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10
11 SUPERIOR COURT OF THE STATE OF CALIFORNIA

12 CITY AND COUNTY OF SAN DIEGO

13
14 THE REGENTS OF THE UNIVERSITY
OF CALIFORNIA, a California
15 Corporation,

16 Plaintiff,

17 vs.

18 PAUL S. AISEN, an individual; JEREMY
PIZZOLA, an individual; DEBORAH
19 TOBIAS, an individual; GUSTAVO
JIMENEZ-MAGGIORA, an individual;
20 PHUOC HONG, an individual; HONG
MEI QIU, an individual; STEFANIA
21 BRUSCHI, an individual; JIA-SING SO,
an individual; MAYYA NESSIRIO, an
22 individual; UNIVERSITY OF
SOUTHERN CALIFORNIA, a California
23 Corporation; and DOES 1-25, Inclusive,

24 Defendants.

CASE NO. 37-2015-00022082-CU-BT-CTL

**DEFENDANTS' EX PARTE
APPLICATION FOR (1) TEMPORARY
RESTRAINING ORDER, (2)
CONTINUANCE OF HEARING ON
PRELIMINARY INJUNCTION, AND (3)
EXPEDITED DISCOVERY**

Complaint Filed: July 2, 2015

Hearing:

Date: July 14, 2015

Time: 8:30 a.m.

Dept.: C-68

Judge: Hon. Judith F. Hayes

[IMAGED FILE]

1 TO THE COURT, ALL PARTIES AND THEIR COUNSEL OF RECORD:

2 PLEASE TAKE NOTICE that Defendants Paul S. Aisen, Jeremy Pizzola, Deborah
3 Tobias, Gustavo Jimenez-Maggiara, Phuoc Hong, Hong Mei Qiu, Stefania Bruschi, Jia-Sing So,
4 Mayya Nessimio, and the University of Southern California (collectively, "Defendants") hereby
5 file this *ex parte* application seeking the following relief:

6 1. An immediate Temporary Restraining Order (TRO) against Plaintiff The Regents
7 of the University of California ("Plaintiff" or "Regents") enjoining Plaintiff, and anyone acting in
8 concert with it, from (a) exercising root control of the electronic data capture platform ("EDC")
9 hosted on the Amazon Web Services ("AWS"), Account No. 675713428646, and containing data
10 from ongoing clinical trials of the Alzheimer's Disease Cooperative Study ("ADCS"); (b)
11 otherwise accessing the EDC as a "root user;" or (c) disabling Defendants' administrative access
12 to the EDC.

13 2. Continuance of the July 24, 2015 hearing on Plaintiff's OSC re Preliminary
14 Injunction (as set forth in the Register of Actions #30) pending discovery into multiple accesses
15 to EDC on AWS from the University of California, San Diego ("UCSD") campus by a root user
16 and the extent of this root use.

17 3. Concurrent with the above, Defendants request expedited discovery.

18 This *ex parte* application is grounded on the fact that there is a need for the Court's
19 immediate relief so as to avoid potential grave and irreparable harm. Plaintiff appears to have
20 surreptitiously accessed, repeatedly and from multiple computers, the EDC as a "root" user. A
21 root account possesses the highest authority or privilege available within an operating system or
22 database, giving the user infinite access to resources, to restrict or deny access to other uses, and
23 also unlimited capability to change or destroy data. Plaintiff's ability to access the EDC as a
24 "root" user, and its repeated use of the root account in the last week to access the EDC, threatens
25 irreparable harm to the EDC system, the scientific integrity and validity of the clinical trial data
26 stored thereon, and the individuals that have volunteered to participate in Alzheimer's research
27 trials. Plaintiff's destabilization of the EDC must be stopped.

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Last week the parties agreed to maintain the status quo, which involved allowing for administrative control of the EDC to maintain with Defendants subject to certain restrictions on the ability of Defendants to make changes or alterations to the system. Plaintiff's conduct, in accessing the root account despite the TRO, undermines the spirit and tenor of the TRO, threatens the status quo, and jeopardizes critical Alzheimer's disease research that relies on the EDC.

This Application is based on the attached Memorandum of Points and Authorities, the Declarations of Paul Aisen, M.D., Gustavo Jimenez-Maggiora, Phuoc Hong, and Michael Kunkel, the pleadings, motions, memoranda, declarations, and other evidence on file in this action, and other such evidence and argument as may be presented to the Court at the hearing.

Timely notice of this ex parte application was given, as reflected in Exhibit A to the Declaration of Panteha Abdollahi.

DATED: July 13, 2015

PAUL HASTINGS LLP

By: 

GLENN D. DASSOFF
Attorneys for Defendants

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1 **I. SUMMARY OF ARGUMENT**

2 *This ex parte application is prompted by a startling discovery requiring the Court's*
3 *immediate attention.* On July 6, Plaintiff pleaded with this Court for urgent relief – in the form of a
4 turnover of administrative control of an electronic data system. Yet before Plaintiff filed its ex
5 parte papers, indeed possibly even before Plaintiff filed its complaint, it had already obtained “root”
6 (i.e., “superuser”) access over the entire database at-issue. That root access allows Plaintiff to
7 completely block Defendants from the database. Thus, Plaintiff never needed Court relief to take
8 control of the database. Plaintiff already had and has it. It appears Plaintiff moved for a high-
9 publicity preliminary injunction to intimidate other employees from following Defendants to USC
10 and to force Defendants to show Plaintiff how to use the system. Defendants now need the
11 emergency assistance of the Court to prevent Plaintiff from exercising its root (superuser) control of
12 the database and potentially disrupting the entire system and clinical trial data housed thereon.

13 On July 2, 2015, Plaintiff The Regents of the University of California (“Plaintiff”) filed suit
14 against the University of Southern California (“USC”), Dr. Paul Aisen, a world-renowned
15 researcher of Alzheimer’s disease, and eight other staff that work under Dr. Aisen’s supervision
16 (the “Aisen team”). The gravamen of Plaintiff’s complaint is that Defendants purportedly usurped
17 control of an electronic data capturing system (the “EDC”) hosted by Amazon.com web services
18 (“AWS”) on its virtual servers. The EDC houses and manages all aspects of clinical trials for the
19 Alzheimer’s Disease Cooperative Study (“ADCS”), a cooperative study by the National Institute of
20 Aging (“NIA”) with the University of California, San Diego (“UCSD”). Plaintiff’s complaint
21 accused Defendants of unlawfully “arrogat[ing] control over ADCS data after resigning from the
22 Regents” and “preventing The Regents from exercising administrative control over the data.”
23 Compl. ¶¶28, 55. Immediately after filing its complaint, Plaintiff rushed to Court for a temporary
24 restraining order (“TRO”) and expedited preliminary injunction hearing. In those papers, Plaintiff
25 requested a preliminary injunction that would order transfer of the EDC “from the control of the
26 Defendants back to the control of The Regents.”

27 But Plaintiff failed to mention one thing to the Court or Defendants: *Plaintiff has had*
28

1 “superuser” control of the EDC and the ADCS Data since at least July 2, 2015. Moreover, it is
2 unknown how Plaintiff obtained this access. Defendants made this alarming discovery on July 9.

3 Exhibits D and E to the Declaration of Lucila Ohno-Machado in support of Plaintiff’s ex
4 parte application (filed on July 6, 2015) (ROA 11) (the “July 6 Ex Parte”) include snapshots of the
5 “log details” and “activity history” of EDC taken by Plaintiff. Dr. Ohno-Machado declared these
6 snapshots were derived from the “limited access” UCSD was able to obtain to the management
7 console with Amazon’s assistance. Ohno-Machado Decl. ¶¶10, 11. But, these snapshots reveal that
8 UCSD has much more than “limited access;” it has ultimate control over the entirety of the system,
9 including the ability to deprive the Aisen team of access to the database. According to the
10 snapshots, beginning at least as of July 2, 2015, there has been activity by the “root user” of the
11 EDC account. As described by AWS, root credentials “allow full access to all resources in the
12 account.” Thus, “a root account possesses the highest authority or privilege available within an
13 operating system, database, or control program. This level of access is sometimes referred to as
14 ‘superuser’ because of its unlimited capabilities within the system. This account has inherent
15 privileges that give the user infinite access to resources, to restrict or deny access to other users, and
16 also unlimited capability to change or destroy data.” Kunkel Decl. ¶6. It is the equivalent of being
17 in control of the “command center.” The IP addresses linked to the “root user” show that someone
18 (or some people) has (or have) been accessing EDC as the root user *multiple times from multiple*
19 *sites on the UCSD campus*. Kunkel Decl. ¶¶12, 13. There are only two individuals on the Aisen
20 team that could log into EDC as a root user. Neither has been to UCSD since June 24, 2015 to
21 access the EDC from that location. Jimenez-Maggiore Decl. ¶13; Hong Decl. ¶7.

22 Plaintiff’s stealth undertaking of control of EDC and multiple entries into the system as a
23 root user pose a serious risk of irreparable harm to ADCS clinical trial data. As laid out below,
24 repeatedly accessing a system like EDC with root credentials is atypical, dangerous, and contra best
25 practices and guidelines for this kind of regulatory-governed data. This is especially the case when
26 Plaintiff lacks the requisite familiarity and experience with the EDC system to properly administer
27 superuser capacities. An inadvertent or mistaken action by an inexperienced root user on the EDC
28 can cause undoable damage to the system and the clinical trial data thereon. Indeed, activity

1 undertaken on the EDC since July 2, 2015 using the root account (such as deactivation of the multi-
2 factor security of the system) is reflective of this inexperience and recklessness with regulatory
3 standards. Plaintiff's root control of the EDC also violates the spirit and tenor of the stipulated
4 TRO that was entered into by the parties and approved by the Court on July 6, 2015. That
5 stipulated order was intended to allow *Defendants* to maintain administrative control of the EDC
6 pending a resolution of Plaintiff's request for a preliminary injunction.

7 In light of the above facts, Defendants seek the Court's assistance and request:

8 • Issuance of a TRO preventing Plaintiff from exercising root control of the EDC or otherwise
9 accessing the EDC as the root user. Accessing the EDC using the root credentials poses a serious
10 risk of irreparable harm to the ADCS clinical trial data.

11 • Delay of the hearing on Plaintiff's request for a preliminary injunction pending discovery
12 into the issue of how the EDC was accessed multiple times from the UCSD campus by a root user
13 and the extent of this root use.

14 • In conjunction with the above, Defendant seeks expedited discovery to ascertain how
15 Plaintiff obtained root access to the EDC and what it has done with such access.

16 Defendants do not bring this ex parte application to the Court lightly. There is a very real
17 and potent risk that use of root user credentials to access the EDC by an untrained user could
18 disrupt years of research and compromise the scientific data. The future of Alzheimer's research
19 should not be put jeopardy by Plaintiff's reckless handling of the data system.

20 **II. STATEMENT OF FACTS**

21 **A. The ADCS and EDC**

22 The ADCS was launched as a cooperative study by the NIA Division of Neuroscience with
23 UCSD to facilitate the discovery, development and testing of new drugs for the treatment of
24 Alzheimer's disease. Compl. ¶¶4, 8. It is a consortium of academic medical centers and clinics
25 collaborating on the development of Alzheimer's treatment and diagnostic tools. Compl. ¶¶8-9.
26 The work of ADCS is funded primarily by the federal government and private company grants.
27 Compl. ¶9; Aisen Decl. ¶5. The study is housed almost entirely off the UCSD campus and pays its
28 own rent and expenses. Aisen Decl. ¶5. Dr. Aisen was the director of ADCS until June 21, 2015,

1 when his resignation became effective. *Id.* ¶4.

2 Data from clinical trials coordinated by ADCS, and other studies with which ADCS is
3 involved, are stored on the EDC platform. Compl. ¶28; Jimenez-Maggiore Decl. ¶5. The EDC
4 enables management of all aspects of clinical trial activities and maintains the entirety of the data,
5 including all data on study participants such as primary outcome data, medical imaging participant
6 randomization, laboratory, and biospecimen information, study medication management, and study
7 source document management. It includes, among other things, highly sensitive information related
8 to participants in clinical trials, including their responses to investigational drugs. The Informatics¹
9 Core at ADCS, under Dr. Aisen’s supervision, developed and has maintained the EDC. Jimenez-
10 Maggiore Decl. ¶3. The EDC is a uniquely formulated program. Only those with knowledge and
11 special training can oversee the EDC to ensure it functions properly. *Id.* ¶4. The entire Informatics
12 Team at ADCS resigned from UCSD to work with Dr. Aisen at USC. *Id.* ¶15.

13 The active version of EDC collecting data from ongoing clinical trials is hosted on AWS.
14 Jimenez-Maggiore Decl. ¶6. The EDC system on AWS has three tiers: (1) the infrastructure; (2) a
15 live operating system; and (3) a web-based access tier. *Id.* ¶7. For each clinical trial, the top two
16 tiers (numbers 2 and 3 described above) are self-contained, and an authorized user receives a
17 username and password to access the data on the tier for a particular trial. A user may even be
18 granted access to tiers 2 and 3 for all clinical trials. *Id.* But access to the top-level tier – the
19 infrastructure – is highly restricted. This is because someone with the authorization credentials to
20 access to the top-level tier, otherwise known as a “root user,” has global administrative access rights
21 to the entire database and can manipulate the whole system, or even delete it in its entirety. *Id.*
22 Generally speaking, a root user to a database can **block administrators and other users, add**
23 **new users, delete study data, and change vital security protocols.** Kunkel Decl. ¶6. As
24 described on AWS’s website:

25 All AWS accounts have root account credentials. These credentials
26 allow full access to the resources in the account. Because you can’t
27 control the privileges of the root account credentials, store them in a
safe place and instead use AWS Identity and Access Management

28 ¹ Informatics is the science of computer information systems. As an academic field it involves the practice of information processing and the engineering of information systems.

1 (IAM) user credentials for day-to-day interaction with AWS.
2 Kunkel Decl. ¶7, Ex.B.

3 The Aisen team established a multi-factor authentication process for root access to EDC –
4 logging in as a root user requires a username, password, and token (a rotating code). Jimenez-
5 Maggiora Decl. ¶9. The root account was formed in the name of Dr. Aisen (under whose name
6 AWS billing went), but he did *not* have the password or token to access the account. *Id.* ¶8.
7 Among the Aisen team, there are only two individuals with root access – Gustavo Jimenez-
8 Maggiora and Phuoc Hong. *Id.* “Because the root account is so powerful, it should be carefully
9 guarded and used only when absolutely necessary.” Kunkel Decl. ¶7. Thus, for daily
10 administration of the database, Mr. Jimenez-Maggiora and Mr. Hong access EDC using IAM
11 credentials. Jimenez-Maggiora Decl. ¶11; Hong Decl. ¶7. Neither individual has accessed EDC
12 as a root user since June 28, 2015. Jimenez-Maggiora Decl. ¶13; Hong Decl. ¶7.

13 **B. Plaintiff’s Complaint**

14 On July 2, 2015, Plaintiff filed its complaint. In its lawsuit, Plaintiff claimed it had been
15 unlawfully deprived of custody and control of the EDC. For example, Plaintiff alleged:

16 • “Defendants have exerted dominion and control over the ADCS data that has been entrusted
17 to UCSD ... and have refused to provide UCSD with account data, passwords and access
18 credentials to enable UCSD to maintain administrative control of ADCS data.” Compl. ¶27.

19 • “Defendants arrogate[d] control over ADCS data[.]” Compl. p.8.

20 • Plaintiff is harmed by Defendants’ “domination and control” of EDC because
21 “[m]anagement of user accounts including the creation of new accounts, updating permissions for
22 existing accounts and removal of deprecated accounts is not possible” and “[t]he type and amount
23 of services procedure from Amazon cannot be controlled.” Compl. ¶40(c), (g).

24 • Defendants’ “dominion and control over Cloud-based storage accounts” has “prevent[ed]
25 The Regents from exercising administrative control over the data contained therein.” Compl. ¶55.

26 • Plaintiff is damaged by “the loss of property owned by the Regents.” Compl. ¶¶45, 49, 70.

27 The intended import of the Complaint was clear: Plaintiff was left without any meaningful
28 access or administration of the EDC.

1 **C. Plaintiff’s Ex Parte Application for TRO and OSC Re Preliminary Injunction**

2 On the heels of its Complaint, Plaintiff filed an ex parte application seeking a TRO and
3 OSC re preliminary injunction (the “July 6 Ex Parte,” ROA 9). In the July 6 Ex Parte, Plaintiff
4 carefully worded its request for a preliminary injunction to enjoin Defendants from exercising
5 dominion and custody of the EDC and directing Defendants to restore to Plaintiff “any such data,
6 software systems, licenses, documentation, passwords, and access credentials” that Defendants
7 maintained in their possession. Mtn. p.2. Plaintiff implied this was necessary because it had no
8 administrative control over the EDC. It repeatedly described Defendants as having “hijacked” the
9 EDC (Pl.’s Mtn. pp.2, 3) and referred to “Defendants’ arrogation of control over ADCS data” (*id.*
10 p.9), thereby giving the impression it no control over the EDC whatsoever. This impression was
11 reinforced throughout Plaintiff’s brief:

- 12 • “Defendants have taken administrative control of the ADCS Data, making it difficult if not
13 impossible for the Regents to perform its obligations under its contracts ...” Pl.’s Mtn. p.9.
- 14 • “The question before this Court is whether this case will be litigated with Defendants
15 holding ADCS Data hostage from its rightful owner, The Regents.” Pl.’s Mtn. p.11.
- 16 • “By wrongfully taking away UCSD’s control of ADCS Data, Defendants have rendered it
17 more expensive and difficult, if not impossible, for UCSD to comply with its obligations under
18 these contracts.” Pl.’s Mtn. p.13.
- 19 • “The Regents’ inability to control ADCS Data further harms the Regents by placing the
20 data at risk of loss...” Pl.’s Mtn. pp.9-10.

21 The Ohno-Machado Declaration submitted in support of the July 6 Ex Parte augmented the
22 illusion that Plaintiff suffered from a virtually complete administrative block out. Dr. Ohno-
23 Machado outlined reaching out to Amazon on June 27 and 28, 2015 to obtain information about the
24 EDC AWS account but being denied information. Ohno-Machado Decl. ¶9. But then in some
25 unexplained way, UCSD was able to “gain limited access to the Amazon web service” “with the
26 assistance of Amazon” on July 2, 2015. *Id.* ¶10. Thus, according to Ohno-Machado, Plaintiff had
27 “limited access to the management console to see the systems, but UCSD still does not have access
28

1 to the individual systems or the applications.” *Id.* ¶10. Using this purported “limited access,”
2 UCSD obtained snapshots of the EDC on AWS, and attached those snapshots as Exhibits D and E
3 to the declaration.² In later parts of her declaration, Ohno-Machado again referred to Plaintiff’s
4 access to AWS and the EDC as “limited” and called for a restoration of the data to UCSD. *See,*
5 *e.g., Id.* ¶16(a) (“UCSD’s current limited access to the Amazon master account...”), ¶20 (“a neutral
6 third-party supervisor is absolutely necessary to ensure that Defendants do what is necessary to
7 adequately and completely restore the data and systems to UCSD”). The declaration’s use of
8 carefully selected language maintained the impression that Plaintiff could do very little with its
9 “limited access” to EDC. This depiction has been repeated. According to Dr. Mobley’s written
10 statements to the ADCS Steering Committee:

11 [T]he ADCS does not now have administrative oversight of our data. We
12 can ‘see’ the data, as can all those who have access to the site. That is, we
13 were only allowed to be users of the system. Lacking administrative
14 oversight, we cannot ensure the integrity and safety of the data. Merely
15 being able to ‘see’ data does not allow us to comply with our obligations
16 under our contracts to the NIH or our sponsors. Aisen Decl. Ex. A.

17 **D. Defendants Make a Startling Discovery – Plaintiff Has Had Full**
18 **Administrative Access to the EDC Since at least July 2, 2015**

19 **1. Exhibits D and E to the Ohno-Machado Declaration Shows Root User**
20 **Access to the EDC Website From UCSD**

21 A closer examination of the above-referenced snapshots to the Ohno-Machado declaration
22 (Exhibits D and E) revealed much more than the “limited access” to which she attested. Rather, the
23 activity log details captured in the snapshots *reveal access of the EDC by a “root user” from the*
24 *UCSD campus.* As explained above, root access is super access – at allows for super control of the
25 entire database. Among techies, the root account is sometimes referred to as the “God account.”

26 An explanation of the snapshots and the information contained therein helps explain this
27 discovery. The screenshots show the command center of the EDC (highlighted relevant excerpts
28 are attached for the Court’s convenience as Exhibit A to the Jimenez-Maggiore declaration). The
command center can be viewed using only one of five accounts – the fact that Plaintiff was able to

² Based on the name appearing in the upper left hand corner of the snapshots attached to the Ohno-Machado declaration, they appear to have been taken on the computer of John Denune. Mr. Denune is the IT Security Director at UCSD.

1 provide the screen shots means Plaintiff had access to the system through one of them. The five
2 accounts are: two administrator accounts (held exclusively by Mr. Jimenez-Maggiora and Mr.
3 Hong), two reserve backup accounts that are never used, and the “root” account. There is no other
4 mechanism for accessing the command center. Jimenez-Maggiora Decl. ¶17.

5 Page 1 of Exhibit D is an activity log from July 1-3, 2015 in reverse chronological order.
6 The first two entries (at the bottom) show routine access by Mr. Jimenez-Maggiora on July 1 and
7 July 2. The log then shows a series of access attempts with a “hidden” username, followed by
8 “root” access on July 2 and July 3. Another snapshot page – API Activity History – shows the
9 “root” user name creating a snapshot of the database (under the “event name”). Neither the
10 referenced hidden user, nor the root user, was Mr. Jimenez-Maggiora or Mr. Hong. Indeed, the
11 mere fact that there has been root access to the system is unusual and alarming. As explained above
12 in Section II.A this is because the “root” account is a superuser account that can control the entire
13 system. For example, the root user can block other users, delete study data, and change vital
14 security protocols. A mistake made while using the root account could have catastrophic
15 consequences. Therefore it is generally considered an unsafe practice to use the root account to
16 access a system, even for copying purposes. Kunkel Decl. ¶6. Root user access to the EDC is
17 reflected in multiple snapshots included within Exhibits D and E, as highlighted in Exhibit A to the
18 Jimenez-Maggiora Declaration.

19 Upon discovering this root access, Defendants investigated further. They looked at the
20 payment screen on the EDC to confirm whether Dr. Aisen was still listed as the “payor” for the
21 monthly account charges. (Only the root account holder can change the payor.) Defendants
22 discovered the payor had been changed to Patty Camacho, the head administrator for the UCSD’s
23 Department of Neurosciences. Jimenez-Maggiora Decl. Ex. C. Defendants also hired a forensic
24 expert to examine the activity logs of the EDC. Kunkel Decl. ¶5. Using the IP addresses, this
25 examination revealed root credentials had been used to access the EDC from multiple IP addresses
26 on the UCSD campus between July 3 and July 10 and one time from an unknown Time Warner
27 Cable IP address (for over 22 accesses in this short time period). Kunkel Decl. ¶13.

1 **2. It is Unclear How the Root User Information Was Obtained**

2 In light of the multiple levels of security placed on the root account, Defendants tried to
3 understand *how* a root user could access the EDC. The Defendants looked at the EDC’s AWS
4 Support Center screen (which shows recent “help tickets”). There, they discovered a trail for a help
5 request sent to AWS on June 28, 2015 asking for assistance with account access. The “help ticket”
6 was sent to the email address on file for the root account holder (paisen@ucsd.edu). That help
7 ticket provided a unique pin number to be repeated back to the AWS Help team by phone to re-set
8 the root user password. The screen shot is attached as Ex. B to the Jimenez-Maggiore Decl.

9 The June 28 date of the help ticket request is significant, especially when put in context.
10 Just the day before, Dr. Ohno-Machado called AWS to understand how to get access to the EDC on
11 AWS. An Amazon representative (Heather Matson) advised:

12 that Account No. 675713428646 is not held in the name of UCSD,
13 and that Amazon considers the account as ‘owned’ by someone else.
14 Ms. Matson informed me that Amazon’s internal policies (i) prevent
15 Amazon from identifying the ‘account holder’ and (ii) prohibit
16 UCSD to reset the password to the account or gain administrative
17 control over the account. Ms. Matson suggested that UCSD *either*
18 *obtain the password from the ‘account holder,’* or get a court order.
19 Ohno-Machado Decl. ¶9 (emphasis added).

20 Dr. Ohno-Machado acknowledged having received access to the system by July 2, 2015 (albeit
21 claiming the access was “limited”) “with the assistance of Amazon.” Ohno-Machado Decl. ¶10.
22 She never explained what “assistance” Amazon provided or how this assistance was obtained in
23 light of Amazon’s stated restrictions on obtaining information about an account.³

24 **III. THE COURT SHOULD ISSUE THE REQUESTED RELIEF**

25 **A. The Standard for Issuance of a TRO or Preliminary Injunction**

26 The general purpose of a preliminary injunction or TRO “is the preservation of the status
27 quo until a final determination of the action on the merits.” *Continental Baking Co. v. Katz*, 68
28 Cal. 2d 512, 528 (1968). The “status quo” is “the last actual, peaceable status which precedent

³ Typically, to begin a password re-set process, an individual would need to call AWS and confirm he is the root account holder, with his identification being verified with several items of personal information, such as the phone number on file for the account, the last four digits of the credit card on file, the exact amount of the last bill, and the account holder’s address. Jimenez-Maggiore Decl. ¶10.

1 the pending controversy.” *Voorhies v. Greene*, 139 Cal. App. 3d 989, 995 (1983); *14859*
2 *Moorpark Homeowner’s Assn. v. VRT Corp.*, 63 Cal. App. 4th 1396 (1998).

3 Two factors are evaluated when considering a request for injunctive relief – the likelihood
4 of the moving party’s success on the merits and the necessity of the relief to prevent “great or
5 irreparable injury.” *Smith v. Adventist Health Sys./W.*, 182 Cal. App. 4th 729, 749 (2010). “[A]
6 trial court’s decision to grant a preliminary injunction [or TRO] “must be guided by a ‘mix’ of the
7 potential-merit and interim-harm factors.” *Law Sch. Admission Council, Inc. v. State of Cal.*, 222
8 Cal. App. 4th 1265, 1299 (2014). The greater the showing of one of the factors, the lower
9 showing required of the other factor. *Id.* Potential harm to the public interest and third parties is
10 an integral focus of a court’s analysis in deciding whether or not to grant injunctive relief. *Cohen*
11 *v. Bd. Of Supervisors*, 40 Cal. 3d 277, 286 (1985). “It is well established that when injunctive
12 relief is sought, consideration of the public policy is not only permissible but mandatory.”
13 *O’Connell v. Super. Ct.*, 141 Cal. App. 4th 1452, 1471 (2006).

14 The Court can issue an injunction at any time to allow it to effectuate appropriate relief.
15 Cal. Civ. Proc. Code § 526(a)(3).

16 **B. A TRO Preventing Plaintiff From Exercising Administrative Control of the**
17 **EDC or Accessing the EDC As a Root User Is Necessary to Prevent Irreparable**
Harm – The Integrity of the ADCS Clinical Trial Data Is in Potential Jeopardy

18 Here, the status quo agreed to and ordered is maintenance of the EDC by the Aisen team.
19 And this status quo is in accord with the interests of the public in maintaining the viability and
20 integrity of clinical trial data. But, Plaintiff has upended that status quo (and, indeed, may have
21 upended it *before* it even sought its provisional relief). *As such, a TRO is necessary (a) to enjoin*
22 *Plaintiff from accessing the EDC using the root user credentials to prevent inadvertent harm to*
23 *clinical trial data and (b) to enjoin Plaintiff from exercising the root user controls to block the*
24 *Aisen team from administering and maintaining the database.* The TRO is justified on the
25 grounds that: (a) Plaintiff’s use of the root user poses a serious risk of destroying the whole system;
26 (b) Plaintiff does not know how to properly administer the system so as to have such super
27 capabilities; and (c) Plaintiff’s conduct is in violation of the TRO already in place. An OSC should
28 issue thereafter to show why the TRO should not be transformed into a preliminary injunction.

1 **1. Plaintiff Should Be Enjoined from Entering the EDC As a Root User**
2 **Given the High Risk Such Use Entails**

3 Plaintiff's apparent use of the root user information to access the EDC undermines the
4 security protocols in place to protect the integrity of the ADCS clinical trial data.

5 First, for an unknown reason, the token level of the multi-factor authorization has been
6 disabled, thereby increasing the likelihood and ease of hacking and unlawful third party access to
7 the system. Kunkel Decl. ¶17. AWS guidelines recommend use of a multi-factor authentication
8 process. *Id.*, Ex. E. Additionally, such disabling could hurt the usability of the data due to a failure
9 to adhere to FDA record-keeping obligations. *See, e.g.*, 21 C.F.R. § 11.10.

10 Second, because of the tremendous control over the system a root user has, it is *not* a best
11 practice to use it to access the EDC; a root user can accidentally delete study data and change vital
12 security protocols, as there are no boundaries or limitations to what a root user can do. Kunkell
13 Decl. ¶6; Jimenez-Maggiore Decl. ¶11. Thus, AWS guidelines suggest root credentials *not* be used
14 for management of production levels of a database. Kunkell Decl. ¶7. The Aisen team uses a lower
15 level administrator access that is in accordance with system best practices, adheres to FDA
16 regulatory requirements for electronic record-keeping, and aligns with the standard operating
17 procedures issued by sponsors for the clinical trials. Jimenez-Maggiore Decl. ¶11.⁴

18 Despite the unsafe practice of using the root account, Plaintiff has used the root account to
19 access the EDC 22 times between July 3 and July 10. Kunkel Decl. ¶13. This root user access has
20 emanated from *multiple* IP addresses, suggesting multiple root users. Such a level of root use, and
21 potentially by multiple users, is astronomically higher than was seen prior to July 2, 2015 (Kunkel
22 Decl. ¶15) and breaches clinical trial compliance protocols. Plaintiff's ongoing use of the root user
23 account creates a major threat of irreparable harm to the future of Alzheimer's research.

24 **2. Plaintiff Should Be Enjoined from Blocking the Aisen Team's Ability to**
25 **Administer and Monitor the System Because the Aisen Team is the Only**
26 **One Presently Capable of Properly Maintaining the System**

27 Plaintiff should also be enjoined from using the root user to block the Aisen team's

28 ⁴ A root is an anonymous account and thus can assume the identity of other accounts within AWS. Because of this, its use for routine activities would violate FDA requirements, such as the obligation for electronic records to have audit trails. 21 C.F.R. §11.10(e).

1 continued maintenance and administration of the EDC. With root access, Plaintiff can block the
2 Aisen team from EDC at whim. If Plaintiff takes such action, and the Aisen team cannot monitor
3 and manage the EDC, the data will be in jeopardy. This is because Plaintiff does not have the
4 personnel familiar with the EDC to maintain the scientific integrity of the data in accordance with
5 regulatory protocols and the clinical trials' applicable procedures. Jimenez-Maggiora Decl. ¶15.

6 The EDC is a unique software created by the Informatics Core of the Aisen team; this entire
7 team has left UCSD to join USC. Aisen Decl. ¶6; Jimenez-Maggiora Decl. ¶15. Federal
8 regulations require a heightened level of quality control and maintenance of specific protocols for
9 using the EDC. If there is interruption to the EDC that impacts its quality, the viability of all active
10 clinical trials is at risk. Jimenez-Maggiora Decl. ¶14. To date, Plaintiff has been unable to identify
11 a single person at UCSD with *current knowledge of EDC* and how to administer it and it has
12 admitted in multiple communications that it lacks the requisite knowledge of the database. It is for
13 this reason that researchers and sponsors expressed vocal support for the continued handling of
14 EDC by the Aisen team. *See* Decl. of Paul Aisen in Opp. to July 6 Ex Parte, ROA 24, Ex. A
15 (“UCSD must allow USC personnel to continue to work on the A4 study with full access and
16 control of the [] database.”), Ex B (“We believe any near term action to remove administrative
17 control from [the Aisen team] could jeopardize patient safety, study quality and otherwise
18 negatively impact our ability to fulfill our Sponsor obligations”). These concerns are now amplified
19 in light of Plaintiff’s apparent reckless use of the root user to access the database. The inexperience
20 of Plaintiff with the EDC also is reflected in UCSD’s recent request to USC employees to assist
21 with an issue related to the randomization system for one of the ADCS trials (for sponsor Toyama),
22 a task requiring the specific expertise of informatics personnel with knowledge of EDC. Jimenez-
23 Maggiora Decl. ¶16.

24 **3. Plaintiff Is In Disregard of the Purpose and Spirit of the Original TRO**

25 On July 6, *Plaintiff* moved this Court for a TRO against Defendants asking the Court to
26 enjoin Defendants from making any changes or alterations to the data and EDC and seeking a OSC
27 for a preliminary injunction to (a) enjoin Defendants from exercising dominion, custody and control
28 over the EDC and (b) directing Defendants to restore to Plaintiff data, passwords and the like for

1 the EDC in their possession. Defendants quickly stipulated to the TRO to protect the data, agreeing
2 to (a) refrain from making any changes to the data that would impact restoration of EDC to Plaintiff
3 and (b) recording any changes or alterations to the system. Stip. TRO, ROA 17.

4 The hindsight irony of Plaintiff's request is confounding. But more importantly, repeatedly
5 accessing the EDC using the root account is violative of the spirit and tenor of the TRO. The TRO
6 was intended to *maintain the status quo* and keep the Aisen team, those with the requisite
7 knowledge, in administrative control of the EDC pending the Court's adjudication of future matters.
8 But the status quo has been abruptly violated with the root user access emanating from UCSD. The
9 root user can make any changes to the EDC that it wants and can delete all records and data of the
10 clinical trials. This is the antithesis of preserving the status quo.⁵ To the contrary, Defendant's
11 requested TRO adheres to the intent of the July 6 stipulated TRO – to keep the administration of the
12 EDC in the hands of the Aisen team until the Court preliminary injunction is ruled upon.

13 **C. The Court Should Continue the Preliminary Injunction Hearing Pending**
14 **Examination of the Issue of How Plaintiff Obtained Access as a Root User**
and What It Did With Such Access

15 The Court should continue the hearing on Plaintiff's motion for preliminary injunction so
16 that an evidentiary presentation can be made on (a) how Plaintiff obtained credentials as a root
17 user and (b) how Plaintiff has used the root user with respect to the EDC. These issues are
18 critical to the preliminary injunction analysis. The Court has the authority to order such relief.
19 Cal. Civ. Proc. Code § 527(d)(4).

20 First, as discussed above, Plaintiff's seemingly reckless use of root credentials (and the
21 oblique manner in which such credentials were obtained) go to the public interest and whether
22 Plaintiff has the requisite capability and knowledge to manage the EDC system.

23 Second, misleading statements made in support of a request for preliminary injunction are
24 grounds to deny such relief. *See, e.g. London v. Marco*, 103 Cal. App. 2d 450, 453 (1951).⁶ This

25 ⁵ A court has the inherent and statutory authority to modify a TRO or preliminary injunction. *See*
Balboa Island Vill. Inn, Inc. v. Lemen, 40 Cal. 4th 1141, 1161 (2007).

26 ⁶ *See also Computer Prepared Accounts, Inc. v. Katz*, 235 Cal.App.3d 428, 432, 437 (1991);
27 *Coastal Corp. v. Tex. E. Corp.*, 869 F.2d 817, 818 (5th Cir. 1989) (“An injunction procured by
28 material misrepresentation may not be sustained.”); *Qad, Inc. v. ALN Assoc., Inc.*, 974 F.2d 834,
837 (7th Cir. 1992) (affirming dissolution of injunction where the trial court “relied on Pam
Lopker's representations in granting the injunction, and that, in retrospect, she had unquestionably

1 is based on the maxim that an injunction is equitable, and a party seeking equity cannot have
2 unclean hands. *Kendall-Jackson Winery, Ltd. v. Superior Court*, 76 Cal. App. 4th 970, 978-79
3 (1999). And there can be no doubt Plaintiff’s statements to the Court and Defendants regarding
4 its “limited access” to the EDC have been misleading. Plaintiff accessed the root account on July
5 2, 2015 and has had been the superuser of EDC since. All the while, Plaintiff has painted a vastly
6 different picture. The contrasts are startling:

7 • On the day Plaintiff filed its Complaint, the EDC account was being accessed from
8 multiple IP addresses on the UCSD campus via the root account.

9 • When Plaintiff filed its request for a TRO on July 6 on the grounds that it had only
10 “limited access” to EDC, it appears Plaintiff had superuser control of the entire system.

11 • When Dr. Ohno-Machado submitted a declaration on July 6 stating Defendants’ “exercise
12 of dominion and control” interfered with Plaintiff’s “ability to administer the ADCS data” in nine
13 different ways (Ohno-Machado Decl. ¶18), Plaintiff had unfettered ability to control the system.

14 • When Plaintiff appeared at the OSC hearing on July 7 and represented to the Court that a
15 preliminary injunction was necessary to prevent Defendants’ unauthorized access of the system,
16 Plaintiff could have blocked such access itself via its control of the root account.

17 The evidence of Plaintiff’s conduct versus the statements made to the Court need to be
18 explained. The Court should continue the preliminary injunction hearing so a complete
19 evidentiary picture can be presented about the nature and extent of Plaintiff’s ability to access and
20 administer the EDC, and the validity of the statements it has made to the Court regarding the same.

21 **D. Defendants Should Be Granted Expedited Discovery to Examine Plaintiff**
22 **About How It Obtained Root Access and What It Did With Such Access**

23 There remains much unknown about *how* Plaintiff obtained access to the root account,
24 especially when it is acknowledged that the AWS account was in the name of Dr. Aisen and he was
25 the individual paying for the account until July 2. Compl. ¶¶ 36, 39; Aisen Decl. ¶9. There also
26 remains much unknown about *what* Plaintiff has done with the EDC with its root user access. In
27 order to present a clear evidentiary picture to the Court and to understand the full scope of

28 been less-than-candid in discussing MFG/PRO’s originality.”).

1 Plaintiff's apparent manipulation of AWS and the EDC, Defendants request expedited discovery to
2 assess these issues. Such discovery is necessary to (1) determine the full extent of Plaintiff's access
3 of EDC as a root user; (2) determine what remedial steps need to be taken to ensure the continued
4 security and viability of the ADCS data; (3) ensure that Dr. Aisen can continue to comply with his
5 regulatory obligations as a clinical investigator of trials; and (4) prevent Plaintiff from further
6 accessing the EDC using the highly potent root account. The discovery Defendants seek is
7 narrowly tailored to information relevant to the Court's adjudication of the above-requested relief.
8 Specifically, Defendants request: (a) the deposition of Lucila Ohno-Machado; (b) the deposition of
9 John Denune, UCSD's IT security specialist; (c) Plaintiff's PMK as relates to its root access and use
10 of the EDC; and (d) a PMK of AWS related to Account No. 675713428646 [the EDC]. Defendants
11 also request the Court order Plaintiff to produce all documents related to (i) its communications
12 with AWS related to Account No. 675713428646 [the EDC] and (ii) Plaintiff's accessing of EDC
13 as a root user. Defendant also will seek documents related to the above.

14 Defendants' request is authorized by Cal. Code Civ. P. §§ 2025.270(d), 2031.020(d), and
15 2031.030(c)(2), which allow for expedited discovery for good cause. Courts frequently grant such
16 discovery when it is required to show the other side's wrongdoing in advance of an OSC hearing or
17 when a preliminary injunction is being considered. *See Am. Credit Indemnity Co. v. Sacks*, 213 Cal.
18 App. 3d 622, 627 (1989); *Whyte v. Schlage Lock Co.*, 101 Cal. App. 4th 1443, 1449 (2002).⁷


19 **IV. CONCLUSION**

20 For the foregoing reasons, Defendants' requested relief should be granted in its entirety.

21 DATED: July 13, 2015

PAUL HASTINGS LLP

22
23
24 By:


25 _____
GLENN D. DASSOFF
Attorneys for Defendants

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27 ⁷ To be clear, Defendant seeks this discovery *in addition* to the discovery requested in Defendants'
28 concurrently filed Ex Parte Application for Expedited Discovery. The discovery in the two separate
requests touch on related, but distinct, issues for consideration at the preliminary injunction hearing.