

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

NEW AMSTERDAM LLC,

Plaintiff,

v.

MTD MICRO MOLDING, INC.,

Defendant.

Case No. -----

JURY TRIAL DEMANDED

ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

New Amsterdam LLC (“Plaintiff”) hereby files this Original Complaint for Patent Infringement against MTD Micro Molding, Inc. (“MTD” or “Defendant”), and alleges, upon information and belief, as follows:

THE PARTIES

1. New Amsterdam LLC is a limited liability company organized and existing under the laws of the State of Delaware with its principal place of business at 163 Bogerts Mill Road, Harrington Park, Bergen County, New Jersey 07640.
2. Upon information and belief, Defendant MTD Micro Molding, Inc. is a corporation organized and existing under the laws of the Commonwealth of Massachusetts with its principal place of business at 15 Trolley Crossing Road, Charlton, Worcester County, Massachusetts 01507.

JURISDICTION AND VENUE

3. This Court has subject matter jurisdiction over this case under 28 U.S.C. §§ 1331 and 1338(a).

4. This Court has personal jurisdiction over Defendant. Defendant has continuous and systematic business contacts with the Commonwealth of Massachusetts. Defendant transacts business within this District and elsewhere in the Commonwealth of Massachusetts. Further, this Court has personal jurisdiction over Defendant based on its commission of one or more acts of infringement of patent-in-suit in this District and elsewhere in the Commonwealth of Massachusetts.
5. Defendant directly conducts business extensively throughout the Commonwealth of Massachusetts, by distributing, making, using, offering for sale, selling, and advertising its products and services in the Commonwealth of Massachusetts and in this District. Defendant has purposefully and voluntarily made its business services, including the infringing systems and services, available to residents of this District and into the stream of commerce with the intention and expectation that they will be purchased and/or used by consumers in this District.
6. Defendant maintains physical brick-and-mortar business locations in the Commonwealth of Massachusetts and within this District, retains employees specifically in this District for the purpose of servicing customers in this District, and generates substantial revenues from its business activities in this District.
7. Venue is proper in the District of Massachusetts as to Defendant pursuant to at least 28 U.S.C. §§ 1391(c)(2) and 1400(b). As noted above, Defendant maintains a regular and established business presence in this District.

BACKGROUND AND PATENTS-IN-SUIT

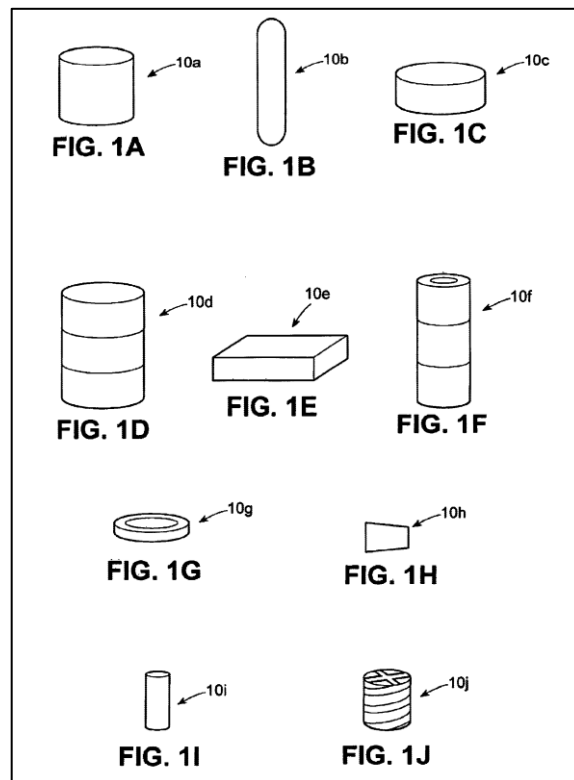
8. Plaintiff is the sole and exclusive owner, by assignment, of U.S. Patent Nos. 6,916,483 (“the ‘483 Patent”) titled “Bioabsorbable Plugs Containing Drugs” relating to controllably

delivering therapeutic agents to an orthopaedic surgical site that requires the implantation of a prosthesis within the site.

9. By operation of law, the '483 Patent was originally issued and exclusively vested to the named inventors, James Ralph and Steven Tater, as of the issue date of the '483 Patent. *See* 35 U.S.C. § 261; *Schwendimann v. Arkwright Advanced Coating, Inc.*, 959 F.3d 1065, 1072 (Fed. Cir. 2020); *Suppes v. Katti*, 710 Fed. Appx. 883, 887 (Fed. Cir. 2017); *Taylor v. Taylor Made Plastics, Inc.*, 565 Fed. Appx. 888, 889 (Fed. Cir. 2014). The inventors, in a written instrument dated June 30, 2003, and filed with the United States Patent and Trademark Office on June 9, 2005, assigned all rights, title, and interest in the '483 Patent to OsetoTools, LLC.
10. OsteoTools, LLC, in a written instrument dated April 1, 2005, and filed with the United States Patent and Trademark Office on April 2, 2005, assigned all rights, title, and interest in the '483 Patent to BioDynamics, LLC.
11. Formed in May 2004, BioDynamics, LLC is a medical design company dedicated to the development of new surgical implants, instruments and techniques that are reliable and less intrusive, that allow a surgeon to be more efficient, and which speed a patient's recovery. Their team of engineers has several decades of combined medical design experience and over 150 patents in the medical arena, ranging from orthopedic implants to biologics.
12. Thereafter, in a written instrument dated June 15, 2021, and filed with the United States Patent and Trademark Office on July 8, 2021, BioDynamics LLC assigned all rights, title, and interest in the '483 Patent to First Commerce Bank related to settling litigation claims.
13. Thereafter, in a written instrument dated September 28, 2021, and filed with the United States Patent and Trademark Office on November 17, 2021, First Commerce Bank assigned all rights, title, and interest in the '483 Patent to the Plaintiff New Amsterdam LLC. As such, Plaintiff

New Amsterdam LLC has sole and exclusive standing to assert the '483 Patent and to bring these causes of action.

14. The '483 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.
15. The inventions described and claimed in the '483 Patent were invented individually and independently by James Ralph and Steven Tater.
16. The '483 Patent includes numerous claims defining distinct inventions. As represented in Figs. 1A-J of the '483 Patent below, the inventions generally relate to implantable devices and methods thereof for dispensing one or more therapeutic agents at a surgical site. More particularly, the invention relates to devices and methods for controllably delivering therapeutic agents to an orthopaedic surgical site that requires the implantation of a prosthesis within the site.



17. The priority date of each of the '483 Patent is at least as early as July 22, 2002. As of the priority date, the inventions as claimed were novel, non-obvious, unconventional, and non-routine.
18. Biodegradable materials are used in medicine for a variety of purposes including drug delivery devices and as aids in tissue repair. The physical and chemical properties of such materials can vary as in the case of different polymeric materials, e.g., melting point, degradation rate, stiffness, etc. The variability in physical and chemical properties of biodegradable polymeric materials allows biodegradable implants made from such materials to be tailored to suit specific applications.
19. At the time of the inventions, the porous bioabsorbable were generally isotropic materials. That is to say, the structure and composition of the materials were uniform in all directions. Any pharmacological therapeutic agents were generally distributed uniformly in the biodegradable carrier materials. This, in turn, means that the active agents were released uniformly into the wound site at a rate determined only by the rate at which the implant material biodegrades and the surface area of the implant. In practice, it would have been preferable to have controlled or phased release of active agents. Alternatively, it would sometimes have been desirable to have an initial rapid release of antiseptic followed by slower release of wound healing factors such as cytokines, EGF, etc.
20. The inventors of the '483 Patent conceived new a modular drug delivery device and method for controllably delivering a therapeutic agent to a surgical site, particularly an orthopaedic surgical site into which a prosthesis has been implanted. The bioabsorbable drug delivery devices in accordance with the various embodiments of the '483 Patent include encapsulating the therapeutic agent in a bioabsorbable polymer, or a modular plug containing more than one

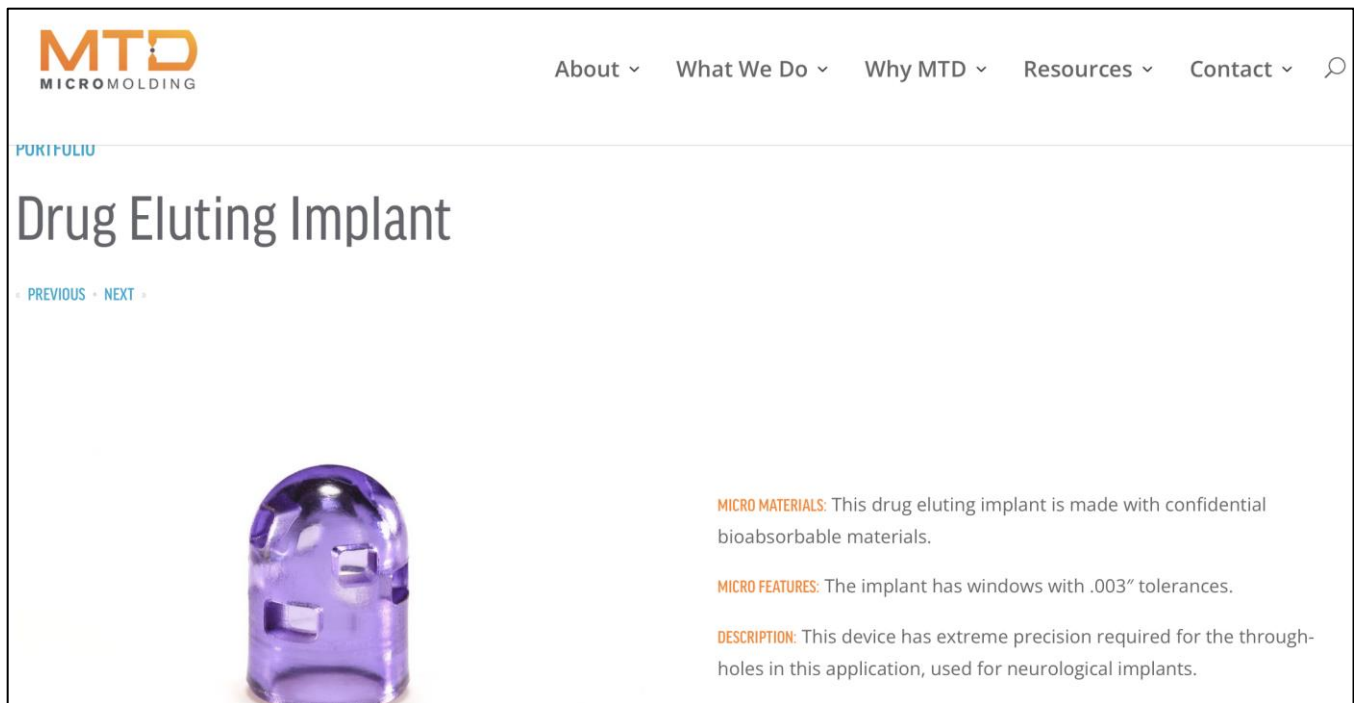
bioabsorbable polymer, which will yield a controllable release of the therapeutic agent over a predefined dosing period (such as a 7-10 day period), with residual therapeutic agent being thereafter delivered only until the bioabsorbable polymer is completely biodegraded.

21. The '483 Patent is a pioneering patent, and has been cited as relevant prior art in 99 subsequent United States Patent Applications, including Applications Assigned to such technology leaders and academia as Tyco Healthcare, MIT, Microchips, Inc., Tyrx Pharma Inc. and Orbusneich Medical, Inc.
22. The claims of the '483 Patent were all properly issued, and are valid and enforceable for the respective terms of their statutory life through expiration, and are enforceable for purposes of seeking damages for past infringement even post-expiration. *See, e.g., Genetics Institute, LLC v. Novartis Vaccines and Diagnostics, Inc.*, 655 F.3d 1291, 1299 (Fed. Cir. 2011) (“[A]n expired patent is not viewed as having ‘never existed.’ Much to the contrary, a patent does have value beyond its expiration date. For example, an expired patent may form the basis of an action for past damages subject to the six-year limitation under 35 U.S.C. § 286”) (internal citations omitted).
23. The expiration date of the '483 Patent is no earlier than June 9, 2023.

MTD’S INFRINGING PRODUCTS

24. Upon information and belief, MTD makes, sells, advertises, offers for sale, uses, or otherwise provides drug eluting implants that utilize the '483 Patent’s patented implantable prosthetic designs. On information and belief, these drug eluting implants are operable for releasing a therapeutic agent into the body of an animal following implantation of the prosthesis within the body of the animal.

25. On information and belief, MTD has manufactured and sold products that infringe the '483 Patent and which include at least, but not limited to, its (1) Drug Delivery Straws; (2) Ultra-Thin Wall Cannulas for Wearable Bolus Injectors or Drug Infusion Sets; (3) Single-Use, Time-Release Pharmaceutical Implants; and (4) Permanent Refillable Drug-Eluting Implants (“Accused Instrumentalities”).
26. As shown in more detail below, MTD’s strip fastener products include each and every limitation of at least, but not limited to, claim 1 of the '483 Patent and therefore literally infringe these claims. Plaintiff reserves the right to assert additional claims and to assert infringement under the doctrine of equivalents in light of information learned during discovery or in view of this Court’s claim construction order.
27. Images of MTD’s drug eluting implants products found in the Osteoplug are shown below. MTD’s strip fastener products include the required (a) biodegradable polymer dimensions to fit snugly within the shaped recess in the prosthesis and (2) therapeutic agent that is released into the body of the animal during biodegradation of the biodegradable polymer over a predefined dosing period, all of the same fundamental components claimed in the '483 Patent.
28. For example, a drug eluting implant is shown in the following images from its website promoting the Accused Instrumentalities, as last visited on February 2, 2023, at <https://mtdmicromolding.com/project/bioresorbable-drug-eluting-implant/>.



29. Features of the Accused Instrumentalities below describe the functionality as required by the '483 Patent are found on MTD's website as last visited on February 2, 2023 at <https://mtdmicromolding.com/micro-medical/drug-delivery/>.

Drug Delivery Applications	Examples of Micro Devices	Common Materials
• Polymer-based drug delivery systems • Bioabsorbable pharmaceutical delivery vehicles/carriers • Drug delivery implants • Bioabsorbable polymer drug-eluting implants—drug/polymer coated or drug/polymer compounded to modulate drug release	• Drug Delivery Straws • Ultra-Thin Wall Cannulas for Wearable Bolus Injectors or Drug Infusion Sets • Single-Use, Time-Release Pharmaceutical Implant • Permanent Refillable Drug-Eluting Implant	• Polypropylene (PP) • PLDL (<i>bioabsorbable</i>) • PLG (<i>bioabsorbable</i>)

COUNT I
Infringement of U.S. Patent No. 6,916,483B2

30. Plaintiff incorporates the above paragraphs by reference.

31. MTD without authority, continues to make, use, sell, offer to sell, and/or import into the United States its Accused Instrumentalities as shown above.

32. MTD thus has infringed and continues to infringe at least claims 1 and 20 of the '483 Patent literally and/or under the doctrine of equivalents.
33. MTD has also actively induced and will continue to actively induce the infringement of at least one of claim 1 of the '483 Patent, in violation of 35 U.S.C. § 271(b), by, among other things, actively and knowingly aiding and abetting infringement of others through activities such as creating and/or distributing videos of use such as the Osteo Video, brochures, manuals, instructional documents, and/or similar materials with instructions on creating, manufacturing, designing, assembling and/or implementing infringing products, with the specific intent to induce others to directly make, use, offer for sale, sell, and/or import into the United States products that fall within the scope of the '483 Patent, without license or authority from Plaintiff. On information and belief, MTD knows that the induced acts constitute infringement of the '483 Patent.
34. MTD individually, collectively, or through others or intermediaries, has contributorily infringed, and/or is contributorily infringing, in violation of 35 U.S.C. § 271(c), at least one claim of the '483 Patent by making, using, offering for sale, selling, and/or importing, material parts of the inventions claimed in the '483 Patent, which are not a staple article or commodity of commerce suitable for substantial non-infringing use, and knowing the accused parts to be especially made or especially adapted for use in an infringement of the '483 claims.
35. MTD has been on actual notice of the '483 Patent at least as early as the date it received service of the Original Complaint in this litigation. MTD's direct and indirect infringement of the '483 Patent has thus been committed with knowledge of the '483 Patent, making MTD liable for direct, indirect, and willful infringement.

36. MTD's infringement of the '483 Patent will continue to damage Plaintiff, causing irreparable harm for which there is no adequate remedy at law, unless it is enjoined by this Court.
37. Plaintiff has been damaged because of the infringing conduct by MTD alleged above. Thus, MTD is liable to Plaintiff in an amount that adequately compensates it for such infringement, which, by law, cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.
38. Plaintiff and/or its predecessors-in-interest have satisfied all statutory obligations required to collect pre-filing damages for the full period allowed by law.

PRAYER FOR RELIEF

WHEREFORE, New Amsterdam LLC respectfully requests the Court enter judgment against Defendant as follows:

1. Declaring that Defendant has infringed the '483 Patent;
2. Awarding New Amsterdam LLC its damages suffered because of Defendant's infringement of the '483 Patent;
3. Awarding New Amsterdam LLC its costs, reasonable attorneys' fees, expenses, and interest;
4. An award to New Amsterdam LLC of enhanced damages, up to and including trebling of Plaintiff's damages pursuant to 35 U.S.C. § 284 for MTD's willful infringement of the '483 Patent;
5. Granting a permanent injunction pursuant to 35 U.S.C. § 283, enjoining Defendants from further acts of infringement with respect to the '483 Patent;
6. Awarding New Amsterdam LLC ongoing post-trial royalties for infringement of the non-expired '483 Patent; and

7. Granting New Amsterdam LLC such further relief as the Court finds appropriate.

JURY DEMAND

New Amsterdam LLC demands trial by jury, under Fed. R. Civ. P. 38.

Respectfully Submitted,

/s/ Paul T. Muniz

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ATTORNEYS FOR PLAINTIFF

NEW AMSTERDAM LLC

Dated: February 6, 2023