UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2006-1634, -1649

CLASSEN IMMUNOTHERAPIES, INC,
Plaintiff-Appellant

v.

BIOGEN IDEC,
Defendant-Appellee
and

GLAXOSMITHKLINE,
Defendant-Appellee
and

MERCK & CO, Inc,
Defendant-Cross Appellant,
and

CHIRON CORPORATION, KAISER-PERMANENTE, INC., KAISER PERMANENTE VENTURES, KAISER PERMANENTE INTERNATIONAL, KAISER PERMANENTE INSURANCE COMPANY, THE PERMANENTE FEDERATION, LLC, THE PERMANENTE COMPANY, LLC, THE PERMANENTE FOUNDATION, THE PERMANENTE MEDICAL GROUP, INC., KAISER FOUNDATION HOSPITALS, KAISER FOUNDATION ADDED CHOICE HEALTH PLAN, INC., and KAISER FOUNDATION HEALTH PLAN INC.,
Defendants.

Appeal from the United States District Court for the District of Maryland in case no. 04-CV-2607, Judge William D. Quarles, Jr.

APPELLANT'S COMBINED PETITION FOR PANEL REHEARING AND FOR REHEARING EN BANC

CERTIFICATE OF INTEREST

Counsel for the Plaintiff-Appellant/Petitioner, Classen Immunotherapies, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Classen Immunotherapies, Inc.

2. The name of the real party in interest represented by me is:

Classen Immunotherapies, Inc.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

Joseph J. Zito of the law firm: ZITO tlp, 1250 Connecticut Avenue, NW, Suite 200, Washington, D.C. 20036

Date 1-13-08

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STATEMENT OF COUNSEL FOR EN BANC CONSIDERATION

Based on my professional judgment, I believe the panel decision is contrary to the following precedent of this court:

In Re Bilski, 545 F.3d 943 (Fed. Cir. 2008)(en banc)

Based on my professional judgment, I believe this appeal requires an answer to one or more precedent setting questions of exceptional importance:

Is the medical treatment of a person which results in a physiological change, a "transformation of matter" that falls within the scope of patentable subject matter under 35 U.S.C. §101?

Attorney of record for:
Classen Immunotherapies, Inc.
Plaintiff-Appellant/ Petitioner

FACTS MISAPPREHENDED BY THE COURT

Appellant moves for panel rehearing and/or rehearing en banc because the decision of the panel is contrary to current law in holding that the recited step "immunizing mammals" is not a "transformation of matter." There is no dispute that the act of immunization of a mammal transforms the matter that constitutes the mammal from an un-immunized state to an immunized state. *In Re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)(en banc) holds that methods that include a step which includes a transformation of matter are patentable subject matter. Therefore, it is contrary to current law to hold that the claims of the Classen patents are invalid for failure to recite patentable subject matter under 35 U.S.C. §101.

BACKGROUND

On September 7, 2006 Appellant, Classen, appealed from three rulings of the District Court for the District of Maryland. One of those rulings was an Order dated August 16, 2006 wherein the District Court granted summary judgement of invalidity, finding the patents invalid under 35 U.S.C. §101 for patenting an abstract idea. The appeal was heard at the Federal Circuit in July 2007, under the "laws of nature, natural phenomena and abstract ideas" test. The oral argument was held two months prior to the initial hearing of *In Re Bilski*, 545 F.3d 943 (Fed.

Cir. 2008)(en banc).

Bilski was argued to a three judge panel on October 1, 2007, was reheard en banc on May 8, 2008 and was decided on October 30, 2008, establishing the "machine or transformation of matter" test for patentable subject matter under 35 USC §101.

The Circuit Court issued a decision in this matter on December 19, 2008, eighteen months after oral argument and two months after the decision in *Bilski*. Although the Federal Circuit decision stated that the decision of the District Court was affirmed in light of *Bilski*, neither the District Court nor the parties ever addressed the *Bilski* "machine or transformation of matter" test. Further, the Circuit Court's decision neither explained the reasoning nor the application of the *Bilski* "machine or transformation of matter" test to the facts of the case.

As recognized by the patent community (see: Hal Wegner's Top Ten for 2008, see also: J. Matthew Buchanan, *After Bilski*) the *Classen* appeal was seen as an important opportunity for the Court to address the application of current trend in the application of 35 USC §101. See also: *Patent Docs,* Kevin E. Noonan, *Classen Immunotherapies, Inc. v. Biogen Idec (Fed. Cir. 2008);:*

> "The result is also anomalous because the Classen case was widely viewed as foreshadowing how the Federal Circuit will address the issues raised by Laboratory Corp. v. Metabolite Labs., Inc. (LabCorp), and Justice Breyer's criticism of the scope of that claim under a

patentability analysis."

The Federal Circuit, in failing to explain its reasoning behind the brief statement of affirmation has left the patent community to wonder what may be patentable and why. See:

Holman's Biotech IP Blog, Friday, December 19, 2008, *Classen v. Biogen: The Federal Circuit Applies Bilski to the Life Sciences*:

> The opinion ducks important issues. Contrary to the holding, the claims do in fact involve a transformation, e.g., claim 1 of 5,723,283 recites a 'method . . . which comprises immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens . . . ." The immunization of a mammal clearly effects a transformation of a particular article [a mammal] into a different state [a state of induced immunity]. It is inconceivable that this does not constitute a transformation; if that were the case, it would logically follow that all method of treatment claims are patent-ineligible.

Also: *No Cartesians Here*, from The Fire of Genius:

> What's intriguing about Classen is that it doesn't appear to rely on the more general considerations stated in Bilski, i.e., the need for "meaningful limits on the claim's scope" and the derogation of "insignificant extrasolution activity." Of course, Classen is highly compressed, clocking in at a total of 68 words (including words in citations), so I may wrong about this. But here's the (one and only) sentence providing the court's rationale:
>
> > Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they "transform[] a particular article into a different state or thing." (Quoting Bilski.)
>
> At first blush, however, Classen Claim 1 *does* appear to recite a transformation of a physical article...

All of the discussions in the patent community, as well as the Court, agree that immunization is not a pure mental step, thus the *Classen* decision brings into question entire classes of pharmaceutical patents which rely on the step of "immunization" as a "transformation of matter."

> Indeed, listening to the Classen oral argument clearly shows that Judge Moore was intensely interested in the patentability of mental processes at the time. She initiated a discussion on the issue by asking counsel for the patentee to ignore the non-mental immunizing step of the claim at issue ("yes, clearly you're absolutely right...these are not exclusively mental process claims.").
>
> (J. Matthew Buchanan, *After Bilski*)

It is important to the establishment of a consistent and predictable body of case law that the Federal Circuit rehear this matter en banc. The patent community deserves an decision which explains the Court's reasoning in finding an immunization patent to be non-statutory subject matter, without the need for speculation.

> Uncertainty is the enemy of innovation. These new uncertainties not only diminish the incentives available to new enterprise, but disrupt the settled expectations of those who relied on the law as it existed.
>
> NEWMAN, Circuit Judge, In re Bilski

DISCUSSION

Claim one of each of the Classen patents includes a step of immunization:

> Patents '139 and '739: "(II) **immunizing said subject** according to a subject immunization schedule...."
>
> Patent '283: "which comprises **immunizing mammals** in the treatment group of mammals with one or more doses of one or more immunogens...."

This step is a transformation of matter. An immunogen is introduced into the organism. The immunogen transforms the organism to a state of induced immunity.

In addition to the inclusion of the immunization step which transforms matter, the claims recognize the transformation and include further steps of analysis of the relative transformations of matter based upon the immunization schedule implemented:

> Patents '139 and '739: "(I) screening .... immunized with one or more doses of one or more infectious disease-causing organism-associated immunogens ... comparing ... inducing a chronic immune-mediated disorder..."
>
> Patent '283: "comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group."

"Inducing a chronic immune-mediated disorder" is clearly also a transformation of

matter.

The decision of the CAFC in *Classen*, in ruling that immumization, and therefore any treatment of the human body, is not a "transformation of matter," is far reaching. If immunization in Classen's patents is not patentable subject matter under the *Bilski* test, then all immunization patents fail to teach patentable subject matter.

The exclusion of treatment method patents from patentable subject matter is not consistent with Congressional intent to allow patenting of new pharmaceutical uses and patenting of medical activities U.S.C. 35 Section 287(c)(2)(a)(ii).

Congress intent regarding patenting medical procedures and methods of using pharmaceuticals was not discussed in the *Bilski* decision but has a clear legislative history. The Hatch Waxman legislation 21 U.S.C. §355(b)(1), states *"The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug"* thus further indicating Congress' intent that methods of using pharmaceuticals are patentable. 21 U.S.C. §355 and 35 U.S.C. §287 clearly evidence Congress's intention for *"medical activity" ("the performance of a medical or surgical procedure on a body")* to be patentable. Immunization is an medical activity. The Court's reasoning for

invalidating Classen's patents under *Bilski* is in conflict with the clear intent of Congress.

Patents covering method of using pharmaceuticals are an essential part of the intellectual property relating to specific pharmaceutical products. For example a review of the Orange Book listing and the internet for biologics shows that of the top 25 selling pharmaceuticals in 2007, all are protected in the US in part by method of use patents. When looking at patents that use a claim containing immunize, immunization, or immunizing there are at least 1,349 US patents claiming "immunizing." Appellee GSK was issued patents covering immunization that use the phraseology "inducing protective antibodies." Merck and Biogen, have patents which recite immunization or similar process. Thus these methods of immunizations could all be challenged under Bilski if "immunization" does not induce "transformation of a particular article into a different state or thing".

Immunization creates a lasting change by transforming the recipient into a protected state that can last for 20 years or more.

Dr. Classen and his discoveries are well known to different branches of the US government. Dr. Classen discovered that common vaccines including childhood vaccines cause autoimmune diseases such as type 1 diabetes often years

after the vaccine is given. Furthermore Classen discovered that certain schedules, in particular schedules giving vaccine early in life, are associated with less risk of developing diabetes than schedules where the vaccine is given later in life. Dr. Classen has been on a crusade to make immunization safer. He was invited by Congress to testify at two Congressional hearings on vaccine safety. The NIH and FDA held a two day seminar on vaccine induced diabetes to discuss Dr. Classen's findings after Dr. Classen's data received international attention on ABC's World News Tonight with Peter Jennings. Dr. Classen has testified on numerous vaccine injury cases. Safer methods of immunization is the central focus of Dr. Classen's research and his patents. Classen's patents ('283, '139, '739) covers a method of using an pharmaceutical (immunogen) for prophylactic treatment (immunization).

A representative claim is claim 1 of the 5,723,283 patent which requires an immunization step. Claim 8 requires that the immunization prevents at least two infectious diseases, clearly a transformation. Claim 20 ties the invention to specific immunogens (i.e. apparatus for preventing infection). 6,420,139 claim 30 is slightly more advanced because it requires immunization of two groups and, after analysis, immunizing an individual according the safer schedule. Claim 31 ties the invention to an hepatitis B immunogen (ie. apparatus for preventing infection).

CONCLUSION

Bilski set the test for patentable subject matter as "tied to a particular machine or apparatus" and/or "method step which includes a transformation of matter." Although this test was not briefed nor argued in Classen, because the *Bilski* decision was issued more than a year after oral argument, the claims of the Classen patents clearly fall within the test for patentable subject matter. "Immunization" which is recited in all of the claims at issue is a "transformation of matter." The panel should rehear this appeal or it should be reheard en banc, addressing the Court's determination of the issue of immunization qualifying as patentable subject matter under the *Bilski* "transformation of matter" standard. The Court should also allow the parties to brief and argue patentablility under 35 U.S.C. §101 in light of the tests set forth in *Bilski*.

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ADDENDUM

NOTE: This disposition is nonprecedential.

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Defendants.

Joseph J. Zito, Zito tlp, of Washington, DC, argued for plaintiff-appellant.

Joshua M. Hiller, Wilmer Cutler Pickering Hale and Dorr LLP, of Boston, Massachusetts, for defendant-appellee, Biogen IDEC. On the brief were David B. Bassett, of New York, New York, and David A. Wilson, of Washington, DC.

George F. Pappas, Covington & Burling LLP, of Washington, DC, argued for defendant-appellee, GlaxoSmithKline. With him on the brief were Jeffrey B. Elikan and Kevin B. Collins. Of counsel was Scott C. Weidenfeller.

Mary B. Graham, Morris, Nichols, Arsht & Tunnell, LLP, of Wilmington, Delaware, argued for defendant-cross appellant. With her on the brief was James W. Parrett, Jr. Of counsel on the brief were Robert L. Baechtold, Fitzpatrick, Cella, Harper & Scinto, of New York, New York; and Edward W. Murray and Mary J. Morry, Merck & Co., Inc., of Rahway, New Jersey.

Appealed from: United States District Court for the District of Maryland

Judge William D. Quarles, Jr.

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

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Defendants.

Appeal from the United States District Court for the District of Maryland in Case No. 04-CV-2607, Judge William D. Quarles, Jr.

DECIDED: December 19, 2008

Before NEWMAN and MOORE, Circuit Judges, and FARNAN, District Judge.*

MOORE, Circuit Judge.

In light of our decision in In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court's grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen's claims are neither "tied to a particular machine or apparatus" nor do they "transform[] a particular article into a different state or thing." Bilski, 545 F.3d at 954. Therefore we affirm.

---

* Hon. Joseph J. Farnan, Jr., United States District Court for the District of Delaware, sitting by designation.

PROOF OF SERVICE

I hereby certify that 2 copies each of Appellant's Combined Petition for Panel Rehearing and for Rehearing En Banc were served upon the below listed counsel on this 13th day of January 2009, via first class mail:

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