95-1066

In The
United States Court of Appeals for the Federal Circuit

FESTO CORPORATION,
Plaintiff-Appellee

v.

SHOKETSU KINZOKU KOGYO KABUSHIKI CO., LTD.,
a/k/a SMC CORPORATION, and SMC PNEUMATICS, INC.,
Defendants-Appellants.

On remand from the Supreme Court of the United States

BRIEF OF *AMICUS CURIAE*
BIOTECHNOLOGY INDUSTRY ORGANIZATION

Counsel of Record
Nancy J. Linck
Sr. Vice President, General Counsel & Secretary
Guilford Pharmaceuticals Inc.
6611 Tributary Street
Baltimore, MD 21224
(410) 631-6460

Of Counsel
Stephan E. Lawton
Biotechnology Industry Organization
1225 Eye St., N.W. Suite 400
Washington, D.C. 20005
(202) 962-9200

Certificate of Interest

Counsel for *Amicus Curiae* Biotechnology Industry Organization certifies the following:

1. The full name of every party or amicus curiae I represent is:

   Biotechnology Industry Organization

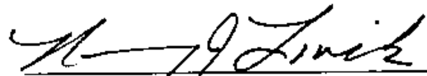
2. The name of the real party in interest I represent is:

   Biotechnology Industry Organization

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* I represent 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 are expected to appear in this court are: None

Nov. 16, 2002
Date



Nancy J. Linck
Counsel of Record

Table of Contents

Page(s)

Certificate of Interest i

Table of Contents ii

Table of Authorities iii

Statement of Identity and Interest of Amicus Curiae 1

Statement of Consent of Both Parties 1

Argument 2

Rebuttal of the Presumption of Surrender Resulting
from a Claim Amendment Should be Determined
by the Court with No Role for the Jury. 2

The Factors Encompassed in the Criteria Set Forth by
The Supreme Court must be Determined on a Case-by-Case Basis
and Should Not Form the Basis for Broad Rules Unnecessary to
Decide Festo that Could have Unintended and Harmful
Consequences for Biotechnology and Chemical Inventions. 3

The Supreme Court Did Not Overrule Its Own Precedent But Rather
Again Reaffirmed the Vitality of the Doctrine of Equivalents 8

Conclusion. 9

Certificate of Service

Certificate of Compliance Under Fed. R. App. P. 32(a)(7)(C)

Table of Authorities

Page(s)

Graver Tank & Mfg. Co. v. Linde Air Prods.,
339 U.S. 605, 85 USPQ 328 (1950) 7

Markman v. Westview Instruments, Inc.,
517 U.S. 370, 38 USPQ2d 1461 (1996) 2

Shoketsu Kinzoku Kogyo Kabushiki Co. v. Festo Corp.,
122 S. Ct. 1831, 62 USPQ2d 1705 (2002) . . . . passim

Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,
520 U.S. 17, 41 USPQ2d 1865 (1997) 2, 3, 5, 7

Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.,
234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000),
vacated and remanded, *Shoketsu Kinzoku Kogyo Kabushiki Co. v. Festo Corp.*, 122 S. Ct. 1831, 62 USPQ2d 1705 (2002) 3, 4, 6

Hilton Davis Chemical Co. v. Warner-Jenkinson Co.,
62 F.3d 1512, 35 USPQ2d 1641 (Fed. Cir. 1995),
reversed and remanded, *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 41 USPQ2d 1865 (1997) 5

Statement of the Identity and Interest of Amicus Curiae Pursuant to Federal Rule of Appellate Procedure 29(c)(3)

Amicus curiae, the Biotechnology Industry Organization (BIO), is a trade association consisting of over 1000 companies, academic institutions, and biotechnology centers. BIO members file thousands of patent applications each year for inventions ranging from fundamental technological breakthroughs to important commercial refinements of existing technology. Patents are extremely critical to our industry because often patents are the sole assets upon which our companies rely to obtain funding necessary to move a discovery to the next phase of development. Thus, BIO is concerned with the application of the doctrine of equivalents and of prosecution history estoppel to that doctrine.

BIO is submitting this amicus brief in response to the Federal Circuit's September 20, 2002 Order. In responding to the Court's questions 1 and 2, BIO does not support either party's position. Further, BIO has no interest in either of the parties or the outcome of this case, other than its interest in insuring that the doctrine of equivalents remains a viable doctrine, including in cases in which the claims have been amended.

Consent of Both Parties (Federal Rule of Appellate Procedure 29(a))

Both parties have consented to the filing of this amicus brief.

ARGUMENT

1. The following is offered in response to the Court's Question 1 (Sept. 20, 2002 Order):

Rebuttal of the Presumption of Surrender Resulting from A Claim Amendment Should be Determined by the Court with No Role for the Jury

Rebuttal of the presumption of surrender resulting from a claim amendment should be determined by the court, with no role for the jury because (1) prosecution history estoppel is a legal limitation on the doctrine of equivalents, see, e.g., *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,* 520 U.S. 17, 39 n.8, 41 USPQ2d 1865, 1875 n.8 (1997); and 2) determining the limits of a patent's reach, analogous to interpreting literal claim scope, is an exercise best left to the court. *See Markman v. Westview Instruments, Inc.,* 517 U.S. 370, 391, 38 USPQ2d 1461, 1470-71 (1996) (stressing the importance of uniformity in determining the limits of a patent's rights).

2. The following is offered in response to the Court's Question 2:

The Factors Encompassed in the Criteria Set Forth by The Supreme Court must be Determined on a Case-by-Case Basis and Should Not Form the Basis for Broad Rules Unnecessary to Decide *Festo* that Could have Unintended and Harmful Consequences for Biotechnology and Chemical Inventions

The factors encompassed in the criteria set forth by the Supreme Court in *Shoketsu Kinzoku Kogyo Kabushiki Co.* v. *Festo Corp.*, 122 S. Ct. 1831, 62 USPQ2d 1705 (2002) ("*Festo*") are those established in a long line of Supreme Court and Federal Circuit cases on the doctrine of equivalents and prosecution history estoppel. See, for example, the cases cited by Judge Michel in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558, 598-618, 56 USPQ2d 1865, 1896-1911 (Fed. Cir. 2000) ("*Festo Corp.*") (Michel, J.) (concurring in part and dissenting in part), vacated and remanded, *Festo*, 122 S. Ct. at 1843, 62 USPQ2d at 1714. In *Festo*, the Supreme Court cited to Judge Michel's discussion of those cases. *Id.* at 1837, 62 USPQ2d at 1709. Those factors require the Federal Circuit to perform a case-by-case analysis using the flexible bar rule, consistent with relevant precedent, and not evoke broad rules that reach beyond the case before it. *See Warner-Jenkinson*, 520 U.S. at 40, 41 USPQ2d at 1876 ("We expect that the Federal Circuit will refine the formulation of the test for equivalence in the orderly course of case-by-case determinations ...."). *See*

also, e.g., Festo Corp., 234 F.3d at 617, 56 USPQ2d at 1911 (Michel, J.) (concurring-in-part and dissenting-in-part) ("Prosecution history estoppel … is an equitable doctrine. By its very purpose, equity jurisprudence provides a remedy individually tailored to the circumstances of the dispute at hand.").

Establishing broad rules that go beyond the facts in *Festo* could well have unintended and harmful consequences in other cases. This is particularly true for patents in the biotechnology and chemical arts, areas in which inventions are described and claimed very differently than those in the mechanical arts, oftentimes leading to different challenges during prosecution. *See id.* at 617-18, 56 USPQ2d at 1911-12 (Michel, J.) (concurring-in-part and dissenting-in-part) (describing the difficulty of drafting biotechnology claims). *See also id.* at 622, 56 USPQ2d at 1915 (Linn, J.) (concurring-in-part and dissenting-in-part) (describing application filings in rapidly evolving fields and the necessity of "fine tuning" the claims).

In *Festo*, the Supreme Court made clear that the complete bar rule would work injustice by permitting copyists to identify an amended element and then make an insubstantial change in that element while identically copying the rest of the invention. 122 S. Ct. 1831, 1837-38, 62 USPQ2d 1705, 1709-10 (2002). This is exactly what the doctrine of equivalents was

designed to prohibit. Just as the complete bar frustrated this purpose, broad rules would likely have the same effect in all but a handful of cases. The flexible bar approach should not permit such piracy, except when it is clear that the alleged infringing subject matter was actually surrendered. Clearly a patentee cannot recapture the full scope of the original claim, *see id.* at 1838, 62 USPQ2d at 1711, or recapture subject matter lacking a claimed element (the all elements rule). *See, e.g., Warner-Jenkinson*, 520 U.S. at 29, 40, 41 USPQ2d at 1871, 1875. Further, a patentee cannot invoke the doctrine of equivalents for anything other than insubstantial changes in the invention. *See Hilton Davis Chemical Co. v. Warner-Jenkinson Co.*, 62 F.3d 1512, 1521, 35 USPQ2d 1641, 1648 (Fed. Cir. 1995), reversed and remanded on other grounds, 520 U.S. 17, 41 USPQ2d 1865 (1997). Beyond these established rules, the Federal Circuit "must be cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo*, 122 S. Ct. at 1841, 62 USPQ2d at 1713 (*citing Warner-Jenkinson*, 520 U.S. at 28).

On a case-by-case basis, the Federal Circuit should determine whether the patentee surrendered more subject matter than dictated by these established rules. "As long as the reason for an amendment is explained, an estoppel by amendment should only bar recapture of the subject matter

actually surrendered, as discerned from the amended claim language and the reasons articulated by the applicant for the change." *Festo Corp.*, 234 F.3d at 620, 56 USPQ2d at 1914 (Linn, J.) (concurring in part and dissenting in part). According to the Supreme Court, the patentee "must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Festo*, 122 S.Ct. at 1842, 62 USPQ2d at 1714. To the extent this language limits the flexible rule, the Federal Circuit should consider whether the applicant had written description in the specification to claim the alleged equivalent. If the necessary language was not available, then clearly one skilled in the art could not reasonably be expected to have drafted such a claim.

Furthermore, one skilled in the art could not reasonably expect a patent applicant to have claimed all insubstantial substitutions in his or her application at the time the application was filed without the benefit of hindsight. That's the very basis for the doctrine of equivalents. *See Festo*, 122 S. Ct. at 1838, 62 USPQ2d at 1710-11 ("The doctrine of equivalents allows the patentee to claim those insubstantial alterations that were not captured in drafting the original patent claim ...."). Further, the fact that the substitute was known at the time of the filing does not bar application of the

doctrine, even to an amended element. Both *Warner-Jenkinson* and *Graver Tank* involved such substitutes, substitutes that were made to an amended element. *See Warner-Jenkinson*, 520 U.S. at 21-23, 41 USPQ2d at 1868; and *Graver Tank & Mfg. Co. v. Linde Air Prods.*, 339 U.S. 605, 615 (1950) (Black, J.) (dissenting).

The fact that an amendment is made does not negate the patentee's ability to later capture insubstantial alterations under the doctrine of equivalents, unless the applicant has clearly surrendered such alterations.

> "The amendment does not show that the inventor suddenly had more foresight in the drafting of claims than an inventor whose application was granted without amendments having been submitted. It only shows that he was familiar with the broader text and with the differences between the two. As a result, there is no more reason for holding the patentee to the literal terms of an amended claim than there is for abolishing the doctrine of equivalents altogether and holding every patentee to the literal terms of the patent."

Festo, 122 S.Ct. at 1841, 62 USPQ2d at 1712-13. *See also id.* at 1840, 62 USPQ2d at 1712 ("reach" of estoppel "requires an examination of the subject matter surrendered by the narrowing amendment").

In biotechnology and chemistry, it would be particularly difficult to include all insubstantial substitutions in the claims, given the extremely large number of variations that can be made, for example, in a claimed polynucleotide or chemical formula. Furthermore, claiming all possible

insubstantial changes would likely make such claims unnecessarily complex and unsearchable.

The Supreme Court Did Not Overrule Its Own Precedent But Rather Again Reaffirmed the Vitality of the Doctrine of Equivalents

In *Festo*, the Supreme Court did not overrule its own precedent relating to the doctrine of equivalents and prosecution history estoppel. See *Festo*, 122 S. Ct. at 1841, 62 USPQ2d at 1713 ("the doctrine of equivalents and the rule of prosecution history estoppel are settled law."). See also the many citations to that authority in *Festo*, 122 S. Ct. 1831, *passim*, 62 USPQ2d 1705, *passim*. Rather, the holdings in *Festo* are limited to the following: (1) prosecution history estoppel applies to 112 amendments; (2) the flexible bar is the appropriate one; and (3) the patentee bears the burden of showing that the amendment does not surrender the particular equivalent in question. Thus, to the extent the Federal Circuit is considering permitting rebuttal only in certain narrowly defined circumstances, that approach would be inconsistent with precedent and could *de facto* maintain the complete bar rule in all but a few cases. That is not the outcome the Supreme Court is seeking. *See Festo,* 122 S. Ct. at 1837-38, 62 USPQ2d at 1709-10.

Conclusion

For the foregoing reasons, BIO respectfully requests the Court to avoid making broad rules beyond those necessary to decide this case and limiting the doctrine to the extent it is no longer viable in all but a handful of cases.

Respectfully submitted,

Counsel of Record
Nancy J. Linck
Sr. Vice President, General Counsel & Secretary
Guilford Pharmaceuticals Inc..
6611 Tributary Street
Baltimore, MD 21224
(410) 631-6460

Of Counsel
Stephan E. Lawton
Biotechnology Industry Organization
1225 Eye St., N.W. Suite 400
Washington, D.C. 20005
(202) 962-9200

Certificate of Service

I hereby certify that I caused copies of the foregoing brief for amicus curiae Biotechnology Industry Organization to be served on this 19th day of November 2002, via express mail on the following counsel of record:

Charles R. Hoffmann
Hoffman & Baron
6900 Jericho Turnpike
Syosset, NY 11791

Arthur I. Neustadt
Oblon, Spivak, McClelland, Maier & Neustadt
1755 Jefferson Davis Highway
Arlington, VA 22202

Jame B. Lampert
Hale and Dorr, LLP
60 State Street
Boston, MA 02109

Morgan Chu
Irell & Manella
1800 Avenue of the Stars
Suite 900
Los Angeles, CA 90067

Lynn E. Eccleston
Morgan, Lewis & Bockius, LLP
1111 Pennsylvania Ave., N.W.
Washington, DC 20004

Christopher Hughes
Morgan & Finnegan
345 Park Ave.
New York, NY 10154-0053

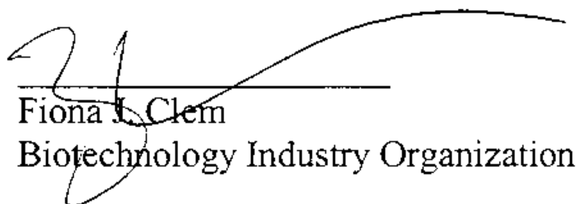
Frederick Lorig
Bright & Lorig
633 West 5th Street
Suite 3330
Los Angeles, CA 90071

J. Michael Jakes
Finnegan, Henderson
1300 I Street, NW
Suite 700
Washington, DC 20005-3315

Roddy M. Bullock
The Proctor
11450 Grooms Road, CNC-03
Cincinnati, OH 45242

Jonathan M. Harris
Conley, Rose
Texas Commerce Tower
Suite 1800
600 Travis Street
Houston, TX 77002

Joshua R. Rich
McDonnell, Boehnen
300 South Wacker Drive
Suite 3200
Chicago, IL 60606

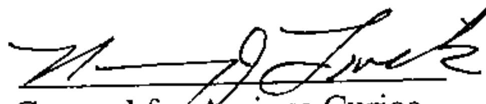


Fiona L. Clem
Biotechnology Industry Organization

Certificate of Compliance Under Fed. R. App. P. 32(a)(7)(C)

Amicus Curiae Biotechnology Industry Organization submits its brief under Rules 32(a)(5)(A) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure. Thus, I hereby certify that Amicus Curiae Biotechnology Industry Organization's brief complies with the type-volume limitation therein provided, and I further certify that the foregoing Brief for Amicus Curiae Biotechnology Industry Organization contains 1,911 words as determined by Microsoft Word, including heading, footnotes and quotations.

Respectfully submitted,



Counsel for Amicus Curiae
Nancy J. Linck
Sr. Vice President, General Counsel & Secretary
Guilford Pharmaceuticals Inc.
6611 Tributary Street
Baltimore, MD 21224

Dated: November 16, 2002