

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JAWED ASRAR, FRANK C. KOHN, and ERNEST F. SANDERS

Appeal 2008-4220
Application 09/968,174
Technology Center 1600

Decided: December 31, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1-7, 10-19, 22-28, and 30. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims are directed to a method of protecting a transgenic corn plant. The method involves providing a corn seed for “a transgenic corn plant” whose DNA has been engineered to reduce damage to the plant by

corn rootworm. In addition to providing the genetically engineered seed, the method calls for treating the seed with the pesticide, thiamethoxam.

Claims 1-7, 10-19, 22-28, and 30 are pending and stand rejected by the Examiner under 35 U.S.C. § 103(a) as obvious over Lee (US Pat. Pub. No. 2003/0050326 A1, Mar. 13, 2003) (Ans. 4). We select claim 1 as representative of the appealed subject matter. 37 C.F.R. § 41.37(c)(1)(vii).

Claim 1 reads as follows:

1. A method for protecting a transgenic corn plant against feeding damage by one or more pests, the method comprising providing a seed for the transgenic corn plant, wherein the seed comprises a transgenic event that is capable of reducing the damage caused by corn rootworm so that the damage to transgenic corn is within the range of from about 10% to about 40% of the damage to non-transgenic corn under the same conditions, when said damage is expressed as a percent of the corn plants having a score of 4 - 6 as measured by Iowa Corn Rootworm 1 - 6 Scale; and treating the seed with from at least about 10 grams to about 2000 grams of thiamethoxam per 100 kilograms of seed.

ISSUE ON APPEAL

The issue in this appeal is as follows:

Did the Examiner provide sufficient evidence (“sound basis”) that Lee’s transgenic corn plants would be “capable of reducing the damage caused by corn rootworm so that the damage to transgenic corn is within the range of from about 10% to about 40% of the damage to non-transgenic corn under the same conditions” as recited in claim 1?

PRINCIPLES OF LAW

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. *See In re Ludtke, supra*. Whether the rejection is based on ‘inherency’ under 35 U.S.C. § 102, on ‘prima facie obviousness’ under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *See In re Brown*, 459 F.2d 531, 59 CCPA 1036, (1972).

In re Best, 562 F.2d 1252, 1255 (CCPA 1977).

“[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990).

FINDINGS OF FACT

Claim 1

1. Claim 1 is directed to a method for protecting a transgenic corn plant against feeding damage caused by corn rootworm. The claim comprises two steps:

2. First, “providing a seed for the transgenic corn plant.”

3. Second, “treating the seed with from at least 10 grams to about 2000 grams of thiamethoxam per 100 kilograms of seed.”

4. The dispute in this appeal involves the following characteristic of the seed recited in claim 1:

wherein the seed comprises a transgenic event that is capable of reducing the damage caused by corn rootworm so that the damage to transgenic corn is within the range of from about

10% to about 40% of the damage to non-transgenic corn under the same conditions.

5. A “transgenic event” is defined in the Specification to result in corn genome DNA that has been genetically engineered, e.g., to express a protein that is active against a pest (Spec. 11: 27-31). “When it is said that a ‘transgenic event has activity against a pest,’ it is to be understood that it is the protein that is encoded by the gene that actually has such activity when the protein is expressed and brought into contact with the pest” (*id.* at 11: 31 to 12: 3). In other words, a transgenic event involves the insertion of a gene coding for an active protein into the corn seed DNA.

6. An example of a transgenic event described in the Specification is the insertion of a Cry gene into the corn seed DNA (Spec. 12: 4-27). Cry encodes a δ -endotoxin protein which was known in the prior art to have insecticidal activity against corn rootworm (*id.* at 12: 17-26; at col. 8, ll. 11-15). Claims 2-7, 12, 13, and 25-27 are specifically directed to methods in which the transgenic event involves the ability to express a Cry protein.

7. Thus, the claim limitation that the seed comprises a “transgenic event” capable of reducing corn rootworm damage “from about 10% to about 40%” would read on insertion of an endotoxin gene (such as, but not limited to, a Cry gene) into the corn seed DNA and its expression of the encoded protein in such a way that it protects the corn from the stated range of damage by corn rootworm. The claim, however, is not limited to a particular gene type or method of producing the transgenic event.

The scope and content of the prior art

8. Lee describes numerous transgenic events which can be utilized to protect crops from pest damage (Lee, ¶¶ 14-16). These events involve using

recombinant DNA technology to insert and express genes coding for toxins, inhibitors, and blockers that control pests (*id.* at ¶ 14-16).

9. Lee also lists numerous genes “targets and expressed principles” (e.g., genes inserted into the DNA) which can be used to produce tolerance against pests in corn (“maize”) (*id.* at ¶ 18).

10. Appellants do not dispute the Examiner’s finding that Lee describes a “transgenic event”, as in claim 1, which includes insertion of a Cry gene into a corn seed as in dependent claims 2-7, 12, 13, and 25-27 (Ans. 4; Lee, at ¶¶ 14-17). *See* App. Br. 13: 18-21.

11. Appellants do not dispute the Examiner’s finding that Lee describes treatment of a transgenic seed comprising a transgenic event with thiamethoxam (Ans. 4; Lee, at ¶¶ 1, 69, 91) and that it would have been routine to have optimized the amounts of thiamethoxam to apply to a seed to have achieved the claimed amounts (Ans. 4). *See* App. Br. 13: 18-21; Reply Br. 4: 5-6.

12. Appellants admit that the skilled worker “would have known that transgenic events resulting in the production of proteins having activity against corn rootworm can have very different levels of activity” ranging “from almost 0% to near 100%” (Reply Br. 6).

13. The Specification teaches that Bt endotoxins were known to have low activity against coleopteran insects (Spec. 4: 31 to 5: 4; Reply Br. 6), leading to the reasonable expectation that a Bt endotoxin would result in low amount of crop tolerance to such insects.

Differences between claim 1 and Lee

14. Lee does not expressly teach that its transgenic corn seed comprises “a transgenic event that is capable of reducing the damage caused by corn

rootworm so that the damage to transgenic corn is within the range of from about 10% to about 40% of the damage to non-transgenic corn under the same conditions” as recited in claim 1.

15. However, the Examiner finds “it is inherent that Lee would produce the same results” since both Lee and claim 1 involve producing a transgenic event to reduce crop damage (Ans. 6: 15 to 7: 4).

ANALYSIS

It is axiomatic that the PTO has no facilities for testing whether a product disclosed in the prior art is the same as one which is claimed. *In re Best*, 562 F.2d at 1255. For this reason, the burden has been placed on the applicant for a patent to prove that a prior art produce does not “necessarily or inherently possess the characteristics” of the product which is claimed. *Id.* This burden is triggered when the Examiner comes forward with a sufficient evidence – a “sound basis” – to support his conclusion. *In re Spada*, 911 F.2d at 708.

In this case, the dispute is whether the Examiner has sound basis for believing that a transgenic event described by Lee would result in a transgenic corn plant that would “reduce the damage caused by corn rootworm” to “within the range of from about 10% to about 40% of the damage to non-transgenic corn under the same condition.” The evidence relied upon by the Examiner to support his conclusion is that Lee’s method utilizes plants that have been genetically engineered in the same way and using the same type of genes as the transgenic corn seeds covered by claim 1 (FF15). Based on this evidence, the Examiner shifted the burden to

Appellants to prove the Lee's method would not result in transgenic plant with the claimed characteristics.

Appellants have not disputed the Examiner's finding that Lee describes transgenic events which fall within the scope of claim 1 (FF10). These events include using recombinant DNA technology to engineer a plant to express a protein which confers pest tolerance (FF 8, 9). Lee lists numerous proteins and targets which can be utilized to achieve this protective result (FF9). Appellants have not provided any evidence that at least one of the expressed proteins among the long list disclosed in Lee would not control pest damage with the claimed range of "from about 10% to about 40%." Appellants admit that the skilled worker "would have known that transgenic events resulting in the production of proteins having activity against corn rootworm can have very different levels of activity" ranging "from almost 0% to near 100%" (FF12; Reply Br. 6). Thus, there is reasonable basis to believe that at least one of the many different events described would achieve damage control in the range of 10-40% – which is about a third to almost a half of the range which Appellants admit would have been expected. Given that the claims are not limited to particular gene or method of producing a transgenic event, we conclude that the Examiner's position that at least one gene explicitly disclosed by Lee would achieve damage control within the claimed range has a sound basis.

Furthermore, as admitted by Appellants, the Specification teaches that Bt endotoxins were known to have "low activity" against coleopteran insects (FF13; Spec. 4: 31 to 5: 4; Reply Br. 6). Thus, a low percentage range of damage control would have reasonably been expected when Bt endotoxins were utilized in Lee's method (FF13).

Appellants argue that the Examiner did not meet the “inherency standard, which requires that the Office provide most [sic, must] provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art” (Reply Br. 7).

This is not true. The Examiner did provide sound technical underpinnings for his conclusion: that is, Lee teaches transgenic events which are indistinguishable from those which are claimed (FF10). Lee even describes the same Cry genes recited in certain dependent claims (FF6, 10). Appellants only argument is that Lee does not teach the 10% to 40% limitation. However, as Lee is otherwise identical in all respects, the Examiner reasonably presumed that it is also identical in the amount of crop protection afforded by the transgenic event. Because the PTO does not have the resources to test the long list of genes in Lee’s disclosure to determine which, when associated with a transgenic event, would meet the claimed limitation, the Examiner properly, based on the similarities between the claimed method and Lee, put the burden on Appellants to prove otherwise.

As Appellants have not provided rebuttal evidence that Lee’s transgenic plants do not meet the claimed limitation, we affirm the rejection of claim 1. Claims 2-7, 10-19, 22, 23, and 30 fall with claim 1 because separate reasons for their patentability were not provided.

CONCLUSION OF LAW

The Examiner provided sufficient evidence to shift the burden to Appellants to prove that Lee’s transgenic corn plants would be “capable of reducing the damage caused by corn rootworm so that the damage to

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transgenic corn is within the range of from about 10% to about 40% of the damage to non-transgenic corn under the same conditions” as recited in claim 1. As Appellants did not meet their burden, we affirm the rejection of claims 1-7, 10-19, 22, 23, and 30. 37 C.F.R. § 41.37(c)(1)(vii).

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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