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11	INC, a California corporation,		
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14 15 16 17 18	PATRICIA D. PÉGRAM, M.D., an individual; SUZANNE L. SERGILE, M.D., an individual; GARRETT M.	 CARTWRIGHT ACT (Bus. & Prof. Code § 16700 et seq.) 2. INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE; 3. DEFAMATION/TRADE LIBEL; 4. CIVIL RICO (18 U.S.C. § 1962(c)); 	
19 20	MICHAEL J. LAUBACH, D.C., an individual; JAY V. WESTPHAL, M.D., an individual: KATHLEEN GRAY.	 5. CIVIL RICO CONSPIRACY (18 U.S.C. § 1962(d)); 6. UNFAIR COMPETITION 	
20 21	M.D., an individual; JOHANNA APPEL, D.C., an individual; and DOES 1 through 100, inclusive,	(Bus. & Prof Code § 17200) Complaint filed: August 12, 2011	
22	Defendants. Trial Date: None		
23			
24	COMES NOW PLAINTIFF, ELECTRONIC WAVEFORM LAB, INC.,		
25	(hereafter "Plaintiff") alleges its Third Amended Complaint against State		
26	Compensation Insurance Fund ("SCIF" - previously added as DOE 2), EK Health		
27	Services ("EK"), and individuals James Lessenger, M.D., Grant Nugent, M.D.,		
28	Alton Wills, M.D., Patricia D. Pegram, M	I.D., Suzanne L. Sergile, M.D., Garrett M.	
		1 - DED COMPLAINT	
	THIRD AMENDED COMPLAINT		

1 Casey, D.C., Michael J. Laubach, D.C., Jay V. Westphal, M.D., Kathleen Gray,

2 M.D., Johanna Appel, D.C., Janet O'Brien, M.D. (previously added as DOE 1 & 51)

3 (collectively referred to as the Utilization "Reviewers"), Richard Thompson, M. D.

4 (previously added as DOE 3), David Ehrenfeld (previously added as DOE 4), and

5 DOES 5 through 50 and 52 through 100, inclusive, (collectively referred to as

- 6 "Defendants")¹, and alleging additional acts and clarifying its allegations:
- 7

INTRODUCTION

8 1. Plaintiff Electronic Waveform manufactures and sells the H-Wave® medical device ("H-Wave"). It is an electrotherapy device used to treat pain, spasm, 9 reduce inflammation, enhance blood flow to afflicted areas of the body, and increase 10 range of motion for injured persons. H-Wave reverses the physical processes that 11 12 cause pain and limit movement, in part by stimulating circulation and the lymphatic 13 system to reduce the inflammation and congestion that is often at the root of symptoms. For 35 years, this top-quality product has been helping injured workers 14 15 get back to work. H-Wave has been proven to give relief to injured workers where other "conservative care" options have reached their beneficial limit, and it allows 16 17 patients to reduce their dependence on narcotics. Narcotic pain medication dependency is currently one of the most serious concerns in the entire California 18 19 workers' compensation system.

20 2. H-Wave has four distinct FDA clearances with 15 indications for use, 21including relaxation of muscle spasm, prevention of disuse atrophy, increasing local 22 blood circulation, muscle re-education, increasing range of motion, treatment of 23 chronic intractable pain and post-operative and traumatic pain, and as anesthesia in 24 dentistry. H-Wave is approved for various uses by California State-sanctioned 25 medical guidelines including but not limited to California's Medical Treatment Utilization Schedule ("MTUS"), as well as finding support in at least fifteen (15) 26

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¹ Joe Hartzog, M.D. was previously dismissed with prejudice following his passing.

published peer-reviewed studies. Thirteen (13) of those studies are indexed by
 PubMed, and eleven (11) of those are also indexed by MEDLINE as required by the
 Utilization Review's regulatory definition for "Evidence-based" medicine in CCR
 §9792.20: "Medical Treatment Utilization Schedule -Definitions," which states, "(e)
 'Evidence-based' means based, at a minimum, on a systematic review of literature
 published in medical journals included in MEDLINE."

7 3. Defendant SCIF provides workers compensation insurance, and is the
8 "insurer of last resort" in California.

94. According to SCIF's "Fact Sheet" found at10www.statefundca.com/news/FactSheet.asp:

- Established in 1914 by the state legislature, State Fund is California's
 largest provider of workers' compensation insurance and a vital asset to
 California businesses.
- With approximately 130,000 policyholders, just over \$1 billion in
 premium, and nearly \$20 billion in net admitted assets, State Fund is a
 necessary, competitive force in California's economy.
- Completely self supporting, State Fund plays a stabilizing role in
 California's economy by maintaining an open door policy that ensures
 that all employers have a strong and stable option for their workers'
 compensation needs.

5. SCIF has the largest WC market share in California – almost double
the percentage of the next biggest carrier in 2011, and much more in prior years.
SCIF's market share of California's workers' compensation market during the
relevant period, as reported by the California Department of Insurance was:

- 25 2004=51.01%
- 26 2005=42.08%
- 27 2006=31.97%
- 28 2007=26.54%

- 1 2008=22.56%
- 2 2009=18.64%
- 3 2010= 16.02%
- 4 2011=12.91%
- 5 The average over these years was 27.71%.

6 6. EK and the Reviewers are engaged individually and collectively in
7 providing "Utilization Review" services ("UR") primarily to SCIF, and other
8 insurance companies in California and across the country. For the majority of 2005
9 to the present, EK provided at or near 100% of all SCIF's UR services.

In 2004, when Senate Bill 899 passed, making UR mandatory before a
 WC insurance company may deny or modify treatment to an injured worker, SCIF
 strategized to move its previously informal UR to an outside "independent" vendor.
 At the time, EK Health Services, Inc. was a very small company whose business
 model was in jeopardy. Recognizing the opportunity of providing UR for the largest
 WC carrier in California, EK became, almost simultaneously, the Independent
 Contractor providing SCIF's UR services.

17 8. In August 2004, when EK entered into its written UR contract with SCIF, SCIF terminated all of its independent contractor doctors who worked on-site 18 at SCIF, and EK promptly signed up those very same doctors as its sub-contractors. 19 Nothing really changed except who wrote the paychecks to these contracted 2021 Reviewers. The same independent contractors continued to sit in SCIF's various district offices, conducting UR review on SCIF computers, meeting with SCIF 22 Personnel now as sub-contractors for EK as opposed to independent contractors for 23 SCIF. 24

9. Plaintiff has learned through this litigation that as of September 14,
2005, SCIF developed and issued a written UR "blanket policy", the primary
purpose of which was to always deny physicians' requests for H-Wave treatment.
That written blanket denial policy is attached hereto as Exhibit "C" and incorporated

as if fully set forth herein. From 2005 to the present, EK and the Reviewers, along
 with all other unnamed reviewers subcontracting with EK or performing UR for
 SCIF, collaborated with SCIF to implement the denial policy, resulting in the denial
 in-fact of over 96% of all H-Wave requests made for SCIF patients.

10. Thus, as alleged herein below, Defendants have turned UR into their 5 personal weapon against Plaintiff, a company they decided to injure in its business. 6 7 Defendants have usurped the power to deny H-Wave treatment, and are exercising 8 that power to prevent Plaintiff from engaging in commerce that arises from work Defendants have conspired to form a monopolistic trade barrier 9 place injuries. 10 between Plaintiff and patients serviced by the worker's compensation system. By combining the Reviewers' unilateral power to deny every H-Wave prescription, 11 with the vast market share of patients serviced by SCIF and other insurers or self-12 13 insurers serviced by EK Health, Defendants are significantly restraining Plaintiff's trade. 14

15 11. Each of the named Defendants are participating in a RICO enterprise made up of the Defendants, associated for the common purpose of engaging in a 16 17 course of conduct designed to unlawfully deny all H-Wave prescriptions, disguised by fraudulent UR decisions, and to retain all of the money owed to Plaintiff for the 18 sales and leases of its H-Wave device. Since about 2005 the named Defendants 19 have directly or indirectly conspired and agreed to, and in fact did, control, 2021participate in, and operate the "Denial Enterprise" as alleged herein below. 22 Defendants conspired and agreed to, and in fact did, commit a stream of predicate 23 acts including mail and wire fraud as alleged herein below.

12. In comparison to the 96% denial rate for SCIF patients that resulted
from SCIF's blanket denial policy, many companies, similar to Defendants EK and
SCIF, over the same period, 2005 to the present, <u>approved</u> more than 70% of their
H-Wave requests, including but not limited to: the U.S. Dept. of Labor, Work Comp
approving 95%, Springfield Insurance approving 75%, and Anthem, Work Comp

approving 80%. The national average approval rate is 70% - excluding California,
 which is tainted by Defendants' denials for SCIF's significant market share of
 California patients.

In addition, Defendants have acted outside the bounds of the UR
process by making unsolicited telephone calls and personal visits to prescribing
doctors, threatening and intimidating them away from prescribing H-Wave in the
first place. In the course of these contacts SCIF's representatives have directly told
doctors that if they continue to prescribe H-Wave they will be removed from SCIF's
Medical Provider Network ("MPN"). The individual Reviewers have issued their
own personal attacks against prescribers, threatening their reputations.

11 14. Therefore, as a proximate result of SCIF's Blanket Corporate Policy
12 and the other Defendants' agreement to carry out SCIF's policy, Plaintiff is barred
13 from doing business with WC patients or faces skyrocketing costs and plummeting
14 revenues as a result of said Defendants' acts. Additionally, doctors confronted by
15 SCIF and other Defendants have significantly reduced, or completely stopped
16 prescribing H-Wave.

17

PARTIES, JURISDICTION, AND VENUE

18 15. Plaintiff ELECTRONIC WAVEFORM is a California corporation.,
19 and at all times relevant to this action was, a corporation organized and existing
20 under the laws of the State of California, and is, and at all times relevant to this
21 action was, operating in the State of California, County of Orange.

16. Defendant STATE COMPENSATION INSURANCE FUND
("SCIF") (DOE 2) is a quasi-state agency engaged in a proprietary function, namely
the business of insurance. SCIF maintains offices throughout California, including
one in Los Angeles County. It is the largest California workers compensation
insurance company in the state, as measured by its market share, and has been so
since at least 2003 or before. On September 14, 2005 SCIF conspired with EK
Health and their sub-contracting reviewers, to institute a blanket denial policy for all

1 UR requests for Plaintiff's H-Wave device.

17. Defendant EK HEALTH SERVICES ("EK") is, on information and
belief, and at all times relevant to this action was, a business entity organized and
existing under the laws of the State of California, and is, and at all times relevant to
this action was, operating in the State of California, Santa Clara County. EK
provides UR services to self-insured employers and numerous workers'
compensation insurance companies, including State Compensation Insurance Fund.

8 18. Defendant JAMES LESSENGER, M.D., is on information and belief,
9 an individual, residing in the State of California, and at all times relevant to this
10 action was performing the acts alleged herein in the State of California, Solano
11 County. Defendant performs Utilization Reviews for EK, and on information and
12 belief, since at least September 14, 2005, denied 100% or nearly 100% of all UR
13 requests for H-Wave.

14 19. Defendant GRANT NUGENT, M.D., is on information and belief, an
15 individual, residing in the State of California, and at all times relevant to this action
16 was performing the acts alleged herein in the State of California, Amador County.
17 Defendant performs Utilization Reviews for EK, and on information and belief,
18 since at least September 14, 2005, denied 100% or nearly 100% of all UR requests
19 for H-Wave.

20 20. Defendant ALTON WILLS, M.D., is on information and belief, an 21 individual, residing in the State of California, and at all times relevant to this action 22 was performing the acts alleged herein in the State of California, Sacramento 23 County. Defendant performs Utilization Reviews for EK, and on information and 24 belief, since at least September 14, 2005, denied 100% or nearly 100% of all UR 25 requests for H-Wave.

26 21. Defendant PATRICIA D. PEGRAM, M.D. is on information and
27 belief, an individual, residing in the State of California, and at all times relevant to
28 this action was performing the acts alleged herein in the State of California, County

of Los Angeles. Defendant performs Utilization Reviews for EK, and on
 information and belief, since at least September 14, 2005, denied 100% or nearly
 100% of all UR requests for H-Wave.

22. Defendant SUZANNE L. SERGILE, M.D. is on information and belief,
an individual, residing in the State of California, and at all times relevant to this
action was performing the acts alleged herein in the State of California, County of
Los Angeles. Defendant performs Utilization Reviews for EK, and on information
and belief, since at least September 14, 2005, denied 100% or nearly 100% of all
UR requests for H-Wave.

10 23. Defendant GARRETT M. CASEY, D.C. is on information and belief,
11 an individual, residing in the State of California, and at all times relevant to this
12 action was performing the acts alleged herein in the State of California, County of
13 Los Angeles. Defendant performs Utilization Reviews for EK, and on information
14 and belief, since at least September 14, 2005, denied 100% or nearly 100% of all
15 UR requests for H-Wave.

16 24. Defendant MICHAEL J. LAUBACH, D.C. is on information and
17 belief, an individual, residing in the State of California, and at all times relevant to
18 this action was performing the acts alleged herein in the State of California, County
19 of Orange. Defendant performs Utilization Reviews for EK, and on information and
20 belief, since at least September 14, 2005, denied 100% or nearly 100% of all UR
21 requests for H-Wave.

22 25. Defendant JAY V. WESTPHAL, M.D. is on information and belief, an
23 individual, residing in the State of California, and at all times relevant to this action
24 was performing the acts alleged herein in the State of California, County of Orange.
25 Defendant performs Utilization Reviews for EK, and on information and belief,
26 since at least September 14, 2005, denied 100% or nearly 100% of all UR requests
27 for H-Wave.

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26. Defendant KATHLEEN GRAY, M.D., is on information and belief,

an individual, residing in the State of California, and at all times relevant to this
 action was performing the acts alleged herein in the State of California, San Diego
 County. Defendant performs Utilization Reviews for EK, and on information and
 belief, since at least September 14, 2005, denied 100% or nearly 100% of all UR
 requests for H-Wave.

6 27. Defendant JOHANNA APPEL, D.C., is on information and belief, an
7 individual, residing in the State of California, and at all times relevant to this action
8 was performing the acts alleged herein in the State of California, San Diego County.
9 Defendant performs Utilization Reviews for EK, and on information and belief,
10 since at least September 14, 2005, denied 100% or nearly 100% of all UR requests
11 for H-Wave.

12 28. Defendant JANET O'BRIEN, M.D. (DOE 1 & 51) is an individual
13 residing in the State of California, and at all times relevant to this action was
14 performing the acts alleged herein in the State of California, Sacramento County.
15 Defendant performs Utilization Reviews for EK, and on information and belief,
16 since at least September 14, 2005, denied 100% or nearly 100% of all UR requests
17 for H-Wave.

18 29. Defendant RICHARD THOMPSON, M.D. (DOE 3) is an individual
19 residing in the State of California, and at all times relevant to this action was
20 performing the acts alleged herein in the State of California, Santa Clara County.
21 Defendant is EK's Medical Director who since at least September 14, 2005, ensured
22 that Reviewers denied H-Wave prescriptions in Utilization Reviews.

- 30. Defendant DAVID EHRENFELD, M.D. (DOE 4) is an individual
 residing in the State of California, and at all times relevant to this action was
 performing the acts alleged herein in the State of California, Santa Clara County.
 Defendant is in charge of EK's Quality Assurance who since at least September 14,
 2005, ensured that Reviewers denied H-Wave prescriptions in Utilization Reviews.
- 28

31. Except as otherwise alleged, Plaintiff is not currently aware of the true

names and capacities of the Defendants designated herein as DOES 5 through 50 or
 52 through 100, inclusive. As such, Plaintiff will hereafter seek leave of court to
 amend this Complaint in order to allege the true names and capacities of each such
 Defendant when such information is ascertained.

32. Plaintiff is informed and believes and thereon alleges that at all times 5 herein mentioned, Defendants, and each of them, were the co-conspirators, co-6 7 collaborators, agents, joint venturers, trustees, servants, partners, alter-egos, parent 8 corporations, subsidiaries, affiliates, contractors, and/or employees of each of the remaining Defendants, and that the acts and/or omissions herein alleged were done 9 10 by them, acting individually and as part of a RICO enterprise, through such capacity or through the scope of their authority, and that said conduct was thereafter ratified 11 by the remaining Defendants. 12

13 33. Jurisdiction and venue are proper in this action as already established
14 through the Defendants' removal of this case from State Court following the
15 Plaintiff's addition of Federal RICO claims.

16

GENERAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION

H-Wave is a remarkable medical device. Its efficacy is best measured 34. 17 by the attention and praise it has received by a particular segment of its users - a 18 group of individuals most reliant on maintaining a full and well-functioning body -19 professional athletes. Since the 1980's, letters of praise for H-Wave have arisen 2021from a wide range of college and professional sports organizations, including but not limited to, the Los Angeles Lakers, the San Francisco 49ers, the Cincinnati 22 23 Reds, Pepperdine University Department of Athletics, and even the Pennsylvania 24 Ballet. See Exhibit "A", letters of praise from athletic organizations. On information and belief, the Green Bay Packers had H-Wave in the locker room 25 during their 2011 Championship Super Bowl game. H-Wave is a California State 26 27 approved treatment as found in the MTUS, and supported by at least fifteen (15) 28 published peer-reviewed studies showing the benefits of H-Wave. See Exhibit "B"

1 (MTUS entry for H-Wave). Thirteen (13) of those studies are indexed by PubMed, 2 and eleven (11) of those are also indexed by MEDLINE as required by the 3 Utilization Review's regulatory definition for "Evidence-based" medicine in CCR §9792.20 "Medical Treatment Utilization Schedule -Definitions," which states, "(e) 4 'Evidence-based ' means based, at a minimum, on a systematic review of literature 5 published in medical journals included in MEDLINE." 6

35. 7 The vast majority of H-Wave prescriptions are written for chronic pain patients, who are otherwise given a costly prescription drug regimen and regular 8 The chronic pain patient can continue with these 9 physical therapy sessions. 10 treatments for years. H-Wave's cost is less than ten months of a typical pharmaceutical regimen, or four months of physical therapy. H-Wave is also more 11 12 effective at creating lasting results than other electro-therapy modalities. H-Wave 13 employs proprietary technology, is manufactured only by Plaintiff Electronic Waveform Lab, Inc., and functions differently than devices commonly lumped 14 together and referred to as "electro-therapy" or "electro-stimulation" devices, such 15 as "TENS" and "interferential" devices. For these reasons, among others, H-Wave's 16 cost is higher than some other devices. The most common such device is the TENS 17 unit. "TENS" is a generic name covering devices that are all relatively similar, but 18 that do not operate like H-Wave, do not employ proprietary technology, are 19 manufactured by many different companies using different specifications, and do 2021not have scientific support equal to H-Wave's. TENS is not a "generic" brand of H-22 Wave. No other electro-therapy device operates like H-Wave.

23 24

On information and belief, SCIF's original view of H-Wave, in years 36. prior to about 2005, was to acknowledge the scientific support for its effectiveness, 25 that its use poses no risk to patients, and that it is not so costly as to raise a concern. Indeed, H-Wave is extremely cost effective, particularly given its documented 26 success rate, and compared to alternative treatment for chronic pain patients.

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37. A large population of potential H-Wave users are people who, like

professional athletes, have been injured on the job and seek the means to return to
work. These patients receive their medical care through the State's highly regulated
workers' compensation framework, in which employers provide no-fault coverage
to injured workers, typically through a workers' compensation insurer, in exchange
for immunity from law suits arising from work place injuries. This is commonly
known as the "workers' compensation bargain" existing between employee and
employer.

8 38. Part of the workers' compensation regulatory framework is a medical care approval process called Utilization Review ("UR"). It is established and 9 10 administered by an employer, its insurer such as SCIF, or a third party URO such as EK. Statutorily, physician reviewers are to make independent decisions to approve 11 12 or deny treatment based on the medical necessity to cure and relieve, consistent with 13 the MTUS's extensive guidelines and recommendations for treatment – which include the use of H-Wave. Under no circumstances are Reviewers to categorically 14 15 deny requests for an MTUS approved treatment (or any treatment), and indeed such a policy does not fulfill their duty to perform individual UR's for each request. 16 17 Rather, SCIF and EK are to ensure that physician reviewers are performing their duties properly, or at the very least, are not to design, or encourage reviewers to 18 adopt, a blanket policy of denying all requests for an MTUS approved treatment. In 19 no way are the Defendants permitted free rein to restrain Plaintiff's trade through 20the UR process. 21

- 39. The largest workers' compensation insurer in California is Defendant
 SCIF. According to SCIF's "Fact Sheet" found at
 www.statefundca.com/news/FactSheet.asp:
- Established in 1914 by the state legislature, State Fund is California's
 largest provider of workers' compensation insurance and a vital asset to
 California businesses.
- 28
- With approximately 130,000 policyholders, just over \$1 billion in

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premium, and nearly \$20 billion in net admitted assets, State Fund is a necessary, competitive force in California's economy.

• Completely self supporting, State Fund plays a stabilizing role in California's economy by maintaining an open door policy that ensures that all employers have a strong and stable option for their workers' compensation needs.

40. SCIF in 2011 had the largest market share of injured workers - twice
that of the second largest company. It had an even larger market share in each of the
five prior years, which are all at issue in this case. Defendants are thereby situated
as a monopolistic "gate keeper" to a significant and substantial market share of
patients who are injured on the job, and using UR to deny treatment requests for
Plaintiff's medical device.

13 41. SCIF originally performed UR with its own "stable" of physician reviewers. This was before UR became mandatory. When Senate Bill 899 passed 14 15 in 2004, SCIF contracted out the UR to so-called "independent" physicians. The purpose of SB 899 was to remove from financially interested insurers, such as SCIF, 16 the power to deny requests for treatment. To get around this requirement, SCIF 17 exercised control over the outcome of H-Wave requests by enlisting EK Heath to 18 contract with SCIF's existing reviewers. The arrangement allowed EK to take-on 19 and manage over 75 new reviewers with relative ease. At SCIF's insistence, the 2021reviewers were required to continue working from their same desks at various SCIF offices throughout the state, where they continued utilizing SCIF's resources, 22 infrastructure, and computer system, continued taking direction from SCIF 23 24 employees, and enforcing SCIF policies. To that end, the reviewers were often 25 engaged in meetings and provided with memos on medical issues, both organized and issued by SCIF. While creating the appearance of reviewer independence, EK 26 27 Health and the reviewers in fact complied with SCIF's policy that all H-Wave requests be denied. 28

42. SCIF's written policy to ensure the denial of all H-Wave requests 1 2 appeared as early as September 14, 2005, in an "Inter-Communication" 3 memorandum regarding electro-stimulation devices, from SCIF's Medical Director Gideon Letz, to all DOHCs. (This stands for "District Office Health Consultants" -4 SCIF's name for physician reviewers.) SCIF's policy was distributed to all 5 reviewers. The memo, uncovered for the first time during discovery in this case, 6 ends with the directive: "The more expensive interferential and 'H-Wave' units will 7 not be authorized." The policy is attached as Exhibit "C." At its most basic level, 8 this policy violates the independent medical decision-making that reviewers are 9 10 required to engage in, and that lays at the heart of the UR legislation's design.

43. The day Dr. Letz issued the SCIF policy, it was further accepted,
endorsed, and ratified in writing by SCIF management, Kathleen Burrows, who at
the time was SCIF's Utilization Review Supervisor for Claims/Rehabilitation in
SCIF's San Francisco home office.

15 44. After September 15, 2005, SCIF engaged in numerous communications with EK Health and the "independent" reviewers reinforcing 16 SCIF's policy by stating that all requests for H-Wave should be denied. 17 On information and belief, these communications occurred by email, during monthly 18 teleconferences organized and attended by SCIF, EK Health, and many reviewers, 19 and in minutes of those meetings approved by both Dr. Letz and EK Health's 2021Medical Director, Richard Thompson, M.D.

22 45. EK's management and all of EK's physician reviewers followed 23 SCIF's blanket denial policy. EK Health and the UR physicians actively 24 collaborated with SCIF to maintain the illegal blanket denial policy. EK Health engaged in efforts to enforce SCIF's policy among its sub-contracting physician 25 reviewers. On information and belief, when a reviewer was found to have approved 26 an H-Wave request, Dr. Richard Thompson and Dr. David Ehrenfeld would counsel 27 the reviewer, or coordinate counseling with other "independent" reviewers known to 28

be stalwarts of the blanket denial policy. On information and belief, the reviewers 1 2 actively participated in enforcing SCIF's corporate policy by encouraging each other to deny H-Wave, and by crafting pretextual rationales for denying H-Wave to hide 3 the fact that they had adopted a blanket denial policy. On information and belief, 4 Dr. Letz and Dr. Thompson knew about and sanctioned the use of these pretexts; 5 one of them was put together by Defendant, Janet O'Brien under Dr. Letz' direction, 6 and was distributed to reviewers in 2007. On information and belief, Dr. Thompson 7 8 instructed reviewers how to use the pretexts in their UR paperwork so that they would not look too scripted. Towards this end, Boilerplate and Templates for 9 denying H-Wave were created for all "independent" reviewers to use to hide their 10 implementation of a blanket denial policy for all H-Wave requests. 11

46. The intent of each collaborator was to restrict Plaintiff from 12 13 conducting its trade – the rental and sale of the H-Wave device – to restrict Plaintiff from receiving compensation for its product and service, and to allow SCIF to retain 14 the money that it would otherwise owe to Plaintiff for H-Wave treatment. Their 15 intent was also to cause doctors to stop prescribing H-Wave treatment by 16 17 demonstrating to them that H-Wave is never approved. Each participant in the scheme either intended these results, or was substantially certain that these results 18 19 would occur.

20 47. Plaintiff has learned through this litigation that on April 4, 2008 21SCIF's Dr. Letz issued a "Medical Decision Statement" ("MDS"), reaffirming the 22 2005 blanket denial policy by again directing all reviewers to deny H-Wave and providing them with a new "template" approved by SCIF with "boilerplate" 23 24 language that functioned as SCIF's official pretext to hide the blanket denial policy. On information and belief, SCIF desired to maintain this MDS as a secret internal 25 document housed on its computer system, for use only between the reviewers, SCIF, 26 27 and EK Health.

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48. On information and belief during teleconferences following the release

of the MDS, SCIF again instructed reviewers to never authorize H-Wave; the MDS
 was then distributed by email to EK Health and all reviewers with this instruction.

49. While the blanket denial policy always violated the individual and 3 independent UR that each Defendant had a duty to perform for injured workers, the 4 policy further violated law when on July 18, 2009 the MTUS was amended to add 5 the Chronic Pain Treatment Guidelines, which included H-Wave as one of its 6 7 enumerated approved treatments. Rather than abandoning the blanket denial policy, 8 on information and belief, in response to the new MTUS amendment, Dr. Letz instructed EK Health and all reviewers during a teleconference to "stick to their 9 10 guns" regarding the blanket policy to deny H-Wave.

50. On information and belief, in late 2008 and in response to the MTUS 11 12 amendment, Dr. Letz and SCIF hired ECRI, a technical assessment company from 13 the East Coast, to perform medical scientific research that they hoped would be critical of H-Wave. When ECRI sent their draft report to Plaintiff for comment 14 around February 2009, Plaintiff informed ECRI of its numerous faults. 15 After Plaintiff corrected "the record" for ECRI concerning H-Wave, Plaintiff never heard 16 from them again. On information and belief, no final report was ever issued because 17 SCIF canceled the report when ECRI informed SCIF that the final report would be 18 positive and supportive of H-Wave and would not provide Defendants with a pretext 19 for their blanket denial policy. Thus, Plaintiff alleges that SCIF intentionally 2021suppressed and withheld the truth about H-Wave from EK Health and the physician reviewers. On information and belief, all Defendants held ECRI's reports in high 22 regard and often took them into consideration when performing bona fide UR for 23 24 other treatment requests.

51. SCIF's written blanket denial policy was intentionally and
fraudulently concealed from Plaintiff. None of the Defendants, or anyone else, ever
informed Plaintiff of the blanket denial policy. And, even when Plaintiff, in 2008,
confronted SCIF and Dr. Letz with factual inaccuracies Plaintiff found in, on

information and belief, what is now understood to be the pretext authored by Janet 1 2 O'Brien, SCIF's secret policy was still not disclosed by any of the Defendants. 3 Plaintiff alleges that Dr. Letz was instructed not to reveal SCIF's policy to Plaintiff. Rather, upon its inquiry, Dr. Letz responded to Plaintiff by assuring them that 4 reviewers had been made aware of the facts supporting H-Wave for their 5 consideration in future UR's. In reality, SCIF and the other Defendants simply 6 7 edited the pretext for use with future denials under the blanket denial policy. 8 Plaintiff was never informed that independent UR's were not being conducted on every H-Wave request to determine if H-Wave was appropriate treatment in each 9 10 individual patient's case. Plaintiff has learned of the 2005 blanket denial policy only recently through discovery in this litigation. 11

52. Additionally, both EK Health and SCIF were required to file with the
Department of Workers' Compensation ("DWC"), and did file, a yearly UR Policy
and Procedure Plan, describing how their UR would comply with law. None of
those plans on file with the DWC contained any mention of the blanket denial
policy.

17 53. The UR denials were and are fraudulent, as UR is not actually
18 performed. The H-Wave prescriptions never had a chance of being approved,
19 because all of the Defendants had agreed to deny all H-Wave requests. The denial
20 letters are also fraudulent, as they contain the boilerplate scripts intended to hide the
21 truth that the Defendants were denying all H-Wave requests as a matter of policy.

54. Patients, treating physicians, and Plaintiff all relied on the fraudulent
denials and the denial letters. This has resulted in patients and doctors abandoning
H-Wave treatment. As a result of the Defendants' fraud, patients have relinquished
their rights to pursue and petition to receive the H-Wave treatment prescribed by
their treating physicians. As a result of the Defendants' fraud, Plaintiff was induced
to relinquish, compromise, and settle claims for reimbursement from the sale and
rental of its H-Wave device. As a result of the Defendants' fraud, SCIF retained

money for H-Wave treatment that Plaintiff was defrauded into relinquishing, and
 money that Plaintiff was entitled to under law. All of these results were intended by
 the Defendants.

4 55. As an intended result of the Defendants' scheme, and in reliance on
5 the fraudulent UR denials, treating physicians have stopped prescribing H-Wave
6 believing that it will never be approved through the UR process.

56. 7 The blanket denial policy that the Defendants conspired to develop, implement, and cover-up, was instituted for the purpose of restraining Plaintiff's 8 As a direct consequence of Defendants' UR denials, Plaintiff has been 9 trade. 10 restrained from conducting its trade of renting and selling H-Wave units to patients who want to use them under the supervision of doctors who have prescribed H-11 12 Wave treatment for their patients. Upon receiving Defendants' fraudulent UR 13 denials by mail or wire, patients and their prescribing doctors relied on the denial letters, defrauded into believing that an independent medical review was performed 14 on their H-Wave requests, when in fact the blanket denial policy was in effect. 15 Based on their reliance patients often abandoned H-Wave treatment and their 16 doctors refused to prescribe H-Wave treatment. 17

18 57. Whenever Plaintiff's trade was not entirely foreclosed, its costs were substantially increased, and its revenues substantially decrease as a result of the 19 blanket denials. Absent a lawful UR denial, Plaintiff has the right to demand and 2021collect its usual and customary charges for its H-Wave device. Plaintiff relied on 22 Defendants' fraudulent UR denials to its detriment. Plaintiff was induced to relinquish, compromise, and settle its claims for full reimbursement for the H-Wave 23 24 devices that it provided pre-denial, as well as for any ongoing and subsequent H-25 Wave treatment that patients and their doctors believed to be medically necessary despite contrary – but fraudulent – UR denials. As a result of the Defendants' fraud, 2627 SCIF retained money that Plaintiff was defrauded into relinquishing, and money that Plaintiff was entitled to receive because no independent medical review was ever 28

1 performed on the patients' H-Wave requests.

58. On information and belief, SCIF and Dr. Letz were conscious of the
obvious disastrous economic impact their blanket denial policy would have on
Plaintiff, but were not concerned with Plaintiff and disregarded the policy's
consequences. On information and belief, the policy and the entire Denial
Enterprise was maintained to save SCIF money by not paying for H-Wave
treatment.

8 59. On information and belief, SCIF and Dr. Letz also intended to stop
9 prescriptions from being written in the first place, by inducing physician to believe
10 that writing such prescriptions would be pointless since they would never be
11 approved by UR.

60. On information and belief, EK Health and all reviewers understood
that the goal of the blanket denial policy was to drive H-Wave out of the market,
restraining Plaintiff's trade by choking it off at the point of UR, and by discouraging
doctors from prescribing it in the first place. On information and belief, in 2006 Dr.
Thompson communicated his belief to EK Health's management, that the blanket
denial policy had already successfully and significantly reduced prescription rates
for H-Wave.

19 61. On information and belief, the 2005 policy has never been altered and is still being promoted by SCIF and followed by its independent contracting URO's 20 including but not limited to EK Health and certain DOES, and all of their sub-2122 contracting reviewers including the individual Defendants sued herein, and certain other DOES. Furthermore, on information and belief, as late as 2012, when SCIF 23 24 would discover any H-Wave approval had occurred, it brought the approval to EK Health's attention so that EK Health could instruct the reviewer to follow SCIF's 25 26 blanket policy.

27 62. On information and belief, since about 2010, dissatisfied that many
28 treating doctors were still prescribing H-Wave, SCIF representatives began calling

prescribing doctors by telephone and showing up in their offices, threatening to 1 2 remove those doctors from SCIF's MPN unless they stop prescribing H-Wave. This 3 would mean the doctors who prescribe H-Wave against SCIF's wishes would be excluded from treating injured workers covered by SCIF's MPN, which has been 4 found to encompass at least half of SCIF's business. SCIF's MPN entails so many 5 patients that exclusion from SCIF's MPN can destroy a medical practice. Although 6 the total number of threatened doctors is unknown, SCIF's threats have caused 7 8 many doctors to cease prescribing H-Wave.

9 63. On information and belief, SCIF has directly communicated with
10 physical therapy offices that it contracts with, instructing them not to treat SCIF
11 patients with H-Wave, or recommend H-Wave to the patients' treating physicians.

12 64. Additionally, the Defendant Reviewers have also been contacting 13 prescribing doctors by telephone and in person, in an attempt to intimidate the prescribing doctors out of prescribing H-Wave. Since around 2010, more than one 14 15 prescribing doctor has been told that H-Wave will never be approved. More than one doctor has been berated for prescribing H-Wave and told that they can expect 16 More than one doctor has been threatened with 17 their reputations to suffer. accusations that their H-Wave prescriptions violate statutes for which legal action 18 19 against the prescribing doctor is appropriate.

20 65. Defendant Reviewers also resorted to disparaging both the H-Wave
21 device and Plaintiff's fitness as a business. On information and belief, Defendants
22 have falsely impugned H-Wave's efficacy, and falsely asserted that Plaintiff is
23 engaged in fraudulent business practices; baseless accusations the Defendants
24 repeated without any evidence that they were true, and they are not true.

25 66. Defendant Reviewers' actions, taken individually and in furtherance of
26 their conspiracy, and acting as part of the Denial Enterprise, include but are not
27 limited to the following:

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a. Defendant James Lessenger, M.D., has on information and belief,

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and inter alia, conspired and combined with EK HEALTH and
SCIF to always deny H-Wave treatment and in conformity, has
denied 100% or nearly 100% of the requests he has "reviewed," and
has contacted prescribing doctors and informed them that H-Wave
will never be approved.

- b. Defendant Grant Nugent, M.D., has on information and belief, and *inter alia*, conspired and combined with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests he has "reviewed," and has contacted prescribing doctors threatening their reputation and threatening them with legal action.
- Defendant Alton Wills, M.D., has on information and belief, and 12 c. inter alia, conspired and combined with EK HEALTH and SCIF to 13 always deny H-Wave treatment and in conformity, has denied 100% 14 or nearly 100% of the requests he has "reviewed," and has contacted 15 prescribing doctors falsely accusing Plaintiff of being a fraudulent 16 company, and falsely disparaging medical evidence that supports H-17 Wave, in addition to improperly asserting baseless restrictions over 18 doctors' H-Wave prescriptions. 19
- Defendant Janet O'Brien, M.D., has on information and belief, and 20 d. inter alia, conspired and combined with EK HEALTH and SCIF to 21 always deny H-Wave treatment and in conformity, has denied 100% 22 or nearly 100% of the requests she has "reviewed." She has also 23 engaged in creating and distributing to other reviewers, pretexts to 24 use when implementing the blanket denial policy. In addition, on 25 information and belief, she authored pretexts that contained false 26 statements of fact concerning H-Wave and its scientific studies that 27 28 were published to individuals in the medical community; like her

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- other pretexts, these were distributed to other reviewers who also published them.
- Defendant Patricia D. Pegram, M.D., has on information and belief, e. and inter alia, conspired and combined with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests she has "reviewed."
- Defendant Suzanne L. Sergile, M.D., has on information and belief, f. and inter alia, conspired and combined with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests she has "reviewed."
- Defendant Garrett M. Casey, D.C., has on information and belief, g. and inter alia, conspired and combined with EK HEALTH and 12 SCIF to always deny H-Wave treatment and in conformity, has 13 denied 100% or nearly 100% of the requests he has "reviewed." 14
 - Defendant Michael J. Laubach, D.C., has on information and belief, h. and inter alia, conspired and combined with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests he has "reviewed."
- Defendant Jay V. Westphal, M.D., has on information and belief, 19 i. and inter alia, conspired and combined with EK HEALTH and 20 SCIF to always deny H-Wave treatment and in conformity, has 21 denied 100% or nearly 100% of the requests he has "reviewed." 22
- Defendant Kathleen Gray, M.D., has on information and belief, and 23 j. inter alia, conspired and combined with EK HEALTH and SCIF to 24 always deny H-Wave treatment and in conformity, has denied 100% 25 or nearly 100% of the requests she has "reviewed." She also has 26 published false statements concerning H-Wave in the form of 27 pretexts issued with her denials. 28

k. Defendant Johanna Appel, D.C., has on information and belief, and *inter alia*, conspired and combined with EK HEALTH and SCIF to
always deny H-Wave treatment and in conformity, has denied 100%
or nearly 100% of the requests she has "reviewed." She also has
published false statements concerning H-Wave in the form of
pretexts issued with her denials.

67. As a result of Defendants' acts Plaintiff has seen prescriptions dropoff dramatically from certain doctors following the personal threatening contacts
from Defendant Reviewers as well as from SCIF representatives. Also as a result of
all Defendants' acts, Plaintiff has been asked to withdraw H-Wave equipment from
doctors' offices and physical therapy clinics, and H-Wave sales representative have
been banned from certain doctors' offices and hospitals.

68. As a direct result of the implementation of SCIF's blanket denial
policy, Defendants are restraining Plaintiff's trade with SCIF's substantial and
significant market share of patients. As a consequence, Plaintiff is alternatively,
foreclosed from doing business or, forced to provide its medical device and service
at substantially increased costs and decreased revenue.

18 69. In addition, on information and belief, EK performs UR services for
19 other insurers whose market share of potential patients is also barred from Plaintiff,
20 because SCIF's policy has been so thoroughly adopted by EK Health and its sub21 contracting reviewers that they enforce the policy now for all insurance companies
22 and employers for whom they perform UR.

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FIRST CAUSE OF ACTION

24 (Violation of the Cartwright Act, Bus. & Prof Code § 16700 et. seq., Against All 25 Defendants)

26 70. Plaintiff realleges and incorporates herein by reference each and every
27 allegation set forth in Paragraphs 1 through 69 as though fully set forth herein.

28 71. As alleged herein, Defendants have conspired with one another,

agreed to pursue, and are carrying out a plan; Defendants have formed a trust by
 combining their capital, skills, and acts, all for the purpose and effect of restricting
 Plaintiff's trade and commerce in the product markets in which Plaintiff's H-Wave
 product is sold.

5 72. As alleged above, the Defendants' combined and colluded to stop
6 Plaintiff from selling or renting its H-Wave device in all instances under their
7 influence.

8 73. On information and belief, the Defendants have also combined and
9 colluded with Safeway, Inc., a self-insured company that, like SCIF, is serviced by
10 EK Health and similarly intended to wrongfully restrain Plaintiff's trade.

11 74. The relevant geographic market in which Plaintiff operates is
12 California, within California's workers' compensation system. The boundaries of
13 that market are set by the workers' compensation laws, including constraints (such
14 as those set by the MTUS) on allowable products/treatments that may compete for
15 business among the population of California's injured workers.

16 75. Each workers' compensation carrier or self-insured employer
17 embodies a separate sub-market, in which the covered population of injured
18 workers/consumers are captives of their insurers.

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76. Plaintiff competes in each of the following relevant product markets:

- Pain management treatment.
- 21 ➤ Non-pharmaceutical pain management treatment.
- 22 > Chronic pain management treatment.
- 23 ► Post-operative pain management treatment.
- 24 ➤ Compromised circulation treatment.
- 25 ► Limited range of motion treatment.
- 26 ➤ Muscle spasms treatment.
- 27 \blacktriangleright Muscle atrophy treatment.
- 28 ➤ Prescription electronic stimulators.

Prescription multi-function electronic stimulators.

Prescription home based physical therapy devices.

Clinical physical therapy devices.

4 77. SCIF's market share of California's workers' compensation market
5 during the relevant period, as reported by the California Department of Insurance
6 was:

7 2004=51.01%

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8 2005=42.08%

- 9 2006=31.97%
- 10 2007=26.54%
- 11 2008=22.56%

12 2009=18.64%

- 13 2010= 16.02%
- 14 2011=12.91%

15 The average over these years was 27.71%. Added to that are all of Safeway's

16 employees, as well as the populations covered by every other insurer serviced by EK17 Health.

18 78. Competition was substantially reduced and injured within the relevant
19 markets due to the Defendants' and other collaborators' blanket denial policy for H20 Wave, to eliminate it as a competing product in every marker under their influence.

21 79. Defendants' acts under the circumstances are so pernicious and
22 inherently anticompetitive that they have no redeeming virtue, rendering them a *per*23 *se* violation of the Cartwright Act.

80. As a direct and proximate result of Defendants' acts Plaintiff's trade
has been restrained. Plaintiff has been prevented outright from selling or renting its
device, and has suffered increased costs and reduced revenue in an effort to mitigate
its damages.

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81. As a further direct and proximate result of Defendants' acts Plaintiff's

trade has been restrained, as many doctors have stopped or significantly decreased
 their prescriptions for the H-Wave device because it is never approved.

82. Plaintiff is thereby statutorily entitled to recover from Defendants its
damages, treble damages, and reasonable attorneys' fees and costs. Plaintiff has
suffered and continues to suffer irreparable harm, and therefore, it is entitled to
injunctive relief and an order requiring Defendants to take affirmative acts, as the
Court sees fit, to protect Plaintiff from such harm.

8 83. Defendants' actions as described herein were oppressive, fraudulent
9 and malicious. Defendants' actions were taken for the express purpose of
10 preventing Plaintiff from conducting its business, or with a conscious disregard for
11 the injury that would surely result, thereby entitling Plaintiff to punitive damages
12 in an amount to be proven at trial:

- a. Defendants have targeted Plaintiff by conspiring to deny every HWave UR request/prescription in violation of the Defendants'
 statutory duties to render independent medical decisions
 concerning the medical necessity to cure or relieve a patient's
 injuries.
- b. SCIF instructed EK Health and the reviewers to maintain the
 blanket denial policy in the face of H-Wave's adoption as an
 approved treatment by the MTUS.
- c. Defendants have contacted doctors who prescribe H-Wave and told
 them to stop prescribing it. They have threatened doctors with
 removal from SCIF's MPN, in an effort to stop them from
 prescribing H-Wave and otherwise discouraged their prescriptions
 by wrongfully orally attacking doctors for prescribing H-Wave.
- d. The Defendants intended to drive H-Wave from the market, and
 intended and expected that their blanket denial policy would injure
 Plaintiff and would reduce H-Wave prescriptions in the first place.

1	e.	Defendants hid their policy by employing pretexts to disguise the
2		fact that they had adopted a blanket denial policy and that H-Wave
3		would not be approved under any circumstances.
4	f.	SCIF instructed the other Defendants to keep the policy a secret,
5		and to keep evidence of the policy, such as the MDS and pretext
6		documents, confined to SCIF's computer system from where they
7		could be accessed.
8	g.	EK Health assisted reviewers on the use of the pretext so that they
9		read like they had arisen from a UR conducted according to law,
10		and not like the "cut and paste" pretext that it was.
11	h.	Neither EK nor SCIF revealed their policy in their respective DWC
12		filings in which they were required to detail their UR plan and
13		procedures.
14	i.	When the opportunity arose, SCIF did not inform Plaintiff that the
15		reviewers' inaccurate statements about H-Wave were the product
16		of a scripted pretext and irrelevant to their UR decisions because
17		the denials were made as a matter of policy.
18	ј.	SCIF not only failed to reveal their denial policy to Plaintiff, but
19		affirmatively represented that SCIF was engaging in remedial
20		measures with its reviewers to ensure that UR's for H-Wave took
21		the facts into consideration, when actually H-Wave requests were
22		being denied in UR as a matter of policy.
23	k.	After SCIF hired ECRI to produce a scientific report to improperly
24		rebut the MTUS, SCIF either buried or canceled the report because
25		of its support for H-Wave.
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		- 27 -
		- 27 - THIRD AMENDED COMPLAINT

SECOND CAUSE OF ACTION 1 2 (For Intentional Interference with Prospective Economic Advantage Against Defendants SCIF, EK Health, James Lessenger, M.D., Grant Nugent, M.D., 3 Alton Wills, M.D., Janet O'Brien, M.D., Kathleen Gray, M.D., Johanna Appel, 4 D.C., and DOES 3 through 50 and 52 through 100) 5 Plaintiff realleges and incorporates herein by reference each and every 84. 6 7 allegation set forth in Paragraphs 1 through 83 as though fully set forth herein. 8 85. Plaintiff enjoys advantageous economic relationships with patients who use H-Wave, doctors who prescribe H-Wave, and patients who want to use H-9 10 Wave. These relationships contain present and future economic benefits and advantages for Plaintiff. 11 12 86. At all times relevant herein, Defendants knew of and know of these 13 relationships and intended to disrupt these relationships. Defendants are engaged in wrongful conduct of discrimination, fraud, 14 87. violation of the UR statutes, defamation/trade libel, a conspiracy to restrain 15 Plaintiff's trade and interfere with Plaintiff's commerce, RICO violations including 16 mail and wire fraud, and wrongfully threatening doctors to stop their prescriptions. 17 Defendants have usurped the power inherent in the UR process, denying requests 18 19 for H-Wave across the board, irrespective of the Defendants' statutory duty to render independent medical decisions concerning the medical necessity to cure or 2021relieve patients' injuries. SCIF has instructed physical therapy clinics under contract with SCIF to stop using H-Wave or recommending it for SCIF patients. 22 23 Defendants have contacted doctors who prescribe H-Wave and told them to stop 24 prescribing it. SCIF has threatened removal from its MPN for doctors who will not 25 stop prescribing H-Wave. This would mean the doctors who prescribe H-Wave against SCIF's wishes would be excluded from treating injured workers covered by 26 27 SCIF's MPN, which has been found to encompass at least half of SCIF's business. 28 SCIF's MPN entails so many patients that exclusion from SCIF's MPN can

destroy a medical practice. The Defendant Reviewers have threatened that H-1 2 Wave will never be approved, so doctors should stop prescribing it. They have accused doctors who prescribe H-Wave of violating the law, and intimated that 3 legal action against the doctors would be appropriate. They have threatened 4 doctors' credibility in the medical community due to their H-Wave prescriptions. 5 They have disparaged H-Wave and Plaintiff with false accusations that Plaintiff 6 engages in fraudulent business practices, without any legitimate basis for making 7 8 such accusations.

9 88. As a direct and proximate result of Defendants' wrongful conduct, 10 Plaintiff has been prevented from servicing a vast market share of patients, has had compensation withheld for its medical device and services for which prescriptions 11 12 were issued by treating doctors, has lost business, and suffered increased costs of 13 doing business and decreased revenue. Additionally, Plaintiff's relationships with prescribing doctors have been disrupted, further injuring Plaintiff's business and 14 15 future business. Doctors have stopped prescribing H-Wave as a direct and proximate result of Defendants' acts. As a result of Defendants' wrongful conduct 16 Plaintiff has and continues to suffer these economic damages in an amount within 17 the jurisdictional limits of this Court, to be proven at trial. 18

- 19 89. Defendants' actions as described herein were oppressive, fraudulent
 20 and malicious. They were taken for the express purpose of preventing Plaintiff
 21 from conducting its business and to stop doctors from using and prescribing H22 Wave for their patients, or with a conscious disregard for the injury that would
 23 surly result, thereby entitling Plaintiff to punitive damages in an amount to be
 24 proven at trial:
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Defendants have targeted Plaintiff by conspiring to deny every H-Wave UR request/prescription in violation of the Defendants' statutory duties to render independent medical decisions concerning the medical necessity to cure or relieve a patient's

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b.	SCIF instructed EK Health and the reviewers to maintain the		
	blanket denial policy in the face of H-Wave's adoption as an		
	approved treatment by the MTUS.		

- c. Defendants have contacted doctors who prescribe H-Wave and told them to stop prescribing it. They have threatened doctors with removal from SCIF's MPN, in an effort to stop them from prescribing H-Wave and otherwise discouraged their prescriptions by wrongfully orally attacking doctors for prescribing H-Wave.
- d. The Defendant Reviewers have threatened that H-Wave will never be approved, so doctors should stop prescribing it.
- e. The Defendant Reviewers have accused doctors who prescribe HWave of violating the law, and intimated that legal action against
 the doctors would be appropriate.
- 15f.The Defendant Reviewers have threatened doctors' credibility in16the medical community due to their H-Wave prescriptions.
- g. The Defendant Reviewers have disparaged H-Wave and Plaintiff
 with false accusations that Plaintiff engages in fraudulent business
 practices, without any legitimate basis for making such
 accusations.
 - h. The Defendants intended to drive H-Wave from the market, and intended and expected that their blanket denial policy would injure Plaintiff and would reduce H-Wave prescriptions in the first place.
- i. Defendants hid their policy by employing pretexts to disguise the
 fact that they had adopted a blanket denial policy and that H-Wave
 would not be approved under any circumstances.
- j. SCIF instructed the other Defendants to keep the policy a secret,
 and to keep evidence of the policy, such as the MDS and pretext

1		documents confined to SCIF's computer system from where they
2		could be accessed.
3	k.	EK Health assisted reviewers on the use of the pretext so that they
4		read like they had arisen from a UR conducted according to law,
5		and not like the "cut and paste" pretext that it was.
6	1.	Neither EK nor SCIF revealed their policy in their respective DWC
7		filings where in they were required to detail their UR plan and
8		procedures.
9	m.	When the opportunity arose, SCIF did not inform Plaintiff that the
10		reviewers' inaccurate statements about H-Wave were the product
11		of a scripted pretext and irrelevant to their UR decisions because
12		the denials were made as a matter of policy.
13	n.	SCIF not only failed to reveal their denial policy to Plaintiff, but
14		affirmatively represented that SCIF was engaging in remedial
15		measures with its reviewers to ensure that UR's for H-Wave took
16		the facts into consideration, when actually H-Wave requests were
17		being denied in UR as a matter of policy without consideration of
18		the facts or even a bona fide UR.
19	0.	After SCIF hired ECRI to produce a scientific report to improperly
20		rebut the MTUS, SCIF either buried or canceled the report because
21		of its support for H-Wave.
22		THIRD CAUSE OF ACTION
23	(For Trade Libel Against Defendants EK Health, James Lessenger, M.D.,	
24	Grant Nugen	t, M.D., Alton Wills, M.D., Janet O'Brien, M.D., Kathleen Gray,
25	Μ	.D., Johanna Appel, D.C., and DOES 52 through 100)
26	90. P	laintiff realleges and incorporates herein by reference each and every
27	allegation set for	orth in Paragraphs 1 through 89 as though fully set forth herein.
28	91. D	efendants, and each of them, have published non-privileged false and
		- 31 -

disparaging statements about Plaintiff and H-Wave. On information and belief, 1 2 starting in as early as 2007 and continuing to the present, Defendants and each of them have engaged in a continuous and continuing practice of contacting 3 prescribing doctors, telling them that H-Wave will never be approved by UR, that 4 H-Wave is medically ineffectual and a fraud, and that Plaintiff is selling a fraudulent 5 product and making money through fraudulent business practices. They have stated, 6 among other things, that H-Wave does not cure or relieve the conditions for which it 7 8 is approved, prescribed, and for which its benefits have been shown through peerreviewed studies; that H-Wave is no different than any other electrical stimulation 9 10 treatment devices that could be used; that Plaintiff is making unsupported and unsupportable claims about the benefits of H-Wave; and, that Plaintiff is dishonest, 11 marketing a medically ineffectual device as a medical treatment. 12

13 92. Defendants knew their statements were false and/or acted in reckless14 disregard for their truth or falsity.

93. As a direct and proximate result of Defendants' defamatory
statements, Plaintiff has suffered and continues to suffer losses in an amount within
the jurisdictional limits of this Court, to be proven at trial in that many individual
doctors have stopped prescribing H-Wave for their patients.

19 94. Additionally, Defendants' statements disparaging Plaintiff's fitness
20 and honesty in their business qualify as defamation *per se*, entitling Plaintiff to
21 damages without proof of pecuniary loss.

95. Defendants' actions as described herein were oppressive, fraudulent and malicious, as these acts were committed in conjunction with a wider campaign to injure Plaintiff as alleged herein. They were taken for the express purpose of preventing Plaintiff from conducting its business, or with a conscious disregard for the injury that would surly result, thereby entitling Plaintiff to punitive damages in an amount to be proven at trial.

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FOURTH CAUSE OF ACTION

(For Civil RICO 18 U.S.C. § 1962(c) Against All Defendants)

3 96. Plaintiff realleges and incorporates herein by reference each and every allegation set forth in Paragraphs 1 through 95 as though fully set forth herein. 4

97. Plaintiff and each Defendant are "persons" as defined in 18 U.S.C. § 5 1961(3). 6

7 98. SCIF, EK, and all individual Defendants, including their employees and agents, formed an association-in-fact enterprise within the meaning of 18 U.S.C. 8 § 1961(4), the "Denial Enterprise." 9

99. 10 The Denial Enterprise is an ongoing organization consisting of a variety of legal "persons" that associated for common and shared purposes, 11 including: (a) to prevent Plaintiff from selling or renting its H-Wave device to 12 injured workers by fraudulently issuing prejudicial UR denials for all H-Wave 13 prescriptions, in violation of Labor Code § 4610; (b) to conceal from injured 14 workers, their treating physicians, and Plaintiff, the unlawful blanket denial policy 15 by mailing fraudulent denials that contained boilerplate scripts to create the 16 appearance that each denial was the result of an independent medical review, rather 17 than the result of the Defendants' denial policy; (c) to avoid paying Plaintiff for H-18 19 Wave treatment, retaining that money by defrauding patients and Plaintiff into relinquishing, compromising and settling their claims for treatment and payment, 2021respectively; and (d) to retain money lawfully owed to Plaintiff.

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100. Defendants coordinated with one another to implement and conceal 23 the Enterprise's scheme. Each Defendant operated and managed the scheme of 24 fraudulently denying all H-Wave prescriptions and using the mail and wires to further their fraudulent scheme. 25

26 101. SCIF designed and implemented a policy that all H-Wave prescriptions would be denied. SCIF's claims adjusters automatically denied every 27 28 prescription for H-Wave, sending the prescriptions to UR without first considering

the medical necessity of any H-Wave prescriptions. 1 Upon receiving H-Wave 2 prescriptions from SCIF's claims adjusters, the Reviewers fraudulently denied them all rather than performing an independent medical review for each patient prescribed 3 the H-Wave device, in violation of Labor Code §4610. The Reviewers generated 4 fraudulent denial letters, using the boilerplate scripts, to make it appear as if an 5 independent medical review had been performed. SCIF then mailed, faxed, and 6 7 emailed the fraudulent denial letters to the injured workers and their treating 8 physicians who believed they constituted and conveyed the result of a reviewer's independent medical review. SCIF also telephoned the prescribing physicians to 9 10 make the same fraudulent representations. When Plaintiff received these UR denial letters, as a matter of right, Plaintiff also relied on them as constituting and 11 12 conveying the result of a reviewer's independent medical review.

13 102. SCIF, including its Medical Director, Gideon Letz, M.D., together with EK, including its Medical Director Richard Thompson, M.D., agreed on the 14 15 blanket prejudicial denial policy for all H-Wave prescriptions. Over the years, these persons, together with other SCIF employees such as nurse Jizell Albright, and the 16 Reviewers, held regular teleconferences during which they organized their activities 17 in furtherance of the Denial Enterprise and made decisions regarding the ongoing 18 implementation of the denial scheme, including making adjustments to their tactics 19 whenever necessary to maintain the scheme in the midst of changing circumstances. 2021For example, they all participated in the creation and implementation of boilerplate scripts to include in H-Wave denial letters. Janet O'Brien was prolific in writing 22 23 boilerplate scripts and providing them to EK and SCIF to distribute to the other 24 Reviewers by email. When H-Wave was added to the MTUS in 2009, the Defendants addressed the change during their teleconferences and responded in part 25 by designing and implementing new scripts. EK, including Richard Thompson, 26 27 M.D., and David Ehrenfeld, M.D. – in charge of EK's Quality Assurance – 28 conducted and participated in the enterprise's scheme by assisting with the use of boilerplate scripts to help make them convincing, and by disciplining and
 reeducating any reviewers who were found to have actually conducted a bona fide
 medical review and approved an H-Wave prescription. Those reviewers were
 coerced into joining the Denial Enterprise. On information and belief, Reviewers
 who consistently performed according to Enterprise standards were enlisted to help
 bring noncompliant reviewers into line.

7 103. The Denial Enterprise has functioned as a continuing unit since at least
8 September 14, 2005, when SCIF first issued its written UR "blanket policy" to
9 always deny H-Wave. Since at least that time the enterprise has denied over 96% of
10 all H-Wave prescriptions written for SCIF patients.

11 104. The goal of the Denial Enterprise was and is to avoid paying for the 12 purchase or lease of H-Wave devices, as stated in SCIF's September 14, 2005 13 memo. The Denial Enterprise intended for patients, treating physicians and Plaintiff 14 to rely on the fraudulent UR denials. The Denial Enterprise intended to defraud 15 patients and Plaintiff into relinquishing their claims for H-Wave treatment and 16 claims for payment, respectively. The Denial Enterprise thereby intended SCIF to 17 fraudulently retain the money it owed to Plaintiff.

18 105. As a result of the Defendants' fraud, patients have relinquished their
19 rights to pursue and petition to receive the H-Wave treatment prescribed by their
20 treating physicians, reducing the number of H-Wave units Plaintiff has sold.

21 106. Absent a lawful UR denial Plaintiff has the right to demand and collect its usual and customary charges for its H-Wave device. Plaintiff relied on 22 23 Defendants' fraudulent UR denials to its detriment, induced to relinquish, 24 compromise, and settle its claims for full reimbursement for its H-Wave devices that 25 it provided pre-denial, as well as for any ongoing and subsequent H-Wave treatment that patients and their doctors believed to be medically necessary despite contrary – 26 27 but fraudulent – UR denials. As a result of the Defendants' fraud, SCIF retained money that Plaintiff was defrauded into relinquishing, and money that Plaintiff was 28

entitled to receive because H-Wave was denied without an independent medical
 review for each patient's H-Wave request.

3 107. Many treating physicians have stopped prescribing H-Wave altogether
4 in reliance on the across-the-board fraudulent denials, believing that H-Wave
5 prescriptions cannot get through UR.

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108. The Denial Enterprise has necessarily used the mail and wires to 6 7 perpetrate its fraud. In the past 10 years the Denial Enterprise has mailed or faxed 8 over 4000 H-Wave denial letters to patients and their treating physicians, all On information and belief, the same number of 9 fraudulent as alleged above. 10 telephone calls were placed to prescribing physicians to communicate the fraudulent denials. All of the Defendants also communicated with each other using the mail, 11 12 fax, email, and the telephone as they managed and operated the Denial Enterprise, 13 including but not limited to the teleconferences alleged herein, for exchanging ideas and instructions for carrying out the Enterprises activities, and for transmitting 14 boilerplate scripts and fraudulent denial letters between Defendants. 15 This constitutes a pattern of racketeering activity by mail fraud, in violation of 18 U.S.C. 16 § 1341, and wire fraud, in violation of 18 U.S.C. § 1343. 17

18 109. The Denial Enterprise affects interstate commerce. The Denial Enterprise could not be carried out without the United States mail or interstate wires, 19 which were used to convey the fraudulent denials. 20Further, the Defendants 21fraudulently retained millions of dollars that rightfully belonged to Plaintiff. Plaintiff operates in multiple states. The cost of Defendants' fraud is passed on, at 22 23 least in part, through the price of the H-Wave device in other states, and to other 24 California patients and their insurers who operate in multiple states. The Denial Enterprise has reduced the total number of H-Wave devices manufactured. H-Wave 25 devices are manufactured in California with parts imported from outside of 2627 California. This affects not only commerce with foreign parts manufacturers, but it 28 also affects the interstate carriers that transport the parts. Additionally, the Denial Enterprise has also denied H-Wave prescriptions for injured workers employed by
 self-insured company Safeway, Inc. On information and belief, Safeway operates
 supermarkets and employs workers in many states across the country. The Denial
 Enterprise also hired ECRI, a technical assessment company from the East Coast, to
 perform medical scientific research, that they hoped would be critical of H-Wave, to
 incorporate into their fraudulent denial letters.

7 110. Defendants' violations of 18 U.S.C. § 1962(c) directly and
8 proximately caused Plaintiff substantial injury to business and property because
9 Defendants' pattern of racketeering activity has reduced the Plaintiff's revenue from
10 the sale and lease of H-Wave devices and caused Plaintiff to incur out-of-pocket
11 costs and related expenses addressing fraudulent UR denials that would otherwise
12 not have been incurred, all as alleged herein above.

13 111. The Denial Enterprises' racketeering activity was fraudulently concealed from Plaintiff as alleged herein above. Even when Plaintiff, in 2008, 14 confronted SCIF and Dr. Letz with factual inaccuracies Plaintiff found in, on 15 information and belief, what is now understood to be the boilerplate script authored 16 by Janet O'Brien, the denial policy was still not disclosed to Plaintiff by any of the 17 Defendants. Rather, Dr. Letz responded to Plaintiff by assuring them that reviewers 18 had been made aware of the facts supporting H-Wave for their consideration in 19 future UR's. In reality, SCIF and the other Defendants edited the boilerplate scripts 2021for use with future fraudulent denials letters to prevent Plaintiff from discovering the Plaintiff was never informed that independent medical reviews were not 22 truth. being conducted on every H-Wave prescription to determine if H-Wave was 23 24 appropriate treatment in each individual patient's case.

112. These misrepresentations of fact made to Plaintiff in writing and by
telephone are additional predicate acts of mail and wire fraud performed by and in
furtherance of the Denial Enterprise. All of these fraudulent representations and
omissions were relied on by Plaintiff to its injury by reinforcing the fraudulent

1 misrepresentation that UR was ever occurring in the first place.

113. As a direct and proximate result of Defendants' unlawful racketeering
activity, Plaintiff suffered and continues to suffer damages in an amount to be
proven at trial. Under the provisions of 18 U.S.C. § 1964(c), Defendants are jointly
and severally liable to Plaintiff for three times the damages that Plaintiff has
suffered, plus the costs of bringing this suit, including reasonable attorneys' fees.

7

FIFTH CAUSE OF ACTION

8

(For Civil RICO Conspiracy 18 U.S.C. § 1962(d) Against All Defendants)

9 114. Plaintiff realleges and incorporates herein by reference each and every
10 allegation set forth in Paragraphs 1 through 113 as though fully set forth herein.

11 115. The Defendants formed an agreement to violate 18 U.S.C. § 1962(c).
12 Each Defendant knew of the Denial Enterprise's conspiracy to defraud Plaintiff,
13 injured workers, and treating physicians, by fraudulently denying H-Wave
14 prescriptions while taking steps to conceal the fraud.

15 116. Each Defendant agreed to join this conspiracy, and each agreed to
16 commit, facilitate, or participate in a pattern of racketeering activity in furtherance
17 of the conspiracy.

18 117. During the existence of the conspiracy, each of the Defendants agreed
19 to the commission of an indefinite stream of predicate acts in furtherance of the
20 conspiracy.

118. SCIF agreed to and did commit multiple instances of mail and wire
fraud in furtherance of the conspiracy by mailing and wiring fraudulent UR denials
to patients and their treating physicians. SCIF also devised the scheme, organized
the Reviewers and the scheme through teleconferences, sent the Reviewers H-Wave
prescriptions via SCIF's claims adjusters/agents, and concealed the scheme from the
Plaintiff in written and oral communications through the mail, email, and telephone.

27 119. The Reviewers agreed to and did commit multiple instances of mail28 and wire fraud in furtherance of the conspiracy by mailing or wiring fraudulent

denials to SCIF for the agreed purpose of transmitting them by mail and wire to
 patients, their treating physicians, and to Plaintiff. The Reviewers participated in
 the teleconferences, helping to manage their own role in the Enterprise and develop
 fraudulent denial letters.

120. EK, Richard Thompson, M.D., and David Ehrenfeld, M.D. agreed to 5 and did commit multiple instances of mail and wire fraud in furtherance of the 6 conspiracy by managing the Reviewers and the implementation of fraudulent denial 7 8 letters via email and through the teleconferences. They additionally promoted and maintained the Reviewers' fidelity to the Enterprise by directing Reviewers to 9 10 fraudulently deny H-Wave, with the intention that such denials and fraudulent denial letters would be transmitted by mail and wire to patients, their treating physicians, 11 and to Plaintiff. 12

13 121. The predicate acts of mail and wire fraud that Defendants agreed to
14 and did commit directly and proximately caused Plaintiff to suffer substantial injury
15 to its business and property as alleged in greater detail above.

16 122. Under the provisions of 18 U.S.C. § 1964(d), each of the Defendants
17 is jointly and severally liable to Plaintiff for three times the damages that Plaintiff
18 has suffered, plus the costs of bringing this suit, including reasonable attorneys'
19 fees.

20

SIXTH CAUSE OF ACTION

21 (For Unfair Competition Business & Professions Code § 17200 Against All 22 Defendants)

23 123. Plaintiff realleges and incorporates herein by reference each and every
24 allegation set forth in Paragraphs 1 through 122 as though fully set forth herein.

124. The Defendants' schemes involving fraudulent misrepresentations and
omissions constitute unlawful, unfair, or fraudulent business acts and practices,
under the California Unfair Competition Law ("UCL"), California Bus. & Prof.
Code § 17200 *et. seq.*

1 125. Each Defendant violated Section 17200's prohibitions against
 2 engaging in an unlawful act or practice through conduct that violates, among other
 3 things, RICO, 18 U.S.C. § 1962, as described herein. Through their unfair and
 4 improper practices, Plaintiff suffered injury by virtue of the Defendants' fraudulent
 5 denials of H-Wave.

6 126. Defendants further violated Section 17200's prohibition against
7 engaging in an unlawful act or practice through conduct that violates the Cartwright
8 Act, Bus. & Prof Code § 16700 *et. seq.*, by conspiring to restrain Plaintiff's trade as
9 alleged herein, above.

10 127. Defendants further violated Section 17200's prohibition against 11 engaging in an unlawful act or practice through conduct that violates the Labor 12 Code § 1871.4 and Penal Code § 550, by making and presenting knowingly false 13 and fraudulent material representations, and conspiring to have them made and 14 presented, for the purpose of denying compensation; along with representations 15 regarding the entitlement to benefits with the intent to discourage injured workers 16 from claiming benefits or pursuing claims.

17 128. Defendants further violated Section 17200's prohibition against
18 engaging in an unlawful act or practice through conduct that amounts to trade liable,
19 by denigrating both the H-Wave device and Plaintiff as alleged herein, above.

129. In addition to being unlawful and fraudulent, each of the Defendants'
schemes to defraud Plaintiff, patients, and treating physicians, and each of the acts
complained of herein above, constituted unfair business acts and practices under §
17200.

24 130. Defendants' unfair and unlawful practices were performed in25 California.

26 131. Plaintiff has suffered injury to its business and property as a direct and
27 proximate result of Defendants' unfair and unlawful practices, as alleged herein
28 above.

1 132. Defendants have fraudulently retained up to millions of dollars that
 rightfully should have been paid to Plaintiff, as a direct and proximate result of their
 unfair and unlawful practices. Defendants have been unjustly enriched and it would
 be inequitable to allow Defendants to retain the benefit that they obtained through
 fraud or other unfair practices. Disgorgement should be awarded so as to achieve
 substantial justice between the parties.

7 WHEREFORE PLAINTIFF PRAYS FOR JUDGMENT AS FOLLOWS: 8 ON THE FIRST CAUSE OF ACTION

9 1. For general and special damages in a sum to be proven at trial with pre10 judgment and post-judgment interest thereon at the maximum rate permitted by law;

- 11 2. For mandatory treble damages;
- 12 3. For reasonable attorneys' fees;
- 13 4. For a preliminary and permanent order enjoining Defendants' conduct;

14 5. For punitive and exemplary damages in an amount appropriate to15 punish and set an example of defendants;

16

ON THE SECOND CAUSE OF ACTION

For general and special damages in a sum to be proven at trial with pre judgment and post-judgment interest thereon at the maximum rate permitted by law;

19 2. For punitive and exemplary damages in an amount appropriate to20 punish and set an example of defendants;

21

ON THE THIRD CAUSE OF ACTION

1. For general and special damages in a sum to be proven at trial with prejudgment and post-judgment interest thereon at the maximum rate permitted by law;

24 2. For statutory *per se* defamation damages;

25 3. For punitive and exemplary damages in an amount appropriate to
26 punish and set an example of defendants;

27

28

ON THE FOURTH CAUSE OF ACTION

1. For general and special damages in a sum to be proven at trial with pre-

1	judgment and post-judgment interest thereon at the maximum rate permitted by law;		
2	2.	For mandatory treble damages;	
3	3.	For reasonable attorneys	s' fees;
4		ON THE FIFT	TH CAUSE OF ACTION
5	1.	For general and special	damages in a sum to be proven at trial with pre-
6	judgment a	and post-judgment interest	thereon at the maximum rate permitted by law;
7	2.	For mandatory treble da	mages;
8	3.	For reasonable attorneys	s' fees;
9		ON THE SIXT	TH CAUSE OF ACTION
10	1.	1. For general and special damages in a sum to be proven at trial with pre-	
11	judgment and post-judgment interest thereon at the maximum rate permitted by law;		
12	2.	For a preliminary and pe	ermanent order enjoining Defendants' conduct;
13	3.	For restitution and disgo	orgement of unjust enrichment, plus interest;
14	4.	For recovery of all attorneys' fees pursuant to California Code of Civil	
15	Procedure § 1021.5;		
16		<u>ON ALL C</u>	AUSES OF ACTION
17	1.	For all costs incurred by	Plaintiff to date and to be incurred by Plaintiff
18	hereafter in	n connection with this action	on;
19	2.	For prejudgment interest	t; and
20	3.	For such other and furth	er relief as the court deems just and proper.
21			
22	DATED:	November 3, 2015	ROXBOROUGH, POMERANCE, NYE
23			& ADREANI, LLP
24			By: /s/ Joseph C. Gjonola NICHOLAS P. ROXBOROUGH
25			JOSEPH C. GJONOLA Attorneys for Plaintiff Electronic Waveform Lab, Inc.
26			Electronic Waveform Lab, Inc.
27			
28			
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	THIRD AMENDED COMPLAINT		