United States Court of Appeals for the Federal Circuit

00-1127

MYCOGEN PLANT SCIENCE, INC. and AGRIGENETICS, INC.,

Plaintiffs-Appellants,

v.

MONSANTO COMPANY,

Defendant-Appellee.

Daniel J. Thomasch, Orrick, Herrington & Sutcliffe LLP, of New York, New York, argued for plaintiffs-appellants. With him on the brief were Richard W. Mark, and Robert M. Isackson; and Craig R. Kaufman, of Menlo Park, California.

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Appealed from: United States District Court for the Southern District of California

Judge Napoleon A. Jones, Jr.

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DECIDED: May 30, 2001

Before CLEVENGER, BRYSON, and LINN, Circuit Judges.

BRYSON, Circuit Judge.

Mycogen Plant Science, Inc., and its licensee, Agrigenetics, Inc., (collectively "Mycogen") filed suit against the Monsanto Company in the United States District Court for the Southern District of California, charging Monsanto with infringing Mycogen's U.S. Patent No. 5,380,831 (the '831 patent). On Monsanto's motions for summary judgment, the district court ruled, inter alia, that the process claims of the '831 patent are invalid under 35 U.S.C. § 102(g); that Monsanto could not have infringed Mycogen's process claims under 35 U.S.C. § 271(g) based on any process Monsanto performed before the '831 patent issued; and that prosecution history estoppel barred application of the doctrine of equivalents to the product claims of the '831 patent. On appeal, Mycogen argues that each of those rulings is wrong. For its part, Monsanto argues that the judgment of invalidity can

be affirmed on the alternative ground of lack of enablement under 35 U.S.C. § 112, paragraph 1.

We conclude that the district court improperly resolved disputed questions of material fact pertaining to the issue of prior invention, and we therefore reverse the court's ruling on summary judgment that the '831 patent is invalid under 35 U.S.C. § 102(g). We decline to affirm the summary judgment of invalidity on the alternative ground of non-enablement, as urged by Monsanto, but leave to the district court the task of determining in the first instance whether there is a genuine issue of material fact as to enablement based on its assessment of the evidence presented to it in the summary judgment proceeding. We affirm the district court's ruling on the interpretation of 35 U.S.C. § 271(g) and its ruling that Monsanto is not liable for infringement under the doctrine of equivalents.

I

This case is closely related to another infringement suit, the first of two related actions involving Mycogen and Monsanto in the District of Delaware. Mycogen Plant Science, Inc. v. Monsanto Co., 243 F.3d 1316, 58 USPQ2d 1030 (Fed. Cir. 2001) ("Delaware I"). The patents at issue in Delaware I were U.S. Patent No. 5,567,600 (the '600 patent) and U.S. Patent No. 5,567,862 (the '862 patent), both of which are owned by Mycogen. Those two patents are child patents of the '831 patent, which is at issue in this case. All three patents are entitled "Synthetic Insecticidal Crystal Protein Gene." The three patents have virtually identical specifications, and they contain similar claims. This court's recent decision in Delaware I affirmed both the district court's claim construction and the jury's verdict finding the claims of the '600 patent and the '862 patent invalid due to prior invention under 35 U.S.C. § 102(g). 243 F.3d at 1320, 58 USPQ2d at 1033.

The ’831 patent, like the ’600 and ’862 patents, involves the technology of genetically engineering plant genes to protect plants from insect pests. The court’s opinion in Delaware I describes the scientific background relating to the insecticidal characteristics of Bacillus thuringiensis (“Bt”), a naturally occurring bacterium that served as the starting point for research into the inventions and the genetic engineering techniques involved. The Delaware I opinion also describes most of the background facts that are material to this decision, particularly with respect to the research activities that culminated in the Mycogen patents and the competing research activities by scientists at Monsanto.

II

Mycogen appeals the district court’s grant of summary judgment holding claims 1, 3, 4, 8, and 11 of the ’831 patent invalid as anticipated by prior invention and holding the remaining process claims of the ’831 patent, claims 2, 5, 6, 7, 9, 10, and 12, invalid as obvious in light of the same prior work. The prior invention on which the court relied consisted of work done by scientists at Monsanto. As the grant of summary judgment was based on the court’s ruling on prior invention, the validity of all 12 claims can be considered together on appeal.

Under 35 U.S.C. § 102(g)(2), an applicant is not entitled to a patent if “before the applicant’s invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it.” Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376-79, 231 USPQ 81, 87-90 (Fed. Cir. 1986). An inventor can establish that he was the first to invent under section 102(g) by showing either that he was first to reduce the invention to practice or that he was first to conceive the invention and then exercised reasonable diligence in attempting to reduce the invention to practice from a

date just prior to the other party's conception to the date of his reduction to practice. 35 U.S.C. § 102(g) ("In determining priority of invention . . . there shall be considered . . . the reasonable diligence of one who was the first to conceive and last to reduce to practice, from a time prior to conception by the other."); Mahurkar v. C.R. Bard, Inc., 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996). Accordingly, for Monsanto to succeed in challenging the validity of Mycogen's '831 patent based on Monsanto's claim to prior inventorship, Monsanto must show by clear and convincing evidence both (1) that it reduced the invention to practice before Mycogen, and (2) that Mycogen did not conceive the invention first and then exercise diligence in reducing it to practice from before the date of Monsanto's conception.

The district court ruled that collateral estoppel from Delaware I required it to conclude that Monsanto had reduced the invention of the '831 patent to practice before Mycogen. The court further ruled, however, that collateral estoppel did not apply to the issue of whether Mycogen had been the first to conceive the invention and then had been diligent in reducing the invention to practice during the critical period, which the court properly defined as beginning just before Monsanto's conception and ending with Mycogen's constructive reduction to practice on September 9, 1988. Addressing the merits of that issue, the court concluded that Monsanto had established that Mycogen had not been diligent during the critical period. The court therefore granted summary judgment of invalidity based on Monsanto's prior invention.

We agree with the district court that collateral estoppel requires the court to conclude that Monsanto reduced the invention to practice before Mycogen, and that collateral estoppel does not resolve the question whether Mycogen was the first to

conceive and then was diligent during the critical period. On the merits of the summary judgment question, however, we do not agree that Monsanto has met its burden of showing that there are no issues of material fact regarding whether Mycogen was the first to conceive the invention and then diligently reduce it to practice.

A

The district court concluded that collateral estoppel required it to adopt findings from the Delaware suit on two issues: claim construction and Monsanto's reduction to practice prior to Mycogen. In Delaware I, this court affirmed the Delaware district court on both of those issues. 243 F.3d at 1330, 1337, 58 USPQ2d at 1041, 1047.

It is undisputed that as a result of collateral estoppel, a judgment of invalidity in one patent action renders the patent invalid in any later actions based on the same patent. Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found., 402 U.S. 313, 349-50, 169 USPQ 513, 527-28 (1971). Collateral estoppel also applies to common issues in actions involving different but related patents. See, e.g., Amgen, Inc. v. Genetics Inst., Inc., 98 F.3d 1328, 1329-32, 40 USPQ2d 1524, 1524-27 (Fed. Cir. 1996) (collateral estoppel renders claims invalid when a narrower claim in a parent patent with the same specification had been held invalid as not enabled in an earlier action); Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1136, 227 USPQ 543, 546 (Fed. Cir. 1985) (collateral estoppel can preclude relitigation of the same issue even in connection with different claims). Thus, the question presented here, with respect to the application of collateral estoppel, is whether any of the issues resolved in the Delaware action are the same as any of the issues presented in this case.

The independent process claim of the '831 patent recites:

1. A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes an insecticidal protein toxin, and

modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence.

'831 patent, col. 38, ll. 25-34.

In comparison, a representative claim of the '600 patent, which was found invalid in the Delaware suit, recites:

1. A method of designing a synthetic Bacillus thuringiensis gene to be more highly expressed in plants, comprising the steps of:

(a) analyzing the coding sequence of a gene derived from a Bacillus thuringiensis which encodes an insecticidal protein toxin,

(b) modifying a portion of said coding sequence to yield a modified sequence which contains a greater number of codons preferred by the intended plant host than did said coding sequence prior to

modification, said modification comprising reducing the number of codons having CG in codon positions II and III in a region between plant polyadenylation signals in said coding sequence,

(c) inserting said modified sequence into the genome of a plant cell, and

(d) maintaining said plant cell under conditions suitable to allow replication of said plant cell to produce additional plant cells having said modified sequence in the genome of said additional plant cells, wherein said Bacillus thuringiensis gene is expressed to produce a pesticidal protein toxin.

'600 patent, col. 31, ll. 37-57.

The two steps recited in claim 1 of the '831 patent are also found in claim 1 of the '600 patent. The two claims differ in that claim 1 of the '600 patent includes two further steps in addition to the two steps that are common to both claims, and it also includes additional limitations requiring removal of a number of codons having the nucleotide bases guanine and cytosine (GC) in codon positions II and III.

With respect to claim construction, the terms of the claims of the '831 patent must be construed consistently with the same terms in the '600 patent. Claim construction was

litigated in Delaware I before both the district court and this court, and determination of that issue was necessary to the judgment in that case.

Similarly, a finding that Monsanto reduced the four-step invention of the '600 patent to practice before September 9, 1988 (the date on which it is undisputed that Mycogen reduced the invention to practice), necessarily means that Monsanto also reduced the two-step invention of the '831 patent to practice before September 9, 1988. As with claim construction, prior invention by Monsanto was argued before the district court and this court in Delaware I and was critical to the judgment.

Monsanto did not argue to the district court or to this court that collateral estoppel dictated a finding on the issues of Mycogen's prior conception and diligent reduction to practice, nor would such an argument have succeeded. Collateral estoppel does not apply to those issues, because the jury in the Delaware action could have found that the Mycogen inventors had first conceived and diligently reduced to practice the two-step invention of the '831 patent but had not conceived or diligently reduced to practice the four-step invention at issue in that case. For example, the Delaware jury could have concluded that Mycogen had not conceived the limitation of reducing the number of codons having the CG base pair in codon positions II and III or had not been diligent in inserting the modified sequence into a plant cell. Such findings would support the Delaware jury's verdict, but would not support a finding of prior invention in this case.

B

Mycogen would be considered to be the first inventor under section 102(g) if it was the first to conceive and was reasonably diligent during the critical period. In order to determine whether Mycogen should be considered the first inventor on that theory, the

district court addressed the following three issues, each of which we discuss below: (1) when Mycogen conceived the claimed invention; (2) when Monsanto conceived the claimed invention; and (3) whether Mycogen was diligent during the critical period between Monsanto's conception and Mycogen's reduction to practice.

1

The district court first concluded that there was a disputed issue of material fact as to when Mycogen conceived the claimed invention. We agree with that conclusion for the reasons given by the court. The court analyzed the evidence relating to the date of Mycogen's conception, including testimony by Dr. Adang and Dr. Murray that they conceived the invention encompassed within claims 1 and 11 of the '831 patent in November 1985, and testimony by three ex-employees who corroborated the inventors' testimony. The court properly concluded that Mycogen's evidence was sufficient to raise a genuine issue of fact as to whether Mycogen conceived the invention as early as November 1985. Because that date was before Monsanto claims to have conceived the invention, the district court properly assumed for purposes of summary judgment that Mycogen was the first to conceive.

2

Having found that there was evidence from which a fact-finder could conclude that Mycogen was the first to conceive the invention of the '831 patent, the district court turned to the question whether Mycogen was diligent in attempting to reduce the invention to practice during the critical period. That inquiry, in turn, required the court to consider when Monsanto conceived the invention, and thus when the critical period of diligence began for Mycogen.

Mycogen argues on appeal that the district court erred when it concluded for purposes of summary judgment that Monsanto conceived the patented invention by October 1986. The district court stated that "Mycogen cannot dispute that by October of 1986, Monsanto had the idea to solve the Bt expression problem by creating a synthetic Bt

gene modified to contain a greater number of codons preferred by plants." The basis of the court's conclusion was testimony by the Monsanto inventors, Dr. Fischhoff and Dr. Perlak, and a memorandum prepared by Dr. Fischhoff on October 30, 1986, that documented their ideas at that time.

While we agree with Monsanto that the October 30, 1986, memorandum and testimony by Drs. Fischhoff and Perlak establish that Monsanto scientists had conceived the idea of a synthetic gene, that does not establish that they had conceived, as the claims require, that the gene would be modified by increasing the number of plant-preferred codons rather than by eliminating particular destabilizing codon sequences. On its face, the October 30, 1986, memorandum focuses on the removal of adenine and thymine base pairs (A+T). It concludes that the problem of low Bt expression was caused by low levels of mRNA and that the instability of the mRNA was a "function of its high A+T content." Monsanto asserts that the statement in the memorandum that gene segments should be replaced with "codons of lower A+T content" necessarily means that those replacement codons would be preferred by plants. However, whether a codon has lower A+T content and whether a codon occurs more frequently in a particular plant are two different concepts. As Mycogen demonstrates in its brief, in some instances eliminating codons with a high A+T content results in codons that are <u>less</u> plant-like.

Although the 1986 memorandum is not totally silent as to the codons found in plants, the memorandum does not state that gains in Bt expression are likely to result from making the codon frequency of the synthetic gene more plant-like. Nothing in the memorandum suggests that examining the codon frequencies in plants is part of the solution to the problem of low expression or that such information is necessary to practice the invention.

Monsanto points to a 1984 Monsanto report that discusses the possibility that determining the frequency with which codons are used by a particular organism may make it possible to obtain higher rates of expression of desired proteins. The October 1986 memorandum, however, does not refer to the 1984 report or the ideas it contains.

Nor does the inventor testimony clearly establish that the Monsanto scientists had conceived the invention by October 1986. In his testimony at the Delaware I trial, Dr. Perlak accurately described the October 1986 memorandum as teaching the two strategies of replacing particular AT-rich regions of the native Bt gene or synthesizing an entire gene of predetermined sequence and base composition. The second strategy would involve replacing segments up to and including the entire native Bt gene with chemically synthesized segments that coded for the same amino acids but utilized codons lower in AT content. Dr. Perlak did not, however, testify that the memorandum suggested the use of plant-preferred codons, although he later filed a declaration in which he stated that the implication of the memorandum was to suggest substituting plant-preferred codons for disfavored codons.

Dr. Perlak further testified in the Delaware I case that in 1987 he used a codon usage table to identify plant-preferred codons as he was designing Bt genes to put into plants. His testimony supports the inference that it was in late 1987 that he focused on the strategy of designing a gene with plant-preferred codons. According to his testimony, he referred to that strategy in his laboratory notebook entry for September 8, 1987. The entry for that day states: "Problem: Poor expression of Bt.K HD-1 toxic genes in plants. Possible causes: (1) regions of AT rich induced instability in RNA; (2) overall AT too rich;

(3) little used codons by plants found in gene. Solution: Order a new gene synthesized, using plant-preferred codons."

Like Dr. Perlak, Dr. Fischhoff described the status of conception in October 1986 as removing parts of the gene sequence such as polyadenylation sites and other parts of the gene that were made up largely of A and T bases, which are not commonly found in plants. He explained that it followed that upon removing some such sequence a researcher would necessarily replace it with something more plant-like. He did not testify, however, that as of October 1986 he and Dr. Perlak had conceived the idea of increasing the number of plant-preferred codons as the key to solving the problem of low protein expression of the Bt gene in plants.

The fact that removing portions of the native Bt gene having high concentrations of A and T bases generally resulted in the substitution of codons preferred by plants is not enough to constitute conception, if that result was merely a by-product of the Monsanto scientists' research program, rather than an independent objective. Conception requires contemporaneous recognition and appreciation of the limitations of the claimed invention, not merely fortuitous inherency. See Heard v. Burton, 333 F.2d 239, 243-44, 142 USPQ 97, 100 (CCPA 1964); see also Estee Lauder, Inc. v. L'Oreal, S.A., 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997). This principle also applies to the other component of invention, reduction to practice, as discussed in detail in Delaware I. See 243 F.3d at 1336, 58 USPQ2d at 1046.

To be sure, Monsanto offered testimony by several co-workers who testified that it was their understanding that one of the goals of Drs. Perlak and Fischhoff was "to move the codon usage more towards what the plants use as opposed to what the bacterial

sequence was" and to use "codons from plants to replace these AT-rich ones to maintain that protein sequence." While that testimony supports Monsanto's position on the issue of conception, it is not specific as to the dates on which Drs. Perlak and Fischhoff conceived the "plant-preferred codon" approach to the problem.

In sum, while Monsanto presented evidence that could support a finding of conception by October 1986, Mycogen has identified sufficient weaknesses in that evidence that a reasonable fact-finder could conclude that Monsanto had not conceived the invention as of that time. Accordingly, we do not agree that the record supports the finding that, as a matter of law, there is clear and convincing evidence that Monsanto had conceived the invention by October 1986.

The question remains whether the record supports any particular date as the date of Monsanto's conception as a matter of law. Monsanto argues that its conception was established by September 8, 1987, at the latest. That was the date on which Dr. Perlak pasted the design of a gene in his lab notebook and wrote that the solution was to "order a new gene synthesized, using plant preferred codons." That statement shows conception of the invention in a clear and convincing way, and Mycogen has not argued to the contrary. Accordingly, we conclude that the record compels the conclusion that Monsanto had conceived the invention by September 8, 1987, at the latest.

That conclusion requires us to consider a third question—whether Mycogen demonstrated diligence in its effort to reduce the invention to practice from just before September 8, 1987, until it constructively reduced the invention to practice by filing the parent application to the '831 patent on September 9, 1988. The district court concluded

that during at least a portion of that period, Mycogen's research efforts were not directed to the claimed invention. Instead, the court concluded, Mycogen was pursuing a different strategy—trying to find particular problem regions of the Bt gene, sometimes called "death sequences," which were inhibiting expression. In the court's view, Mycogen's goal in searching out specific problem regions of the Bt gene was not related to rebuilding the entire gene to make it more plant-like. Because Mycogen was "working on unrelated experiments," the court concluded, it was "clearly not diligent."

Mycogen argues that the district court erred when it concluded that looking for specific problem sequences to alter within the Bt gene did not constitute diligence in reducing to practice the invention of rebuilding the entire gene to make it more plant-like. We disagree. The invention was not simply to modify the Bt gene so that a plant would express Bt toxin. Instead, the invention was to devise a method of designing a synthetic Bt gene by analyzing the coding sequence of the native Bt gene and modifying a portion of that coding sequence so that the modified sequence would contain a greater number of plant-preferred codons. Accordingly, Mycogen's research efforts directed at identifying specific problem areas that were inhibiting expression did not constitute diligence toward reduction to practice of the claimed invention.

That conclusion does not end the inquiry, however, because not all of Mycogen's work was directed at the concept of locating and making changes to particular problem areas of the native Bt gene. Dr. Murray, one of the inventors of the '831 patent, began compiling codon usage tables on August 27, 1987, prior to the beginning of the critical period that we have defined for summary judgment purposes. She testified that she put together a codon usage table at that time, "to use to show people so we could proceed

with rebuilding the gene," and that her work at that time was the beginning of the effort to create the tables that were ultimately included in the '831 patent. Her declaration states that she "continued to work on obtaining gene sequences for the purpose of generating and compiling the codon usage tables from August 27, 1987 to June 28, 1988," and that the "preparation of the codon usage tables was carried out without any significant gaps or delays."

Those statements are supported by several notebook entries. In particular, Dr. Murray's entries for August 27, 1987, indicate that she developed codon usage tables for both the Bt bacterium and for plants. She pasted an article into her notebook that showed, in her words, that changing "favored codon usage to unfavored codon usage destabilized the gene's translation," and she wrote that the "general idea is we should change the coding sequence of the Bt gene to make it look more like a plant gene." Later entries also demonstrate continued work directed at creating codon usage tables.

Monsanto relies on the "admission" by Dr. Adang, another one of the inventors of the '831 patent, that his company did not decide to undertake synthesis of a complete Bt gene until January 1988. However, the corporate decision to focus principally on another line of inquiry is less important than the acts of the individual inventors in attempting to reduce the invention to practice. Dr. Murray testified that although funding for synthesizing the entire gene was not approved until March 1988, her work on codon usage tables beginning in August 1987 was directed at determining how to structure a synthetic Bt gene to make it more plant-like than the native Bt gene. Her testimony is supported by her laboratory notebook entry of March 3, 1988, which states that the Mycogen scientists held a meeting on the Bt project and "decided to push ahead with rebuilding Bt gene based on

codon usage tables (I developed these)." The same entry states that the "effort to look for so-called death sequences . . . will also proceed." Moreover, Dr. Adang testified that the synthetic gene that he began to design in January 1988 was prepared using Dr. Murray's codon usage tables. The evidence before the court further showed that once the corporate decision had been made to synthesize a modified Bt gene, Dr. Murray and the other Mycogen inventors continued to work on the invention until its constructive reduction to practice in September 1988.

In order to prevail on this issue for summary judgment purposes, Monsanto must show that a reasonable fact-finder would have to conclude, by clear and convincing evidence, that the Mycogen inventors were not diligent during the critical period. In light of the documentary and testimonial evidence before the district court, we hold that there is a triable issue of fact as to whether Dr. Murray's efforts beginning in August 1987 constituted reasonable diligence in attempting to reduce the invention to practice. To be sure, the evidence suggests that there were short gaps in the work that was done on the codon usage tables during the critical period. Proof of reasonable diligence, however, does not require a party to work constantly on the invention or to drop all other work. See Bey v. Kollonitsch, 806 F.2d 1024, 1028, 231 USPQ 967, 970 (Fed. Cir. 1986); In re Nelson, 420 F.2d 1079, 1081, 164 USPQ 458, 459 (CCPA 1970); Gould v. Schawlow, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966). Thus, we conclude that the evidence of record raises a genuine issue of material fact as to whether Mycogen was diligent throughout the critical period. We therefore reverse the district court's grant of summary judgment that the process claims of the '831 patent are invalid as anticipated by prior invention by Monsanto or as obvious in light of the same prior invention.

III

Monsanto argues that, in the event the '831 process claims are not found invalid under section 102(g), we should nonetheless affirm the district court's summary judgment of invalidity on the ground that the claims are not enabled under 35 U.S.C. § 112, paragraph 1. Monsanto previously had moved for summary judgment of invalidity because of lack of enablement. The district court, however, did not reach that issue, finding it to be moot in light of the court's judgment that the claims were invalid under section 102(g). Because we have reversed the district court's summary judgment of invalidity under section 102(g), we consider Monsanto's alternative basis to affirm the decision.

A

Monsanto's first argument is based on the doctrine of collateral estoppel. The district court in Delaware I granted judgment as a matter of law that the claims of the '600 patent were invalid as not enabled. Monsanto argues that based on that judgment the process claims of the '831 patent must also be found to be not enabled.

The Delaware I judgment does not give rise to collateral estoppel on enablement for two reasons. First, this court did not reach the issue of enablement when the Delaware I judgment was appealed to this court. Delaware I, 243 F.3d at 1337, 58 USPQ2d at 1047. Accordingly, that judgment does not preclude reconsideration of the issue in other actions. See 18 Charles Alan Wright et al., Federal Practice and Procedure: Jurisdiction § 4421 n.25 (2d ed. 1988 & 2000 supp.) ("once an appellate court has affirmed on one ground and passed over another, preclusion does not attach to the ground omitted from its decision"). Second, because the '600 patent recites a four-step claim and the '831 patent recites a two-step claim, a finding that the four-step claim was not enabled does not necessarily

mean that the two-step claim was not enabled. Thus, even if this court had addressed and upheld the enablement ruling in Delaware I, collateral estoppel would not apply to the enablement issue in this case.

B

Monsanto further contends that we should uphold the summary judgment of invalidity based on lack of enablement even though the district court did not reach the enablement issue in its summary judgment ruling. We are reluctant to decide an issue that the district court has declined to address, at least in a case such as this one in which the resolution of the issue is not plain on its face.

Monsanto's argument on appeal is that the claims are too broad to be enabled by a specification that provides only one example of an embodiment of the invention. The specification of the '831 patent, however, includes more than just a single example: it contains codon usage tables, recommendations on the preferred level of homology, and means for calculating deviation of the frequency of preferred codon usage. The proper resolution of the enablement issue is thus not sufficiently clear for us to direct the district court to enter summary judgment on that issue before the district court has addressed it. Accordingly, we leave it to the district court to determine whether there is a genuine issue of material fact as to enablement.

IV

Mycogen also appeals from the district court's ruling on summary judgment that Monsanto could not be liable under 35 U.S.C. § 271(g) for selling products containing genes made before the '831 patent issued. The district court concluded that section 271(g) does not apply to products made by a process that was not patented at the time the

products were made, even though the products were sold after the patent issued. Mycogen argues on appeal that section 271(g) applies to the post-issuance sale of any product made by a patented process, regardless of when the accused infringer performed the process. This issue presents a purely legal question of statutory construction.

Section 271(g) provides:

> Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States, a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent.

Mycogen's primary argument is that the statute provides that liability attaches if the importation, offer to sell, sale, or use of the product occurs during the patent term but does not refer to the process itself being performed, or the product being made, during the term of the patent. Thus, Mycogen asserts, even if Monsanto did not perform the process claimed by the '831 patent after the patent issued, Monsanto would still be liable if it sold or used such products during the patent term.

Mycogen supports its argument by citing Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553, 38 USPQ2d 1321 (Fed. Cir. 1996). That case, however, does not answer the question posed by this one. In the Bio-Technology General case, the court held that one who imported products made by a patented process was liable under section 271(g) even though the process was performed prior to the enactment of the

statute. 80 F.3d at 1560, 38 USPQ2d at 1326. In reaching that decision, the court focused on the importation of the product, rather than its manufacture, as the triggering event. The court concluded that because liability did not attach until importation occurred, application of the statute to products that were made before the effective date of the statute did not create a retroactivity problem. Id. Because the process was performed in 1983, within the term of the 1982-issued patent, the court had no occasion to consider the question presented here—whether section 271(g) would apply to the importation of a product produced by a process that was performed before the issuance of the patent. Id.

Monsanto counters that while it is true that the use must occur during the patent term, the statute also requires that the product be "made by a process patented in the United States," and that products made before the patent issues are not made by a "process patented in the United States." In other words, Monsanto argues that "patented in the United States" means "then patented in the United States," not "later patented in the United States."

We think Monsanto has the better of the argument based on the language of section 271(g). In the phrase "a product which is made by a process patented in the United States" the verbs "made" and "patented" are part of a parallel construction, which suggests that for infringement to be found the process must be patented at the time the product is made.

The legislative history of the statute also supports the construction adopted by the district court. The congressional reports make clear that the principal purpose of the statute was to prevent a patent owner's competitors from avoiding the patent by producing products outside the United States and then importing them. See, e.g., S. Rep. No. 100-

388, at 33 (1988); H.R. Conf. Rep. No. 100-576, at 1085-87 (1988), reprinted in 1988 U.S.C.C.A.N. 1574, 2118-20. In that regard, the statute was intended to grant patent holders the same protection against overseas infringers as they already enjoyed against domestic entities. Because domestic entities do not infringe a process patent if they practice the process before the beginning of the patent term, even if they sell the products of the process during the term of the patent, see Joy Techs., Inc. v. Flakt, Inc., 6 F.3d 770, 773-74, 28 USPQ2d 1378, 1381-82 (Fed. Cir. 1993), parallel treatment of overseas entities indicates that the statute does not reach pre-issuance use of the later-patented process.

Mycogen argues that Monsanto's approach defines too narrowly the loophole that Congress intended to fix. Instead, Mycogen contends, Congress meant to impose liability for commercializing a process in addition to practicing it. The legislative history however, does not support Mycogen's position. Mycogen's only citation to the history of the statute is to a bill introduced five years before the date of enactment that expressly required the product to be made during the term of the patent. H.R. 4526, 98th Cong. (1983). Mycogen asks us to infer from the difference between the language of that bill and the language ultimately enacted that Congress altered the language in order to expand the reach of the statute. Without much stronger support in the legislative history, however, that inference is too weak to overcome the construction dictated by the plain terms of the statute that Congress enacted.

We hold, therefore, that in imposing liability for selling or using products "made by a process patented in the United States," section 271(g) requires that the patent be issued and in force at the time that the process is practiced and the product is made. Accordingly,

we affirm the district court's grant of summary judgment that Monsanto did not infringe Mycogen's process claims based on any process it performed before the patent issued.

V

In the district court, Mycogen conceded that Monsanto did not literally infringe product claims 13 and 14 of the '831 patent. Mycogen, however, asserted infringement of those claims under the doctrine of equivalents. The district court ruled on summary judgment that prosecution history estops Mycogen from relying on the doctrine of equivalents to show infringement of those claims, and Mycogen challenges that ruling on appeal.

The two claims at issue read as follows:

> 13. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1793.
>
> 14. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1833.

'831 patent, col. 40, ll. 3-8. Both claims refer to figure 1 of the '831 patent, which graphically displays a genetic sequence of 1,833 specific nucleotides. These are the only two product claims in the '831 patent.

During the course of prosecution of the '831 patent, Mycogen cancelled several claims that were originally submitted to the PTO. Among the claims canceled were application claims 1, 2, 5, and 6:

a1. A synthetic gene designed to be highly expressed in plants comprising a DNA sequence encoding an insecticidal protein which is functionally equivalent to a native insecticidal protein of Bt.

a2. A synthetic gene of claim 1 wherein said DNA sequence is at least about 85% homologous to a native insecticidal protein gene of Bt.

a5. A synthetic gene of claim 1 wherein the overall frequency of preferred codon usage within the entire coding region of said synthetic gene is within about 75% of the frequency of codon usage preferred in plants.

a6. A synthetic gene of claim 1 wherein the overall frequency of preferred codon usage within the entire coding region of said synthetic gene is within about 90% of the frequency of codon usage preferred in plants.

The prosecution history shows that those claims were rejected on the grounds of obviousness and lack of enablement, and that they were replaced by product claims 13 and 14.

This court recently held in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 563, 56 USPQ2d 1865, 1868 (Fed. Cir. 2000), that "an amendment that narrows the scope of a claim for any reason related to the statutory requirements of a patent will give rise to prosecution history estoppel with respect to the amended claim element." In this case, the product claims were not amended. Instead, the initial claims

defining the synthetic gene by a broadly specified DNA sequence were cancelled and replaced with claims containing a more narrowly specified DNA sequence. The more narrowly specified claims then issued with the '831 patent. We do not discern any legally significant difference between canceling a claim having a broad limitation and replacing it with a claim having a narrower limitation, and amending a claim to narrow a limitation. To do so would place form over substance and would undermine the rules governing prosecution history estoppel laid out in Festo by allowing patent applicants simply to cancel and replace claims for reasons of patentability rather than to amend them. This notion is not new, as this court has previously treated canceling and replacing claims as analogous to amending them. See Haynes Int'l, Inc. v. Jessop Steel Co., 8 F.3d 1573, 1578-79, 28 USPQ2d 1652, 1656-57 (Fed. Cir. 1993). In fact, some of the "amendments" at issue in Festo involved cancellations. 234 F.3d at 588, 56 USPQ2d at 1887.

On appeal, Mycogen does not argue that the district court erred in concluding that the cancellation of the product claims with the broad DNA sequence in favor of claims with a more narrowly defined DNA sequence gave rise to prosecution history estoppel. Instead, Mycogen argues that despite the estoppel the district court erred when it did not hold that claims 13 and 14 were entitled to some range of equivalents. That argument, however, is at odds with our decision in Festo. When a claim amendment (or in this case the cancellation of a claim with a broad limitation in favor of one with a narrower limitation) creates prosecution history estoppel, no range of equivalents is available for the amended claim limitation. Festo, 234 F.3d at 564, 56 USPQ2d at 1868. Accordingly, we affirm the district court's ruling that Mycogen is estopped from asserting the doctrine of equivalents with respect to claims 13 and 14.

Each side shall bear its own costs for this appeal.

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.