SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK
----------X
MORGAN AND MENDEL GENOMICS, INC.,

Plaintiffs,

-against-

Index No. 161405/2019
AMENDED COMPLAINT

AMSTER ROTHSTEIN & EBENSTEIN, LLP,

Defendant.
----------X

Plaintiff Morgan and Mendel Genomics, Inc. ("Plaintiff" or "MMG"), by and through its attorney Andrew Lavoott Bluestone as and for its Complaint against Defendant Amster Rothstein & Ebenstein, LLP ("Defendant" or "ARE"), states as follows:

1. This is a case of legal malpractice arising from ARE's failure to properly advise its long-time client, Albert Einstein College of Medicine ("Einstein"), regarding the deadline for filing a patent application (filed as U.S. Patent Application 14/150,207; the "Application") for a genetic-testing technology invented by Dr. Harry Ostrer and Mr. Johnny Loke, both Einstein employees, that fell within a category known as flow variant assays ("FVAs"). As set forth in greater detail below, Einstein assigned this malpractice claim to MMG.

2. FVAs are functional cellular assays that examine the effects of genetic mutations and environmental exposures on genetic pathways, including the core functions of physical activities in cells: protein and modified protein quantification (proteins are the building blocks and signaling molecules of cells), protein localization in cells, protein-protein interactions and protein-nucleic acid interactions (the nucleic acids DNA and RNA are the key information carriers in cells). These methods can be performed directly on patients' cells for predicting their risk of disease. They can also be performed on treated cells and tissue cultures for developing

drugs, among other purposes. Moreover, they can be used in the lab as a predictor of deleterious effects of genetic variants in cells. Dr. Ostrer and Mr. Loke discovered and refined a technique for improving the sensitivity of these tests, which allows for more rapid and accurate testing with less genetic material.

3. To support its mission of excellence in medical and graduate research and education, Einstein is focused on commercial development of its scientific discoveries, particularly in the exploding field of genetic analysis and testing.

4. ARE was retained to manage the process of obtaining patent protection for this discovery and was thus responsible for all aspects of the patent application process. Its obligations included advising on the manner in which to prepare the Application and providing proper guidelines, such as the permissible time in which to file the Application, the applicable deadlines and the necessary calculation of those deadlines. Timely performance of tasks in the patent application process is of paramount importance. The proper calculation of deadlines is complicated, and one of the most legally sensitive issues is the public availability or disclosure of evidence relevant to a patent's claim that its invention is novel—what is commonly known as "prior art."

5. ARE breached its duty of care and departed from good practice as attorney for Einstein in a manner that will result in the loss of tens of millions of dollars in potential and ascertainable revenue (damages) to Einstein and MMG, which was formed by Dr. Ostrer and Mr. Loke and which thereafter licensed the technology from Einstein.

6. More specifically, ARE breached its duty of care in failing to advise Einstein of the proper deadline to file the Application to avoid rejection by the United States Patent and Trademark Office ("PTO") based upon a prior publication of an article by Dr. Ostrer and Mr.

Loke describing the foregoing technology (the "Loke Article")

7. To obtain a patent, an invention must be "novel" and not "obvious." Pre-AIA Title 35, Sections 102 and 103 of the United States Code governed the conditions of novelty and obviousness for patentability at the time of the Application, and one of the strictest conditions of novelty was in pre-AIA Title 35, Section 102(b)[1] which stated that:

> A person shall be entitled to a patent unless –
>
> (b) ***the invention was patented or described in a printed publication in this or a foreign country,*** or in public use or on sale in this country, ***more than one year prior to the date of the application for patent in the United States*** (Emphasis added)

8. Unlike many of the other conditions for patent applications at the time of the Application, pre-AIA Section 102(b) offered no ability for an inventor to "swear behind" a publication and prove that the invention predated it; its bar is absolute. As a result, knowledge of the first date of any publication or disclosure of an invention—including by its inventor—was critical to the calculation of the deadline for the Application. The Application had to be filed less than a year after it was "described in a printed publication in this or a foreign country."

9. Another condition of the pre-AIA application process was found in Title 35, Section 103 which bars a patent if it would have been "obvious" to a person skilled in the field of the invention based upon the prior art. A patent examiner can combine prior art references to find that an invention would have been obvious under Section 103. The standard of practice includes the principle that the conditions of Section 102, including the inability to "swear behind" a publication that qualifies under Section 102(b), apply to obviousness rejections under Section 103.

[1] Although Section 102 was amended with an effective date of March 16, 2013, the pre-AIA Patent Act governs this Application, which was submitted in January 2013.

10. ARE departed from good practice in its handling of this aspect of the Application. ARE had an obligation to independently investigate whether any prior art triggered deadlines for the Application. To independently investigate this aspect of the Application, it was standard practice to determine whether there was any "prior art" extant, and whether any prior publications were applicable to this Application such that the prior publication commenced the one-year period found in Section 102.

11. Moreover, ARE took it upon itself to search for the earliest publication date of the Loke Article. Its search was inadequate and did not identify the earliest publication date, and its advice based on that inadequate search failed to meet the requisite standard of care. In this age of internet publication, no inquiry was made whether the Loke Article had been published or made available on-line prior to the electronic publication of the "final" version.

12. ARE's extraordinary failure to determine the earliest publication date led it to improperly advise the inventors, neither of whom is a patent lawyer, of the correct one-year deadline. In fact, an earlier on-line "Early View" publication became the critical publication date in determining the deadline for filing the Application. As a result of ARE's failure to investigate and file the Application within one year of the earliest publication of the Loke Article, the PTO used the inventors' *own work* to reject vital claims of the Application as unpatentable under Section 103.

PARTIES

13. MMG is a Delaware Corporation with its principal place of business in New York, New York.

14. ARE is a New York limited liability partnership, acting as a law firm, with its principal place of business in New York, New York.

STATEMENT OF FACTS

15. Prior to December 2, 2015, Dr. Ostrer and Mr. Loke were employed by Einstein.

16. They discovered a method for increasing the sensitivity of certain FVAs and started work to make the discovery into an invention that could be commercialized.

17. In order to commercialize Dr. Ostrer's and Mr. Loke's invention, it had to be protected by patent coverage, which would provide Einstein and MMG with the exclusive right to practice the methods and systems that Dr. Ostrer and Mr. Loke had pioneered.

18. In addition, Dr. Ostrer and Mr. Loke planned to publish their work in an academic journal. Publishing original research is vital both for individual researchers and for academic institutions, as it demonstrates their ability to contribute to the state of the art and is a significant factor in obtaining grants.

19. On December 12, 2011, a manuscript of the Loke Article was accepted for publication by the scholarly journal, *Clinical Genetics*.

20. On December 15, 2011, that manuscript became available on-line pursuant to what was called the "Early View" service of the journal's publisher, Wiley-Blackwell, which makes articles available on-line before the official electronic or hard-copy publication date.

21. On January 11, 2012, the Loke Article was then published in the electronic version by Clinical Genetics.

22. In March 2012, the Loke Article was published in hard copy by Clinical Genetics.

23. On October 15, 2012, ARE was asked to manage the process of obtaining patent protection for this discovery.

24. On October 19, 2012, ARE contacted Dr. Ostrer to work on the Application.

25. Neither Mr. Loke nor Dr. Ostrer are patent lawyers and neither was familiar with the time

limits that applied to the Application. Neither knew of the critical difference between "Early View," official electronic publication of the Loke Article, the electronic publication or hard-copy publication of the Loke Article.

26. When they were asked by ARE for the publication date of the Loke Article, they responded with the date of the hard-copy publication in March 2012.

27. ARE took it upon itself to search for the earliest publication date of the Loke Article but never asked either inventor about electronic publication, nor sought the date of any electronic publication which pre-dated the hard-copy publication from either of them. ARE's investigation negligently failed to identify the first publication of the Loke Article and incorrectly claimed the official electronic publication as the critical date for the Application.

28. The PTO Manual of Patent Examining Procedure (§ 2128) states that "an electronic publication, including an online database or Internet publication…is considered to be a printed publication within the meaning of 35 U.S.C. 102(a)(1). Pre AIA 35 U.S.C. 102(a) and (b) provided that the publication was that which was accessible to persons concerned with the art to which the document relates" and that "[p]rior art disclosures on the Internet or on an online database are considered to be publicly available as of the date the item was publicly posted."

29. On November 26, 2012, Alan Miller, Esq., ("Miller"), an attorney at ARE who was primarily responsible for the management of the Application, sent an email to Mr. Loke and Dr. Ostrer noting that Miller believed that, based upon his own research, the Loke Article was published electronically on January 11, 2012.

30. ARE's investigation failed to identify the first publication and misstated the actual earliest publication on the Internet by 27 days.

31. Had ARE adequately investigated the Loke Article's publication history or inquired of

Mr. Loke or Dr. Ostrer about the process of publication, or had ARE identified the first publication of the Loke Article they would have become aware of the three-step process in this publication and would have become aware of the correct time limits for the Application.

32. On November 27, 2012, ARE sent the first draft of the Application to Mr. Loke and Dr. Ostrer.

33. The draft Application required substantial revisions, required significant technical input from Dr. Ostrer and Mr. Loke through Miller. Miller requested and had Dr. Ostrer and Mr. Loke actually work on the Application at Miller's office.

34. Miller reported on December 19, 2012, that after working on the Application for two months, substantial revisions made to the Application were inexplicably lost from ARE's computer network, which apparently had no back-ups or other security against electronic loss. The work had to be re-created from the beginning, causing additional and inexcusable delay.

35. By this time, seemingly unknown to ARE, more than one year had already passed since the initial publication of the Loke Article.

36. On January 8, 2013, a provisional version of the Application was filed with the PTO. ARE later enunciated its position that this was a timely Application when measured against the January 11, 2012, official electronic publication, but not when measured against the December 15, 2011, "Early View" publication.

37. On January 8, 2014, a non-provisional version of the Application was filed with the PTO.

The License Agreement

38. On March 9, 2016, Einstein and MMG entered into a License Agreement pursuant to which Einstein licensed to MMG the FVA technology that was the subject of the Application.

39. The purpose of this license agreement was the commercialization of the invention by

MMG. The licensing agreement substituted MMG for Einstein for all purposes. It did not alter the relationship between Einstein and ARE.

40. Commercialization of the invention was intended to take place in the following manner: development of FVAs for basic research for human, animal and plant diseases, basic research for normal human, animal and plant development, drug discovery to treat disease or enhance development and genetic testing for disease and development for commercial clients with revenue derived from direct services, sales of reagents and royalties from new products. These activities generated contracts and grants with plans for sale of commercial products.

41. Prior to the execution of the License Agreement, ARE interacted almost exclusively with Einstein through Dr. Ostrer and Mr. Loke in working on the Application.

42. In addition to its earlier work, ARE represented Einstein concerning the License Agreement and was the primary drafter of the License Agreement.

43. Pursuant to the Licensing Agreement, MMG was permitted to exploit and commercialize the FVA technology while Einstein retained ownership of the technology.

44. Pursuant to the Licensing Agreement, Einstein remained a client of ARE, MMG assumed the responsibility to pay ARE's legal fees, and ARE continued interacting with Dr. Ostrer and Mr. Loke.

45. Pursuant to the Licensing Agreement, MMG was granted rights to claims against ARE for potential legal malpractice issues in its handling of the Application.

The PTO's Rejection of the Application

46. On September 14, 2016, the PTO issued a First Office Action letter, rejecting all claims of the Application, including certain key claims that the PTO said were barred by the Loke Article. Via this rejection, the PTO noted that the Loke Article was available on-line on

December 15, 2011, more than a year before the Application was filed on January 8, 2013.

47. The same day, Brian Amos of ARE sent an email to Dr. Ostrer and Mr. Loke attaching the foregoing rejection. Notably, Mr. Amos failed to acknowledge, much less explain, how ARE failed to timely file the Application.

48. Timely filing of the Application could have been accomplished prior to December 15, 2012.

49. MMG, which as the licensee of Einstein was contractually permitted to exploit the technology, prosecute the Application and manage the legal representation, terminated ARE as counsel regarding the Application on December 2, 2016.

50. ARE had continuously represented Einstein (and MMG as licensee) from October 19, 2012, through December 2, 2016, regarding the Application.

51. ARE worked on the Application during May 2016, billed for work concerning the Application in October 2016 and performed work in September and October 2016. They continued as attorney through December 2, 2016.

52. On July 21, 2017, after MMG had retained new counsel to file a response to the PTO's objection, the PTO issued a final rejection of all claims in the Application, again rejecting key claims based upon the greater than one-year period from the December 15, 2011, publication to the January 8, 2013, filing.

53 Notwithstanding this final rejection, from 2017 onward MMG has worked continuously to commercialize the FVA technology that was the subject of the Application, including as described below.

54. MMG was awarded a contract from Laboratory Corporation of America in the amount of $96,000 to develop methods using FVAs and CRISPR/Cas9 gene editing to identify deleterious

variants in the *BRCA1* and *BRCA2* genes.

55. MMG won two technology transfer grants from the National Cancer Institute ("NCI"), each in the amount of $ 300,000 – one for a breast cancer germline risk test kit development and one for a colon cancer germline risk test kit development. These kits could be used at any clinical laboratory to quantify a person's risk for developing breast or colon cancer based upon their age cohort and would provide a guide for taking suitable preventative steps.

56. MMG applied for a $2,000,000 Phase II technology transfer continuation grant from NCI for the breast cancer germline risk test kit development.

57. As part of the related activity of analytically validating the breast cancer risk assessment kit, MMG has established relationships with Labcorp and Quest Diagnostics, the largest clinical laboratories in the United States.

58. MMG has initiated the FDA clearance process by submitting a Breakthrough Device Designation application to the FDA for its kit. Breakthrough Device Designation is a process designed to expedite the development and review of drugs and devices that are intended to treat serious diseases.

59. All of these efforts confirm MMG's seriousness in building a business founded on the technology and its licensed rights to commercialize the technology.

60. A salvage patent application has been filed, and subsequent applications for patent protection on related issues have been filed, but none of them rescue or reinstate any lost protections on this subject invention made in the Application.

Assignment of Einstein's Malpractice Claims

61. In March 2019, Einstein and MMG entered into an agreement pursuant to which Einstein assigned its legal malpractice claim against ARE relating to the Application to MMG.

62. No release by MMG to Einstein is part of the assignment.

63. Moreover, the validity of the assignment of this malpractice claim by Einstein to MMG is not impacted by any alleged failure of MMG to satisfy obligations of the License Agreement.

Damages

64. But for the failure to file the Application within one year of the first publication of the Loke Article, MMG or Einstein would have successfully obtained patent protection.

65. Although the PTO cited bases in addition to the Loke Article in rejecting the Application's claims, Einstein or MMG would have been able to address sufficiently those other bases for rejection such that a patent ultimately would have issues covering the core aspects of the Application.

66. But for the PTO's finding that the Loke Article was Section 102(b) prior art, which by itself successfully prevented the issuance of a patent covering at least the core aspects of the Application, Einstein or MMG would have successfully obtained a patent covering the core aspects of the Application.

67. Had the core aspects of the Application been granted, MMG would have been positioned to exploit Dr. Ostrer and Mr. Loke's FVA technology to tremendous financial success.

68. By way of example only, the market for breast cancer risk assessment, a viable application for the subject FVA technology is viewed as a replacement for the current method of gene sequencing, is valued in excess of $1 billion. Without patent protection, anyone can copy the invention described in the Application, which will negatively impact MMG's ability to exploit the patent and the invention commercially.

69. Any ability presently to exploit the FVA technology to commercial success will pale in comparison to the potential revenue stream MMG would have enjoyed but for ARE's departure

from good practice in its handling of the Application.

FIRST CAUSE OF ACTION

LEGAL MALPRACTICE

70. From October 19, 2012, through December 2, 2016, at the earliest, ARE acted as attorneys for Einstein concerning the Application.

71. Between March 9, 2016, and December 2, 2016, ARE acted as attorney for Einstein and MMG. ARE responded to an Office Action to restrict the claims after conferencing with the inventors, received a rejection and discussed the rejection with Einstein and MMG.

72. ARE was retained to, and agreed to, act as attorney for Einstein in the preparation of the Application.

73. ARE departed from good practice, failed to exercise a reasonable degree of skill, failed to be familiar with the applicable rules of practice in the field of patent prosecution, and failed to exercise reasonable care in representation of Einstein, its client.

74. ARE was obliged to investigate the facts and circumstances of the Application, and in this particular situation to understand and comply with time limits that are set forth regarding an Application for a patent.

75. ARE was obliged to know of the one-year period set forth in Section 102 and to investigate the dates of all publications concerning the invention and whether and when there was publication of the invention which set the one-year period running.

76. It was a departure from good practice not to determine conclusively when the first publication, as defined in Section 102, took place.

77. Informal questioning of persons involved with the writing of an article is an insufficient

investigation of when the publisher first made the material available within the meaning of Section 102, as is Mr. Miller's search on the PubMed database.

78. Defendants were aware of the name of the publisher and were required to investigate the entire publishing history of the Loke Article.

79. ARE was retained with sufficient time to investigate the origins of the Loke Article, determine the date of the first actual publication of the Loke Article within the meaning of Section 102, and to file the Application within that one-year period.

80. ARE's failure to investigate and determine the deadline for filing the Application, and its failure to file the Application within that time period was a departure from good practice which proximately led to the rejection of the Application.

81. In failing to investigate whether there was any prior publication of the Loke Article, or any appearance on-line prior to the January 11, 2012, electronic publication date, ARE failed to exercise the skill, care and diligence commonly possessed by and exercised by an attorney in this setting.

82. "But for" this failure of investigation and determination of the one-year period, Einstein would have succeeded in the Application and MMG would not now be barred from the benefits of a patent of the core materials of the Application.

83. This failure proximately led to a negative result, with the rejection of the Application the proximate result of a negligently prepared and late filed Application.

84. Rejection of the Application rendered this proprietary information, invention, and knowledge available to the entire world. Once the information is available to the entire world, its value plummets and MMG can no longer commercialize Dr. Ostrer's and Mr. Loke's invention; commercializing intellectual property requires that it be protected from infringement

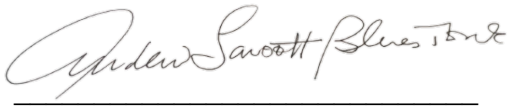
by others.

85. MMG stands in Einstein's shoes for the purposes of this malpractice claim.

86. The current amount of damages can be calculated to be in excess of $10 Million.

WHEREFORE, Plaintiff requests a judgment awarding compensatory damages as determined by this Court and for such other, different and further relief as to this Court may seem just and proper.

Dated: New York, New York
February 20, 2020



Andrew Lavoott Bluestone
233 Broadway, Suite 2702
New York, New York 10279
(212) 791-5600
alb@bluestonelawfirm.com