SCLIMENTI as a rightful inventor. STANFORD has further failed to pay PLAINTIFF royalties as provided by written contract between STANFORD and PLAINTIFF. Defendant MICHELE CALOS and STANFORD have intentionally misrepresented facts to PLAINTIFF'S detriment and has violated PLAINTIFF'S copyright. CALOS has also intentionally interfered with the contract between PLAINTIFF and STANFORD, and has been unjustly enriched by her unlawful conduct. STANFORD approved of CALOS'S conduct and continued to prosecute patents that it knew were not solely invented by CALOS. CALOS also intentionally misrepresented facts to the United States Patent Office ("USPTO") relying exclusively on the work of PLAINTIFF, all to the detriment of PLAINTIFF. STANFORD and CALOS have also disparaged, belittled and impugned PLAINTIFF and his work product to further their efforts to misappropriate PLAINTIFF'S work. Accordingly, PLAINTIFF alleges and complains of Defendants STANFORD and CALOS as follows:

## I. PARTIES

- 1. PLAINTIFF is an individual residing in San Diego County, California.
- 2. Defendant STANFORD is a corporation organized and existing under the laws of the State of California and has a principal place of business at Stanford University, Bldg. 10 Main Quad, Stanford, CA 94305. The designated agent for service of process for STANFORD is Debra L. Zumwalt, Stanford Univ Bldg. 170 3rd Floor Main Quad, Stanford, CA 94305.
- 3. On information and belief, Defendant CALOS is an individual residing in San Mateo County, California.

## II. JURISDICTION AND VENUE

- 4. This Court has personal jurisdiction over Defendant STANFORD under Fed. R. Civ. P. 4(k)(1)(A) and California's long-arm statute, Cal. Civ. Proc. Code § 410.10, as Defendant STANFORD is a California corporation, and has committed the complained-of acts in California, thereby causing damage to PLAINTIFF in this judicial district.
  - 5. This Court has personal jurisdiction over Defendant CALOS under Fed. R. Civ. P.

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27 28 4(k)(1)(A) and California's long-arm statute, Cal. Civ. Proc. Code § 410.10, as Defendant CALOS is a California resident.

- 6. This Court has subject matter jurisdiction over copyright infringement pursuant to the copyright laws of the United States, 17 U.S.C. §§ 101 et seq., and pursuant to 28 U.S.C. § 1331 and 28 U.S.C. §1338(b).
  - 7. Venue is proper in this district under 28 U.S.C. § 1391.

#### III. **BACKGROUND FACTS**

## a. DEFENDANTS' Initial Filings and Publications Confirm That PLAINTIFF Is An Inventor

- 8. PLAINTIFF began studying at STANFORD in September 1996 as a Research Associate, ultimately obtaining his doctorate degree from STANFORD in 2002. While obtaining his degree, he invented, designed and performed experiments and other scientifically valuable intellectual property in a laboratory ran by CALOS, who was employed by STANFORD.
- 9. PLAINTIFF'S graduate work at STANFORD was directed towards genetics. including creating and screening altered recombinases for use in biotechnology such as gene therapy. An altered recombinase is an enzyme that has been changed from its natural form that facilitates recombination between DNA recognition sequences. This technology could allow scientists to insert genes into a cell at a desired location of the genome, thus allowing the gene to be expressed. As is obvious to those in this art, this type of genomic modification may have a host of significant and useful purposes.
- 10. On or about December 23, 1999, CALOS filed an "Invention and Technology Disclosure" disclosing some of the material that was ultimately encompassed by the '925 and '426 Patents. Interestingly, in this disclosure CALOS explicitly attributes conception to PLAINTIFF and explicitly attributes reduction to practice to PLAINTIFF.
- 11. On February 12, 2001, PLAINTIFF and CALOS filed a patent application naming them both as joint inventors. (See U.S. Patent Application 09/788,297 ("the '297 Application"), published as U.S. 2002/0094516 the cover page of which is attached as Exhibit 1 hereto). Both PLAINTIFF and CALOS were named in the '297 Application because they both conceived of the invention claimed.

- 12. On August 23, 2001, STANFORD filed an International Patent Application under the Patent Cooperation Treaty naming both CALOS and PLAINTIFF as inventors. (*See* WO 01/61049, the cover page of which is attached as Exhibit 2).
- 13. Later that month on August 29, 2001, PLAINTIFF is credited as the first-named author on a peer-reviewed paper that details the invention claimed in the above-referenced patent applications. (See "Directed Evolution Of A Recombinase For Improved Genomic Integration At A Native Human Sequence," C.R. Sclimenti, B. Thyagarajan, and M.P. Calos, Nucleic Acid Research, 200, Vol. 29, No. 24, pgs 5044-51 (the "NAR paper"), attached hereto as Exhibit 3).

## b. STANFORD and CALOS Explicitly Confirmed that PLAINTIFF Conceived of Critical Aspects of the '925 and '426 Patents.

- 14. In about June 2004, DEFENDANTS commissioned an opinion of counsel ("the Opinion") that was sent to the "Stanford Office of Technology Licensing" that confirmed several issues pertinent to inventorship:
  - a. Confirmed that PLAINTIFF was critical to the success of the invention, stating "Dr. Sclimenti designed the particular protocol for producing altered  $\Phi$ C31 integrases and screening the resultant mutants for integration efficiency with particular target sites. ... Dr. Sclimenti cloned and sequenced the specific mutant  $\Phi$ C31 integrases reported in the application."
  - b. Confirmed that "Dr. Sclimenti did have a role in conception of the mutant generation and screening protocols...."
  - c. Confirmed that "if claims were presented in a continuation application to the specifically disclosed mutant production and screening assay and/or the specific mutant integrases disclosed in the application, Dr. Sclimenti may well have made an invention contribution to invention of these types of claims [] and therefore may be an inventor of such claims." (A copy of the Opinion is attached as Exhibit 4).
- 15. The Opinion argued that CALOS solely conceived of the invention at least by June 10, 1998. Yet this position is directly contradicted by the December 23, 1999 "Invention

and Technology Disclosure" (attached as an exhibit to the Opinion, but marked confidential) in which CALOS states that conception occurred in spring/summer 1999 "with Chris Sclimenti." The Opinion does not reconcile these critical factual discrepancies.

- 16. And finally, the Opinion argued that "Dr. Calos solely conceived of the general idea of using ΦC31 integrase mutants for site-specific integration." But the Opinion provides no support whatsoever for CALOS'S conception of each and every element of the allowed claims. In fact the Opinion has only a one-page document to support conception. This must be contrasted with thirty-five (35) notebooks authored by PLAINTIFF totaling over three thousand five hundred (3,500) pages much of which is directed to the inventions embodied by the '925 and '426 Patents. At best, CALOS can argue that she had a general research plan, but this is not enough "the policy behind the patent laws [] is to 'promote disclosures of inventions, not research plans." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206 (Fed. Cir. 1991), *citing Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993).
- 17. And as recently as September 2007, CALOS once again confirmed in a voicemail message that PLAINTIFF was responsible for the mutagenesis (i.e., creating the altered recombinases) and the screening of those recombinases. In that message, CALOS stated the following:

"We are not pursuing anything that's your intellectual property, that's the screen that you developed or the mutants, those are the things you're involved with, we're not pursuing those." (Transcription attached as Exhibit 5).

## c. Defendants Have Misappropriated PLAINTIFF'S Work

## i. Relevant Prosecution History of the '925 Patent

- 18. On February 12, 2001, DEFENDANTS filed U.S. Patent Application 09/788,297 naming both CALOS and PLAINTIFF as inventors. This application ultimately matured into the '925 Patent.
- 19. On July 1, 2002, the United States Patent Office ("USPTO") issued a restriction requirement forcing STANFORD to select a particular species. One of the species group was VIII-X:
  - "VIII-X. Claims 19-22, drawn to a method of site-specifically integrating a polynucleotide sequence in a genome of a cell wherein the cell comprises an

<sup>1</sup> Each of these mutants was admittedly conceived, created and screened by PLAINTIFF.

integrase; there is no disclosure of what amino acids are essential to DNA recognition and/or what amino acids are in the catalytic site of the integrase, or the types of changes that would expect to alter DNA recognition specifically or alter catalytic activity. Indeed, there is no disclosure of common structural elements of integrases in general (including integrases such as TP901-1 and R4) with regard to their functions of DNA recognition and binding, and catalytic activity. Therefore, the specification does not describe the claimed mutant, unidirectional site-specific integrases in such full, clear, concise and exact terms so as to indicate that Applicant has possession of these mutant integrases at the time of filing the present application. Thus, the written description requirement has not been satisfied."

23. In its June 11, 2003 response, DEFENDANTS argued that the invention was

indeed enabled and sufficiently described because all one had to do to practice the invention was

to perform the mutagenesis and selection methods disclosed in the specification:

"One of skill in the art would merely have to follow the in *vitro* mutagenesis/selection methods provided in the specification to produce an altered integrase and use it in the claimed methods: there is no requirement that the structure of the altered integrase be known. ... As such, one of skill in the art merely has to identify a bacteriophage integrase (e.g. the integrases from  $\Phi$ C31 R4 and TP901-1, or another phage integrase that is known in the art), alter it using the selection methods provided in the specification, and use it to practice the claims."

24. The USPTO issued a final Office Action on August 26, 2003, maintaining the same §112 rejection and further stating:

"The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably covey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

25. On November 14, 2003, DEFENDANTS responded by amending the claims to include specific limitations on the structure of the integrase and its biological activity: "wherein said integrase is at least 95% identical to SEQ ID NO: 21 and has integrase activity." They continued:

"One of skill in the art merely has to follow the in vitro mutagenesis/ selection methods provided in the specification to produce an altered integrase and use it in the claimed methods."

26. Based on the amendment that brought specific structure and biological activity into the claims, the USPTO allowed the application.

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not needed to practice the claimed method. Rather, merely following the mutagenesis/selection methods was enough for someone to practice the invention, and therefore the inventor was in possession of the invention. Nevertheless, DEFENDANTS did amend the claims by including a

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description on March 28, 2006, stating: "The specification does

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"The specification does not provide guidance for using polypeptides related to (i.e., 80%-95% identity) but not identical to SEQ ID NO: 21 which do not have the single specific disclosed activity."

The USPTO was still not convinced, and rejected the claims for lack of written

- 33. DEFENDANTS then amended the claims to also include "integrase activity", and stated that the claims are directed "only [to] those integrases that have the specific structure and correlating function claimed." With these specific structural and functional limitations, the USPTO allowed the claims.
- 34. On November 28, 2006, the '426 Patent was granted by the USPTO naming as sole inventor CALOS. The sole assignee for this patent is STANFORD.

# d. PLAINTIFF is an Inventor as Confirmed by DEFENDANTS' Representations to the USPTO During Prosecution and to PLAINTIFF in the Opinion and Voicemail.

- 35. During the prosecution history, the USPTO examiner twice raised the written description rejection under §112 that "[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably covey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The primary purpose of the "written description" requirement is to confirm there has been conception i.e., "to clearly convey the information that an applicant has invented (i.e., show possession of) the subject matter which is claimed." *In re Barker*, 559 F.2d 588 (CCPA 1977).
- 36. From DEFENDANTS' own representation, it is clear that DEFENDANTS relied on the mutagenesis/selection methods to support her claim that she was in possession of the invention, and therefore the §112 rejection could not stand. This is an admission that the mutagenesis (i.e., mutant production) and selection (i.e., screening) were integral to conceiving of the invention as claimed. Indeed, "[t]he conception analysis necessarily turns on the inventor's

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ability to describe his invention with particularity. Until he can do so, he cannot prove possession of the complete mental picture of the invention." Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1228 (Fed. Cir. 1994).

- 37. The question then becomes, who conceived of the mutagenesis and/or the selection methods disclosed in the application. That question was unequivocally answered by DEFENDANTS themselves in the Opinion:
  - "With respect to the nature of Dr. Sclimenti's involvement, it is Dr. Calos' a. recollection that Dr. Sclimenti designed the particular protocol for producing altered  $\Phi$ C31 integrases and screening the resultant mutants for integration efficiency with particular target sites."
  - b. "Dr. Sclimenti did have a role in conception of the mutant generation and screening protocol as described in the application."
- 38. This was also answered by CALOS in the voicemail: "your intellectual property, that's the screen that you developed or the mutants, those are the things you're involved with...."
- 39. Not only is conception of the mutagenesis and selection methods by PLAINTIFF conceded, but PLAINTIFF also has thirty-five (35) notebooks, totaling approximately three thousand five hundred (3,500) pages that provide contemporaneous corroboration. CALOS'S showing of conception pales in comparison with only a couple of pages, which do not disclose any mutagenesis or selection methods for the  $\Phi$ C31 integrases.
- 40. Also, CALOS cannot show sole conception of each and every element of the claims, which she must to prevail on inventorship. It is black-letter law that a party must show possession of every feature recited in the claim, and that every limitation of the claim must have been known to the inventor at the time of the alleged conception. Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985). Specifically, all of the '925 and '426 claims require that the altered integrase be at least 95% identical (80% for the '426 Patent) to SEQ ID NO:21 and have integrase activity. DEFENDANTS added these limitations to place the claims in condition for allowance; thus these limitations are critical to patentability. Nothing in the couple of pages provided by CALOS in the Opinion shows any discussion, or appreciation, of these limitations.

41. The case of *Hitzeman v. Rutter*, 243 F.3d 1345 (Fed. Cir. 2001) is directly on point. In *Hitzeman*, the claimed invention required that yeast express a certain type of protein with a certain structure – i.e., particles of 22nm. The court stated:

"Hitzeman specifically claimed the result of a biological process (i.e., expression by the yeast [] followed by assembly of [] into particles) with no more than a hope, or wish, that yeast would perform this assembly process that had never before been achieved in yeast. Such bare hope is insufficient for conception." *Id.* at 1357; *citing Amgen*, 927 F.2d at 1206.

- 42. The court did not find conception because Hitzeman lacked "a definite and permanent understanding that yeast ...would not only express the S-protein, but would also assemble it into particles." *Id*.
- 43. For precisely the same reason, CALOS cannot show conception here. The claims require a particular structure and biological process i.e., 95% identical (or 80% in the '426 Patent) and integrase activity. The documentation provided by CALOS makes no mention of either of these two limitations; therefore, it is clear that she did not and could not have a "definite and permanent understanding." In fact, the Opinion argues that CALOS had a "general idea of using an altered ΦC31 integrase for genomic site-specific integration." But "the policy behind the patent laws [] is to 'promote disclosures of inventions, not research plans." *Id.*; *citing Fiers v. Revel*, 984 F.2d 1164, 1169 (Fed. Cir. 1993).
- 44. This is in stark contrast with PLAINTIFF'S lab books, which have ample support for mutants with such features, and the screening methods that determine the integrase activity. Indeed DEFENDANTS have already conceded this during prosecution, confirming that PLAINTIFF did in fact conceive of the invention.
- 45. Finally, because the claims of the '925 and '426 Patents claim a chemical structure of DNA, either as part of a method claim or as a kit claim, then at a minimum, the sequence itself and a method of obtaining it are necessary for conception to occur. *Amgen*, 927 F.2d at 1206:

"It is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. ... We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated."

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- 46. In fact, the requirement of actually having the structure for conception was confirmed by the USPTO during the prosecution of the '426 Patent.
- 47. Here the DNA sequences and methods to obtain them were admittedly developed and conceived by PLAINTIFF. And DEFENDANTS' arguments in prosecution further support that the "mutagenesis/selection methods" were necessary to prove possession of the complete claimed invention.
- 48. From the start of prosecution, DEFENDANTS elected claims that read on SEQ ID NO. 22, which was admittedly constructed and selected by PLAINTIFF'S novel methods. Then later in prosecution, PLAINTIFF'S mutagenesis and selection methods were the key to overcome the §112 rejection. And DEFENDANTS amended their claims to include specific reference to sequences with a particular structure and a particular integrase activity, and the only ones disclosed – indeed the only ones that have any corroborating evidence – were constructed and selected by PLAINTIFF.
- 49. It is absolutely clear that without PLAINTIFF'S contributions, DEFENDANTS could not have obtained either the '925 or '426 Patents. Therefore, it is completely incredulous DEFENDANTS continue to assert, until recently, that PLAINTIFF was not an inventor.
- 50. And it is completely reprehensible that DEFENDANTS continue to misappropriate PLAINTIFF'S work in the pending application related to the '925 and '426 Patents, and in the unrelated U.S. Pat. App. 2006/0128020 (11/198,885), U.S. Pat. App. 2005/0208021 (11/003,941), International application PCT/US03/17702 published as WO/2005/017170, and United States Provisional Applications 60/385,954; 60/385,933; 60/386,325; 60/385,934; 60/385,929; 60/386,597; 60/385,944; and 60/416,989 as described in detail below.
- PLAINTIFF Is and Always has been an Inventor as Confirmed by the Binding ADR Regarding the Inventorship of the '925 and '426 Patents.
- 51. Despite the clear admissions from DEFENDANTS and the strong documentary evidence detailed above, DEFENDANTS refused to voluntarily amend the inventorship of the

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- '925 and '426 Patents. Instead, DEFENDANTS would only agree to a neutral evaluation of the inventorship dispute of the '925 and '426 Patents to ADR.
  - On March 31, 2009 the ADR neutral unequivocally confirmed that PLAINTIFF 52. was indeed a co-inventor on the '925 Patent and the '426 Patent. Only then would DEFENDANTS concede the inventorship of PLAINTIFF vis-à-vis the '925 and '426 Patents. This concession came only after the ADR decision and despite previously admitting repeatedly that "Dr. Sclimenti designed the particular protocol for producing altered ΦC31 integrases and screening the resultant mutants for integration efficiency with particular target sites. ... Dr. Sclimenti cloned and sequenced the specific mutant  $\Phi$ C31 integrases reported in the application." And also confirming that "Dr. Sclimenti did have a role in conception of the mutant generation and screening protocols..." (Exhibit 4).
  - 53. Nevertheless, the parties have petitioned the USPTO for corrected inventorship of the '925 and '426 Patents. Thus, the original complaint in this matter has been amended to delete the causes of action under 35 U.S.C. § 256 for correction of inventorship.

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## **DEFENDANTS Removed PLAINTIFF to Assure that CALOS Received More Money** from Licensing Revenue.

- 18 54. PLAINTIFF entered into a contract during his tenure at STANFORD.
  - As part of the contract between PLAINTIFF and STANFORD, STANFORD was 55. obligated to pay a portion of the money and stock derived from an invention conceived of by PLAINTIFF. To date, STANFORD has not provided any money or stock to PLAINTIFF.
  - 56. Specifically, as per STANFORD'S licensing protocols, the inventors would be entitled to about 28.3% of the license fee. That fee will be divided among any and all inventors.
  - 57. Simultaneous to the time that DEFENDANTS improperly removed PLAINTIFF from the inventorship of the patents, DEFENDANTS entered into a license agreement with Poetic Genetics, Inc. At the time, CALOS was an officer of Poetic Genetics, Inc.
  - 58. Because PLAINTIFF was removed improperly from the invention, the entire amount due to the inventors would presumably have been given to the sole named inventor

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things you're involved with, we're not pursuing those." (Exhibit

- 63. Yet on March 28, 2008, DEFENDANTS once again amended the claims in pending U.S. Patent Application 11/582,836 to include *the specific* altered recombinase admittedly invented and developed by PLAINTIFF:
  - "23. A nucleic acid encoding an altered unidirectional site-specific bacteriophage integrase that is at least 90% identical to SEQ ID NO:23 and has integrase activity.

wherein said altered unidirectional site-specific bacteriophage integrase has improved recombination efficiency towards wild-type or pseudo attachment sites as compared to a corresponding wild-type unidirectional site-specific bacteriophage integrase."

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- Not surprisingly, DEFENDANTS made no effort to amend inventorship to include 64. PLAINTIFF or to contact PLAINTIFF to notify him that he was an inventor. CALOS remains as the sole inventor in this pending application.
- 65 DEFENDANTS' misappropriation of PLAINTIFF'S work is not limited to the '925 Patent family just discussed. Rather, this appears to be a pattern that includes stealing work and publishing it as their own in United States patent applications, and international patent applications:
  - U.S. App. 2006/0128020 (11/198,885) lists CALOS as a sole inventor, and the application is co-assigned to STANFORD. (Relevant pages attached as Exhibit 6). But paragraphs 666-684 include word-for-word verbatim the work solely conceived, performed and authored by Dr. Sclimenti as published in his Ph.D. dissertation entitled "Novel Approaches for Long" Term Gene Therapy." (Relevant pages of this dissertation are attached as Exhibit 7). Nowhere is PLAINTIFF given credit as an author or inventor. rather this work is advanced in the patent application as that of CALOS. Also the mutagenesis and selection methods in the '925 and '426 Patents (admittedly conceived by PLAINTIFF) were disclosed in the peerreviewed article in which PLAINTIFF is the first-named author – i.e., the NAR paper. U.S. published Pat. App. 2006/0128020 (11/198,885) at paragraph 629 states that "the following examples are put forth so as to provide those of ordinary skill in the art with a complete disclosure and description of how to make and use the present invention." The first example cited in this application (beginning at paragraph 631) describes the screening assay presented in the NAR paper, which was admittedly developed and implemented by PLAINTIFF. But CALOS remains as the sole inventor and no effort has been made to amend inventorship to include

PLAINTIFF or to contact PLAINTIFF to notify him that he is an inventor. Paragraphs 689-703 (i.e., Example 4) and 741-748 (i.e., Example 10) also represent the exclusive work products of PLAINTIFF. PLAINTIFF not only designed and performed the experiments described in those Examples but also wrote the Examples as they appear in the application. Yet CALOS advances this work as her own.

- b. U.S. Pat. App. 2005/0208021 (11/003,941) lists CALOS as a sole inventor, and the application is co-assigned to STANFORD. (Relevant pages attached as Exhibit 8). But paragraphs 625-644 include word-for-word verbatim the work solely conceived, performed and authored by Dr. Sclimenti as published in his Ph.D. dissertation entitled "Novel Approaches for Long Term Gene Therapy." (Compare paragraphs 625-644 of Exh. 8 to Exh. 7). Nowhere is PLAINTIFF given credit as an author or inventor, rather this work is advanced in the patent application as that of CALOS. Paragraphs 645-662 (i.e., Example 4) and 700-707 (i.e., Example 10) also represent the exclusive work products of PLAINTIFF. PLAINTIFF not only designed and performed the experiments described in those Examples but also wrote the Examples as they appear in the application. Yet CALOS advances this work as her own.
- c. International application PCT/US03/17702 published as WO/2005/017170 (relevant pages attached as Exhibit 9) lists CALOS as the sole inventor. But pages 167-173 include word-for-word verbatim the work solely conceived, performed and authored by Dr. Sclimenti as published in his Ph.D. dissertation entitled "Novel Approaches for Long Term Gene Therapy." (Compare pgs 167-173 of Exh. 9 to Exh. 7). Nowhere is PLAINTIFF given credit as an author or inventor, rather this work is advanced in the patent application as that of CALOS. Pages 173-175 (i.e., Example 4) and 186-188 (i.e., Example 10) also represent the exclusive

- work products of PLAINTIFF. PLAINTIFF not only designed and performed the experiments described in those Examples but also wrote the Examples as they appear in the application. Yet CALOS advances this work as her own.
- d. DEFENDANTS have also misappropriated PLAINTIFF'S work by copying verbatim PLAINTIFF'S copyrighted work in United States Provisional Applications 60/385,954; 60/385,933; 60/386,325; 60/385,934; 60/385,929; 60/386,597; 60/385,944; and 60/416,989. Nowhere is PLAINTIFF given credit as an author or inventor, rather these works are advanced in the patent applications as that of CALOS.
- 66. What is perhaps most disturbing is that CALOS was the Principal Adviser on the committee that approved PLAINTIFF'S dissertation. As such, CALOS knew that PLAINTFF solely conceived, designed and performed the work, and that he solely authored the portion of his dissertation that she extensively and faithfully copied in her patent applications.
- 66. The fraud and deceit of DEFENDANTS do not end with this despicable plagiarism and copyright violation. In U.S. Patent Application 11/003,941, DEFENDANTS submitted a declaration dated August 15, 2007 signed by CALOS under penalty of perjury in a response to an Office Action and once again in an Appeal Brief dated November 16, 2007. (A copy of the August 15, 2007 Declaration is attached as Exhibit 10). This declaration was critical to the argument that CALOS had previously conceived the invention before the effective date of the prior art in other words, without this declaration CALOS had no basis to claim priority to the invention and the patent application would fail. Turning to the declaration, CALOS unequivocally states:

"I conceived of a targeting vector having a vector attachment site and a mutant, unidirectional site-specific integrase or a nucleic acid encoding the same that has an improved recombination efficiency towards wild-type or pseudo attachment sites compared to a corresponding wild-type unidirectional site-specific bacteriophage integrase prior to November 21, 2000. The dates have been redacted from Exhibit A. All redacted dates are prior to November 21, 2000." Exhibit 10, ¶ 3.

68. Then to make matters even worse, CALOS appears to have submitted patently false information to obtain a patent. Specifically, CALOS declared on August 15, 2007 (submitted to the USPTO on August 17, 2007 and once again on November 16, 2007) that "all redacted dates are prior to November 21, 2000," but this is plainly false. Looking at the unredacted lab notebooks at Exhibit 11 which DEFENDANTS have had since their creation, it is clear as day that each and every date is significantly after November 21, 2000. This is not a trivial point; rather this is the entire purpose of the declaration – that is to antedate a reference that is dated November 21, 2000. This is simply another chapter in the long campaign of DEFENDANTS' attempts to steal the work product of PLAINTIFF.

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- 69. DEFENDANTS actually submitted this same declaration (modifying the date of invention to antedate various pieces of prior art) at least two other times during the prosecution of the '941 Patent application. Each time CALOS claimed to have invented the subject matter and used as her sole support the work of PLAINTIFF and his lab notebooks.
- 70. Not content with stealing PLAINTIFF'S work, DEFENDANTS also submitted several declarations to disparage, belittle and impugn the true contributions of PLAINTIFF. They did this with the knowledge that these statements were false, fraudulent and deceitful. Specifically, during the prosecution of the '941 Patent application CALOS on December 15, 2006 submitted a declaration to overcome a reference that listed PLAINTIFF as the lead author. CALOS states:

"I, as co-author of *Sclimenit et al.*, (2001), conceived of and reduced to practice the invention disclosed and claimed within this application. The remaining authors, Sclimenti and Thyagarajan, are not inventors of the claimed invention, but were named as co-authors due to technical contribution they provided. Sclimenti and Thyagarajan did not scontribute inventive input with respect to the

- invention disclosed and claimed in this application." (A copy of this declaration is attached at Exhibit 12).
- 71. This statement is knowingly false because PLAINTIFF was indeed a co-inventor of the methods and substances disclosed in *Sclimenti et al.* This is confirmed by the fact that on this same date (i.e., December 15, 2006) CALOS submitted a declaration wherein she states: "I conceived of a targeting vector having a vector attachment site and a mutant, unidirectional site-specific integrase or a nucleic acid encoding the same that has an improved recombination efficiency towards wild-type or pseudo attachment sites compared to a corresponding wild-type unidirectional site-specific bacteriophage integrase prior to February 6, 2002. The dates have been redacted from Exhibit A. All redacted dates are prior to February 6, 2002." Exhibit 13, ¶ 3.
- 72. CALOS'S sole support for conception and reduction to practice is exhibit A to her declaration, which consists of excerpts from laboratory notebooks. Again, as described above, the problem is that these notebooks, despite CALOS'S unequivocal declaration, were not her notebooks or even her work. This was PLAINTIFF'S work and PLAINTIFF'S lab notebooks, and DEFENDANTS knew it.
- 73. And recall that DEFENDANTS had confirmed that "Dr. Sclimenti designed the particular protocol for producing altered  $\Phi$ C31 integrases and screening the resultant mutants for integration efficiency with particular target sites. ... Dr. Sclimenti cloned and sequenced the specific mutant  $\Phi$ C31 integrases reported in the application." (*See* Exhibit 4). These specific  $\Phi$ C31 integrases are the same exact sequences disclosed in the *Sclimenti et al.* paper. So CALOS'S statement that "Sclimenti [ ] did not contribute inventive input with respect to the invention disclosed and claimed in this application" is plainly and admittedly false.
- 74. Clearly, DEFENDANTS knew that their statements disparaging, belittling and impugning PLAINTIFF'S work were fraudulent and false, intending to deprive PLAINTIFF of his work product and otherwise to cause him injury.

## IV. FIRST CAUSE OF ACTION

## (Intentional Misrepresentation)

75. PLAINTIFF incorporates each of the preceding paragraphs as though the same were set forth in full herein.

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PLAINTIFF has been damaged by STANFORD'S breach.

#### VI. **THIRD CAUSE OF ACTION**

## (Copyright Infringement)

- PLAINTIFF incorporates each of the preceding paragraphs as though the same 86. were set forth in full herein.
  - 87. PLAINTIFF has registered his dissertation with the U.S. Copyright Office (Reg.

- 88. DEFENDANTS had ready and easy access to PLAINTIFF'S registered works, as CALOS (an employee of STANFORD) was a thesis advisor for PLAINTIFF.
- 89. PLAINTIFF has identified multiple examples of DEFENDANTS' misappropriation and wholesale verbatim copying of PLAINTIFF'S registered work. *See* paragraphs 64(a) –(d) above. These infringing works have assisted DEFENDANTS' scheme to free-ride on PLAINTIFF'S work product.
- 90. PLAINTIFF is informed and believes, and based thereon alleges, that DEFENDANTS knowingly and willfully copied PLAINTIFF'S registered works for the specific purpose of infringing PLAINTIFF'S copyrights for DEFENDANTS' commercial gain.
- 91. DEFENDANTS then filed the copied work with the USPTO and caused the copied registered work to be published as their own.
- 92. DEFENDANTS' conduct infringes PLAINTIFF'S exclusive copyrights in its original creative works in direct violation of the Copyright Act of 1976, 17 U.S.C. § 101, et seq.
- 93. As a direct and proximate result of DEFENDANTS' wrongful acts alleged above, PLAINTIFF has been damaged, and DEFENDANTS have been unjustly enriched, in amounts to be determined at trial. Alternatively, PLAINTIFF may elect to seek statutory damages under 17 U.S.C. § 504(c).
- 94. As a direct and proximate result of DEFENDANTS' unlawful acts, PLAINTIFF has suffered, and continues to suffer, irreparable harm and injury. PLAINTIFF has no adequate remedy at law.
- 95. PLAINTIFF is informed and believes, and thereon alleges, that DEFENDANTS' copyright infringement will continue unless enjoined by this Court.

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## VII. FOURTH CAUSE OF ACTION

## (Intentional Interference With Contractual Relations)

- 96. PLAINTIFF incorporates each of the preceding paragraphs as though the same were set forth in full herein.
- 97. A contract existed between STANFORD and PLAINTIFF, and that contract obligated STANFORD to provide a portion of the licensing fee to PLAINTIFF.
- 98. CALOS knew of that contract and indeed was under the same contractual obligations with STANFORD.
- 99. CALOS intended to disrupt the performance of this contract, by claiming that she was the sole inventor.
- 100. CALOS'S conduct prevented performance of the contract, and indeed obtained the entire portion of the inventor licensing fee.
- 101. PLAINTIFF was harmed and CALOS'S conduct was a substantial factor in causing PLAINTIFF'S harm.

## VIII. FIFTH CAUSE OF ACTION

## (Inducing Breach of Contract)

- 102. PLAINTIFF incorporates each of the preceding paragraphs as though the same were set forth in full herein.
- 103. A contract existed between STANFORD and PLAINTIFF, and that contract obligated STANFORD to provide a portion of the licensing fee to PLAINTIFF.
- 104. CALOS knew of that contract and indeed was under the same contractual obligations with STANFORD.
- 105. CALOS intended to cause and induce STANFORD to breach this contract, by claiming that she was the sole inventor.
- 106. CALOS'S conduct caused STANFORD to breach this contract, and indeed obtained the entire portion of the inventor licensing fee.

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1	107. PLAINTIFF was harmed and CALOS'S conduct was a substantial factor in
2	causing PLAINTIFF'S harm.
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4	IX. SIXTH CAUSE OF ACTION
5	(Intentional Interference With Prospective Economic Relations)
6	108. PLAINTIFF incorporates each of the preceding paragraphs as though the same
7	were set forth in full herein.
8	109. An economic relationship existed between PLAINTIFF and STANFORD that
9	probably would have resulted in an economic benefit to PLAINTIFF, and that relationship
10	obligated STANFORD to provide a portion of the licensing fee to PLAINTIFF.
11	110. CALOS knew of the relationship, and indeed was under a similar relationship wit
12	STANFORD.
13	111. CALOS intended to disrupt that relationship by her misrepresentation including
14	her assertions that she was the sole inventor of the aforementioned patents and patent
15	applications, and that she was not pursuing protection on any specific recombinases
16	created/developed by PLAINTIFF.
17	112. The relationship between PLAINTIFF and STANFORD was disrupted.
18	113. PLAINTIFF was harmed and CALOS'S wrongful conduct was a substantial factor
19	in causing PLAINTIFF'S harm.
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21	X. <u>SEVENTH CAUSE OF ACTION</u>
22	(Negligent Interference With Prospective Economic Relations)
23	114. PLAINTIFF incorporates each of the preceding paragraphs as though the same
24	were set forth in full herein.
25	115. An economic relationship existed between PLAINTIFF and STANFORD that
26	probably would have resulted in a future economic benefit to PLAINTIFF, and that relationship
27	obligated STANFORD to provide a portion of the licensing fee to PLAINTIFF.

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## (Defamation Per Quod)

- 127. PLAINTIFF incorporates each of the preceding paragraphs as though the same were set forth in full herein.
  - 128. DEFENDANTS made statements to a third party other than PLAINTIFF;

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#### **ELEVENTH CAUSE OF ACTION** XIV.

## (Ratification – Vicarious Responsibility)

- 25 PLAINTIFF incorporates each of the preceding paragraphs as though the same 138. 26 were set forth in full herein.
  - 139. STANFORD is responsible for the harm caused by CALOS'S conduct.
  - CALOS intended to act on behalf of STANFORD in her capacity as an employee. 140.

competition and fraudulent business practices as defined in California Business and Professions

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from inventorship on these patents.

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defamation per se;

### 1 9. That PLAINTIFF be awarded actual and/or special damages for DEFENDANTS' 2 defamation per quod; 3 10. That DEFENDANTS be enjoined from further copyright infringement; 4 11. A finding that STANFORD approved of its employee's tortious and wrongful acts, and 5 that PLAINTIFF be awarded damages for STANFORD'S employee's tortious and 6 wrongful acts; 7 12. That PLAINTIFF be awarded damages for STANFORD'S negligence; 8 13. That DEFENDANTS disgorge all proceeds that have unjustly enriched them from her 9 illegal conduct; 10 14. That PLAINTIFF be awarded damages for DEFENDANTS' unfair competition in 11 violation of B&P Code § 17200; 12 15. That the Court order punitive damages for DEFENDANTS' conduct; 13 16. That the Court order a rescission of the contract with STANFORD; 14 17. That PLAINTIFF be awarded reasonable attorney fees under 17 U.S.C. § 505; 15 18. That PLAINTIFF be awarded pre-judgment and post-judgment interest and costs of this 16 action to PLAINTIFF against DEFENDANTS; and 19. 17 For such other and further relief as the Court deems just and proper. 18 19 DATED: June 11, 2009 Respectfully submitted, 20 THE LAW OFFICE OF MANUEL DE LA CERRA 21 22 By: /Manuel F. de la Cerra/ Manuel de la Cerra 23 Attorney for Plaintiff CHRISTOPHER R. SCLIMENTI 24 25 26 27 28

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