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# UNITED STATES DISTRICT COURT EASTERN DISTRICT OF VIRGINIANIA FEB 10 12: 43

W.H.P.M., INC., 5358 Irwindale Avenue Irwindale, California 91706

Plaintiff.

v.

BIOTECHPHARMA, LLC,

Please Serve:
Registered Agent:
Raouf A. Guirguis
1712 Brookside Lane
Vienna, Virginia 22182
and

Please Serve: 1712 Brookside Lane Vienna, Virginia 22182

RAOUF A. GUIRGUIS,

Defendants.

CLERK US DISTRICT COURT ALEXAMORIA, VIRGINIA

Case No.  $\frac{\frac{1}{2}}{2}$  Cury Trial Demanded

## **COMPLAINT**

W.H.P.M., Inc. ("WHPM"), by counsel, brings its complaint for injunctive relief and monetary damages, including treble damages, against Defendants, BiotechPharma, LLC ("BTP") and Raouf A. Guirguis ("Guirguis"), jointly and severally:

#### THE PARTIES

W.H.P.M., Inc. is a corporation, organized and existing under the laws
of the State of California. WHPM's principal place of business is at 5358 Irwindale
Avenue, Irwindale, California 91706.

- 2. BiotechPharma, LLC is a limited liability company, organized and existing under the laws of the Commonwealth of Virginia. BTP's principal place of business is at 1712 Brookside Lane, Vienna, Virginia 22182.
- 3. Raouf A. Guirguis is BTP's Chairman and CEO. He has a residence in Vienna, Virginia and his business address is that of BTP's principal place of business.

## JURISDICTION AND VENUE

- 4. This action arises under the patent statutes, 35 U.S.C. § 101 et seq., in particular 35 U.S.C. § 271.
- 5. This Court has subject-matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).
- 6. This Court has personal jurisdiction over BTP, because BTP is incorporated and resides in the Commonwealth of Virginia.
- 7. This Court has personal jurisdiction over Guirguis because Guirguis is a principal of BTP and resides in the Commonwealth of Virginia.
- 8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1400(b).

## THE PATENT-IN-SUIT

9. WHPM is the owner by assignment of U.S. Patent No. 7,927,562 (the "'562 patent"), entitled "Collection and Assay Device for Biological Fluid," which was duly and legally issued on April 19, 2011 from an application filed

December 13, 2007. A true and correct copy of the '562 patent is attached as Exhibit A.

## STATEMENT OF FACTS

## WHPM's Technology

- 8. Established in 1992, WHPM is a bioresearch and technology company that specializes in one-step rapid membrane immunoassay tests. Over the last decade, WHPM has developed a variety of innovative one-step tests for applications in cancer screening, environmental monitoring, fertility testing, infectious disease and microorganism testing, and forensic drugs of abuse testing. In addition to its immunoassay products, WHPM offers business-to-business services, including product design, manufacturing, and packaging.
- 9. Dr. John Wan is the President, CEO, and sole owner of WHPM.

  Dr. Wan is an innovator whose ideas have resulted in successfully developing sixteen FDA-approved products; six other products are pending FDA approval.

  Dr. Wan's innovations are the subject of a number of U.S. and international patents and applications, including the '562 patent, on which Dr. Wan is a named inventor.
- 10. The '562 patent is directed to a device for collecting and analyzing a biological fluid. One example of such a device collects and analyzes saliva for the presence of drugs of abuse such as alcohol, marijuana, and cocaine. WHPM manufactures a cylindrical saliva drugs-of-abuse test product covered by claims of the '562 patent and distributed in the United States under the registered trademark StatSwab® ("WHPM tube device"). Dr. Wan and WHPM researchers

developed the WHPM tube device sometime before December 13, 2007, the filing date of the application granted as the '562 patent.

## Facts Relating to Infringement

- 11. In May 2008, Catherine Dain of BTP emailed Carmen Saenz of Hemosure Inc., another company owned by Dr. Wan. Dain asked whether Hemosure could provide original equipment manufacturing of test strips for use in BTP's Drug of Abuse Rapid Test Kit product with a fingerprinting feature, sold under the name "FP-DRG." Sherry Wang of WHPM responded to the email. Wang and Dain exchanged e-mails concerning price quotes for test strips.
- 12. Guirguis held a first meeting with Dr. Wan on or about May 29, 2008 at WHPM's headquarters, then located in El Monte, California. Guirguis expressed a desire to have WHPM serve as the original equipment manufacturer ("OEM") for a drugs-of-abuse test device with a fingerprinting feature, which BTP designated "DRG-8260."
- 13. During that first meeting, Dr. Wan described to Guirguis some of WHPM's products and services. This included showing Guirguis a sample of WHPM's tube device and telling him that a patent application on the product had been filed.
- 14. After that first meeting, until on or about October 14, 2009, WHPM and BTP worked to fabricate a mold for, and to produce samples and finished products of, the DRG-8260. On information and belief, BTP's DRG-8260 device was offered for sale sometime in or around April 2009, but the device was commercially

unsuccessful. From on or about October 15, 2009 until on or about June 4, 2010, WHPM received no communications from BTP.

- 15. Guirguis contacted WHPM on or about June 4, 2010 and asked for bulk pricing for three cylindrical parts of WHPM's tube device that could not be used in the DRG-8260 (which is only partly cylindrical): (1) a cylindrical saliva collection sponge; (2) a cylindrical saliva carrier and (3) a cylindrical saliva collection tube. Guirguis indicated that these parts would be packaged and labeled in BTP's facility in Wisconsin. The request to WHPM was urgent, inasmuch as Guirguis sought "immediately \$5,000 of each part ordered." Guirguis also informed WHPM that the DRG-8260 project was to remain on hold.
- 16. Dr. Wan responded to BTP on June 9, 2010, explaining that its request could not be honored in the U.S. owing to an exclusive agreement with a distributor. WHPM did offer to be an OEM for BTP in China and to drop-ship products for BTP's overseas customers.
- 17. On information and belief, Guirguis and BTP developed a cylindrical saliva drugs-of-abuse test product based on WHPM's tube device which BTP identified by the product name "DRG-SA06 Drug Testing & Identity Verification System" ("DRG-SA06 device" or "BTP tube device") (see *Exhibit B* attached hereto).
- 18. Guirguis held another meeting with Dr. Wan and others at WHPM on or about August 10, 2010 at WHPM's El Monte headquarters to discuss the DRG-SA06 device. Guirguis brought a device sample to the meeting to demonstrate it to the attendees. At the meeting's conclusion, WHPM declined to enter an agreement

for WHPM to manufacture BTP's DRG-SA06 device as Guirguis proposed. Dr. Wan also notified Guirguis that the BTP tube device looked like the WHPM tube device, and that a patent was pending on WHPM's device.

- 19. On information and belief, BTP and/or Guirguis deliberately copied the WHPM tube device's design and/or ideas embodied in the WHPM tube device.
- 20. The BTP tube device is advertised in a promotional video accessible through its website: www.biotechpharma.com.
- 21. On information and belief, since the '562 patent issued, BTP's DRG-SA06 device has been sold or has been offered for sale in the United States by BTP and/or Guirguis.
- 22. On information and belief, since the '562 patent issued, the DRG-SA06 device has been manufactured in the United States by Guirguis and/or BTP, at a BTP facility in Wisconsin.
- 23. On information and belief, BTP and/or Guirguis knew or should have known of the '562 patent at least as early as May 2011.

## COUNT 1 (PATENT INFRINGEMENT)

- 1. WHPM adopts by reference  $\P\P$  1-23.
- 2. BTP has been and now is directly infringing at least claim 1 of the '562 patent by making, using, selling, and/or offering for sale within the United States, and/or importing into the United Sates, at least the DRG-SA06 device.
- 3. BTP is liable for infringement of at least claim 1 of the '562 patent under 35 U.S.C. § 271(a).

- 4. WHPM has been damaged and injured by the infringement of at least claim 1 of the '562 patent by BTP. Because of their infringing acts, BTP is liable for damages in an amount no less than a reasonable royalty for their unauthorized use of the inventions claimed in the '562 patent.
- 5. WHPM has been irreparably harmed by the infringement of at least claim 1 of the '562 patent by BTP.
- 6. BTP's infringement of at least claim 1 of the '562 patent by BTP has been and is willful.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

- 1. adjudge that BTP has violated 35 U.S.C. § 271(a) by infringing at least claim 1 of the '562 patent;
- 2. enjoin BTP preliminarily and permanently from further acts of infringement under 35 U.S.C. § 283;
- 3. award WHPM damages adequate to compensate for BTP's infringement under 35 U.S.C. § 284;
  - 4. find that BTP's infringement was willful under 35 U.S.C. § 284;
  - 5. award WHPM treble damages;
  - 6. find this action to be an exceptional case under 35 U.S.C. § 285;
  - 7. award WHPM attorney fees under 35 U.S.C. § 285;
  - 8. award WHPM prejudgment and postjudgment interest; and

9. award WHPM such other and further relief as this Court deems just, equitable and proper.

#### **DEMAND FOR A JURY TRIAL**

Plaintiff demands a trial by jury for all issues so triable.

Dated: February 10, 2012

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