

United States Court of Appeals for the Federal Circuit

01-1058, -1059

BIOGEN, INC.,

Plaintiff-Cross Appellant,

v.

BERLEX LABORATORIES, INC.,

Defendant-Appellant,

and

SCHERING AG,

Defendant.

William F. Lee, Hale and Door LLP, of Boston, Massachusetts, argued for plaintiff-cross appellant. With him on the brief was David B. Bassett. Of counsel on the brief were James F. Haley, Jr., and Gerald J. Flattmann, Jr. Fish & Neave, of New York, New York; and Professor Charles Fried, Harvard Law School, of Cambridge, Massachusetts.

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

Judge Mark L. Wolf

United States Court of Appeals for the Federal Circuit

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DECIDED: January 31, 2003

Before NEWMAN, Circuit Judge, FRIEDMAN, Senior Circuit Judge, and RADER, Circuit Judge.

Opinion for the court filed by Circuit Judge NEWMAN. Concurring opinion filed by Circuit Judge RADER.

NEWMAN, Circuit Judge.

In this declaratory action brought by Biogen, Inc., Berlex Laboratories appeals the decision of the United States District Court for the Southern District of New York, granting Biogen's motion for summary judgment of non-infringement of United States Patents No. 5,376,567 (the '567 patent) and No. 5,795,779 (the '779 patent). Biogen has filed a conditional cross-appeal on the issue of patent

validity.

BACKGROUND

The '567 and '779 patents relate to recombinant DNA technology and the production of human interferon; the conditions of this production form the issues in this litigation. The inventors are Francis P. McCormick and Michael A. Innis of Cetus Corporation, and Gordon M. Ringold of Stanford University. Berlex acquired the Cetus rights in 1991.

The principal issue as to the '567 patent is whether certain claims directed to the production of human interferon in Chinese hamster ovary cells were correctly construed as limited to use of a single DNA "construct" to introduce both a selectable marker gene and the human interferon gene into the host cell. The process whereby a DNA construct (also called a "vector" or "vector construct" or "plasmid") carrying foreign (called "heterologous") genes is introduced into and accepted by a host cell is called "transformation" or "transfection." The process is called "linked co-transformation" when multiple genes are linked in a single DNA construct, and "unlinked co-transformation" when multiple genes are introduced using separate DNA constructs.

The district court observed that integration of heterologous genes is a rare event, typically successful in less than one cell in 100,000, and that it is both difficult and important to detect whether cells have been successfully transformed, as well as to isolate the transformed cells in order to obtain an uncontaminated protein product upon expression of the gene. A selectable marker gene has been used to aid in detecting and isolating transformed cells. In accordance with this procedure, cells lacking a gene that encodes a substance essential to the cell are prepared as host cells, and a DNA construct is prepared to embody the missing gene; then the cells that are successfully transformed with the DNA marker will survive when placed in a medium that is toxic to cells lacking the encoded substance. For the patents in suit, Chinese hamster ovary cells that lack the gene that encodes the enzyme dihydrofolate reductase (DHFR) are used as the host cells.

The patents in suit describe the linked co-transformation of Chinese hamster ovary cells using a

single construct carrying both the human interferon gene and the gene for the marker DHFR. In the Biogen process the same genes are used for the same purpose in the same cells, but the interferon gene and the DHFR gene are introduced by separate constructs, that is, by way of unlinked co-transformation. Berlex states that its cell and method claims, correctly construed, literally cover this variation, and alternatively that the construct claims are infringed in terms of the doctrine of equivalents.

I

THE '567 PATENT

The court gives plenary review to interpretation of the scope of patent claims and to the grant of summary judgment based thereon. See Cybor Corp. v. FAS Technologies, Inc., 138 F.3d 1448, 46 USPQ2d 1169 (Fed. Cir. 1998) (en banc) (claim construction is performed de novo on appeal).

Claims 42, 66, 68, and 70 are representative of the "method" and "cell" claims of the '567 patent, claims that Berlex asserts are not limited to the use of a single DNA construct carrying both the human interferon gene and the marker gene:

42. A method for the production of human interferon in a Chinese hamster ovary cell, comprising growing a Chinese hamster ovary cell having incorporated therein a DNA construct comprising human α - or β -interferon gene, which construct is effective for expression of said human interferon gene, under conditions whereby the interferon gene in said construct is expressed.

66. A Chinese hamster ovary cell having incorporated therein an expressible gene encoding human α - or β -interferon, or a progeny thereof.

68. A Chinese hamster ovary cell having incorporated into its chromosome an expressible gene encoding human interferon, or a progeny thereof.

70. A method of producing human interferon comprising growing a progeny cell of a Chinese hamster ovary cell which has been transformed with an expressible interferon gene and an expressible gene for dihydrofolate reductase, under conditions effective for expression of said human interferon gene.

Of these claims, only claim 70 mentions the dihydrofolate reductase marker gene, and none of these claims mentions the use of a single DNA construct. However, the district court, on review of the specification and the prosecution history, and receiving the testimony of expert witnesses for both sides, construed all the claims as requiring use of a single construct and linked co-transformation with both the

interferon and marker genes.

A. Claim Construction

The district court found that the '567 specification discusses only the invention wherein a single DNA construct, linking the interferon gene and the marker gene, is used to introduce the foreign DNA into the Chinese hamster ovary cells, and held that this procedure limits all the claims, including the cell and method claims. Berlex argues that the single construct is only a preferred embodiment, and that it is incorrect to limit the claims to the preferred embodiment. The district court, also reviewing the prosecution history, concluded that the asserted broader scope is not warranted.

Berlex argues that the '567 patent includes the larger discovery of the advantageous use of cells of the Chinese hamster ovary to produce human interferon, and that claims 42, 66, 68, and 70 reflect this larger concept. Berlex states that it is irrelevant to the cell and method claims whether transformation of the Chinese hamster ovary cell is achieved by single or multiple constructs, and that these claims are not limited to use of a selectable marker. Berlex states that the specification describes two separate aspects of the invention: 1) the use of Chinese hamster ovary cells to produce high levels of human interferon without expression of the hamster interferon, and 2) the use of a single DNA construct carrying the genes for both human interferon and a selectable marker. Berlex points out that the divisional '567 application was filed after claims specific to the single DNA construct had been allowed in the parent application, now United States Patent No. 4,966,843 (the '843 patent), and that the '567 claims were intended to be, and are, of different scope.

Biogen responds that Berlex's asserted breadth of the '567 claims is not supported in the specification and that if the claims were interpreted as broadly as Berlex proposes, they would be invalid for lack of an adequate written description. Biogen states that the patent examiner did not view the '567 claims as having the breadth now asserted. Each side cites portions of the specification and prosecution history as supporting its position, and each side provided expert testimony that a person in the field of the invention would understand the patent record in accordance with its position.

Berlex cites the following statements in the specification in support of its proposed broad construction of the claims:

Col. 1, lines 14-17:

This application relates to human interferons and their production in Chinese hamster ovary cells and therapeutic formulations including the human interferon so produced.

Col. 3, lines 1-8:

In preferred embodiments, DNA fragments which code for one or more IFNs [interferons] are isolated from appropriate human cells; introduced into CHO cells by DNA transfection, or by penetration of viral vectors carrying the DNA fragments, or by transfection of cloned plasmids into cells that express T-antigens; and expressed by the host cells; and the expressed product is isolated and purified.

Berlex stresses that the above statements make no mention of a single construct and linked genes.

Berlex also cites the statement at col. 15, lines 32-47:

[A]ny approach may be used to introduce the cloned DNA into CHO cells and to select and grow the transformed cells for expression of the protein.

Berlex places particular emphasis on the above statement, as meaning that the '567 cell and method claims are not limited to any specific method of introduction of the human interferon DNA, and that the larger invention is the use of selected Chinese hamster ovary cells to produce the human interferon. Berlex argues that the interchangeability of linked and unlinked methods of co-transformation was known before the '567 application was filed, and submitted expert statements that a person skilled in the field of the invention would have understood that either method could be used to introduce both interferon DNA and marker DNA into these cells. Berlex also directs attention to the patent's statement, quoted supra, that the DNA may be introduced by means of a virus, and presented expert testimony that a person skilled in this field would know that a selectable marker is not generally used in viral transformation. Berlex argues that the above-quoted parts of the specification establish that the cell and method claims are not limited to use of a single construct of linked genes.

Biogen responds that except for these few general undeveloped sentences the entire specification is directed solely to the invention whereby a single DNA construct is used to carry linked interferon and marker genes into the Chinese hamster ovary cell, starting with the Summary of the Invention:

Accordingly, the present invention provides a DNA construct for the expression of the

human interferon gene in Chinese hamster ovary cells or progeny thereof comprising an operable linkage of:

(a) a nucleotide sequence from a cloning vector which allows for replication in a prokaryotic cell;

(b) a first gene capable of transcription and translation in Chinese hamster ovary cells or progeny thereof operably linked to a selectable marker for the selection of Chinese hamster ovary (CHO) cell transformants or progeny thereof; and

(c) a human interferon gene capable of transcription and translation in Chinese hamster ovary cells or progeny thereof. [Col. 2, lines 33-46]

The Abstract of the invention states:

DNA constructs are prepared which operably link human interferon genes, selective, eukaryotic marker genes, and promoter and expression control sequences for the expression of human interferon in Chinese hamster ovary (CHO) cells or progeny thereof. [Page 1]

The Description of the Preferred Embodiments states:

The method of effecting expression of heterologous genes in CHO host cells or progeny thereof generally involves preparing DNA constructs as defined above operably linked to a nucleotide sequence for replicating in a prokaryotic cell . . . ; a marker gene . . . ; and an interferon gene from a human source This DNA construct is then introduced in CHO cells [Col. 5, line 64 to col. 6, line 11]

The specification describes only linked DNA sequences and transformation procedures using single constructs linking human interferon and dihydrofolate reductase marker genes to transfect Chinese hamster ovary cells. Although there is mention of viral vectors, as quoted supra, it is well recognized that for complex biological processes a reference to known general techniques does not establish whether or how such techniques may be successfully adapted to a particular activity. Further, the specification acknowledges that prior studies failed to solve "technical problems involved with introducing DNA fragments into animal tissue culture cells [and] . . . other problems relating to the production of the host IFN [interferon]." The specification does not describe or present details of any other configuration for introducing these genes.

Although Berlex concedes, as it must, that the specification exemplifies only co-transformation using a linked construct, Berlex argues that the prosecution history shows that the true scope of the invention is broadly the use of Chinese hamster ovary cells for recombinant production of human interferon, independent of the construct used. The district court did not agree with this view of the prosecution history. Nor do we.

The prosecution record shows that the claims in suit were amended to their present scope during prosecution of the '567 patent, which issued from a divisional application filed after allowance of the

parent '843 patent. All of the '843 claims explicitly state the single construct of linked interferon and marker genes. The claims of the divisional application filed in 1990 were similarly limited, but on refiling Berlex introduced claims that did not mention the single construct, stating:

The foregoing claims are being added to cure an inadvertent oversight during ancestor prosecution leading to U.S. Patent 4,966,843. . . . The oversight cured above involves the unnecessary language in the '843 claims concerning prokaryotic cell nucleotide sequences and selectable marker-related sequences. Whereas such sequences are useful in various cloning experiments and procedures, they clearly are not necessary to a prime aspect of '843, i.e., "production in Chinese hamster ovary cells."

Preliminary Amendment, April 30, 1992.

On September 22, 1992, Berlex filed a terminal disclaimer whereby the '567 claims would expire concurrently with the '843 patent. The examiner, finding a technical flaw in the terminal disclaimer, issued an obviousness-type double-patenting rejection. In this rejection the examiner described the '567 claims as not patentably distinct from the '843 single construct claims. The examiner stated that the '567 claims were simply a change to "functional language" and that this language "effectively limits the claims to the vector construct of the '843 application":

In the parent patent, the claims recite the DNA construct by listing each element of the vector construct. The instant application seeks to remove the detailed language of the construct elements, and replaces it with functional language. This functional language effectively limits the claims to the vector construct of the '843 application. The DNA construct, either described by its physical elements or by its function, is the same in the prior patent and the instant application.

Examiner's Action, October 5, 1992.

Berlex corrected the flaw in the terminal disclaimer, and thereafter the examiner allowed the DNA construct claims, but rejected the other claims on an issue relating to "muteins," against which prior art was cited. Following an interview the applicant deleted all reference to muteins, amended the allowed construct claims to recite the dihydrofolate reductase marker gene, and amended the method and cell claims whereby most but not all of these claims included the single linked DNA construct. In the accompanying Remarks the applicant described the amendments as "clarifying," discussed that there was no adverse prior art, and stated that "no further searching is required by these amendments." The

applicant also "clarified" the parent '843 record, which had stressed linked co-transformation based on an admittedly erroneous reading of a reference to Axel et al.:

. . . certain aspects of prosecution which led to ancestor U.S. Patent No. 4,996,843 merit clarification. Where the record of this application differs from that of ancestor prosecution . . . it is the current record which is relevant. . . . It is not relevant whether the Axel et al. prior art patent disclosures of record actually employ only unlinked co-transformed genes in their work. (Axel et al. do generically disclose linked such genes. See, e.g., column 7, lines 3-31, of, e.g., U.S. Patent No. 4,399,216.) Patentability and breadth of the current claims reflect the non-obviousness of the first expression of human IFN in CHO cells and do not depend on any particular nucleic acid construct configuration.

Applicant's Remarks, Sept. 21, 1994. The applicant also stated:

The resultant scope [of the amendments] falls within the scope of subject matter already allowed over prior art.

There ensued a telephonic interview on November 14, 1994, and a Notice of Allowability was issued, cancelling a few claims by Examiner's Amendment, and stating the examiner's Reasons for Allowance as follows:

Applicants' claims are directed to a DNA construct comprising a vector, an interferon gene, and a dhfr marker gene. The construct is expressed in CHO cells. The instant claims are similar to the claims in parent Patent 4,966,843 ('843), however the instant claims recite the marker gene to be dhfr, whereas the '843 claims do not. Since a terminal disclaimer has been filed over the '843 claims, the instant claims are held allowable.

Notice of Allowability, November 16, 1994. Thus the examiner stated that the claims are directed to the single DNA construct with linked genes, and that allowance depended on the terminal disclaimer. No recognition was given to the applicant's statement in the Remarks quoted supra that "the current claims . . . do not depend on any particular nucleic acid construct configuration."

Berlex responded to the examiner's Reasons for Allowance, as the Notice of Allowability mentioned and the Rules authorize.^[1] This response, apparently through PTO error, was not included in the certified prosecution record, and the district court declined to give it any weight because the public did not have access to it. The district court erred on this aspect, for the document is indeed part of the official record, despite the PTO error in omitting it. Nonetheless the district court, exercising sound discretion, reviewed the document, observing the statement by the applicant that "as is factually

clear from the involved texts of record, the claims of both this application and '843 reflect aspects other than those mentioned by the examiner, e.g., for this application, methods and cells, no need for a prokaryotic sequence, etc.," from which the applicant concluded that there was not double patenting. Although the district court declined to give weight to this document, it is consistent with the other prosecution statements by Berlex and does not, indeed cannot, change the examiner's Reasons for Allowance.

The examiner in allowing the claims did not distinguish among the construct, cell, and method claims. Berlex argues that it had made clear during the prosecution that its cell and method claims were directed broadly to use of the Chinese hamster ovary cell to produce human interferon, but the district court viewed the entire prosecution record as showing that the examiner never so viewed the invention under examination. Berlex argues that the district court misconstrued the record, and that the examiner's Reasons for Allowance relate only to the construct claims. Although the examiner's responses are unresponsive to the applicant's representations, they are unambiguous. Indeed, objective reading of the prosecution history shows that the examiner recognized that the only supportable scope of the claims was for the linked construct. This scope was recited in the Reasons for Allowance and applied by the district court.

Berlex states that the district court improperly relied on the arguments in prosecution of the parent '843 patent, and erroneously limited the '567 claims to the same scope as the '843 claims. In prosecution of the '843 patent the applicant had argued that the use of a single linked construct of interferon/marker DNA was a distinction from and advantage over the use of multiple unlinked constructs shown in the Axel prior art. Berlex states that it later discovered that the applicant had misunderstood Axel, and corrected the error in the '567 prosecution record. The district court acknowledged this correction, which is quoted ante, but did not view the correction as establishing the broad claim construction being asserted for the '567 claims.

Berlex is correct that arguments made in a related application do not automatically apply to different claims in a separate application. The applicant's discovery that the Axel reference had been

mischaracterized in the '843 prosecution indeed necessitated a change to comport with the correct content of the reference. Thus in the '567 prosecution the applicant pointed out that Axel describes both linked and unlinked genes, and argued that the difference was irrelevant. However, this correction does not change the content of the specification or its description of the invention as using a single construct for linked co-transformation. The applicant's statements to the examiner that the '567 claims "fall within the scope of subject matter already allowable over the prior art" weigh heavily against Berlex's now-proposed broad construction.

The district court found that the single DNA construct was the basis on which all of the '567 claims were allowed by the patent examiner, and declined to interpret the cell and method claims as free of this limitation. See Modine Mfg. Co. v. Int'l Trade Comm'n, 75 F.3d 1545, 1551, 37 USPQ2d 1609, 1612 (Fed. Cir. 1996) ("when the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment"). The court correctly viewed the prosecution history not for the examiner's or the applicant's subjective intent, but as an official record that is created in the knowledge that its audience is not only the patent examining officials and the applicant, but the interested public. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 985-986, 34 USPQ2d 1321, 1334-1335 (Fed. Cir. 1995) (en banc) ("The subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim (except as documented in the prosecution history). . . . [T]he focus is on the objective test of what one of ordinary skill in the art at the time of the invention would have understood the term to mean.") (citations omitted), aff'd 517 U.S. 370, 38 USPQ2d 1461 (1996). Any ambiguity, as may be raised when dispute arises, requires the decisionmaker to focus objectively on the patent specification and claims, for the specification is the basic presentation by the applicant, and the claims represent the final product of a sometimes imperfect process. Representations during prosecution cannot enlarge the content of the specification, and the district court was correct in relying on the specification in analyzing the claims. See, e.g., Slimfold Mfg. Co. v. Kinkead Industries, Inc., 810 F.2d 1113, 1116-17, 1 USPQ2d 1563, 1566 (Fed. Cir. 1987) (claims are interpreted in light of the specification); Texas Instruments, Inc. v. Int'l Trade Comm'n, 846 F.2d 1369, 1371-72, 6 USPQ2d 1886, 1889 (Fed. Cir. 1988) (invoking the

principle of the reverse doctrine of equivalents and holding that "when the claims are written more broadly than the disclosure warrants" they may be construed "to preserve the validity of the claims with respect to their original intended scope"). Implementing these principles, the district court construed the claims to conform with the basis on which the invention was presented in the specification.

The district court correctly ruled that the specification defines the invention as the use of a single DNA construct to introduce the linked human interferon gene and selectable marker gene into the host Chinese hamster ovary cell, and that the method and cell claims, as well as the construct claims, are so limited. See Network, LLC v. Centraal Corp., 242 F.3d 1347, 1352, 58 USPQ2d 1076, 1079 (Fed. Cir. 2001) ("Although the specification need not present every embodiment or permutation of the invention and the claims are not limited to the preferred embodiment of the invention, neither do the claims enlarge what is patented beyond what the inventor has described as the invention.") (citations omitted); cf. SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc., 242 F.3d 1337, 1341, 58 USPQ2d 1059, 1062-63 (Fed. Cir. 2001) ("Where the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.")

We affirm the district court's construction of claims 42, 66, 68, and 70 of the '567 patent.

B. Infringement

On the district court's correct claim construction, the summary judgment that there is not literal infringement necessarily follows, and is affirmed.

The district court also granted Biogen's motion for summary judgment of non-infringement of the '567 patent under the doctrine of equivalents, based on prosecution history estoppel. The court found that during prosecution of the parent '843 application, the applicant had disclaimed the use of multiple constructs. As we have observed, the applicant in the '843 prosecution argued the advantages

of a single construct, in distinguishing the Axel reference. However, in prosecuting the '567 application Berlex pointed out the erroneous understanding of the Axel reference in the '843 prosecution, and explained that this aspect of Axel was not relevant to patentability of the '567 claims.

Whether estoppel arises based on arguments made in a related application depends on the circumstances, and is not a matter of rote. See Read Corp. v. Portec, Inc., 970 F.2d 816, 824, 23 USPQ2d 1426, 1433 (Fed. Cir 1992) ("Every statement made by a patentee during prosecution to distinguish a prior art reference does not create a separate estoppel. Arguments must be viewed in context.") In prosecuting a related application the applicant is not barred from raising new arguments or correcting past errors. When the applicant is seeking different claims in a divisional application, estoppel generally does not arise from the prosecution of the parent. See Middleton, Inc. v. Minnesota Mining and Manufacturing Co., 311 F.3d 1384, 1388, 65 USPQ2d 1138, 1141 (Fed. Cir. 2002) (considering meaning of word "uniform" as used in parent and continuing patents, and limiting estoppel to the arguments needed to overcome prior art). Thus the '567 patentee, having in the '843 prosecution argued that a single linked construct has advantages over multiple unlinked constructs, is not thereby estopped from asserting that the multiple construct infringes under the doctrine of equivalents. See Laitram Corp. v. Cambridge Wire Cloth Co., 863 F.2d 855, 859, 9 USPQ2d 1289, 1294 (Fed. Cir. 1988) (inefficient infringement may still be infringement).

We conclude that no estoppel to assertion of equivalence of the '567 claims arose based on the argument distinguishing the Axel reference in prosecution of the '843 claims. The facts of equivalency were not reviewed by the district court, who summarily decided the question as a matter of estoppel. This court's en banc decision in Festo issued soon after the district court's decision, Festo Corp. v. Skoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 56 USPQ2d 1865 (Fed. Cir. 2000), and Berlex conceded on this appeal that its claim for equivalency was defeated by the Festo absolute bar, leaving the issues unbriefed. Upon the Supreme Court's vacatur of our decision and rejection of the absolute bar, Festo, 535 U.S. 722; 122 S. Ct. 1831, 12 USPQ2d 1705 (2002), Berlex's arguments concerning equivalency may be considered by the district court, along with any relevant defenses. Thus we vacate the summary judgment on this issue and remand for determination of infringement of the '567 patent

under the doctrine of equivalents.

II

THE '779 PATENT

The '779 patent is a continuation of the '567 patent, and claims the Chinese hamster ovary cell culture composition of the transformed cells wherein human beta-interferon is secreted in the concentration range of 150,000-600,000 IU/ml of medium. Claim 1 is the broadest claim is suit:

1. A CHO cell culture composition comprising (a) CHO cells transformed with DNA encoding human IFN- β , or progeny thereof, and (b) medium comprising IFN- β produced by expression of said DNA, said culture composition directly resulting from secretion of said IFN- β from said CHO cells and wherein the amount of said IFN- β is 150,000-600,000 IU/ml of medium.

The district court decided the issue of infringement upon construing the '779 claims to mean that 150,000-600,000 IU/ml is the interferon activity obtained after "confluence and superinduction,"^[2] that is, at the end of the production process. The Biogen composition's final interferon concentration exceeds 1,200,000 IU/ml. Biogen stipulated that its product passes through the 150,000-600,000 IU/ml range en route to its final concentration. The district court held that it is irrelevant that the Biogen composition passes through the claimed concentration, and granted Biogen's motion for summary judgment of non-infringement.

Berlex argues that a composition that has the claimed concentration of interferon at any time during the production process infringes claim 1. The district court described Berlex's interpretation as contrary to the claim language, the specification, and the prosecution history. The specification reports the interferon concentration at the completion of several experimental runs, and describes these measurements as the activity after confluence and superinduction. The court recognized that a composition of higher activity will normally traverse a lower range while it is being produced, and described the 150,000-600,000 IU/ml claim limitation as meaningless unless it is directed to the activity of the final product.

Berlex states that the district court's interpretation renders the subordinate claims superfluous, in violation of the doctrine of claim differentiation, and offers other arguments to support its proposed view of the claims. For example, during prosecution the applicant wrote the examiner that these activity limits were included in the claims only to expedite prosecution. However, we are not persuaded of error in the district court's interpretation of the claims. As in Genentech, Inc. v. Wellcome Foundation Ltd., 29 F.3d 1555, 1564, 31 USPQ2d 1161, 1167 (Fed. Cir. 1994), claims that were deliberately limited in order to expedite prosecution by avoiding examination cannot regain that scope for infringement purposes.

On the district court's correct claim interpretation, the summary judgment of non-infringement of the '779 patent must be affirmed. The question of infringement of the '779 patent under the doctrine of equivalents was also decided adversely to Berlex by the district court, and is not appealed.

SUMMARY

We affirm the district court's claim construction for the '567 and the '779 patents. The summary judgment that there is not literal infringement of the '567 patent, and no infringement of the '779 patent, is affirmed. We vacate the summary judgment of non-infringement of the '567 patent under the doctrine of equivalents, and remand for determination of this question. Biogen's conditional cross-appeal is moot, and is dismissed.

Each party shall bear its costs.

AFFIRMED IN PART, VACATED IN PART, and REMANDED;
CROSS-APPEAL DISMISSED

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RADER, Circuit Judge, concurring-in-part.

I agree with my colleagues in the outcome of this decision, although I reach that outcome with slightly different reasoning on the issue of infringement of the '567 patent under the doctrine of equivalents.

In 1985, Berlex added a new Summary of the Invention section to its original patent application as a continuation-in-part, which ultimately issued as the '843 patent. Berlex later filed a divisional application of this continuation-in-part, a continuation of which issued as the '567 patent. At issue are the 80 new claims Berlex added to this continuation patent application in a 1992 preliminary amendment, and an additional 39 new claims added during prosecution in 1994. The examiner made clear throughout the pendency of the '567 patent application that these newly added claims were not patentably distinct from the claims that issued in the '843 patent.

This court reasons that arguments made in the prosecution of the '843 patent "do not automatically apply to different claims in a separate application." Opinion at 12. In the abstract, I agree. Here, however, the record indicates that the '567 claims are not patentably distinct from the previously issued '843 claims. These two patents, according to record evidence, claim the same subject matter. Members of the public reading the file histories of these two patents would not discern a difference between these '567 claims and the parent '843 claims, nor do I.

To extend the '567 patent claims to ensnare multiple unlinked constructs under the doctrine of equivalents, the fact finder must disregard the patentee's comments made to distinguish the single linked construct of the patentably indistinguishable '843 patent claims from the prior art. Berlex, having surrendered multiple constructs in the '843 patent prosecution, cannot recapture such constructs by filing

patentably indistinguishable claims in a related patent. Because the claims of the '567 and '843 patents are patentably indistinguishable, the prosecution history of the parent application may well apply to its progeny.

For this reason, I write to suggest that estoppel distinguishing the '843 claims from the Axel reference may well affect the equivalence calculus for the '567 claims. After all, both patents claim the same subject matter. Moreover, a broad reading of the '567 patent claims would run afoul of the prohibition against introduction of new matter in amended claims. The claims at issue were added between ten and twelve years after the filing date of the 1982 priority application. The district court correctly determined that the specification does not support an interpretation of these new claims that encompasses multiple constructs. In the final analysis, the '843 and '567 patents simply cannot concurrently recite "patentably indistinguishable" claims of substantively different scope. Therefore, on remand for assessment of the Supreme Court's Festo factors, I would have the district court fully consider arguments made by the patentee in the prosecution of the '843 patent to determine the issue of infringement by equivalents.

[1] An applicant's "comments on statement of reasons for allowance" may be submitted no later than the submission of the issue fee. See MPEP §1302.14 (7th ed. 1998) ("comments [on

statement of reasons for allowance] will be entered in the application file").

[2] "Confluence" is the point at which the transformed CHO cells reach their maximum density on the culture medium. "Superinduction" means that those cells have been chemically stimulated to produce interferon.