

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

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ERESEARCHTECHNOLOGY, INC.,

Plaintiff,

v.

CRF, INC. d/b/a CRF HEALTH,

Defendant.

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**No. 2:15-cv-00918-NBF**

**ELECTRONICALLY FILED**

**JURY TRIAL DEMANDED**

**FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT  
AND DEMAND FOR JURY TRIAL**

Plaintiff eResearchTechnology, Inc. (“ERT”), hereby alleges for its Complaint against Defendant CRF, Inc. d/b/a CRF Health (“CRF”) on personal knowledge as to its own actions and on information and belief as to the actions of others, as follows:

**NATURE OF THE ACTION**

1. ERT has redefined how clinical trials are successfully conducted. ERT is a leading provider of high-quality patient safety and efficacy endpoint data collection solutions for use in clinical drug and medical device development.

2. ERT’s technology and services are used in clinical trials to track, predict, manage, and enhance subject compliance, to increase the accuracy, reliability, and usability of patient data, and to improve the efficiency of the clinical research process.

3. ERT’s ePRO (electronic Patient Report Outcome) system was an initial innovation that demonstrated that data captured electronically through an eDiary can increase trial sensitivity by reducing error variance, resulting in dramatically smaller, faster, and less-expensive studies.

4. ERT's innovations in the area of clinical trial implementation have resulted in numerous issued patents and pending patent applications.

5. ERT's technology has been used in hundreds of worldwide clinical trials and has resulted in at least 20 drug approvals worldwide.

6. Nevertheless, ERT's innovations have been the subject of widespread copying by CRF, which has unfairly attempted to capitalize on ERT's pioneering efforts and success by imitating ERT's innovative technology and product offerings.

7. Instead of pursuing independent product development, CRF has chosen to use ERT's innovative technology and product offerings, in violation of ERT's valuable intellectual property rights. As alleged below in detail, CRF has made its products work through widespread patent infringement.

### **THE PARTIES**

8. Plaintiff ERT is a Delaware corporation with its largest division at 225 West Station Square Drive, Suite 220, Pittsburgh, Pennsylvania 15219.

9. Defendant CRF is a Delaware Corporation with its principal place of business at 4000 Chemical Road, Suite 400, Plymouth Meeting, Pennsylvania 19462.

10. On information and belief, CRF is doing business and infringing one or more claims of each of ERT's patents-in-suit in Pennsylvania and elsewhere in the United States.

### **JURISDICTION AND VENUE**

11. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. §§ 271 *et. seq.* and 281-285. Jurisdiction is conferred on this Court pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. On information and belief, this Court has personal jurisdiction over CRF because CRF's principal place of business is in Pennsylvania.

13. On information and belief, venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) because CRF is subject to personal jurisdiction in this District, and therefore, resides in this District.

### **GENERAL ALLEGATIONS**

14. ERT holds all right, title, and interest in and to United States Patent No. 8,065,180 (“the ’180 patent”), entitled “System for Clinical Trial Subject Compliance,” which was duly and legally issued by the U.S. Patent and Trademark Office (“USPTO”) on November 22, 2011. A copy of the ’180 patent is attached as Exhibit A.

15. ERT holds all right, title, and interest in and to United States Patent No. 8,145,519 (“the ’519 patent”), entitled “System for Clinical Trial Subject Compliance,” which was duly and legally issued by the USPTO on March 27, 2012. A copy of the ’519 patent is attached as Exhibit B.

16. ERT holds all right, title, and interest in and to United States Patent No. 8,433,605 (“the ’605 patent”), entitled “System for Clinical Trial Subject Compliance,” which was duly and legally issued by USPTO on April 30, 2013. A copy of the ’605 patent is attached as Exhibit C.

17. ERT holds all right, title, and interest in and to United States Patent No. 6,879,970 (“the ’970 patent”), entitled “Apparatus and Method for Prediction and Management of Subject Compliance in Clinical Research,” which was duly and legally issued by the USPTO on April 12, 2005. A copy of the ’970 patent is attached as Exhibit D.

18. ERT holds all right, title, and interest in and to United States Patent No. 7,415,447 (“the ’447 patent”), entitled “Apparatus and Method for Prediction and Management of Participant Compliance in Clinical Research,” which was duly and legally issued by the USPTO on August 19, 2008. A copy of the ’447 patent is attached as Exhibit E.

### **Count 1: Infringement of U.S. Patent No. 8,065,180**

19. ERT refers to and incorporates herein the allegations of Paragraphs 1-18 above.

20. On information and belief, CRF has infringed and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '180 patent, by performing, implementing, and carrying out, processes, methods and/or computer readable mediums with respect to at least the Accused Instrumentalities defined below, in violation of 35 U.S.C. § 271(a). In addition, on information and belief, CRF has infringed and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '180 patent, by making, using, selling, offering for sale, importing, exporting, supplying, making available, and/or distributing within, to and/or from the United States products, systems, and/or apparatuses including, but not limited to, at least the eCOA solution, alone, in combination, or parts thereof; the parts of the eCOA solution including, but not limited to, the TrialMax Touch, TrialMax Slate, TrialMax Web, TrialMax App, TrialStudio, asma-1 PEF meter, MyGlucoHealth wirelessmeter, TrialManager, TrialMax Synapse, Project Management, Collaborative Design, Data Management, and Data Collection Networks (collectively, the "Accused Instrumentalities"), in violation of 35 U.S.C. § 271(a).

21. On information and belief, CRF has actively induced and continues to actively induce others, including clinical trial sponsors, clinical trial participants, and researchers, to infringe one or more claims of the '180 patent at least by knowingly aiding and abetting, causing, urging, encouraging, instructing, and/or enabling them to infringe one or more claims of the '180 patent. In this regard, on information and belief, CRF has actively induced and continues to actively induce others by advertising, marketing, supplying, and/or making available products, systems, apparatuses, and/or services including, but not limited to, at least the Accused Instrumentalities. Thus, CRF is liable for induced infringement of one or more claims of the '180 patent under 35 U.S.C. § 271(b).

22. On information and belief, CRF has sold/offered to sell, has made available, and/or has supplied, and continues to sell/offer to sell, make available, and/or supply components, including, but not limited to, at least the Accused Instrumentalities, which constitute a material part of one or more claims of the '180 patent and lack any substantial non-

infringing use, knowing those components to be especially made or especially adapted for use in infringement of one or more claims of the '180 patent. Thus, CRF is liable for contributory infringement of one or more claims of the '180 patent under 35 U.S.C. § 271(c).

23. On information and belief, CRF has had prior knowledge of the '180 patent at least as early as July 5, 2012. From July 5, 2012 to January 16, 2015, ERT and invivodata, Inc. ("invivodata"), ERT's predecessor, sent multiple letters to CRF regarding licensing of the '180 patent. Upon information and belief, CRF has been and is aware of its infringement, and has been and is willfully infringing one or more claims of the '180 patent.

24. ERT has been irreparably harmed by CRF's acts of infringement of one or more claims of the '180 patent, and will continue to be harmed unless and until CRF's acts of infringement are enjoined and restrained by order of this Court. ERT has no adequate remedy at law to redress CRF's continuing acts of infringement. The hardships that would be imposed upon CRF by an injunction are less than those faced by ERT should an injunction not issue. Furthermore, the public interest would be served by issuance of an injunction. Accordingly, ERT is entitled to permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

25. As a result of CRF's acts of infringement of one or more claims of the '180 patent, ERT has suffered and will continue to suffer damages. ERT is entitled to compensation for such damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

**Count 2: Infringement of U.S. Patent No. 8,145,519**

26. ERT refers to and incorporates herein the allegations of Paragraphs 1-25 above.

27. On information and belief, CRF has infringed and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '519 patent, by performing, implementing, and carrying out, processes, methods, systems and/or computer readable mediums with respect to at least the Accused Instrumentalities defined above in paragraph 20, in violation of 35 U.S.C. § 271(a). In addition, on information and belief, CRF has infringed and continues

to infringe, literally or under the doctrine of equivalents, one or more claims of the '519 patent, by making, using, selling, offering for sale, importing, exporting, supplying, making available, and/or distributing within, to and/or from the United States products, systems, apparatuses, and/or services, including, but not limited to, at least the Accused Instrumentalities, in violation of 35 U.S.C. § 271(a).

28. On information and belief, CRF has actively induced and continues to actively induce others, including clinical trial sponsors, clinical trial participants, and researchers to infringe one or more claims of the '519 patent at least by knowingly aiding and abetting, causing, urging, encouraging, instructing, and/or enabling them to infringe one or more claims of the '519 patent. In this regard, on information and belief, CRF has actively induced and continues to actively induce others by advertising, marketing, supplying, and/or making available products, systems, apparatuses, and/or services including, but not limited to, at least the Accused Instrumentalities. Thus, CRF is liable for induced infringement of one or more claims of the '519 patent under 35 U.S.C. § 271(b).

29. On information and belief, CRF has sold/offered to sell, has made available, and/or has supplied, and continues to sell/offer to sell, make available, and/or supply, components, including, but not limited to, at least the Accused Instrumentalities, which constitute a material part of one or more claims of the '519 patent and lack any substantial non-infringing use, knowing those components to be especially made or especially adapted for use in infringement of one or more claims of the '519 patent. Thus, CRF is liable for contributory infringement of one or more claims of the '519 patent under 35 U.S.C. § 271(c).

30. On information and belief, CRF has had prior knowledge of the '519 patent at least as early as July 5, 2012. From July 5, 2012 to January 16, 2015, ERT and invivodata, ERT's predecessor, sent multiple letters to PHT regarding licensing of the '519 patent. Upon information and belief, PHT has been and is aware of its infringement, and has been and is willfully infringing one or more claims of the '519 patent.

31. ERT has been irreparably harmed by CRF's acts of infringement of one or more claims of the '519 patent, and will continue to be harmed unless and until CRF's acts of infringement are enjoined and restrained by order of this Court. ERT has no adequate remedy at law to redress CRF's continuing acts of infringement. The hardships that would be imposed upon CRF by an injunction are less than those faced by ERT should an injunction not issue. Furthermore, the public interest would be served by issuance of an injunction. Accordingly, ERT is entitled to permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

32. As a result of CRF's acts of infringement of one or more claims of the '519 patent, ERT has suffered and will continue to suffer damages. ERT is entitled to compensation for such damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

**Count 3: Infringement of U.S. Patent No. 8,433,605**

33. ERT refers to and incorporates herein the allegations of Paragraphs 1-32 above.

34. On information and belief, CRF has infringed and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '605 patent, by performing, implementing, and carrying out, processes, methods, systems and/or computer readable mediums with respect to at least the Accused Instrumentalities defined above in paragraph 20, in violation of 35 U.S.C. § 271(a). In addition, on information and belief, CRF has infringed and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '605 patent, by making, using, selling, offering for sale, importing, exporting, supplying, making available, and/or distributing within, to and/or from the United States products, systems, apparatuses, and/or services, including, but not limited to, at least the Accused Instrumentalities, in violation of 35 U.S.C. § 271(a).

35. On information and belief, CRF has actively induced and continues to actively induce others, including clinical trial sponsors, clinical trial participants, and researchers to infringe one or more claims of the '605 patent at least by knowingly aiding and abetting, causing,

urging, encouraging, instructing, and/or enabling them to infringe one or more claims of the '605 patent. In this regard, on information and belief, CRF has actively induced and continues to actively induce others by advertising, marketing, supplying, and/or making available products, systems, apparatuses, and services, including, but not limited to, at least the Accused Instrumentalities. Thus, CRF is liable for induced infringement of one or more claims of the '605 patent under 35 U.S.C. § 271(b).

36. On information and belief, CRF has sold/offered to sell, has made available, and/or has supplied, and continues to sell/offer to sell, make available, and/or supply, components, including, but not limited to, at least the Accused Instrumentalities, which constitute a material part of one or more claims of the '605 patent and lack any substantial non-infringing use, knowing those components to be especially made or especially adapted for use in infringement of one or more claims of the '605 patent. Thus, CRF is liable for contributory infringement of one or more claims of the '605 patent under 35 U.S.C. § 271(c).

37. On information and belief, CRF has had prior knowledge of the '605 patent at least as early as October 24, 2014. From October 24, 2014 to January 16, 2015, ERT sent multiple letters to CRF regarding licensing of the '605 patent. Upon information and belief, CRF has been and is aware of its infringement, and has been and is willfully infringing one or more claims of the '605 patent.

38. ERT has been irreparably harmed by CRF's acts of infringement of one or more claims of the '605 patent, and will continue to be harmed unless and until CRF's acts of infringement are enjoined and restrained by order of this Court. ERT has no adequate remedy at law to redress CRF's continuing acts of infringement. The hardships that would be imposed upon CRF by an injunction are less than those faced by ERT should an injunction not issue. Furthermore, the public interest would be served by issuance of an injunction. Accordingly, ERT is entitled to permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.



39. As a result of CRF's acts of infringement of one or more claims of the '605 patent, ERT has suffered and will continue to suffer damages. ERT is entitled to compensation for such damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

**Count 4: Infringement of U.S. Patent No. 6,879,970**

40. ERT refers to and incorporates herein the allegations of Paragraphs 1-39 above.

41. On information and belief, CRF has infringed and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '970 patent, by performing, implementing, and carrying out, processes, methods, systems and/or computer readable mediums with respect to at least the Accused Instrumentalities defined above in paragraph 20, in violation of 35 U.S.C. § 271(a). In addition, on information and belief, CRF has infringed and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '970 patent, by making, using, selling, offering for sale, importing, exporting, supplying, making available, and/or distributing within, to and/or from the United States products, systems, apparatuses, and/or services, including, but not limited to, at least the Accused Instrumentalities, in violation of 35 U.S.C. § 271(a).

42. On information and belief, CRF has actively induced and continues to actively induce others, including clinical trial sponsors, clinical trial participants, and researchers to infringe one or more claims of the '970 patent at least by knowingly aiding and abetting, causing, urging, encouraging, instructing, and/or enabling them to infringe one or more claims of the '970 patent. In this regard, on information and belief, CRF has actively induced and continues to actively induce others by advertising, marketing, supplying, and/or making available products, systems, apparatuses, and services, including, but not limited to, at least the Accused Instrumentalities. Thus, CRF is liable for induced infringement of one or more claims of the '970 patent under 35 U.S.C. § 271(b).

43. On information and belief, CRF has sold/offered to sell, has made available, and/or has supplied, and continues to sell/offer to sell, make available, and/or supply,

components, including, but not limited to, at least the Accused Instrumentalities, which constitute a material part of one or more claims of the '970 patent and lack any substantial non-infringing use, knowing those components to be especially made or especially adapted for use in infringement of one or more claims of the '970 patent. Thus, CRF is liable for contributory infringement of one or more claims of the '970 patent under 35 U.S.C. § 271(c).

44. On information and belief, CRF has had prior knowledge of the '970 patent at least as early as November 14, 2011. As of November 14, 2011, CRF Box Oy, CRF's parent corporation, was the assignee of patent application number 13/047,467 (the "'467 application"). During the prosecution of the '467 application, a submission under 37 C.F.R. § 1.99 was filed on November 14, 2011, listing a number of references including the '970 patent, for consideration by the Patent Office. At the same time, a letter was sent to the prosecution counsel for the '467 application notifying CRF of the references submitted to the Patent Office under 37 C.F.R. § 1.99, including a copy of the '970 patent. Further, starting from at least as early as July 5, 2012, ERT and invivodata sent multiple letters to CRF regarding licensing of the '180 and '519 patents, each of which explicitly states that it is related to the '970 patent and incorporates by reference the '970 patent. Additionally, the '180 patent refers to the '970 patent multiple times throughout its specification. Upon information and belief, CRF has been and is aware of its infringement and has been and is willfully infringing one or more claims of the '970 patent.

45. ERT has been irreparably harmed by CRF's acts of infringement of one or more claims of the '970 patent, and will continue to be harmed unless and until CRF's acts of infringement are enjoined and restrained by order of this Court. ERT has no adequate remedy at law to redress CRF's continuing acts of infringement. The hardships that would be imposed upon CRF by an injunction are less than those faced by ERT should an injunction not issue. Furthermore, the public interest would be served by issuance of an injunction. Accordingly, ERT is entitled to permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

46. As a result of CRF's acts of infringement of one or more claims of the '970 patent, ERT has suffered and will continue to suffer damages. ERT is entitled to compensation for such damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

**Count 5: Infringement of U.S. Patent No. 7,415,447**

47. ERT refers to and incorporates herein the allegations of Paragraphs 1-46 above.

48. On information and belief, CRF has infringed and continues to infringe, literally or under the doctrine of equivalents, one or more claims of the '447 patent, by performing, implementing, and carrying out, processes, methods, systems and/or computer readable mediums with respect to at least the Accused Instrumentalities defined above in paragraph 20, in violation of 35 U.S.C. § 271(a).

49. On information and belief, CRF has actively induced and continues to actively induce others, including clinical trial sponsors, clinical trial participants, and researchers to infringe one or more claims of the '447 patent at least by knowingly aiding and abetting, causing, urging, encouraging, instructing, and/or enabling them to infringe one or more claims of the '447 patent. In this regard, on information and belief, CRF has actively induced and continues to actively induce others by advertising, marketing, supplying, and/or making available products, systems, apparatuses, and services, including, but not limited to, at least the Accused Instrumentalities. Thus, CRF is liable for induced infringement of one or more claims of the '447 patent under 35 U.S.C. § 271(b).

50. On information and belief, CRF has sold/offered to sell, has made available, and/or has supplied, and continues to sell/offer to sell, make available, and/or supply, components, including, but not limited to, at least the Accused Instrumentalities, which constitute a material part of one or more claims of the '447 patent and lack any substantial non-infringing use, knowing those components to be especially made or especially adapted for use in infringement of one or more claims of the '447 patent. Thus, CRF is liable for contributory infringement of one or more claims of the '447 patent under 35 U.S.C. § 271(c).

51. On information and belief, CRF has had prior knowledge of the '447 patent at least as early as November 14, 2011. As of November 14, 2011, CRF Box Oy, CRF's parent corporation, was the assignee of the '467 application. During the prosecution of the '467 application, a submission under 37 C.F.R. § 1.99 was filed on November 13, 2011, listing a number of references including the '447 patent, for consideration by the Patent Office. At the same time, a letter was sent to the prosecution counsel for the '467 application notifying CRF of the references submitted to the Patent Office under 37 C.F.R. § 1.99, including a copy of the '447 patent. Further, starting from at least as early as July 5, 2012, ERT and invivodata sent multiple letters to CRF regarding licensing of the '519 patent, which explicitly lists the '447 patent in the "References Cited" section. Upon information and belief, CRF has been and is aware of its infringement and has been and is willfully infringing one or more claims of the '447 patent.

52. ERT has been irreparably harmed by CRF's acts of infringement of one or more claims of the '447 patent, and will continue to be harmed unless and until CRF's acts of infringement are enjoined and restrained by order of this Court. ERT has no adequate remedy at law to redress CRF's continuing acts of infringement. The hardships that would be imposed upon CRF by an injunction are less than those faced by ERT should an injunction not issue. Furthermore, the public interest would be served by issuance of an injunction. Accordingly, ERT is entitled to permanent injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

53. As a result of CRF's acts of infringement of one or more claims of the '447 patent, ERT has suffered and will continue to suffer damages. ERT is entitled to compensation for such damages pursuant to 35 U.S.C. § 284 in an amount to be determined at trial.

### **PRAYER FOR RELIEF**

WHEREFORE, ERT requests the following relief:

- a. That CRF and its parents, affiliates, subsidiaries, officers, agents, servants, employees, attorneys, successors, and assigns, and all those persons in active concert or participation with them, or any of them, be preliminarily and permanently enjoined from making, using, offering for sale, selling, causing to sell, importing, exporting, supplying and/or distributing within, to and/or from the United States any product or service practicing any claim of the '180 patent, the '519 patent, the '605 patent, the '970 patent, or the '447 patent or otherwise infringing or contributing or inducing infringement of any claim thereof;
- b. A finding that CRF has infringed literally and/or under the doctrine of equivalents, directly and/or indirectly, one or more claims of the '180 patent, the '519 patent, the '605 patent, the '970 patent, and the '447 patent;
- c. A finding that CRF's infringement has been willful;
- d. That ERT be awarded its actual damages, including without limitation royalties and lost profits;
- e. That ERT be awarded pre-judgment interest and post-judgment interest at the maximum rate allowed by law, including an award of pre-judgment interest, pursuant to 35 U.S.C. § 284, from the date of each act of infringement of one or more claims of the '180 patent, '519 patent, the '605 patent, the '970 patent, and the '447 patent by CRF to the day a damages judgment is entered, and a further award of post-judgment interest, pursuant to 28 U.S.C. § 1961, continuing until such judgment is paid, at the maximum rate allowed by law;
- f. That the Court order an accounting for damages through judgment and post-judgment until CRF is permanently enjoined from further infringing activities;
- g. That the Court declare this to be an exceptional case pursuant to 35 U.S.C. § 285 and require CRF to pay the costs of this action (including all disbursements) and attorney's fees as provided by 35 U.S.C. § 285;
- h. That the Court award enhanced damages pursuant to 35 U.S.C. § 284;

- i. That the Court award supplemental damages for any continuing post-verdict infringement up until CRF is permanently enjoined from further infringing activities;
- j. That the Court award a compulsory future royalty in the event an injunction is not awarded;
- k. That the Court require CRF to pay interest on such damages at the legal rate; and
- l. That ERT be awarded such other and further relief as the Court deems just and proper.

### **DEMAND FOR JURY TRIAL**

Pursuant to the provisions of Rule 38(b) of the Federal Rules of Civil Procedure, ERT demands a trial by jury of all issues so triable in this matter.

Respectfully submitted,

FOX ROTHSCHILD LLP

Dated: October 22, 2015

/s/ William L. Stang

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*Counsel for Plaintiff,*  
*eResearchTechnology, Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that, pursuant to Local Rule 5.6 of the United States District Court for the Western District of Pennsylvania, the foregoing First Amended Complaint and Demand for Jury Trial has been served by electronic means through the Court's transmission facilities on the following counsel of record:

Andrews P. Nemiroff, Esquire  
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122 Rose Street  
Metuchen, NJ 08840  
[anemiroff@nemilaw.com](mailto:anemiroff@nemilaw.com)  
*Counsel for Defendant,*  
*CRF, Inc.*

I further certify that the foregoing First Amended Complaint and Demand for Jury Trial has been served by electronic mail upon the following individual, who has represented that she is counsel for Defendant CRF, Inc.

Julie Negovan, Esquire  
Spruce Law Group, LLC  
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Date: October 22, 2015

s/ William L. Stang  
William L. Stang