

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, for plaintiffs-appellants. With him on the brief were Richard W. Mark, Robert M. Isackson, and Geoffrey W. Millsom, of New York, New York; and Craig R. Kaufman, of Menlo Park,

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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: August 14, 2001

ON PETITION FOR REHEARING

Before CLEVINGER, BRYSON, and LINN, Circuit Judges.

BRYSON, Circuit Judge.

Based on the prosecution history of Mycogen's U.S. Patent No. 5,380,831 (the '831 patent), we held in our initial opinion in this case that Mycogen is not entitled to invoke the doctrine of equivalents with respect to claims 13 and 14 of the patent. 252 F.3d 1306, 1319-20, 58 USPQ2d 1891, 1901-02. In its petition for rehearing, Mycogen contends that we misunderstood the prosecution history of the '831 patent and, as a result, mistakenly held the doctrine of equivalents inapplicable to claims 13 and 14.

The prosecution history leading to the issuance of claims 13 and 14 of the '831 patent is complex. We did not describe it in detail in our initial opinion, but have done so here.

Although Mycogen contends that the details of the prosecution history require a different analysis of the doctrine of equivalents issue, we are not persuaded that anything in the prosecution history to which Mycogen has called our attention justifies a different result from the one reached in our original opinion.

In brief summary, the prosecution history of claims 13 and 14 reveals that Mycogen first applied for claims providing broad coverage, and then subsequently engaged in a long prosecution negotiation with the Patent and Trademark Office (“PTO”). During the course of the prosecution, Mycogen narrowed the scope of its application through a series of increasingly narrow claims. The PTO, however, rejected all of those claims and ultimately proposed language that limited what became claims 13 and 14 to segments of a specific DNA sequence disclosed in the application. Mycogen agreed to the proposed language and agreed to cancel its broader related claims. It is that series of events, described in more detail below, that provides the factual background for Mycogen’s doctrine of equivalents argument.

Mycogen’s application No. 07/242,482 (the ‘482 application), filed on September 9, 1988, included application claims 1, 3, and 4:

1. 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.

3. A synthetic gene of claim 1 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1793.

4. A synthetic gene of claim 1 wherein said DNA sequence is that presented in Figure 1 spanning nucleotides 1 through 1833.

Those claims were rejected on a number of grounds. Claim 1 was rejected under the second paragraph of 35 U.S.C. § 112 as being indefinite, and all claims were rejected under the first paragraph of section 112 because the specification was enabling only for claims limited to dicot plant cells. The examiner observed that the disclosure was enabling only for the specific sequence shown in Figure 1, and that in view of the unpredictability of foreign gene expression, it did not appear that any functionally equivalent synthetic gene would be effective in any plant cell. Finally, the claims were rejected as obvious.

In response to arguments made by Mycogen, the examiner again concluded that the disclosure was enabling only for the specific sequence shown in Figure 1. The examiner further remarked that Mycogen had not provided evidence that the sequence of Figure 1 or any other sequence is highly expressed in plants and reiterated that, in light of the unpredictability of expression, even very similar genes might not express a protein that would be an effective toxin.

Following final rejection of the '482 application, Mycogen filed a continuation that became application No. 07/827,844 (the '844 application). In that application, claims 3 and 4 from the '482 application were amended to depend from new application claim 31, which was significantly narrower than '482 application claim 1. The change in dependency had the effect of narrowing the scope of claims 3 and 4. Claim 31 provided as follows:

31. A synthetic gene designed to be highly expressed in plants comprising a DNA sequence encoding a Bt insect toxic polypeptide which is

functionally equivalent to a native insecticidal protein of Bt, having toxicity to a specific insect, and wherein said synthetic gene is designed by modifying a native Bt gene by at least one of a plurality of factors affecting Bt mRNA synthesis or degradation in plants selected from the group of factors consisting of (a) preferred codon usage, (b) A+T base content, (c) CG and TA doublet avoidance indices, (d) RNA destabilizing sequence, (e) translation initiation sequence, (f) plant polyadenylation signal, (g) RNA degradation signal, (h) polymerase II termination sequence, (i) CUUCGG hairpin and (j) plant consensus split site.

The claims of the '844 application were rejected under the second paragraph of 35 U.S.C. § 112 for indefiniteness. In addition, claim 31 was rejected under the first paragraph of 35 U.S.C. § 112 on written description and enablement grounds. The examiner again noted that the disclosure was enabling only for the specific sequence shown in Figure 1 of the specification. Although the application recited a synthetic gene encoding a functional equivalent of any native Bt protein, the examiner pointed out that the applicants had shown only one Bt-derived synthetic gene, the sequence of which was shown in Figure 1. The examiner concluded that the applicants "have provided insufficient guidance to justify the breadth of the claims." The examiner reiterated that there must be a reasonable predictability that following the teaching of the disclosure will result in the claimed invention, and found no assurance that any of the claims recited any operable species. Although Mycogen had submitted declarations attempting to provide such assurance, the examiner found the declarations insufficient. In particular, the examiner found that the testing supporting the declarations did

not support the broad claims because only one construct was tested, and the testing did not support claims 3 and 4 because the declaration did not refer to the construct of Figure 1. In addition, the examiner rejected claim 31 for obviousness.

In response to that office action, Mycogen amended the '844 application. It canceled claim 31, substituted new claim 35 in its place, and added claim 36. Claims 35 and 36, from which claims 3 and 4 were made to depend, were narrower than claim 31. Once again, then, the amendment had the effect of narrowing the scope of claims 3 and 4. Also, independent claim 51 and dependent claim 52, which contained the Figure 1 limitations, were added. The new and modified claims provided as follows:

36. A synthetic gene designed to be highly expressed in plants comprising a DNA sequence encoding a Bt insecticidal protein, said synthetic gene having modified codons in a Bt coding region.

35. A synthetic gene of claim 36 wherein said DNA sequence is characterized by at least one of a plurality of factors selected from the group of factors consisting of: (a) utilization of plant preferred codon usage to within about 75% of the frequency of codon usage preferred by plants as in Table 1, (b) utilization of an A+T base content substantially equal to the A+T base content found in plant structural genes as in Table 1, (c) utilization of CG and TA doublet avoidance indices substantially equal to those of selected a host plant, (d) utilization of a plant translation initiation sequence, (e) elimination of plant polyadenylation signals comprising those having AATAAA, AATGAA, AATAAT, AATATT, GATAAA and AATAAG motifs, (f) elimination of polymerase II

termination sequences, CAN₇₋₉AGTNNA, (g) elimination of CUUCGG hairpins and (h) elimination of plant consensus splice sites, including 5'=AAG:GTAAGT and 3'=TTTT(Pu)TTT(Pu)T(Pu)T(Pu)T(Pu)TGCAG:C.

3. A synthetic gene of claim 35 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1793.

4. A synthetic gene of claim 35 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1833.

51. A synthetic gene designed to be highly expressed in plants comprising a DNA sequence encoding a Bt insecticidal protein, said DNA sequence being that presented in Figure 1, spanning nucleotides 1 through 1793.

52. A synthetic gene of claim 51 wherein said DNA sequence spans nucleotides 1 through 1833.

All of those claims were rejected under the first paragraph of 35 U.S.C. § 112 on written description and enablement grounds. Claims 3, 4, and 35 were also rejected under the second paragraph of 35 U.S.C. § 112 for indefiniteness. In addition, the examiner rejected claims 3, 4, 51, and 52 under the fourth paragraph of 35 U.S.C. § 112 for being in improper dependent form or failing to further limit the subject matter of a previous claim. The examiner

again found that the disclosure enabled only the Figure 1 sequence and found, in light of the unpredictable effect of changes in gene sequences, that even if the declarations offered by Mycogen clarified that the Figure 1 construct was tested and operable, that evidence would be helpful only if the claims were limited to the sequence set forth in Figure 1.

Following an interview, new claim 53 was added, and claims 3 and 4 were again amended, this time to make them depend from claim 53. The other pending claims were cancelled. The new claims provided as follows:

53. A synthetic Bt gene derived from a native Bt gene and expressible in plants at a level higher than the corresponding native Bt gene, wherein the DNA sequence of the native Bt gene has been modified in the synthetic gene to contain a frequency of codon usage that more closely resembles the frequency of codon usage of the plant in which it is to be expressed, and wherein the modified DNA sequence encodes substantially the same amino acid sequence as did the native Bt DNA sequence from which it was derived.

3. A synthetic gene of claim 53 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1793.

4. A synthetic gene of claim 53 wherein said DNA sequence is that presented in Figure 1, spanning nucleotides 1 through 1833.

Claim 53 was then rejected under the second paragraph of section 112 as indefinite. Again, the examiner stated that there must be reasonable predictability that following the

teaching of the disclosure will result in the claimed invention, and found that there was no assurance that the claimed invention was enabled for the scope recited. The examiner withdrew the prior rejection of claims 3 and 4 under the first paragraph of section 112 in view of the amendments and arguments made, specifically the clarification that the construct tested as described in the submitted declarations was that of Figure 1. Finding the declarations persuasive with regard to claims 3 and 4 only, the examiner stated that it was “impossible to determine how much experimentation was required to obtain the one success exemplified.” Accordingly, the examiner concluded that “the claims should be limited to the sequence shown in Figure 1 as disclosed in the Examples of the instant application.” The examiner stated that claims 3 and 4 would be allowable if rewritten in independent form. Following another interview, Mycogen agreed to cancel the non-allowed claims and agreed to the examiner’s proposed language amending claims 3 and 4 as follows:

3. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1793.

4. A synthetic gene comprising the DNA sequence presented in Fig. 1, spanning nucleotides 1 through 1833.

Those claims issued as claims 13 and 14 in that form.

As we explained in our initial opinion in this case, the court in Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 234 F.3d 558, 588, 56 USPQ2d 1865, 1887 (Fed. Cir. 2000) (en banc), cert. granted, 121 S. Ct. 2519 (2001), held that cancellation of a claim and

replacement with another claim having an added limitation had the effect of narrowing the scope of the original claim and therefore should be treated as a claim amendment that created a total bar to the doctrine of equivalents with respect to the limitation that was in effect added to the original claim. In Festo, as here, the court had under consideration a claim limitation that was not present in the original independent claim but was present in an original dependent claim and was imported from the dependent claim into the independent claim that ultimately issued.

In Festo, one of the issued claims of the Stoll patent recited “a sleeve made of magnetizable material.” Id. at 580, 56 USPQ2d at 1881. The independent claim of the application, claim 1, did not include that limitation, although a dependent claim, claim 8, did include it. Id. at 582-83, 56 USPQ2d at 1883. Following rejection of the original claims, the applicant submitted new claims, including an independent claim that contained the “magnetizable sleeve” element. That claim was subsequently allowed and issued.

In analyzing that sequence of events, we concluded that prosecution history estoppel applied because the amendment narrowed the literal scope of the original independent claim, even though the narrowing was effected through the addition of a new claim rather than through an amendment to the original claim. We explained:

To determine whether a claim amendment gives rise to prosecution history estoppel, we first must determine whether the amendment narrowed the literal scope of the claim. Here we are presented with the situation where the added claim element was introduced through a new claim, instead of through an amendment to an original claim. Nevertheless, the addition of the magnetizable sleeve claim element can be said to have narrowed the scope of the original

claim because the new claim replaced the original claim. Specifically, the only original independent claim, which did not recite a magnetizable sleeve, was replaced with an independent claim which does recite a magnetizable sleeve. Because the amendment narrowed the literal scope of the claim, we must determine whether Festo has established that it was made for a reason unrelated to patentability.

Festo, 234 F.3d at 587-88, 56 USPQ2d at 1887. Because Festo had not shown that the scope of the independent claim was changed for a purpose unrelated to patentability, we held that application of the doctrine of equivalents was barred as to that claim element. Id. at 588, 56 USPQ2d at 1888.

That analysis is equally applicable to the claims at issue in this case. As in Festo, the limitations at issue in this case were included in dependent application claims and were later incorporated into the independent claims that were allowed and issued. As in Festo, the scope of the independent claim was clearly limited when it was replaced by a claim the language of which was drawn from a prior dependent claim.

As described above, the examiner in this case made clear that in light of the unpredictability of expression of synthetic genes, demonstration of enablement was required for allowance. The examiner also was clear that when only one synthetic gene was shown to be enabled, no broader claim scope was allowable. Faced with these rejections, Mycogen acquiesced in the examiner's proposal to cancel all claims except those specifically reciting the Figure 1 sequence. Thus, the prosecution history reveals that what the examiner ultimately proposed, and Mycogen accepted, was claim language limited to sequences taken from the

preferred embodiment set forth in Figure 1. Under these circumstances, it is appropriate to limit Mycogen to the literal scope of the claims to which it agreed. We therefore conclude, as we did in our original opinion, that prosecution history estoppel applies to the Figure 1 limitations that were imported into independent claims 13 and 14 from the original dependent claims, and that Mycogen is barred from asserting the doctrine of equivalents with regard to those claim limitations.

The petition for rehearing is denied.