defendant Theragenics and again pre-loaded in the "BrachyStar FastFill" needle assembly in direct violation of the '760 Patent.

49. Defendant Bard also offers stranded or connected seed product in the "BrachyStar FastFill" pre-plugged, pre-loaded needle assembly in violation of the '760 Patent. Defendant Bard's annual revenue in infringing product since 2005 is estimated to be well in excess of $10.0 million per year.

Best Medical International, Inc.

50. Defendant Best originally manufactured only I-125 seeds and subsequently added Pd-103 seeds which it marketed and distributed in pre-plugged, pre-loaded needle assemblies in violation of the '760 Patent. More recently Best acquired through its wholly owned subsidiary Brachytherapy Services, Inc. the manufacturing facilities out of bankruptcy of NASI and has continued NASI's manufacturing of both I-125 and Pd-103 isotope seeds under

NASI's "Prospera" name. Defendant Best has also continued to market the clones of NASI's "SurTrak" product line in direct violation of both the '760 Patent and the Orders of the California bankruptcy court (*In Re North American Scientific, Inc.*, N.D. Cal. Case No. 1:09-BK-12675).

51. Defendant Best advertises that its brachytherapy products are utilized by more than 700 healthcare facilities around the world. Defendant Best's annual revenue in infringing product since 2005 is estimated to be well in excess of $7.0 million per year.

Theragenics Corporation

52. Defendant Theragenics originated the Palladium isotope (Pd-103) seed for treatment of prostate cancer in 1987. Theragenics added the Iodine isotope (I-125) seed in 2003. Defendant Theragenics has manufactured and distributed its seeds in pre-plugged, pre-loaded needle assemblies since well before 2005 and currently markets a line of needles under the name of NeedleTech Products, Inc. which Theragenics acquired in 2008.

53. Defendant Theragenics manufactured and distributed I-125 and Pd-103 isotope seeds for prostate treatment in seed and spacer configuration and stranded configuration—each type in pre-plugged, pre-loaded needle assemblies in violation of the '760 Patent. Annual revenue for Defendant Theragenics in infringing product is estimated since 2005 to be well in excess of $6.0 million per year.

Isoray Medical, Inc.

54. Defendant IsoRay originated the Cesium (Cs-131) isotope for brachytherapy and treated its first patient in October 2004. Defendant IsoRay advertises that over fifty (50) clinics across the United States offer brachytherapy treatment for prostate cancer using the Cs-131 isotope seed. Defendant IsoRay manufactures and distributes the Cs-131 isotope seeds in pre-plugged, pre-loaded needle assemblies in violation of the '760 Patent. Annual revenue for Defendant Theragenics in infringing product is estimated since 2005 to be well in excess of $4.0 million per year.

COUNT I
PATENT INFRINGEMENT
Violation Of 35 U.S.C. §§ 1 *et seq.*

Coloplast Corporation,Core Oncology, Inc., And Johnson & Johnson, as Successors to Mentor Corporation

55. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 54 set forth above.

56. Defendants Coloplast, Core, and J&J are infringing and have infringed and contributed to and induced infringement of the '760 Patent under one or more provisions of 35 U.S.C. §§271 (a)-(g).

57. Defendants Coloplast, Core, and J&J are aware and have been aware of the existence of the '760 Patent. The infringement of Defendants Coloplast, Core, and J&J of the '760 Patent has been and continues to be willful and deliberate.

58. The infringement of Defendants Coloplast, Core, and J&J of the '760 Patent has caused and is causing irreparable harm to Plaintiffs World Wide and Advanced Care.

WHEREFORE Plaintiffs World Wide and Advanced Care have suffered injury and are suffering injury as a direct result of the willful and deliberate breach of the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, by Defendants Coloplast, Core, and J&J. Plaintiffs World Wide and Advanced Care demand judgment against Defendants for compensatory damages, prejudgment interest, and such other relief as the Court deems appropriate.

COUNT II
PATENT INFRINGEMENT
Violation Of 35 U.S.C. §§ 1 *et seq.*

Oncura, Inc.

59. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 54 set forth above.

60. Defendant Oncura is infringing and has infringed and contributed to and induced infringement of the '760 Patent under one or more provisions of 35 U.S.C. §§271 (a)-(g).

61. Defendant Oncura is aware and has been aware of the existence of the '760 Patent. Defendant Oncura's infringement of the '760 Patent has been and continues to be willful and deliberate.

62. The infringement of Defendant Oncura of the '760 Patent has caused and is causing irreparable harm to Plaintiffs World Wide and Advanced Care.

WHEREFORE Plaintiffs World Wide and Advanced Care have suffered injury and are suffering injury as a direct result of the willful and deliberate breach of the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, by Defendant Oncura. Plaintiffs World Wide and Advanced Care demand judgment against Defendant Oncura for compensatory damages, prejudgment interest, and such other relief as the Court deems appropriate.

COUNT III
PATENT INFRINGEMENT
Violation Of 35 U.S.C. §§ 1 *et seq.*

C.R. Bard, Inc.

63. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 54 set forth above.

64. Defendant Bard is infringing and has infringed and contributed to and induced infringement of the '760 Patent under one or more provisions of 35 U.S.C. §§271 (a)-(g).

65. Defendant Bard is aware and has been aware of the existence of the '760 Patent. Defendant Bard's infringement of the '760 Patent has been and continues to be willful and deliberate.

66. The infringement of Defendant Bard of the '760 Patent has caused and is causing irreparable harm to Plaintiffs World Wide and Advanced Care.

WHEREFORE Plaintiffs World Wide and Advanced Care have suffered injury and are suffering injury as a direct result of the willful and deliberate breach of the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, by Defendant Bard. Plaintiffs World Wide and Advanced Care demand judgment against Defendant Bard for compensatory damages, prejudgment interest, and such other relief as the Court deems appropriate.

COUNT IV
PATENT INFRINGEMENT
Violation Of 35 U.S.C. §§ 1 *et seq.*

Best Medical, Inc.

67. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 54 set forth above.

68. Defendant Best is infringing and has infringed and contributed to and induced infringement of the '760 Patent under one or more provisions of 35 U.S.C. §§271 (a)-(g).

69. Defendant Best is aware and has been aware of the existence of the '760 Patent. Defendant Best's infringement of the '760 Patent has been and continues to be willful and deliberate.

70. The infringement of Defendant Best of the '760 Patent has caused and is causing irreparable harm to Plaintiffs World Wide and Advanced Care.

WHEREFORE Plaintiffs World Wide and Advanced Care have suffered injury and are suffering injury as a direct result of the willful and deliberate breach of the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, by Defendant Best. Plaintiffs World Wide and Advanced Care demand judgment against Defendant Best for compensatory damages, prejudgment interest, and such other relief as the Court deems appropriate.

COUNT V
PATENT INFRINGEMENT
Violation Of 35 U.S.C. §§ 1 *et seq.*

Theragenics Corporation

71. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 54 set forth above.

72. Defendant Theragenics is infringing and has infringed and contributed to and induced infringement of the '760 Patent under one or more provisions of 35 U.S.C. §§271 (a)-(g).

73. Defendant Theragenics is aware and has been aware of the existence of the '760 Patent. Defendant Theragenics's infringement of the '760 Patent has been and continues to be willful and deliberate.

74. The infringement of Defendant Theragenics of the '760 Patent has caused and is causing irreparable harm to Plaintiffs World Wide and Advanced Care.

WHEREFORE Plaintiffs World Wide and Advanced Care have suffered injury and are suffering injury as a direct result of the willful and deliberate breach of the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, by Defendant Theragenics. Plaintiffs World Wide and Advanced Care demand judgment against Defendant Theragenics for compensatory damages, prejudgment interest, and such other relief as the Court deems appropriate.

COUNT VI
PATENT INFRINGEMENT
Violation Of 35 U.S.C. §§ 1 *et seq.*

IsoRay Medical, Inc.

75. Plaintiffs reallege and incorporate by reference Paragraphs 1 through 54 set forth above.

76. Defendant IsoRay is infringing and has infringed and contributed to and induced infringement of the '760 Patent under one or more provisions of 35 U.S.C. §§271 (a)-(g).

77. Defendant IsoRay is aware and has been aware of the existence of the '760 Patent. Defendant IsoRay's infringement of the '760 Patent has been and continues to be willful and deliberate.

78. The infringement of Defendant IsoRay of the '760 Patent has caused and is causing irreparable harm to Plaintiffs World Wide and Advanced Care.

WHEREFORE Plaintiffs World Wide and Advanced Care have suffered injury and are suffering injury as a direct result of the willful and deliberate breach of the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*, by Defendant IsoRay. Plaintiffs World Wide and Advanced Care demand judgment against Defendant IsoRay for compensatory damages, prejudgment interest, and such other relief as the Court deems appropriate.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief as follows:

A. That the Court adjudge that each Defendant has infringed one or more claims of the '760 patent;

B. That the Court adjudge that each Defendant's infringement of the '760 Patent has been willful and deliberate;

C. That the Court award Plaintiffs their damages in accordance with 35 U.S.C. § 284, and increase those damages up to three (3) times by reason of the willful and deliberate infringement;

D. That the Court award Plaintiffs their costs in connection with this action;

E. That the Court declare the patent infringement claims herein to be an "exceptional" case within the meaning of 35 U.S.C. § 285, and award Plaintiffs their reasonable attorney fees, expenses and costs in this action;

F. That the Court award Plaintiffs such other and further relief as the Court may deem to be just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs request trial by jury pursuant to Rule 38(b), Fed.R.Civ.P., of all claims and issues so triable under law.

Respectfully submitted this 6 day of December, 2011.

/s/ John Wiley Horton

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