UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
Case No. 5:08-CV-119-H2

Cellectis SA, *Plaintiff,* *v.* Precision BioSciences, Inc., *Defendant.*	**SUPPLEMENTAL COMPLAINT**

Plaintiff Cellectis SA ("Cellectis") hereby alleges for its Supplemental Complaint against Defendant Precision BioSciences, Inc. ("Precision) as follows:

THE PARTIES

1. Plaintiff Cellectis is a corporation organized under the laws of France, and maintains its principal place of business at 102 Avenue Gaston Roussel, F-93235, Romainville Cedex, Paris, France.

2. Defendant Precision is a corporation organized under the laws of Delaware, and maintains its principal place of business at 104 T.W. Alexander Dr., Bldg. 7 Durham, NC 27713.

NATURE OF THE ACTION

3. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1, et seq., and seeking damages and injunctive relief under 35 U.S.C. §§ 281-285.

4. In addition, this is an action for unfair competition arising under the Federal Trademark Act, 15 U.S.C. §1051 *et seq.*, and for unfair competition and liber *per se* under N.C. Gen. Stat. § 75-1.1 and the common law.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of the patent infringement allegations of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a). With regard to the remaining allegations of this action directed to unfair competition and libel *per se*, this Court has jurisdiction over their subject matter 28 U.S.C. §§ 1331, 1332 and 1367(a).

6. This Court has general and specific personal jurisdiction over Precision based on the location of its principal place of business in North Carolina, and the fact that Precision has been and is committing in North Carolina both acts of infringement of Cellectis' patents and acts of unfair competition and libel *per se*.

7. Venue is proper in this judicial district based on 28 U.S.C. § 1400 (b) and/or 28 U.S.C. § 1391 (b) and (c).

BACKGROUND

The Patents In Suit

8. United States Patent No. 7,309,605 ("the '605 patent") was duly and legally issued by the United States Patent and Trademark Office ("the PTO") on December 18, 2007. A copy of the '605 patent is attached as Exhibit A.

9. United States Patent No. 6,610,545 ("the '545 patent") was duly and legally issued by the PTO on August 26, 2003. A copy of the '545 patent is attached as Exhibit B.

10. Each of the '605 patent and '545 patent is entitled "Nucleotide Sequence Encoding the Enzyme I-SceI and the Uses Thereof." These two patents are directed to methods

of using Group I intron encoded endonucleases as a means for producing a site directed double-stranded break in DNA, for promotion of genetic recombination in an organism. Using the inventive methods of these patents, scientists can insert genes at specific target sites in the DNA of a given organism (such as a plant, for example), such that the altered organism will advantageously express the inserted genes following that insertion.

11. The ’605 patent and the ’545 patent are owned by Institut Pasteur (“Pasteur”) and Universite Pierre et Marie Curie, both of Paris, France. Cellectis has been and is the exclusive licensee of the patent owners under the ’605 patent and ’545 patent. Pursuant to its exclusive license, Cellectis has the right to sue Precision for infringement of those patents and to seek and obtain monetary and injunctive damages for such infringement.

Defendant’s Infringing Activities

12. On information and belief, Precision has been and is using what it calls the Directed Nuclease Editor (DNE) to make certain endonucleases that are specifically intended for use in methods of preparing transgenic organisms, including plants, wherein those endonucleases target site-specific DNA breaks and effect a desired genome modification in the organism. The methods for which Precision has been and is specifically making its endonucleases are covered by one or more claims of the ’605 patent and ’545 patent.

13. More specifically, on information and belief, for example, Precision has been and is making Group I intron encoded endonucleases that are specifically intended for use by others in methods for inducing at least one site directed double-stranded break in the DNA of an organism, such as a plant, wherein the methods include (a) providing an isolated cell of that organism containing at least one Group I intron encoded endonuclease recognition site at a location in the DNA of the cell, and (b) providing the Group I intron encoded endonuclease to

that cell by genetically modifying the cell with a nucleic acid comprising the Group I intron encoded endonuclease or by introducing the Group I intron encoded endonuclease protein into the cell, such that the Group I intron encoded endonuclease cleaves the Group I intron encoded endonuclease site at the location in the DNA of the cell.

14. In addition, on information and belief, for example, Precision has been and is making such Group I intron encoded endonucleases as set forth in paragraph 11 that are specifically intended for use by others in methods that include the steps of (a) providing a transgenic cell, like a transgenic plant cell, having a Group I intron encoded endonuclease recognition site inserted at a unique location in a chromosome, (b) providing an expression vector that expresses that endonuclease in the transgenic cell, (c) providing a plasmid comprising a gene of interest and a DNA sequence homologous to the sequence of the chromosome and allowing homologous recombination, (d) transfecting that transgenic cell with the foregoing plasmid, (e) expressing that endonuclease from the expression vector in the above cell, and (f) cleaving the Group I intron encoded endonuclease recognition site with the endonuclease, whereby that cleavage promotes the insertion of said gene of interest into the chromosome of the organism at a specific site.

15. Finally, on information and belief, Precision has been and is using the above endonucleases that it makes to practice the foregoing methods covered by one or more claims in the ’605 patent and ’545 patent.

16. As a direct and proximate consequence of this infringement by Precision, Cellectis has been and will continue to be injured in its business and property rights unless the infringement is enjoined by this Court, and has suffered and will continue to suffer injury and damages for which it is entitled to relief.

Defendant's Unfair Competition Activities and Libel *Per Se*

17. On March 18, 2009, Precision filed two separate requests with the PTO for *inter partes* reexamination of two other patents that are exclusively licensed to Cellectis by Pasteur, namely U.S. Patent Nos. 7,214,536 and 6,833,252 (respectively, "the '536 patent" and "the '252 patent" and, collectively, "the re-exam patents"), in light of certain prior art references that Precision alleges in those reexamination requests should render the claims of the '536 and '252 patents invalid. These two re-exam patents are related to, but separate from, the '545 and '605 patents-in-suit. More specifically, the two re-exam patents are in the same patent family as the two patents-in-suit (*i.e.*, all four patents issued from the same original application filed in 1992) and the two re-exam patents have the same specification as the '605 patent-in-suit. However, the claims of the '536 and '252 re-exam patents are different in scope from the claims of the '545 and '605 patents-in-suit, although they share some of the same claim terms.

18. Around May 27, 2009, the PTO issued two, separate orders granting Precision's reexamination requests for all claims in the '536 patent and claims 1-18 in the '252 patent, which starts the *inter partes* proceedings as to those claims in the two re-exam patents. At the same time, the PTO's order as to the '252 patent confirmed the patentability of claim 19 of that patent, notwithstanding Precision's request that it be reexamined over certain prior art. The re-exam patents' owner will now have the opportunity in the *inter partes* reexamination proceedings to demonstrate to the PTO that the invalidity positions expressed in Precision's requests for reexamination are wrong and that the patentability of all claims in both re-exam patents should be confirmed.

19. On June 8, 2009, Precision issued a press release ("the June 8 press release," attached as Exhibit C) relating to the PTO's orders granting Precisions' request to reexamine claims in the '536 and '252 patents, as well as to the '545 and '605 patents-in-suit. Precision's June 8 press release is entitled "US Patent Office Rejects Key Claims to Cellectis' Core Technology" and constitutes an advertisement or promotional material for Precision's products and/or services that contains false and/or misleading statements or representations about them.

20. More specifically, Precision's June 8 press release is misleading and deceptive because, *inter alia* : (a) it intentionally makes false representations about the PTO's orders of reexamination of the '536 and '252 re-exam patents relative to Precision's accused products and processes and their infringement of the separate '545 and '605 patents-in-suit in this action, as well as about the validity and enforceability of those patents-in-suit; (b) it deceptively conflates the initial statements of the PTO regarding the re-exam patents (to which the owner of the re-exam patents had not yet even responded) with positions taken and presumed outcomes in this separate, district court action on separate patents from those in the reexaminations; and (c) it falsely communicates to Precision's customers that, based on the PTO's statements in the re-examinations of the '536 and '252 patents, Precision's products and/or services do not infringe Cellectis's separate patents-in-suit, namely the '545 and '605 patents.

21. The '536 and '252 re-exam patents have not been asserted against Precision in this action or any other. Moreover, as Precision knows, the PTO does not and cannot make determinations regarding infringement of the re-exam patents or the patents-in-suit. Nevertheless, for example, Precision's June 8 press release misleadingly and deceptively suggests to the public and industry that the PTO has determined in ordering the reexaminations of the '536 and '252 patents that Precision's products and/or services do not infringe the separate

‘545 and ‘605 patents-in-suit in this action by, *inter alia*, stating “[i]n one of the recent [reexamination] office actions, the PTO specifically states that Cellectis’ patent claims do not include genetically engineered enzymes, which means they do not cover Precision’s technology.” Notably, the foregoing June 8 press release statement does not distinguish between which Cellectis patents Precision is asserting the PTO orders pertain to. This conflation and deception is further compounded by the statements in the press release attributed to Jeff Smith, the Chief Scientific Officer of Precision, who is quoted as saying “[w]e have always been confident that Precision’s DNE technology does not infringe any reasonable interpretation of the claims asserted against us.”

22. As another example of the misleading and deceptive nature of Precision’s June 8 press release, Matthew Kane, CEO of Precision, is quoted in the press release as stating “[i]f the court adopts the same interpretations of the claim terms and prior art references as the Patent Office, there is no doubt that Precision will ultimately prevail in its ongoing litigation with Cellectis . . . We believe that, by failing to disclose those references, the inventors, the assignees or Cellectis engaged in inequitable conduct, and that these patents were obtained by fraud.” Again, and notably, the foregoing press release statement does not distinguish (in referring to “these patents”) between which Cellectis patents Precision is asserting the PTO orders pertain to. Moreover, even as to a patent the PTO is reexamining (such as the ‘536 and ‘252 re-exam patents), much less as to a related patent not being reexamined by the PTO, the PTO does not and cannot decide issues of alleged fraud, inequitable conduct, or violation of duty of disclosure in the reexamination proceedings. In any event, Cellectis contends that the patent owners and those individuals involved with the prosecution of the patent applications that led to patents-in-

suit and the re-exam patents fully complied with their duties of disclosure throughout their prosecution in the PTO and no such alleged fraud or inequitable conduct occurred.

23. After learning of Precision's June 8 press release and the harm caused thereby, Cellectis prepared an original supplemental complaint in this action in the following week, alleging unfair competition and libel *per se* in the same manner and for the same reasons expressed in the above paragraphs. A copy of that original supplemental complaint was provided to Precision's counsel on June 19, 2009, along with a message indicating that Cellectis would file a motion for leave to file that supplemental complaint unless Precision agreed to remove the June 8 press release from its website and cease any further dissemination of that press release.

24. Precision replied to the above offer on June 22, stating that Precision would only agree to remove its June 8 press release from its website and stop any further dissemination of that press release if Cellectis also would agree to remove from its website its own press release of June 10 (issued in response to Precision's June 8 press release) and cease any further dissemination of that responsive June 10 press release. Cellectis's June 10 press release, entitled "Cellectis SA Clarifies Competitor's Comments on Preliminary US Patent Office Action," was made in an attempt to clarify the misleading and deceptive statements made by Precision in its June 8 press release. Cellectis fully stands by the statements in its June 10 press release. Therefore, on June 24, 2009, Cellectis declined the foregoing June 22 Precision proposal and indicated that it would proceed with filing a motion for leave to file the original supplemental complaint to allege unfair competition and libel *per se* based on Precision's June 8 press release. Precision responded that same day and indicated it was removing the June 8 press release from its website at that time. The following day, June 25, Precision confirmed it had removed the

June 8 press release from its website and would not disseminate that press release further. Accordingly, Cellectis did not to file its motion for leave to file the original supplemental complaint.

25. However, shortly following the above events, on July 6, 2009 Precision issued a second press release ("the July 6 press release," attached as Exhibit D) that once again is directed to the PTO's orders granting Precision's request to reexamine claims in the '536 and '252 patents, as well as to the '545 and '605 patents-in-suit. Precision's July 6 press release is entitled "Precision BioSciences Issues Update Regarding Recent Patent Office Action Concerning Cellectis' Patents." Precision's July 6 press release notes that the '252 and '536 re-exam patents "belong to a family of thirteen issued U.S. patents, which includes U.S. Patent Nos. 7,309,605 and 6,610,545 that are being asserted against Precision BioSciences," and then goes on to state (with the emphasis in the original):

> Precision filed requests seeking reexamination of U.S. Patent No. 7,214,536 (the '536 patent) and U.S. Patent No. 6,833,252 (the '252 patent) on the grounds that these claims of these patents are obvious in view of a variety of references which had not been previously considered by the patent examiners. On May 27, 2009, the PTO granted Precision's requests and issued initial rejections of all 17 claims of the '536 patent, and 18 of 19 claims of the '252 patent.
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> In rejecting the claims of the '252 patent, the PTO concluded:
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> The terms "an I-SceIV site, an I-Csml site, I-Pan1 site, I-Scell site, an I-CeuI site, an I-PpoI site, an I-SceIII site, anI-CreI site, an I-TevI site, an I- TevII site, **an** I-TevIII site, and **an** I-SceI site" are each interpreted to mean a segment of DNA having a sequence that is recognized by the corresponding Group I intron encoded endonuclease, which includes the insertion site for the corresponding Group I intron. The terms include the naturally-occurring endonucleases ***but not genetically engineered endonucleases with altered specificities or activities***. (Emphasis added.)
>
> The PTO went on to conclude:
>
> "Group I intron encoded endonuclease site" is interpreted to mean a segment of DNA having a sequence that is recognized by a Group I intron encoded endonuclease and, as shown in Figure 6 of the '252 patent, that

includes the insertion site for the corresponding Group I intron.
(Emphasis added.)

Similar claim terms are used in the '605 patent and '545 patent that are the subject of ongoing litigation between Cellectis and Precision.

The enzymes which are the basis of Precision's Directed Nuclease Editor™ technology are ***genetically-engineered endonucleases with altered specificities.*** The recognition sites of these rationally-designed enzymes ***do not include the intron insertion site*** of a naturally-occurring Group I intron encoded endonuclease.

In rejecting all but one of the claims of the '536 patent and the '252 patent as obvious, the PTO relied on a number of the same references that Precision contends also render the asserted claims of the '605 patent and '545 patent obvious or anticipated.

According to data released by the PTO for all *inter partes* reexaminations which had been concluded since the procedure was first introduced in 1999 through March 31, 2009, 73% of the reexaminations resulted in all issued claims being canceled, and 93% of the reexaminations resulted in at least some issued claims being canceled or amended.

Precision BioSciences is now evaluating whether or not it will request that every patent in this family be reexamined, including those currently asserted against Precision.

26. Precision's July 6 press release constitutes an advertisement or promotional material for Precision's products and/or services that contains false and/or misleading statements or representations about them. More specifically, Precision's July 6 press release is misleading and deceptive because, *inter alia* : (a) it intentionally and misleadingly ascribes and exaggerates a supposed significance to the PTO's initial orders of reexamination for the re-exam patents relative to Precision's accused products and processes and their infringement of the separate '545 and '605 patents-in-suit, as well as to the validity of those patents-in-suit; (b) it deceptively conflates the initial statements of the PTO regarding the re-exam patents (to which the owner of the re-exam patents had not yet even responded) with positions taken and presumed outcomes in this separate, district court action on separate patents from those in the reexaminations; and (c) it

falsely communicates to Precision's customers that, based on the PTO's statements in the re-examination of the '252 patent, Precision's products and/or services do not infringe Cellectis's separate patents-in-suit, namely the '545 and '605 patents (with regard to which, Precision later requested *inter partes* reexamination by the PTO, as it indicated it was considering in the July 6 press release, and those requests for reexamination have since been granted, although the '545 and '605 patents' owner has not yet had the opportunity to respond to those initial PTO actions).

27. For example, Precision's July 6 press release misleadingly and deceptively suggests to the public and industry that the PTO has determined in ordering the reexamination of the '252 patent that Precision's products and/or services do not infringe the separate '545 and '605 patents-in-suit in this action by, *inter alia:* (a) first stating that the PTO concluded in granting the request for reexamination of the '252 patent that certain claim terms in the '252 patent "include the naturally-occurring endonucleases ***but not genetically engineered endonucleases with altered specificities or activities"***; (b) next stating that "[s]imilar claim terms [to those in the '252 patent] are used in the '605 patent and '545 patent that are the subject of ongoing litigation between Cellectis and Precision"; and (c) finally concluding that "the enzymes which are the basis of Precision's Directed Nuclease Editor™ technology are ***genetically-engineered endonucleases with altered specificities"***, thereby improperly and deceptively suggesting that those same enzymes, which are part of the processes accused of infringement in this action, in fact have been determined by the PTO not to infringe the '545 and '605 patents-in-suit. Precision's July 6 press release also misleadingly and deceptively suggests that the PTO's orders of reexamination of the '252 and '536 patents indicates that the asserted claims of the '545 and '605 patent will be held invalid since they have "similar claim terms" to the '252 patent and, "[i]n rejecting all but one of the claims of the '536 patent and the '252 patent

as obvious, the PTO relied on a number of the same references that Precision contends also render the asserted claims of the '605 patent and '545 patent obvious or anticipated."

28. Moreover, Precision made the foregoing deceptive and misleading statements in its July 6 press release without explaining to the public or industry that the PTO action was an initial action to which the patent owners had not yet even responded, that the cited PTO "conclusion" regarding certain claim terms in the '252 patent was made at the express written suggestion of Precision to the PTO in its reexamination request, and that similar written suggestions made by Precision to the PTO regarding the supposed meaning of claim terms in the '536 patent were not followed by the PTO in its order of reexamination as to that patent. Further, notwithstanding Precision's improper, misleading and deceptive touting in its press releases of the PTO's initial orders of reexamination of the '252 and '536 patents relative to issues of patent infringement and validity in this action regarding the separate '545 and '605 patents-in-suit, Precision never informed the PTO of this action or the '545 and '605 patents-in-suit when it requested reexamination of the '252 and '536 patents and made no mention of having not done so in either press release.

29. Precision's July 6 press release is even further damaging and harmful to Cellectis because it is directed to the same subject matter and makes some of the same misrepresentations (although using different wording) as its earlier June 8 press release, which Precision removed from its website following receipt of a copy of Cellectis's original supplemental complaint based on that first press release. As a result, the July 6 press release serves to resurrect and revitalize the improper June 8 press release before the public and industry in which Cellectis and Precision compete, particularly since the June 8 press release remains publicly available on the internet as of the date of this supplemental complaint, even if Precision is no longer disseminating the

June 8 press release on its own. Those members of the public and industry who previously accessed the June 8 press release certainly will revisit that first June 8 press release following exposure to the latest July 6 press release on the same subject matter. Accordingly, in addition to harming Cellectis in its own right, Precision's July 6 press release also compounds and exacerbates the original and ongoing harm to Cellectis that was initiated through the June 8 press release.

30. As a direct and proximate consequence of these misleading and deceptive press release statements by Precision, Cellectis has been and will continue to be damaged unless this behavior is enjoined by this Court, and has suffered and will continue to suffer injury and damages for which it is entitled to relief.

COUNT I
PATENT INFRINGEMENT OF THE '605 PATENT

31. The allegations of paragraphs 1 to 30 are incorporated by reference as if fully set forth herein.

32. Through its above activities, Precision has been directly infringing one or more claims of the '605 patent, and contributing to and inducing the direct infringement of those claims by third parties who use the endonucleases made by Precision for use in the claimed methods of that patent.

33. On information and belief, Precision's infringement of the '605 patent has been and continues to be willful and deliberate.

COUNT II
PATENT INFRINGEMENT OF THE '545 PATENT

34. The allegations of paragraphs 1 to 33 are incorporated by reference as if fully set forth herein.

35. Through its above activities, Precision has been directly infringing one or more claims of the '545 patent, and contributing to and inducing the direct infringement of those claims by third parties who use the endonucleases made by Precision for use in the claimed methods of that patent.

36. On information and belief, Precision's infringement of the '545 patent has been and continues to be willful and deliberate.

COUNT III
UNFAIR COMPETITION AND LIBEL *PER SE*

37. Plaintiff repeats, reiterates and realleges each and every allegation in paragraphs 1 through 36, inclusive, of this Supplemental Complaint with the same force and effect as if fully set forth herein.

38. Defendant Precision committed unfair or deceptive acts or practices.

39. Defendant Precision's unlawful and improper actions as set forth above in paragraphs 17-30, are likely to mislead the industry and Cellectis's customers into mistakenly believing that the PTO determined that accused processes using Precision's DNE do not infringe the '545 and '605 patents-in-suit and that those patents are invalid and unenforceable, thereby improperly impeaching Cellectis in its business activities. Moreover, the misleading and deceptive nature of the Precision press releases likely will further curtail and prejudice Cellectis's business activities in the field in which Cellectis and Precision compete. Cellectis already has suffered significant harm to its business reputation, patent portfolio valuation and

stock valuation as a direct and proximate result of these Precision press releases, which embody and exemplify an improper effort by Precision to litigate through the press the patent infringement, validity and enforcement issues at stake in this action.

40. Accordingly, Defendant Precision's activities constitute unfair competition in violation of 15 U.S.C. § 1125(a), N.C. Gen. Stat. §75-1.1 and the common law of North Carolina, as well as libel *per se* in violation of N.C. Gen. Stat. §75-1.1 and the common law of North Carolina.

41. Defendant Precision's conduct was in or affecting commerce.

42. Defendant Precision's acts of willful patent infringement, unfair competition and libel *per se*, unless enjoined by this Court, has caused and will continue to cause Plaintiff to sustain irreparable damage, loss and injury, for which Plaintiff has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Cellectis hereby prays for the entry of a judgment from this Court:

a. that Defendant Precision is directly infringing one or more claims of the '605 patent and '545 patent, and contributing to and inducing direct infringement by third parties of those claims;

b. that Precision's infringement is willful and that this is an exceptional case under 35 U.S.C. § 285;

c. that the '605 patent and the '545 patent are valid and enforceable;

d. permanently enjoining Precision, its respective officers, agents, servants and employees, and those persons in active concert or participation with any of them, from: (1) infringing the '605 patent and the '545 patent; and (2) engaging in any further acts of unfair competition and libel *per se* against Cellectis;

e. awarding Plaintiff Cellectis damages in accord with 35 U.S.C. § 284 for said infringement;

f. awarding Plaintiff Cellectis damages, including lost profits, in accord with 15 U.S.C. § 1125(a) and N.C. Gen. Stat. §75-16, and that those damages be trebled in accordance with N.C. Gen. Stat. §75-16;

g. awarding Plaintiff Cellectis damages, including lost profits, in accord with the N.C. common law for unfair competition and libel *per se* and ordering Precision to retract and correct its June 8 and July 6, 2009 press releases referenced herein;

h. awarding Plaintiff Cellectis its attorneys fees, costs and expenses with regard to all counts in this supplemental complaint; and

i. awarding Plaintiff Cellectis such other and further relief as this Court may deem to be just and proper.

JURY DEMAND

Plaintiff Cellectis respectfully demands a jury trial pursuant to Rule 38(b) of the Federal Rules of Civil Procedure on all issues so triable.

Respectfully submitted this 23rd day of October 2009.

/s/ James L. Gale
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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing SUPPLEMENTAL COMPLAINT with the Clerk of Court using the CM/ECF system which will send notification of such filing to the following counsel of record:

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This the 23rd day of October, 2009.

/s/ James L. Gale
James L. Gale