

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS**

GREAT PLAINS LABORATORY, INC.,)
)
Plaintiff,)
)
v.)
)
METAMETRIX CLINICAL LABORATORY)
)
and)
)
GREAT SMOKIES DIAGNOSTIC)
LABORATORY,)
)
Defendants.)

Case No. _____

COMPLAINT AND JURY DEMAND

Plaintiff Great Plains Laboratory, Inc. complains against Metamatrix Clinical Laboratory and Great Smokies Diagnostic Laboratory (collectively “Defendants”) as follows:

THE PARTIES

1. Great Plains Laboratory, Inc. (“Great Plains”) is a Kansas corporation having its principal place of business at 11813 West 77th Street, Lenexa, Kansas 66214.

2. Metamatrix Clinical Laboratory (“Metamatrix”) is a Georgia corporation having its principal place of business at 4855 Peachtree Industrial Boulevard, Suite 201, Norcross, Georgia, 30092. Upon information and belief, NuBasix Nutritional Wellness Center (“NuBasix”) is a division of Metamatrix having its principal place of business at 4855 Peachtree Industrial Boulevard, Suite 202, Norcross, Georgia, 30092.

3. Great Smokies Diagnostic Laboratory (“Great Smokies”) is a North Carolina corporation having its principal place of business at 63 Zillicoa Street, Asheville, North Carolina, 28801.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1332, and 1338(a).

5. Upon information and belief, this Court has personal jurisdiction over Metametrix and Great Smokies, as they (1) transact business within this judicial district, (2) have committed infringing acts within this judicial district by selling, offering to sell, and/or providing certain infringing products and/or services within this judicial district, and (3) have caused to persons within this judicial district injury arising out of infringing acts committed outside of this judicial district while Metametrix and Great Smokies were engaged in solicitation or service activities within this judicial district.

6. Venue in this judicial district is proper under 28 U.S.C. §§ 1391 and 1400.

GENERAL ALLEGATIONS

7. Metametrix provides analytical products and services related to nutritional and metabolic testing of patients. Metametrix represents on its website, www.mmetamatrix.com, that it offers a broad range of testing procedures for physicians, hospitals, clinical laboratories, and researchers, that it is committed to helping health professionals identify nutritional influences on health and disease, and that it applies advances in clinical biochemistry to diagnosis and treatment.

8. Metametrix's website allows individuals to order test kits and to view test results. Metametrix represents on its website that it produces and provides materials to guide interpretation of test results and that its medical specialists consult with clients concerning the significance of test results.

9. Metametrix represents on its website that its amino acid analysis is a primary tool for the diagnosis of metabolic disorders and that such analysis provides clinicians with a useful and powerful tool for diagnosing metabolic diseases and monitoring amino acid supplementation. Metametrix further represents on its website that its amino acid analysis is indicated in autism and a variety of other metabolic abnormalities and chronic conditions.

10. Metametrix represents on its website that increasing numbers of autistic children are experiencing dramatic improvements in development and achievement due to supplementation based on the results of Metametrix's Individualized Optimal Nutrition (ION™) profile.

11. Metametrix, through its NuBasix division, provides analytical products and services related to nutritional and metabolic testing of patients.

12. Metametrix, through its NuBasix division, sells and offers to sell amino acid test kits and associated services via the NuBasix website, www.nubasix.com. Metametrix represents on the NuBasix website that autistic spectrum disorders can have an amino acid insufficiency involvement. Metametrix further represents on the NuBasix website that it provides guidance in interpreting test results.

13. Metametrix's Dysbiosis Metabolic Marker Profile test report lists the measured quantities of certain metabolic markers including citramalate, β -ketoglutarate, tartarate, and arabinose and indicates, under the heading "Clinical Significance," that a variety of symptoms, including behavioral disorders and autism have been associated with overgrowth of microbes that lead to increased production of citramalate, β -ketoglutarate, tartarate, arabinose, and other markers. The report also indicates that citramalate, tartarate, and β -ketoglutarate are thought to have toxic metabolic interference.

14. Metametrix, through NuBasix, advertises that it assists in obtaining and interpreting appropriate metabolic and nutritional testing to identify nutrition and metabolic imbalances and provides medically supervised implementation of the “Defeat Autism Now!” (“DAN”) protocols for autistic spectrum disorders. One NuBasix advertisement (entitled “Mickey, 4 ½, Autistic Spectrum, He never stops screaming”) lists “Mickey’s” elevated levels of citramalate and other dysbiosis markers.

15. Great Smokies provides analytical products and services related to nutritional, metabolic, and gastrointestinal testing of patients.

16. Great Smokies sells and offers to sell test kits and associated services via its website, www.gsdl.com. Individuals wishing to purchase test kits related to a particular condition may select the condition (e.g., autism) on the Great Smokies website. The website then presents the individual with one or more test kits (e.g., amino acids analysis) from which to choose.

17. Great Smokies represents on its website that the results of its metabolic analysis profiles can be used to address chronic systemic complaints, that levels of amino acids secreted in urine can also provide important clues about dietary and digestive factors influencing autism, and that its intestinal permeability assessment is a critical tool for developing holistic intervention strategies to treat autism.

18. Great Smokies represents on its website that its medical science staff works with clients on a daily basis and delivers insight into how functional laboratory testing from Great Smokies directly connects to conditions that healthcare providers encounter daily in practice.

19. Great Smokies also offers an Autism Resource Center (“ARC”) website, www.gsdl.com/autism. Great Smokies lists and offers several “assessments for autism” on its ARC website. Great Smokies represents on its ARC website that most autistic children show abnormalities that can be measured by urine or plasma amino acid analysis and that several functional assessments performed by Great Smokies can provide important clues for developing effective treatment strategies for autistic individuals.

20. Great Smokies advertises that its Metabolic Analysis Profile offers “unique report features” including “pediatric reference ranges (ages 2-12) for diagnosing developmental disorders and individualizing treatment plans in children.”

PATENT INFRINGEMENT

21. U.S. Patent No. 5,686,311 (“the ‘311 patent”), entitled “Diagnosis of Autism and Treatment Therefor,” duly and legally issued to The Children’s Mercy Hospital on November 11, 1997. A copy of the ‘311 patent is attached hereto as Exhibit A.

22. Great Plains is the current owner by assignment of all right, title, and interest in and to the ‘311 patent and has the right to sue and recover for past infringements of the ‘311 patent.

23. Metametrix and Great Smokies have infringed and continue to infringe the ‘311 patent by practicing and performing the methods claimed in and covered by one or more claims of the ‘311 patent.

24. Metametrix and Great Smokies have induced and continue to induce infringement of the ‘311 patent and have contributed to their customers’ infringement of the ‘311 patent by selling products and services constituting a material part of the invention of the ‘311

patent knowing the same to be especially made for use in an infringement of the '311 patent, and not staple articles of commerce suitable for substantial non-infringing uses.

25. The acts of infringement by Metamatrix and Great Smokies have been and continue to be willful.

26. The acts of infringement by Metamatrix and Great Smokies have caused Great Plains damage and irreparable harm, for which there is no adequate remedy at law.

27. The acts of patent infringement by Metamatrix and Great Smokies will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Great Plains prays for judgment against Defendants as follows:

(a) That Metamatrix and Great Smokies have infringed one or more claims of the '311 patent;

(b) That Metamatrix and Great Smokies have induced infringement of the '311 patent;

(c) That Metamatrix and Great Smokies have contributorily infringed the '311 patent;

(d) That Metamatrix and Great Smokies be enjoined from further infringement of the '311 patent;

(e) That Metamatrix and Great Smokies be enjoined from inducing or contributing to the infringement of the '311 patent;

(f) That Metamatrix and Great Smokies be required to pay all damages sustained by Great Plains as a result of their various acts of infringement of the '311 patent, and that such damages be trebled due to their knowing and willful infringement;

(g) That this is an exceptional case pursuant to 35 U.S.C. § 285 and that Great Plains be awarded its reasonable attorney fees;

(h) That Great Plains be awarded its costs and prejudgment interest on all damages; and

(i) That Great Plains be awarded such other and further relief as the Court deems just and proper.

JURY DEMAND

Great Plains hereby demands and requests trial by jury of all issues raised that are triable by jury.

DESIGNATION OF PLACE OF TRIAL

Great Plains requests that the trial of this matter be held at the Kansas City, Kansas Courthouse of the United States District Court for the District of Kansas.

Respectfully submitted,

SHOOK, HARDY & BACON L.L.P.

/s/ Michael B. Hurd

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