

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

LMG 3 MARKETING AND DEVELOPMENT
CORP.,

Plaintiff,

v.

SAFE GUARD MEDI-SYSTEM CORP.

Defendant.

Civil Action No.

JURY TRIAL DEMANDED

COMPLAINT

I. INTRODUCTION

1. In 2002, Plaintiff LMG 3 Marketing and Development Corporation (“LMG” or “Plaintiff”) invented a revolutionary technology to help the chronically ill regain a semblance of their personal freedom. For a person with a serious health condition, travel, family gatherings and even going to work is a risk: in the case of an emergency, he or she might need to receive treatment from an unfamiliar medical team without access to the patient’s full medical history. To address this, LMG developed a portable, secure device to store a patient’s medical history. What’s more, the device could be rapidly accessed by virtually any health care provider in just about any setting so that treatment decisions could be made using all relevant patient data. For its efforts, LMG was awarded two patents by the U.S. Patent and Trademark Office.

2. Safe Guard Medi-Systems Corp. (“Safe Guard”) makes and sells a portable device medical device that infringes LMG’s patents (“Infringing Products”). In fact, Safe Guard’s Infringing Products are nearly identical to the preferred embodiments in LMG’s patents. It is

clear that the core of Safe Guard's Infringing Products is based on the very technology that is claimed in LMG's Patents.

II. THE PARTIES

1. Plaintiff LMG is a privately-held domestic corporation organized under the laws of the State of New Jersey, with its headquarters located at 91 Deer Trail Road, Hillsdale, New Jersey 07642. LMG holds all substantial rights, titles and interests in U.S. Patent 8,195,479 (Maintaining Person's Medical History in Self-Contained Portable Memory Device) (the "'479 Patent," a true and authentic copy of which is attached hereto as Exhibit A) and U.S. Patent 8,195,480 (System for Maintaining Person's Medical History in Portable Memory Device) (the "'480 Patent," a true and authentic copy of which is attached hereto as Exhibit B). These patents claim priority to United States nonprovisional patent application No. 10/605,127 filed September 10, 2003.

2. Defendant Safe Guard is a Florida corporation headquartered at 21301 NE 20th Avenue, Miami, Florida 33179-1605. Upon information and belief, Safe Guard does business throughout the United States, including in the State of New York and within this Judicial District.

III. JURISDICTION

1. This is a civil action arising out of the infringement of the '479 Patent and the '480 Patent (collectively, "the Asserted Patents") under the patent laws of the United States of America, 35 U.S.C § 1 *et seq.*

2. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.

3. Venue is proper within this Judicial District under, *inter alia*, 28 U.S.C. § 1400.

IV. FACTS

A. LMG's Invention

4. The Asserted Patents disclose devices, systems and technologies developed by inventors Michael Lubell, Robert Guinta and Albert Moran, Jr. (collectively, the "Inventors") in or before 2002 and 2003.

5. The development path that eventually led to the Asserted Patents started with a basic observation by Mr. Lubell and Mr. Moran: generally speaking, the more information medical providers had about a patient's medical history, the more effectively they could treat the patient in routine or emergency medical scenarios. Yet those patients with the most significant health problems often had medical histories comprising thousands of pages of paper records. A patient could not be expected to carry these records to each provider. Thus, in the event of a medical emergency, for example, unless the patient received treatment from a medical team already in possession of his or her medical history, diagnostic and treatment decisions might be made without the benefit of highly relevant medical information.

6. Mr. Lubell and Mr. Moran believed that storing a patient's medical information (including, for example, the patient's list of active prescriptions, diagnoses, drug allergy information, treatment history, diagnostic scan images and insurance data) on a portable nonvolatile memory device could improve the patient's treatment outcomes, cut down on medical mistakes and control health care costs.

7. Storing a patient's medical history on a nonvolatile memory device, however, is only a starting-point for realizing these benefits because medical data is fundamentally distinct

from other types of data. Unique legal and technical limitations apply to medical data; storing such data on a portable device exacerbates these limitations.

8. The mandatory patient privacy regime created under the federal Health Insurance Portability and Accountability Act's ("HIPAA") represents one such limitation. HIPAA, among other things, requires that patient medical information be safeguarded against unauthorized access, including any portable device containing a patient's medical history.

9. Another principal limitation relating to storing medical data on a portable nonvolatile memory device stems from the diversity of data management solutions in the medical industry. There is no guarantee that patient data compiled at a large medical institution using sophisticated records management systems will be accessible by the patient's family doctor on the office's retail computer installed with little more than the software included on a basic operating system—or, for that matter, that it would be accessible by another large medical institution using an equally sophisticated but different system.

10. Accordingly, as noted above, making medical records portable is a necessary but insufficient step in ensuring that treatment decisions are made with a comprehensive set of the patient's medical data. To deliver on its potential, any portable medical records storage device would also need to (a) safeguard the stored medical data from unauthorized access, (b) but in such a way that allows authorized users to rapidly access it (c) regardless of the specific record management software and hardware employed by a health care provider.

11. These three requirements can, for present purposes, be referred to, respectively, as the requirements of (a) data security, (b) rapid accessibility and (c) universal compatibility.

12. These requirements represented formidable challenges that, in 2002, no invention had yet been able to fully overcome.

13. Importantly, these challenges were not merely technical or mechanical. Rather, they constituted a development paradox: data security, rapid accessibility and universal compatibility represented objectives that could potentially compete with one another. Put differently, meeting one of these objectives might undermine or subvert the other two objectives.

14. For instance, encrypting a portable device's medical data could potentially safeguard the data from unauthorized access. But later decrypting that data would demand additional steps that would either require prior coordination between the patient and the provider or on-the-fly installation of decryption software by the medical provider in the midst of providing treatment. Thus, facilitating the security of medical data by way of encryption can diminish the rapidity with which that data might be accessed and/or the number of medical providers who could effectively access that data.

15. To elaborate, decrypting the data would involve the medical provider either (a) anticipatorily coordinating with the patient to install decryption software configured to the patient's portable device or (b) initially treating the patient without the benefit of this data until the requisite decryption software can be identified, downloaded, installed and configured to the specific device.

16. In either scenario, the development paradox is triggered: safeguarding the data via encryption can impede rapid access to it and/or its universal compatibility.

17. The first scenario can facilitate data security and rapid deployment, but it fails to facilitate universal compatibility—for the device data to be accessible, the patient's emergency must occur at or near a pre-selected facility(ies); if the patient has an emergency while travelling, he or she is out of luck.

18. On the other hand, the latter scenario secures the data while providing universal compatibility, but at the expense of rapid access: the patient will be undergoing treatment while potentially relevant data waits to be unencrypted by software that needs to be downloaded, configured and installed by his or her health care provider.

19. In the summer of 2002, Mr. Moran and Mr. Lubell approached Mr. Guinta, hoping to develop a portable medical records device and, by extension, to resolve this development paradox. They asked Mr. Guinta to create the software, hardware and overall methods of a system that could securely store personal medical data such that it could be accessed at any facility where the patient might seek treatment, by any medical professional the patient might authorize and with sufficient rapidity that it could be successfully deployed in emergency treatment (as well as other treatment scenarios).

20. After meeting with Mr. Moran and Mr. Lubell, Mr. Guinta began to develop the specific systems, processes, software and other technologies eventually disclosed in the Asserted Patents for a secure, portable medical data storage system.

21. To overcome the development paradox and the conflicting requirements of security, rapid accessibility and universal compatibility, Mr. Moran, Mr. Lubell and Mr. Guinta had to invent a novel technology. Generally speaking, this technology—for which the U.S. Patent Office eventually awarded the Asserted Patents to the Inventors—created a device, system and method to store, access and deploy medical data in a manner that simultaneously safeguarded the data yet allowed medical professionals to universally access and deploy it.

22. One of the ways the Asserted Patents overcame the development paradox is as follows.

23. First, data security would be provided by way of software contained on the device that would encrypt the device's stored medical data. In order to ensure that encrypting the data did not subvert a medical provider's ability to rapidly access it, the device carried on it a parallel decryption algorithm. As such, medical providers would not typically need to download, install and/or maintain on their systems special software to unencrypt and access the device's data. Accordingly, because the device's data encryption and decryption mechanisms were self-contained, the device could maintain security without undermining the rapid accessibility and universal compatibility requirements. To access and deploy the device's medical data, the patient's treatment team would generally only need to plug the device into one of the medical facility's computers. In this way, fulfilling the data security requirement, far from undermining the objectives of universal accessibility and rapid deployment, could actually further them.

24. Second, the Asserted Patents facilitated universal compatibility by storing on the device all software needed to display the stored medical data; in other words, the device's data could be accessed and displayed on virtually any computer system at any medical facility using only the device's self-contained access and display software. Thus, the device's self-contained access and display software sidestepped the inherent interoperability issues noted above that arise from the myriad bespoke and incompatible medical recordkeeping platforms and computer systems employed by different medical facilities. The medical data on the device could be universally accessed, regardless of the medical facility; the device's utility would not be limited to use at a single, pre-identified medical facility near the patient's home with computers specifically preconfigured to access the data. A patient carrying the device would be free to travel with a reasonable assurance that, in the event of a medical emergency, any treatment

facility would have the benefit of the patient's stored medical data to quickly deploy it and improve medical outcomes.

25. Similarly, rapid accessibility of the medical data would be possible as there would generally be no need for the health care facility's computer system to identify, search for, download and configure drivers before accessing the device's data. The drivers necessary to access the device were already installed on the device.

26. By late 2002, Mr. Guinta, alongside Mr. Moran and Mr. Lubell, had developed a fully functional system (including the portable device and related software) embodying, in part, the Asserted Patents. This prototype was named MyRECS™. The MyRECS™ device could securely store on its nonvolatile memory, among other things, a patient's allergy information, emergency contact details, medication regimen, surgical history, immunization records, medical alerts, medical conditions, insurance information, treatment history and contact details for the patient's physician(s).

27. The Asserted Patents and their subsequent embodiment in the MyRECS™ device represented a leap in the field of portable health information devices and systems: at last, a portable medical-information storage technology had been disclosed which encrypted a patient's sensitive medical data, thus facilitating compliance with applicable patient privacy laws and, at the same time, allowing for that data to be rapidly unencrypted and accessed by virtually any health care provider on any computer.

28. The development paradox of meeting conflicting security, access and compatibility requirements was essentially overcome. Put more simply, patient medical data on the device could be at once be protected from unauthorized access, made universally accessible

to those authorized to view it and allow for rapid deployment of the data to improve diagnosis and treatment outcomes.

29. The Inventors have assigned their rights to the Asserted Patents to their company, Plaintiff LMG.

30. By December 2002, Plaintiff initiated its efforts to market and sell devices embodying some or all of the claims in the Asserted Patents. Thereafter, Plaintiff developed further devices embodying the Asserted Patents, including the MyPMR™ device (“PMR” is an abbreviation for “Personal Medical Record”).

31. LMG contracted with a major electronics manufacturer to produce devices embodying the Asserted Patents. The devices were manufactured in China and imported to the United States for resale.

32. Since 2003, LMG has promoted the relevant inventions and technologies in meetings and presentations with executives from some of the most familiar players in the U.S. health care industry, including major health insurers and public-sector entities.

33. LMG offers its devices for sale through various distribution channels, including eBay.

34. In 2005, LMG entered into an agreement with a domestic commercial reseller to target sales of the devices to emergency medical technicians.

35. Further, LMG has engaged marketing and distribution consulting resources to augment its sales efforts.

36. LMG has attempted to raise additional capital from prospective investors to continue developing devices and technologies embodying the Asserted Patents, including claims relating to transmission of medical data stored on the devices via the Internet.

B. Safe Guard's Infringement

37. Defendant Safe Guard's Infringing Products consist of several portable, hand-carried devices that allows users to record, update and access their medical history. Safe Guard lists several of its Infringing Products on its website. (<http://www.sgmscorp.com/product-category/key-2-life-emr-category>.)

38. Safe Guard's Infringing Products include at least 24 different models ranging in price from \$29.99 to \$49.99..

39. Safe Guard's Infringing Products use nonvolatile memory to store patients' medical records.

40. Safe Guard's Infringing Products allow health care providers to access users personal medical information on a variety of computer systems.

41. Safe Guard's Infringing Products provide security features that limit unauthorized access to users medical information. Safe Guard's Infringing Products are also password protected and have encrypted files.

**CLAIM ONE
INFRINGEMENT OF THE '479 PATENT**

42. Plaintiff LMG repeats and re-alleges the allegations set forth above, as though fully set forth herein.

43. In violation of 35 U.S.C. § 271, Defendant Safe Guard has designed, used, offered to sell, sold and/or imported into the United States, and on information and belief, is still designing, using, offering to sell, selling, and/or importing into the United States, products that infringe directly or indirectly through contributory and/or induced infringement, at least one claim of the '479 Patent, without LMG's authorization or consent.

44. Safe Guard will, on information and belief, continue to infringe upon LMG's rights under 35 U.S.C. § 271, unless and until it is enjoined by this Court. LMG has been and is likely to continue to be irreparably injured unless Safe Guard is enjoined. LMG has no adequate remedy at law.

CLAIM TWO
INFRINGEMENT OF THE '480 PATENT

45. Plaintiff LMG repeats and re-alleges the allegations set forth above, as though fully set forth herein.

46. In violation of 35 U.S.C. § 271, Defendant Safe Guard has designed, used, offered to sell, sold and/or imported into the United States, and on information and belief, is still designing, using, offering to sell, selling, and/or importing into the United States, products that infringe directly or indirectly through contributory and/or induced infringement, at least one claim of the '480 Patent, without LMG's authorization or consent.

47. Safe Guard will, on information and belief, continue to infringe upon LMG's rights under 35 U.S.C. § 271, unless and until it is enjoined by this Court. LMG has been and is likely to continue to be irreparably injured unless Safe Guard is enjoined. LMG has no adequate remedy at law.

V. RELIEF REQUESTED

WHEREFORE, by reason of the foregoing, Plaintiff LMG requests that this Court:

- a. enter judgment in LMG's favor and against Safe Guard on all claims;

- b. adjudge and decree that Safe Guard has unlawfully infringed, contributorily infringed and/or induced infringement of the '479 Patent and the '480 Patent;
- c. preliminarily and permanently enjoin Safe Guard and its agents and all those acting in concert or participation with them from importing, distributing, advertising, promoting, selling, or offering for sale any products that infringe any claim of the '479 Patent and/or the '480 Patent;
- d. require Safe Guard to pay LMG any damages LMG has suffered arising out of and/or as a result of Safe Guard's patent infringement, including LMG's lost profits and/or reasonable royalties for Safe Guard's patent infringement, and any other relief provided for in 35 U.S.C. § 284; and
- e. grant such other relief as this Court deems appropriate.

DEMAND FOR JURY TRIAL

Plaintiff LMG hereby demands a jury trial on all issues and claims so triable.

Dated: 9/25/2015

Respectfully submitted,

/s/ Brian D. O'Reilly

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