

David E. De Lorenzi, Esq.
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102-5310
Telephone: (973) 596-4743
Facsimile: (973) 639-6235

Attorneys for Plaintiff
TET Systems Holding GMBH & Co. KG

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

TET SYSTEMS HOLDING GMBH & CO. KG,

Plaintiff,

-v-

PHARMASSET, INC.,

Defendant.

Civil Action No. _____

**COMPLAINT FOR PATENT
INFRINGEMENT AND JURY
DEMAND**

Document filed electronically

Plaintiff TET Systems Holding GMBH & Co. KG ("TET"), by and through its undersigned attorneys, Gibbons P.C., as and for its Complaint, alleges as follows:

OVERVIEW

1. TET was founded by prominent academic researchers, two of whom together invented and patented a system to modify cells. Using the invention made by Professor Dr. Hermann Bujard and Dr. Manfred Gossen, higher cells and entire organisms can be used as hosts in screening assays controlling target gene expression via external stimuli. In particular, cell-based screening assays can be useful in discovering and profiling chemical compounds active against medically -relevant targets, including antiviral activity against Hepatitis virus.

2. TET's patented technology has proven to be so commercially valuable that academic institutions, pharmaceutical companies, and other drug development companies worldwide, of varying sizes, license its use from TET.

3. Drs. Bujard and Gossen and the TET system have been recognized in numerous peer-reviewed scientific journals throughout the world. Dr. Bujard chairs the Supervisory Board of TET while continuing his work as a scientist. Presently, Dr. Bujard is the Director of the European Molecular Biology Organization (EMBO) in Heidelberg, Germany. He also maintains an active research laboratory at the University of Heidelberg's Department of Parasitology where his current research focuses on the development of vaccines against malaria.

4. TET brings this action for patent infringement under 35 U.S.C. § 271 *et seq.*, as a result of Pharmasset's continued and willful unauthorized use of TET's patented technology.

THE PARTIES

5. TET is a corporation organized and existing under the laws of Germany, having its principal place of business at the University of Heidelberg at Im NeuenheimerFeld 582, 69120 Heidelberg, Germany. TET is the owner, by assignment, of all right, title and interest in United States Patent No. 5,464,758, entitled "Tight Control of Gene Expression in Eucaryotic Cells by Tetracycline-Responsive Promoters" ("the '758 Patent" or sometimes referred to as the "TET System").

6. Upon information and belief, Pharmasset is a public corporation organized and existing under the laws of Delaware, having its principal place of business at 303-A College Road East, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

7. This Court has original jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).
8. This Court has personal jurisdiction over Pharmasset by virtue of, *inter alia*, Pharmasset maintaining its corporate headquarters in the State of New Jersey.
9. Venue is proper in this Court under 28 U.S.C. §§ 1391(c), 1391(d), and 1400(b).

U.S. PATENT NO. 5,464,758

10. The '758 Patent was duly and legally issued by the United States Patent and Trademark Office on November 7, 1995. A copy of the '758 Patent is attached hereto as Exhibit 1.
11. Claims of the '758 Patent cover, *inter alia*, a two component system consisting of hybrid polynucleotide molecules encoding a transactivator fusion protein and a transcription unit, which is responsive to the transactivator fusion protein and contains a gene of interest. When these polynucleotide molecules encoding the fusion protein and the responsive transcription unit, respectively, are inserted into suitable vectors and transfected into a cell, they can provide accurate and reproducible control of expression of a gene of interest using tetracycline or a tetracycline analogue as the controlling effector molecule, thus allowing companies like Pharmasset to use that cell and its progeny to screen new drug compounds.
12. Claims of the '758 Patent also cover, *inter alia*, a method of using the cell transfected with a vector containing the hybrid polynucleotide molecule in a tetracycline or a tetracycline analogue medium as a means of controlling gene expression, thus enabling companies like Pharmasset to determine the activity of compounds in the presence of stimuli, on the activity of viral proteins required for replication and/or pathogenicity.

13. Claims of the '758 Patent further cover, *inter alia*, a kit that provides the novel reagents of the invention for convenient use by companies like Pharmasset to set up an assay system useful to identify the activity of compounds to evaluate their potential use as drugs.

14. The novel reagents and method provided by the TET System have been recognized in the scientific literature as a broadly and successfully applied system for controlled gene expression in eukaryotes. This novel technology allows a drug development company like Pharmasset to control the activity of a target gene specifically, quantitatively, and reversibly, both *in vivo* and *in vitro*. It has been applied in cultured cells, as well as in a wide spectrum of organisms, from animals and plants to various unicellular systems.

15. The advantages of the TET System have provided scientists with exciting new insights into complex biological processes of development, disease, and behavior. An impressive example involves cell lines in which the Hepatitis B viral genome was placed under TET control leading to the discovery of new antiviral compounds and also useful for the testing of marketed antiviral drugs against Hepatitis viruses.

16. The TET System has also been employed in the development of new animal models for human diseases.

PHARMASSET'S INFRINGING ACTIVITIES

17. Pharmasset describes itself on its Web site as "a clinical-stage pharmaceutical company committed to discovering, developing and commercializing novel drugs to treat viral infections . . . [its] primary focus is on the development of oral therapeutics for the treatment of hepatitis B virus ("HBV"), hepatitis C virus ("HCV"), and human immunodeficiency virus ("HIV")."

Available at: <http://www.pharmasset.com/about/>.

18. Upon information and belief, Pharmasset has three compositions currently in clinical trials: (a) Clevudine, for the treatment of chronic HBV infection, (b) R7128, a pro-drug of PSI-6130 for the treatment of HCV, and (c) Racivir, for the treatment of HIV.

19. Upon information and belief, Pharmasset has two other compositions in development: (a) dexelvucitabine (“DFC”) for the treatment of HIV, and (b) PSI-7851 for the treatment of HCV.

20. Upon information and belief, each of the above compositions were developed by Pharmasset with the unauthorized use of the TET System and Pharmasset has used and continues to use the TET System without compensating TET for its use.

EVIDENCE OF PHARMASSET’S WILLFULNESS

21. TET put Pharmasset on notice that its use of the inventions described in the ‘758 Patent were unauthorized.

22. Pharmasset is well aware of the existence of the ‘758 Patent.

23. Pharmasset has ignored TET and its offer to license Pharmasset its TET System.

COUNT I. INFRINGEMENT UNDER 35 U.S.C. § 271 (a)

24. TET realleges paragraphs 1–23 as if set forth again.

25. As evidenced above, *inter alia*, Pharmasset has used and continues to use a method that infringes, either directly or under the doctrine of equivalents, each of the elements of one or more claims of the ‘758 Patent, without license from TET, in this judicial district and possibly elsewhere.

26. Upon information and belief, Pharmasset’s infringement of the ‘758 Patent has been and continues to be willful.

COUNT II. INFRINGEMENT UNDER 35 U.S.C. § 271(b)

27. TET realleges paragraphs 1–26 as if set forth again.
28. Upon information and belief, Pharmasset has induced others to infringe, directly or under the doctrine of equivalents, each of the elements of one or more claims of the ‘758 Patent, without license from TET, in this judicial district and possibly elsewhere.
29. Upon information and belief, Pharmasset’s induced infringement has been active and intentional.

COUNT III. INFRINGEMENT UNDER 35 U.S.C. § 271(c)

30. TET realleges paragraphs 1–29 as if set forth again.
31. Upon information and belief, Pharmasset has contributorily infringed, directly or under the doctrine of equivalents, each of the elements of one or more claims of the ‘758 Patent, without license from TET, in this judicial district and possibly elsewhere.
32. Upon information and belief, Pharmasset has offered for sale, sold, or imported into the United States, a material or apparatus for use in practicing the method disclosed in the ‘758 Patent, and such material or apparatus constitutes a material part of the method disclosed in the ‘758 Patent.
33. Upon information and belief, Pharmasset had knowledge that the material or apparatus described in paragraph 32, which Pharmasset offered for sale, sold, or imported into the United States, was especially made or especially adapted for use in practicing the method disclosed in the ‘758 Patent, and such material or apparatus was and is not a staple article or commodity of commerce suitable for substantial noninfringing use.

PHARMASSET'S HARM TOTET

34. TET realleges paragraphs 1–33 as if set forth again.

35. As a direct and proximate cause of Pharmasset's infringing acts, TET has been injured and, unless such infringing acts are enjoined by this Court, will continue to be injured in its business and property rights, and has suffered and will continue to suffer injury and damages for which it is entitled to relief under 35 U.S.C. § 284.

36. As a direct and proximate cause of Pharmasset's infringing acts, Pharmasset has caused and, unless such acts are enjoined by this Court, will continue to cause irreparable harm to TET for which there is no adequate remedy at law, and for which TET is entitled to preliminary and permanent injunctive relief under 35 U.S.C. § 283.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests of this Court the following relief:

(a) A judgment and decree that Pharmasset has directly infringed, contributorily infringed, and/or induced infringement of one or more claims of the '758 Patent;

(b) An Order preliminarily and permanently restraining and enjoining Pharmasset and its subsidiaries, and each of their officers, agents, servants and employees and all others in concert or participation with them, from committing further acts of infringement under 35 U.S.C. § 271 of any one or more claims of the '758 Patent pursuant to 35 U.S.C. § 283;

(c) An award of damages for Pharmasset's infringement, which should be trebled pursuant to 35 U.S.C. § 284;

(d) That this case be declared "exceptional" and award TET its reasonable attorneys' fees, expenses, and costs in this action pursuant to 35 U.S.C. § 285; and

(e) Such other and further relief as the Court may deem just and proper.

Dated: May 11, 2009

Respectfully submitted,

s/David E. De Lorenzi

David E. De Lorenzi

GIBBONS P.C.

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JURY DEMAND

TET hereby demands a jury on all issues so triable in this action.

s/David E. De Lorenzi
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