IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IDEXX LABORATORIES, INC. and IDEXX DISTRIBUTION, INC.,	)	Civil Action No. 15-668-RGA
Plaintiffs,	)	JURY TRIAL DEMANDED
v.	)	
CHARLES RIVER LABORATORIES, INC. and CHARLES RIVER LABORATORIES INTERNATIONAL, INC.,	)	
Defendants.	)	

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

This is an action for patent infringement. Plaintiffs IDEXX Laboratories, Inc. and IDEXX Distribution, Inc. (collectively referred to herein as "IDEXX") bring this First Amended Complaint against Defendants Charles River Laboratories, Inc. and Charles River Laboratories International, Inc. (collectively referred to herein as "Charles River"), and allege as follows:

INTRODUCTION

1. Plaintiff IDEXX is a global leader in the research and development of diagnostic capabilities and information management solutions for veterinary and animal care professionals. IDEXX products and services improve the efficiencies of veterinary and animal care personnel, which ultimately leads to growing revenues for the IDEXX veterinary customers and better care for the animal patients. As relates to the issues in this lawsuit, IDEXX provides health monitoring and diagnostic testing services to bioresearch customers who maintain animal (i.e., rats and mice) test subjects, including global, mid-tier, and smaller bioresearch entities, as well as academic and government laboratories.

PARTIES, JURISDICTION AND VENUE

2. Plaintiff IDEXX Laboratories, Inc. ("ILI") is headquartered at One IDEXX Drive, Westbrook, Maine 04092.

3. Plaintiff IDEXX Distributions, Inc. ("IDI") is headquartered at One IDEXX Drive, Westbrook, Maine 04092.

4. Defendant Charles River Laboratories, Inc. ("CRL") is incorporated in Delaware and headquartered at 251 Ballardvale Street, Wilmington, Massachusetts 01887.

5. Defendant Charles River Laboratories International, Inc. ("CRLI") is incorporated in Delaware and headquartered at 251 Ballardvale Street, Wilmington, Massachusetts 01887.

6. This action arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over Charles River because CRLI and CRL are each incorporated in Delaware and because Charles River advertises, markets, sells, offers to sell, and provides the results of the infringing activities to its customers throughout the United States, including this judicial District.

8. Venue is proper in this district under 28 U.S.C. § 1400(b) and § 1391(b) and (c).

9. The claims asserted herein against CRLI and CRL arise out of "the same transaction, occurrence, or series of transactions, or occurrences relating to the making, using, importing into the United States, offering for sale, or selling of the same accused product or process." Further, this action will raise "questions of fact common to all defendants." As such, joinder of these Defendants is appropriate under 35 U.S.C. § 299(a)(1)-(2).

BACKGROUND

10. Animal colonies are typically used in pharmaceutical research where they are given experimental compounds as an initial screen for the efficacy and safety of the compounds. The health of the members of the colonies is critical to the value and accuracy of the research results. Animals used in pharmaceutical and other types of research are susceptible to various disease conditions. Such animals (typically rodents such as rats and mice) present particular problems for researchers because they can harbor viruses or germs or other biological elements that exhibit an observable pathology. Many such animals, however, harbor viruses or germs or other biological elements that do not exhibit a recognized pathology but which, nonetheless, can affect research test results. This problem is greatly amplified by the size of colonies used in testing, which can include up to 100,000 rodents. As a result, many diseases can potentially go undetected. Thus, it is critically important to monitor the health of rodent populations by analyzing (e.g., by immunoassay) rodent blood for one or more biomarkers of infectious disease. Such infectious disease testing is only one of several potential tests that can be performed on blood; others include detecting markers for cancer, metabolism, autoimmune disease, genetic abnormality, pharmaceutical metabolites and diabetes or determining oxygen, hemoglobin or other blood constituent levels.

11. Historically (i.e., prior to the 1970s), there was no systematic way to assure that research animals were free of viral and bacterial agents and other contaminants that might otherwise disrupt research operations and distort research results. Each research laboratory tended to develop its own ways of dealing with the infectious disease conditions that arose within its animal populations, including regular testing of the animals to detect diseases within the population. The problem is exacerbated by the fact that monitoring the health of rodent

populations by analyzing (e.g., by immunoassay) rodent blood for one or more biomarkers of infectious disease requires, at minimum, specialized apparatus and chemical reagents. Further, to support the substantial level of testing required to monitor rodent populations, costly diagnostic analyzers must be used.

12. More recently, research laboratories have centralized the testing of the animal populations at off-site locations that can function as testing centers for multiple research labs. The geographical distance between the animal populations and testing centers creates a cascade of complicated interconnected problems that are solved by the patents-in-suit. In particular, biological samples (blood samples) from the research animals are fragile and not suited for transportation. By the 1980s, scientists had developed relatively standardized procedures for addressing the problem. The conventional procedure included (i) drawing a relatively large amount of blood from the animal, (ii) clotting the blood, separating the serum from the cellular matter in the sample, then freezing the serum, and (iii) shipping frozen serum to a central testing lab. Sometimes an animal itself was shipped to a central laboratory for testing. The steps of the conventional procedures were inconvenient and expensive, not only because they required substantial time from specialized technicians but also because they typically required euthanizing a significant number of animals.

13. For the past 20-30 years, these procedures were deemed to be the conventional protocol for providing biological samples to monitor the health of rodent populations by analyzing (typically by immunoassay) rodent blood for one or more biomarkers of infectious disease.

14. The pharmaceutical research industry that uses the rodent colonies is very conservative. Colonies often involve hundreds, or even many tens of thousands of rodents. The

animals are used in painstakingly careful scientific research by medical, pharmaceutical and biotechnology scientists. The underlying research typically takes many years and huge amounts of money. If something unexpectedly goes wrong with monitoring the animals' health, the resulting loss may include not only all animals in the colony but also the years of expensive research that was conducted using the animals.

15. Against this background, Dr. Matthew Myles discovered that a technique known as DBS ("dry blood spot") could be used successfully for the kinds of tests that needed to be performed on rodent colonies in order to determine the presence or absence of an infectious disease in a population of rodents. Dr. Myles did not invent the DBS technique; DBS testing was originally developed in connection with neonatal testing of individual human babies. But until Dr. Myles undertook substantial work, DBS sampling was not used for monitoring infectious diseases in rodent colonies. It was neither a conventional approach nor was its efficacy in monitoring health of rodent colonies even understood. The claimed methods applied an entirely new and untested approach in the management of infectious diseases in rodent colonies, namely, DBS using blood collection cards, to collect, transport and/or receive blood samples that could then be extracted for analysis of infectious disease markers, such as antibodies. There was no way to know in advance that DBS sampling would work for the immunoassay tests needed to allow safe and effective management of rodent colonies by detecting the presence or absence of infectious agents and diseases in rodent colonies. Given the scale and accuracy required for detection of infectious diseases in such colonies, and in many cases the battery of immunoassays that have to be performed on the samples, there was simply no way for someone in the art to be able to predict whether extracting blood from a dried blood spot would provide adequate results to permit monitoring of the health of rodent colonies.

16. Dr. Myles, at the time, was working with animals having unique endocrinology, cellular materials, and cellular contaminants, in the context of using different immunoassay tests looking for different diseases and at a very different scale. It was unknown whether these differences would have an impact on the ultimate tests to be conducted with the sample. Moreover, the quantity of the sample was quite small, and it was unknown whether a dried blood spot would be sufficient for the ultimate tests.

17. Dr. Myles had to determine whether the DBS approach might have a negative impact on any of the many biological tests that would or could be conducted to monitor the health of rodent populations by analyzing (or immunoassaying) rodent blood for one or more biomarkers of infectious disease. Nor was it known whether the DBS approach would effectively permit the wide range of immunoassays that are required in many cases from a single blood spot. If the DBS approach had a negative impact on any of the tests, the result would be a death knell to the project. No customer would have interest in a method that might negatively affect a test result, or limit the range of immunoassays that need to be conducted, regardless of potential cost savings. There was no way to know the outcome of this unconventional approach until the result was reached and proven. It took Dr. Myles and his group approximately eighteen months to discover and develop the invention.

IDEXX, RADIL, AND THE PATENTS-IN-SUIT

18. Radil Laboratories ("Radil") started in late 1960s, operating as a university facility within the University Of Missouri College Of Veterinary Medicine. Radil's goal was to create a dependable, systematic, and cost-effective means to assure that animal populations in biologic laboratories are free of viral and bacterial agents and other contaminants that might otherwise disrupt research operations and distort research results. The Radil scientists provided

this service not only for the University Of Missouri College Of Veterinary Medicine but also, at a fee, for numerous third parties.

19. During the 1970s and later, Radil scientists developed and implemented numerous test formats, including Enzyme Linked Immunosorbant Assays ("ELISA"), to determine whether the pertinent animal populations were free of the viral and bacterial agents and other contaminants that might otherwise disrupt research operations and distort research results. Multiple institutions also developed assays based upon the ELISA platform around the same time frame. Charles River, a producer of rodent models for biomedical research, used these assays for their own internal testing purposes but also, by at least the 1990s, for selling competitive testing services to third parties that included Radil's customers and potential customers.

20. In 2004, Radil developed a testing format based on Multiplex Fluorescent Immunoassay ("MFI") technology. The MFI format greatly increased testing throughput and, because it had the ability to conduct assays for several diseases at the same time ("multiplexing"), allowed for truly comprehensive health screening. However, being the first company in this field to change from the ELISA format to the MFI format was very difficult. This industry is generally very conservative, and customers do not accept new technologies easily because the consequence of even a small mistake can be catastrophic to the animals and research results. Thus, Radil not only had to develop multiple MFI test products to identify numerous virus, bacterial, and other contaminants, but also had to conduct substantial validation work on each of the new test products in order to establish the dependable accuracy of such MFI tests. Radil's switch from ELISA to MFI first became public knowledge in about 2004. After Radil had paved the way and established the dependable accuracy of the MFI test format,

Charles River subsequently began to copy Radil's efforts on MFI testing for Charles River's own internal testing purposes. By at least 2008, Charles River began selling competitive MFI-based testing services to third parties that included Radil's customers and potential customers.

21. IDEXX acquired Radil in 2011.

22. In early 2012, IDEXX started investigating how to make it easier for the Radil customers to use its products and services. Through substantial investigation, research, testing, and validation, Dr. Matthew H. Myles created the inventions covered by United States Patent Nos. 8,927,298; 8,945,945; and 9,040,308 (collectively "the Patents-in-Suit").

23. Dr. Myles's inventions eliminated the need to draw substantial amounts of blood from the animal subject, and allowed customers to ship a dried whole-blood sample without isolating the serum and without freezing the sample. Further, Dr. Myles's inventions allowed the sample preparation work to be done by less skilled technicians and without sacrificing test animals.

24. IDEXX publically announced Dr. Myles's inventions on June 10, 2013, and commercially launched the Opti-Spot® product in Europe in June 2013 and in North America on July 7, 2013. Charles River knew full well about these events.

25. Dr. Myles's inventions caused a fundamental industry shift in the preferred protocols for monitoring the health of laboratory rodent animal populations. Overcoming the aforementioned conservative nature of the industry, 90% of IDEXX's customers switched to the technology of the Opti-Spot® product by the end of 2014 – only 18 months later – an incredibly swift adoption of new technology in this conservative industry.

26. On January 6, 2015, the United States Patent and Trademark Office duly and legally issued United States Letters Patent No. 8,927,298 ("the '298 Patent"), entitled "Sample

Collection and Analysis," in the name of inventor Dr. Matthew H. Myles. IDEXX is the assignee of the entire right, title, and interest in and to the '298 Patent. A true and correct copy of the '298 patent is attached as Exhibit A to this complaint.

27. On February 3, 2015, the United States Patent and Trademark Office duly and legally issued United States Letters Patent No. 8,945,945 ("the '945 Patent"), entitled "Sample Collection and Analysis," in the name of Dr. Matthew H. Myles. IDEXX the assignee of the entire right, title, and interest in and to the '945 Patent. A true and correct copy of the patent is attached as Exhibit B to this complaint.

28. On May 26, 2015, the United States Patent and Trademark Office duly and legally issued United States Letters Patent No. 9,040,308 ("the '308 Patent"), entitled "Sample Collection and Analysis," in the name of Dr. Matthew H. Myles. IDEXX the assignee of the entire right, title, and interest in and to the '308 Patent. A true and correct copy of the patent is attached as Exhibit C to this complaint. Collectively, the '298, '945 and '308 patents are referred to herein as "the patents-in-suit."

29. During the prosecution of the patents-in-suit, the Examiner found that each of the claims of the patents-in-suit were neither anticipated by nor rendered obvious by the Beaudette reference ("Beaudette et al., Journal of Chromatography B., Vol. 809, pp. 153-158 (2004)"), which disclosed the testing of rodent blood extracted from blood collection cards for the presence of pharmaceutical compounds. The Examiner found that the claims of the '298 patent were not taught by nor rendered obvious by the prior art because the prior art did not "teach or fairly suggest analyzing the extracted blood for a presence or absence of at least one biological marker for an infectious agent indicative of an infectious disease." '298 patent file history, Notice of Allowance, p. 3. The Examiner made similar findings as to the '945 and '308 patents.

'945 patent file history, Notice of Allowance, p. 3 (the closest prior art of record "does not teach or fairly suggest analyzing the extracted blood for a presence or absence of at least one antibody for an infectious agent indicative of an infectious disease"); '308 patent file history, Notice of Allowance, p. 2 (same).

30. The Examiner also specifically addressed the issue of unpatentability under 35 U.S.C. § 101. After initially rejecting the claims in the '298 patent application as unpatentable under § 101, the Examiner considered IDEXX's response, withdrew that rejection, and made the following finding:

> Further the claims as amended are directed to statutory subject matter since [the] steps of providing the instructions, transporting, receiving the plurality of collections cards as a single unit from the user, extracting dried blood from the cards, analyzing the extracted blood for a presence or absence of the biological marker and reporting the results to the user recite something significantly different than the judicial exception.

'298 patent file history, Notice of Allowance, Page, 3. The Examiner made a corresponding finding in the prosecution of each of the '945 and '308 patents:

> Further the claims as amended are directed to statutory subject matter since [the] steps of providing the instructions, transporting, receiving the plurality of collections cards as a single unit from the user, extracting dried blood from the cards, analyzing the extracted blood for a presence or absence of the biological marker and reporting the results to the user recite something significantly different than the judicial exception.

'945 patent file history, Notice of Allowance, p. 3.

> Further the claims as amended are directed to statutory subject matter since they have the steps of receiving the plurality of collections cards as a from the user, extracting dried blood from the cards, conducting an immunoassay for analyzing the extracted blood and reporting the results. Thus, the claims include additional elements that are sufficient to amount to significantly more than the judicial exception.

'308 patent file history, Notice of Allowance, pp. 2-3.

CHARLES RIVER

31. In October 2013, just a few months after the IDEXX announcement of Dr. Myles's invention, Charles River announced that it was developing a competing product, which it now markets as its EZ-Spot® product, using the same methods as Dr. Myles's inventions.

32. Charles River's promotional materials for the EZ-Spot® product tout all the same features and benefits as the IDEXX promotional materials for the Opti-Spot® product, namely the savings that accrue from eliminating the need to sacrifice animals for blood testing as well as eliminating the activities of blood clotting, separation, and serum extraction, freezing, and shipping. Indeed, in an obvious effort to trade on and damage IDEXX's good will, Charles River has copied IDEXX's marketing presence, starting with the names themselves ("EZ-Spot®" vs. "Opti-Spot®"), the use of similar type-face, the incorporation of a red blood spot into the logo itself, and the use of similar product images and marketing materials.

33. Charles River tells its customers that "EZ-Spot® is simply another option for sample collection" and that Charles River will continue to accept vials with serum samples for testing. Thus, Charles River has maintained its conventional technique for serum collection and testing.

34. In spite of the rapid adoption of IDEXX's patented technology, CRL still offers this conventional collection method to its customers for testing rodent blood in the detection of infection disease.

35. A substantial portion of Charles River's business revenue is derived from the production and sale of rodent research models, principally genetically and microbiologically defined purpose-bred rats and mice. The success of this portion of Charles River's business

depends critically upon the ability to confirm that the animal models are free of viral and bacterial agents and other contaminants that might otherwise disrupt research operations and distort research results. On information and belief, Charles River develops the evidence that its internal animal models are free of viral and bacterial agents and other contaminants by illegally practicing the IDEXX technology covered by the Patents-in-Suit.

36. Charles River also develops and maintains rodent populations on behalf of third party entities, including global, mid-tier, and specialized biopharmaceutical companies, as well as academic and government institutions. The success of this portion of Charles River's business depends critically upon Charles River's ability to confirm that these rodent populations are free of viral and bacterial agents and other contaminants that might otherwise disrupt research operations and distort research results, and doing so in a cost competitive manner. On information and belief, Charles River develops the evidence that these rodent populations are free of viral and bacterial agents and other contaminants by illegally practicing the IDEXX technology covered by the '298, the '945, and the '308 Patents.

37. Charles River also provides contract services to third parties, testing their rodent populations to make sure that those rodent populations are free of viral and bacterial agents and other contaminants. The success of this portion of Charles River's business depends critically upon Charles River's ability to confirm that these rodent populations are free of viral and bacterial agents and other contaminants that might otherwise disrupt research operations and distort research results, and upon doing so in a cost competitive manner. On information and belief, Charles River develops evidence that these rodent populations are free of viral and bacterial agents and other contaminants by illegally practicing the IDEXX technology of the '298, the '945, and the '308 Patents.

38. The third parties for whom Charles River illegally practices the IDEXX technology covered by the '298, the '945, and the '308 Patents include customers and potential customers of IDEXX.

39. Charles River's business goals include positioning itself as the sole-source testing laboratory for third parties or as the sole alternative-source to the third party's internal laboratory capabilities. The success of these portions of Charles River's business depends critically upon its illegal practice of the IDEXX technology invented by Dr. Myles and covered by the '298, the '945, and the '308 Patents, which Charles River is commercializing as its EZ-Spot® product.

COUNT I
Infringement of the '298 Patent

40. IDEXX re-alleges and incorporates paragraphs 1-39 above.

41. Without license or authorization, Charles River has been and is infringing the '298 Patent by offering, selling, using and/or providing the methods covered by the '298 Patent throughout the United States.

42. Charles River's activities infringe the '298 Patent under 35 U.S.C. §§ 271 (a).

43. Charles River's conduct not only illegally usurps IDEXX's technology embodied in the '298 Patent, but also undermines IDEXX's reputation and goodwill, such that IDEXX has no adequate remedy at law.

44. The extent of damage suffered by IDEXX and caused by Charles River is not yet known, but the damage is substantial and will be determined in the course of litigation.

45. It is apparent that Charles River will continue its infringing activities, damaging IDEXX, unless and until enjoined by this Court.

COUNT II
Infringement of the '945 Patent

46. IDEXX re-alleges and incorporates paragraphs 1-39 above.

47. Without license or authorization, Charles River has been and is infringing the '945 Patent by offering, selling, using and/or providing the methods covered by the '945 Patent throughout the United States.

48. Charles River's activities infringe the '945 Patent under 35 U.S.C. §§ 271 (a).

49. Charles River's conduct not only illegally usurps IDEXX's technology embodied in the '945 Patent, but also undermines IDEXX's reputation and goodwill, such that IDEXX has no adequate remedy at law.

50. The extent of damage suffered by IDEXX and caused by Charles River is not yet known, but the damage is substantial and will be determined in the course of litigation.

51. It is apparent that Charles River will continue its infringing activities, damaging IDEXX, unless and until enjoined by this Court.

COUNT III
Infringement of the '308 Patent

52. IDEXX re-alleges and incorporates paragraphs 1-39 above.

53. Without license or authorization, Charles River has been and is infringing the '308 Patent by offering, selling, providing and/or using the methods covered by the '308 Patent throughout the United States.

54. Charles River's activities infringe the '308 Patent under 35 U.S.C. §§ 271 (a).

55. Charles River's conduct not only illegally usurps IDEXX's technology embodied in the '308 Patent, but also undermines IDEXX's reputation and goodwill, such that IDEXX has no adequate remedy at law.

56. The extent of damage suffered by IDEXX and caused by Charles River is not yet known, but the damage is substantial and will be determined in the course of litigation.

57. It is apparent that Charles River will continue its infringing activities, damaging IDEXX, unless and until enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, IDEXX respectfully demands the following relief for itself and against the Charles River Defendants:

(a) That this Court find and enter judgment that the Charles River Defendants have infringed each of the Patents-in-Suit;

(b) That this Court issue an injunction enjoining the Charles River Defendants and their officers, agents, servants and employees, privies, and all persons in active concert or participation with them from further infringing each of the Patents-in-Suit;

(c) That this Court ascertain and award IDEXX damages sufficient to compensate for the Charles River Defendants' infringement of each of the Patents-in-Suit; and

(d) That this Court grants such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

In accordance with Federal Rule of Civil Procedure 38(b), Plaintiff IDEXX demands a trial by jury on all issues so triable.

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