

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
SOUTHERN DIVISION**

IGEN INTERNATIONAL, INC.)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. _____
)	
ROCHE DIAGNOSTICS CORP., and)	
ROCHE DIAGNOSTICS GmbH)	
)	
Defendants.)	
_____)	

COMPLAINT AND DEMAND FOR JURY TRIAL

The plaintiff, IGEN International, Inc. (“IGEN”), for its complaint against defendants, Roche Diagnostics Corp. and Roche Diagnostics GmbH (collectively “Roche”), alleges:

NATURE OF ACTION

1. This is an action for a judgment declaring Roche guilty of infringing of U.S. Patent Nos. 5,221,605 (“the ’605 patent”), 6,140,138 (“the ’138 patent”), 6,325,973 (“the ’973 patent”), and 6,451,225 (“the ’225 patent”). For Roche’s acts of infringement, IGEN seeks, *inter alia*, a preliminary and a permanent injunction against Roche.

PARTIES

2. IGEN is a Delaware corporation with its principal place of business in Gaithersburg, Maryland.

3. Upon information and belief, defendant Roche Diagnostics Corp. is an Indiana corporation with its principal place of business in Indianapolis, Indiana.

4. Upon information and belief, defendant Roche Diagnostics GmbH is a German corporation with its principal place of business in Mannheim, Germany.

JURISDICTION AND VENUE

5. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 et seq. This Court has subject matter jurisdiction over the claims in this Complaint under 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

6. Venue is proper pursuant to 28 U.S.C. §§ 1391(c) and (d).

7. On information and belief, defendant Roche Diagnostics Corp. is registered to do business in Maryland, has appointed The Corporation Trust Inc., 300 East Lombard Street, Baltimore, Maryland 21202, as its resident agent in Maryland, owns personal property in Maryland, pays taxes in Maryland, and sells the accused diagnostic products in Maryland.

8. On information and belief, this Court has personal jurisdiction over Roche Diagnostics Corp.

9. On information and belief, defendant Roche Diagnostics GmbH has purposely conducted and continues to conduct business in Maryland in furtherance of its obligations to IGEN, which business gave rise to this cause of action, and has placed the accused diagnostic products in the stream of commerce knowing and intending that Maryland was and is a likely destination of these products.

10. On information and belief, this Court has personal jurisdiction over Roche Diagnostics GmbH.

IGEN'S PATENTS

11. The '605 patent, entitled "Luminescent Metal Chelate Labels and Means For Detection," was lawfully issued by the United States Patent and Trademark Office on June 22, 1993, to the inventors

Allen J. Bard and George M. Whitesides. The entire right, title, and interest in the '605 patent is owned by IGEN.

12. The '605 patent discloses reagents including one or more electrochemiluminescent (ECL) organometallic compounds. For example, the '605 patent discloses ECL reagents that are linked to biological substances, chemicals that bind to biological substances, or chemicals that compete with biological substances in competitive binding assays. The '605 patent also discloses methods for detecting small amounts of the chemical moiety using electrochemiluminescence.

13. The '138 patent, entitled "Electrochemiluminescent Metal Chelates and Means for Detection," was lawfully issued by the United States Patent and Trademark Office on October 31, 2000, to the inventors Allen J. Bard and George M. Whitesides. The entire right, title, and interest in the '138 patent is owned by IGEN.

14. The '138 patent discloses methods and systems for detecting and quantifying ECL reagents. For example, the '138 patent discloses a method that includes 1) forming a mixture containing an ECL reagent, 2) exposing the ECL reagent to electrochemical energy, and 3) detecting the emitted electrochemiluminescence. The '138 patent also discloses a system that includes 1) a mixture containing an ECL reagent, 2) an electrode for inducing the ECL reagent to electrochemiluminesce by exposing it to electrochemical energy, and 3) a light detector for detecting the emitted electrochemiluminescence.

15. The '973 patent, entitled "Methods and Apparatus for Improved Luminescence Assays," was lawfully issued by the United States Patent and Trademark Office on December 4, 2001, to the inventors Jonathan K. Leland, Haresh P. Shah, John H. Kenten, Jack E. Goodman, George E. Lowke,

Yuzaburo Namba, Gary F. Blackburn, and Richard J. Massey. The entire right, title, and interest in the '973 patent has been assigned to IGEN.

16. The '973 patent discloses instruments for performing assays in which an analyte of interest is detected by measuring electrochemiluminescence at an electrode surface. For example, the '973 patent discloses an instrument comprising (a) a cell for holding the sample containing the analyte of interest, (b) an electrode exposed to the sample, (c) a voltage controller for impressing electrochemical energy on the electrode, (d) a magnetic particle collector for collecting magnetic particles on the electrode, and (e) a light detector for measuring luminescence generated at the electrode.

17. The '225 patent, entitled "Electrochemiluminescent Reaction Utilizing Amine-Derived Reductant," was lawfully issued by the United States Patent and Trademark Office on September 17, 2002, to the inventors Jonathan Kent Leland and Michael Joseph Powell. The entire right, title, and interest in the '225 patent has been assigned to IGEN.

18. The '225 patent discloses compositions for use in ECL assays. For example, the '225 patent discloses a composition comprising (a) a metal-containing ECL compound, (b) an amine that, when oxidized by exposure to electrochemical energy, forms a strong reducing agent, and (c) an electrolyte.

FACTS

19. IGEN is the lawful owner with right, title and interest in the '605, '138, '973, and '225 patents.

20. On September 23, 1992, IGEN and Roche entered into a License and Technology Development Agreement ("the 1992 Agreement"). By entering into the 1992 Agreement, Roche

acquired the rights to develop, to manufacture, and to market within a prescribed field, diagnostic products based on IGEN's proprietary ECL, or ORIGEN[®], technology.

21. Roche's practice of the ECL technology, including, *inter alia*, the technology claimed in the '605, '138, '973, and '225 patents, was authorized under the 1992 Agreement.

22. Paragraph 11.2 of the 1992 Agreement provides that IGEN may terminate the agreement by giving written notice to Roche, if Roche materially breaches the agreement.

23. In Paragraph I.B. of its Final Order of Judgment in Case No. PJM 97-3461 dated February 15, 2002 ("Final Order"), this Court declared that Roche had materially breached the 1992 Agreement and that IGEN was entitled to terminate the agreement.

24. By a letter, served February 20, 2002, IGEN notified Roche that the 1992 Agreement would immediately terminate without further action in the event that the United States Court of Appeals for the Fourth Circuit ("Fourth Circuit") issued an order or decision that did not reverse or vacate those portions of this Court's Final Order that entitle IGEN to terminate the 1992 Agreement.

25. On July 9, 2003, the Fourth Circuit issued a order that did not reverse or vacate those portions of this Court's Final Order that entitle IGEN to terminate the 1992 Agreement.

26. Despite the termination of the license, Roche, on information and belief, continues and will continue to exploit IGEN's patented technology.

COUNT I - DECLARATION OF INFRINGEMENT OF IGEN'S PATENT

27. IGEN incorporates the allegations as set forth in Paragraphs 1 through 26.

28. Roche sells machines and reagents that use the ECL technology to perform specific binding assays to measure or detect pharmaceuticals, hormones, vitamins, proteins, and other materials of diagnostic value. The presence of these materials is determined by exploiting the high degree of

specificity with which these materials bind to other known substances. Typical examples of specific binding reactions include binding between an antigen and its antibody and binding between a protein and its ligand. Specific binding is measured by the use of a detectable ECL label that is attached to one of the specific binding components.

29. On information and belief, Roche is infringing IGEN's '605, '138, '973, and '225 patents by making, using, offering to sell, selling and/or importing and/or inducing and/or contributing to others' making, using, offering to sell, selling and/or importing equipment that embody or use IGEN's inventions.

30. IGEN is suffering, and will continue to incur irreparable injury by Roche's infringement, for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, IGEN requests the Court to enter judgment:

- A. Declaring that Roche has infringed the '605 patent;
- B. Declaring that Roche has infringed the '138 patent;
- C. Declaring that Roche has infringed the '973 patent;
- D. Declaring that Roche has infringed the '225 patent;
- E. Declaring Roche's infringement of the '605, '138, '973, and '225 patents willful and deliberate;
- F. Enjoining Roche, its officers, agents, employees, privies, successors, and assigns, and those acting in concert or participation with them, from infringing the '605, '138, '973, and '225 patents;
- G. Declaring this case an exceptional case pursuant to 35 U.S.C. § 285 and awarding IGEN their costs, expenses, and disbursements in this action, including reasonable attorney fees; and


H. Ordering that IGEN be awarded such other and further relief as this Court deems just.

JURY DEMAND

IGEN hereby demands a trial by jury of all issues so triable.

Respectfully submitted,

Dated: July 9, 2003



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